## **COMMERCIALISATION OF THE HUMAN**

## **BODY AND BODILY MATERIALS**

THESIS SUBMITTED TO THE NATIONAL UNIVERSITY OF ADVANCED LEGAL STUDIES

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## **DOCTOR OF PHILOSOPHY**

BY

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October, 2018

### DECLARATION

I do hereby declare that this thesis titled "Commercialisation of the Human Body and Bodily Materials" for the award of the degree of Doctor of Philosophy is the record of the original research work carried out by me under the guidance and supervision of Dr. Anil R. Nair, Associate Professor, The National University of Advanced Legal Studies. I further declare that this thesis has not previously formed the basis for the award of any degree, diploma, associateship, fellowship or any other title or recognition from any University/Institution.

Kochi 25<sup>th</sup> of October, 2018 Veena Roshan Jose (Research Scholar)



## CERTIFICATE

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Associate Professor, The National University of Advanced Legal Studies, Kochi.

This is to certify that this thesis titled "**Commercialisation of the Human Body and Bodily Materials**" submitted by Veena Roshan Jose, for the award of the degree of Doctor of Philosophy is to the best of my knowledge, a *bona fide* record of research work carried out by at the National University of Advanced Legal Studies under my guidance and supervision. This thesis, or any part thereof, has not been submitted elsewhere for any degree.

Kochi 25<sup>th</sup> of October, 2018 **Dr. Anil R. Nair** (Supervising Guide)



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### PROLOGUE

"There is nothing which so generally strikes the imagination, and engages the affections of mankind, as the right of property; or that sole and despotic dominion which one man claims and exercises over the external things of the world, in total exclusion of the right of any other individual in the universe."

-William Blackstone

#### INTRODUCTION

The human body has been a subject matter of special interest and fascination which in turn has also generated legal issues. The human body is of significant interest to the scientific and the medical world. Procurement, use and retention of human cadavers has evoked legal concerns since the post renaissance advancements in anatomical knowledge through dissection. Latter half of the twentieth century has witnessed remarkable progress in organ and tissue transplantation, research using human tissues and cells, creation of embryos outside the human body, etc. This has brought to forefront the commercial potential of the human body, its parts and materials derived from it. The human body has thus turned out to be a commercially exploitable property; a resource to be harvested, patented and traded for profits. Questions in relation to property interests in the human body and bodily materials; about death and time of death; rights related to possession, transfer and ownership of cadavers and excised human tissues; claims over stored human materials such as gametes and embryos, etc., have raised legal concerns.

If market principles are brought into transactions involving the human body and bodily materials, it reduces the same to the status of a 'commodity'. At the same time, there is a scarcity of available cadavers, organs and tissues, either for therapeutic or research purposes, which has led to the growth of international black markets in the human body and bodily materials. These factors definitely call for re-examining the legal frame work with respect to the human body and bodily materials.

There is an intrinsic interrelationship between the body of a person and his/her personhood. An attempt to bring in a legal framework to control the commodification of the human body should not ignore the personal dignity and autonomy of the person concerned. The availability of cadavers and human organs, tissues and other bodily materials, be it for the purpose of transplantation or for research, is important. Getting access to these human materials without compromising the sanctity of the human body and the interrelated concepts of personal dignity and personhood is a serious concern. More than the recipient in a transplantation process or the beneficiaries in research processes, the legal framework needs to address these concerns from the perspective of the source of the bodily material. This makes it imperative that the legal framework for access to human biological materials should focus on increasing the availability of the same as well as on the protection of the rights of the originator of such human material. Two propositions were identified in research on the legal treatment of the human body and bodily materials. The first proposition tries to consider the entire subject under the existing jurisprudence relating to property. This human body as a property approach - recognizes that the human body as well as the materials derived from it can constitute commercially valuable 'things'. The second approach gives importance for the 'self' and leaves the decision making power with the individual by respecting his bodily autonomy, his right to informed consent and privacy.

The researcher identifies three distinct levels of classification for substantive matter that constitute a human being. At the first level, the person and the persona, enjoys all rights bestowed by the law. A living person cannot be treated as property, whereas, there can be 'property-like interest' in a dead human body, which is generally exercised by legal heirs or the persons in charge of that dead body. The functional body units such as a person's organs, blood or other tissues, transferrable to another person for their functional utility can be placed at the second level. The third level of classification focus on the cells, which is the smallest unit that makes up the human material, and has significance in biomedical research. The second and third levels mentioned above are subjected to the 'property like interests'.

#### SIGNIFICANCE OF THE PRESENT STUDY

This study becomes relevant in the modern context with scientific advancements in medicine and related fields. Science has made it possible to take away the 'diseased' organs and replace it with new ones just like one change the worn out or punctured tyre of a motor car. What is needed is another spare part in good condition to replace the sick one. Medical science has proved that it is possible with the growing success rates of transplant surgeries. However, the question of availability of transplantable human organs and tissues remains a challenging issue.

With the progress in medical science and biotechnology, every single cell in a human body has become important for research. Unlike other scientific researches, the subject matter of this research are materials procured from the human body. Sometimes it may be taken from a person's body with his consent and knowledge, whereas sometimes researchers make use of the excess tissues collected from the pathology labs, or even the surgical leftovers. Since there is involvement of the human body and bodily materials, such research and studies are also a concern.

Increasing use of Artificial Reproductive Techniques for infertility treatments and research has led to the attribution of commercial value to the human reproductive cells. Gametes are procured and stored for future uses and are transported widely for infertility treatments and the related research. With this, the commercial value attached to gametes has increased. As part of Artificial Reproductive Technologies, human fertilization is artificially done under lab conditions and the resultant embryos may have to be stored for many years. The legal status of such embryos is under the spot light as the cryopreserved embryos raise a plethora of legal and ethical issues, especially with regard to the property interest in the same.

The increased demand for human cadavers, transplantable organs and other bodily materials remains unfulfilled owing to absence of a proper facilitating legal framework. This has led to the rise in black markets in the human body and bodily materials. Bringing in a legal framework in one country may not resolve this issue because commodification in human biological materials has already developed into an international problem with a much wider magnitude. Affluent people travel to the countries where transplantation and infertility treatments can be availed at low cost and with less legal constraints. This practice has given rise to new avenues such as transplant tourism, reproductive tourism, etc. Hence it is necessary that the legal issues involving commodification of the human body and bodily materials are addressed in a comprehensive way by regulating the procurement, use, retention and destruction of human biological materials in an intra and international legal framework.

#### **OBJECTIVE OF THE STUDY**

The study focuses on the following aspects:

- 1. The legal status of the human body when alive, brain-stem dead, and after death in the context of developments in medical science.
- 2. The commercial and legal significance of 'human bodily materials' in the light of advancements in transplantation surgeries and researches in biomedical technology using human tissues and cells.
- 3. The origin and development of the concept of property to evaluate whether the jurisprudential framework of property is adequate to discuss the concerns in commercialisation of the human body and bodily materials.
- 4. The special treatment in law given to human gametes and *in vitro* human embryos compared to other human bodily materials.
- 5. Attributing commercial value to the human body and bodily materials.
- 6. The significance and usage of the concept of 'consent' in the legal framework of various jurisdictions.
- 7. The legal framework of various jurisdictions and initiatives of international organisations in respect of transactions in the human body and bodily materials.

### **RESEARCH HYPOTHESIS**

In the light of focal areas mentioned above, the following hypothesis shall be tested through this research:

"The existing legal framework is inadequate to deal with the commercialisation of the human body and bodily materials."

#### **RESEARCH QUESTIONS**

The following research questions are raised, the answer to which, it is expected, will help in the testing of the hypothesis:

- 1. Whether the existing legal concept of 'property' is appropriate while discussing the status of the human body and bodily materials?
- 2. Whether the human body and bodily materials can be treated as entities amenable to commercial transactions?
- 3. What is the role of 'consent' in transactions involving the human body and bodily materials?

#### **Research Methodology**

The research is intended to be doctrinal and the research design used for the study is largely descriptive. The research relies on primary and secondary sources. It uses primary materials such as legislations from India and other countries, cases across various jurisdictions, international and other instruments. Secondary sources relied upon includes research papers, books, articles, working papers, etc., published in various journals and other online resources. All material relied on have been enumerated and acknowledged at appropriate places.

#### **STRUCTURE OF THE THESIS**

The research is carried out by dividing the entire work into nine chapters.

Chapter I titled '*The Human Body and Bodily Materials*' tries to define the 'human body' and 'human bodily materials' in a legal framework. It broadly classifies the human body as either a living body or a dead body and examines how law treats the human body when alive and after death. Law acknowledges the concept of 'brain-stem death' and recognises that the human organs can be procured from a 'beating-heart cadaver'. Various human bodily materials are procured for varied purposes including transplantation surgery and research. The chapter introduces the main legal questions that arises in dealing with the human body and bodily materials, and are discussed in detail in subsequent chapters.

Chapter II titled '*Defining Property*' provides an insight into the concept of property, its definitions and classifications over the ages. Modern readings on 'property' in the light of the human body and its parts are also discussed in this chapter. A study of various theories of property reveals how the concept of property has been perceived at different places at different points of time. It can be seen that the notion of property has undergone vast changes. What is property in one age may cease to be property in another age. Likewise, forms and standards of property may also vary from place to place. Developments in science and technology have had its impact on the meaning of property to afford protection to its different forms.

Chapter III titled '*Property in Relation to the Human Body and Bodily Materials*' discusses the property interests specific to the human body and bodily materials.

The human body as a whole is analysed from the perspective of a living human body and a dead human body - as sources of various materials used for transplantation and in research. Property interests in excised human tissues are also discussed in detail. The impact of new technologies and research on the human body, which has raised a number of novel questions related to property interests in the human body and bodily materials are discussed. The chapter evaluates the question of attribution of property rights in the human body and bodily materials. Analysis of cases which has examined property interests in excised human body parts, decided by various courts across different jurisdictions is carried out in this chapter.

Chapter IV titled '*Legal Status of Human Gametes*' details legal treatment of gametes and the basis for a differential treatment of the same from other human materials, even though technically they are also materials procured from the human body. The reason why gametes are given special status apart from other bodily materials is because of the fact that only the gametes have reproductive capacity, and it carries an individual's lineage to the next generation. Hence transactions involved in the human gametes are not treated like transactions in other body tissues and organs. Moreover, there is a wide expanding market in human reproductive materials, which has resulted in its commercialization. The chapter discusses the development of property interests in relation to the stored gametes and the claims for damage or destruction of the same. Special focus is made on the legal regulation of commercial transactions in the human gametes.

As compared to other human bodily materials, the courts have recognised property interests in the stored human gametes.

Chapter V is titled as '*Legal Status of Human Embryos*'. Embryos are created from the reproductive cells of a man and a woman and may be stored for years for future use in assisted reproduction. Questions on the storage, use, destruction, etc., of embryos creates serious legal issues. Human embryo has been a subject matter of legal disputes in various cases, especially in matrimonial settlements. The question analysed here is whether embryos created *in vitro* can be treated as 'potential human beings' or as 'property'. The creation of, and commercial transactions of embryos poses serious legal and ethical questions. On one hand, embryos are treated as 'persons' and on the other they are treated as 'property'. A much accepted middle view claims that embryos can neither be treated as 'persons' nor as 'property' in its strict sense. They are considered as 'special entities' that have the potential to become persons and, therefore, warrant special status and respect.

Chapter VI is titled as '*Commodification of the Human Body and Bodily Materials*'. There is an ever growing market for the human body and body parts. The question here is; can the human body and its parts be treated as a 'thing' which is capable of having a commercial value? Generally, the terms sale, purchase, market, etc., are used only in relation to a commodity. But today, we can see that these words are used even in relation to the human body and bodily materials. It is an undeniable fact that there is a huge demand for human corpses, transplantable organs and tissues, gametes and foetal tissues. Arguments in support of commercialization and arguments against commercialization are analysed in this chapter. Supporters of commercialization in human materials stresses on the utilitarian principles whereas those who opposes such a move base their arguments on the principles of dignity of a person and bodily integrity.

Chapter VII titled '*Consent: Relevance in Transactions Involving the Human Body and Bodily Materials*' is focused on the legal requirement of a valid consent for the uses of the human body and bodily materials for therapeutic and research purposes. Consent is a precondition for autonomous decision making and a requirement for a lawful interference with another person's body. It is very important in relation to donation, use, storage and retention of human tissues. The chapter analyses how different legal systems recognizes the aspect of consent in the legislations on organ harvesting. In the context of use of the human body and bodily materials two types of consent are generally used. Informed Consent, also known as 'opt-in' system, stresses on autonomy, human dignity, etc. Presumed Consent, also known as the 'opt-out' system, is another system which is based on the utilitarian approach.

Chapter VIII is titled as '*Legal Framework in Relation to Commercialisation of the Human Body and Bodily Materials*'. It is a study on the regulatory framework of the commercial transactions in human organs and tissues in different jurisdictions. International responses in relation to the transactions involving the human bodily materials for transplantation and research is dealt with under this chapter in detail. The chapter examines the capability of the existing laws to deal with emergent issues consequent to the development of medical science and related technologies. It tries to identify and focus on reforming the law to deal with advancements in medicine and research.

Chapter IX contains the concluding analysis and suggestions to improve the existing legal framework in the background of commercialisation of the human body and bodily materials. Massive profit potential realized from medical technology has elevated the monetary worth of human tissue to astronomical levels. This has led to the demand for stringent and fool proof laws in order to tackle issues involving the retention and use of human body and bodily materials for therapeutic as well as research purposes. Today, in the absence of clarity about the legal status of the human body, courts have constructed a collection of circumstantially defined categories for resolving the question of property interests in the human body. This patchwork approach is awkward and incoherent. Throughout the study, it could be seen that the law has not been able to keep pace with the scientific and technological advances. Thus there is a need to bring in changes in the existing legal system. Original proposals resulting from this research are submitted in this regard.

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hSSC

Hofstra L. Rev.

	ADDREVIATIONS
ACT	Australian Capital Territory
A.J.P.C.T	American Journal of Phytomedicine and Clinical Therapeutics
AM. L. Rev.	American Law Review
Ann. R. Coll. Surg. Engl.	Annals of the Royal College of Surgeons of England
Annals Health L.	Annals of Health Law
ART	Assisted Reproductive Technology
Biotechnol. J.	Biotechnology Journal
BJA	British Journal of Anaesthesia
BMC	British Medical Council
BMJ	British Medical Journal
BYU L. Rev.	Brigham Young University Law Review
CIOMS	Council for International Organizations of Medical Sciences
Clin. J. Am. Soc. Nephrol.	Clinical Journal of American Society of Nephrology
CMAJ	Canadian Medical Association Journal
EMHJ	Eastern Mediterranean Health Journal
Emory L. J.	Emory Law Journal
ESC	Embryonic Stem Cells
EU	European Union
EWCA	England and Wales Court of Appeal
GIFT	Gamete Intra fallopian Transfer
Harv. L. & Pol'y Rev.	Harvard Law and Policy Review
Harv. L. Rev.	Harvard Law Review
hEGC	Human Embryonic Germ Cells
hESC	Human Embryonic Stem Cells
HFEA	Human Fertilization and Embryology Act

### **ABBREVIATIONS**

Hofstra Law Review

Human Somatic Stem Cells

HTA	Human Tissue Act
HTGA	Human tissue Gift Act
HTODA	Human Tissue and Organ Donation Act
ICMR	Indian Council for Medical Research
IHLR	Indiana Health Law Review
IJU	Indian Journal of Urology
Ind. Health L. Rev	Indiana Health Law Review
Ind. J. of Global Legal Studies	Indiana Journal of Global Legal Studies
Ind. L. Rev.	Indiana Law Review
Int. J. Fertil. Steril.	International Journal of Fertility & Sterility
Iowa L. Rev	Iowa Law Review
ISN	International Society of Nephrology
Isr. J. Health Policy Res.	Israel Journal of health Policy Research
ISSCR	International Society for Stem Cell Research
IVF	In Vitro Fertilisation
IVF J.	In Vitro Fertilisation Journal
J.	Journal
J. J. Anat.	Journal Journal of Anatomy
J. J. Anat. J. Assist. Reprod. Genet. J. Contemp. Health Law	Journal Journal of Anatomy Journal of Assisted Reproduction & Genetics
J. J. Anat. J. Assist. Reprod. Genet. J. Contemp. Health Law Pol'y	Journal Journal of Anatomy Journal of Assisted Reproduction & Genetics Journal of Contemporary Health Law & Policy
J. J. Anat. J. Assist. Reprod. Genet. J. Contemp. Health Law Pol'y J. Fert. In Vitro J. Indian Acad. Forensic	Journal Journal of Anatomy Journal of Assisted Reproduction & Genetics Journal of Contemporary Health Law & Policy Journal of Fertilization In Vitro
J. J. Anat. J. Assist. Reprod. Genet. J. Contemp. Health Law Pol'y J. Fert. In Vitro J. Indian Acad. Forensic Med.	Journal Journal of Anatomy Journal of Assisted Reproduction & Genetics Journal of Contemporary Health Law & Policy Journal of Fertilization In Vitro Journal of Indian Academy of Forensic Medicine
J. J. Anat. J. Assist. Reprod. Genet. J. Contemp. Health Law Pol'y J. Fert. In Vitro J. Indian Acad. Forensic Med. J. M. E	Journal Journal of Anatomy Journal of Assisted Reproduction & Genetics Journal of Contemporary Health Law & Policy Journal of Fertilization In Vitro Journal of Indian Academy of Forensic Medicine
J. J. Anat. J. Assist. Reprod. Genet. J. Contemp. Health Law Pol'y J. Fert. In Vitro J. Indian Acad. Forensic Med. J. M. E J. Med. & L.	Journal Journal of Anatomy Journal of Assisted Reproduction & Genetics Journal of Contemporary Health Law & Policy Journal of Fertilization In Vitro Journal of Indian Academy of Forensic Medicine Journal of Medicine and Ethics Journal of Medicine and Law
J. J. Anat. J. Assist. Reprod. Genet. J. Contemp. Health Law Pol'y J. Fert. In Vitro J. Indian Acad. Forensic Med. J. M. E J. Med. & L. J. Tech. L. & Pol'y	JournalJournal of AnatomyJournal of Assisted Reproduction & GeneticsJournal of Contemporary Health Law & PolicyJournal of Contemporary Health Law & PolicyJournal of Fertilization In VitroJournal of Medicine and EthicsJournal of Medicine and LawJournal of Technology Law and PolicyJournal of the American Academy of Matrimonial

Loy. L.A. Int'l & Comp. L. Rev.	Loyola of Los Angeles International and Comparative Law Review
Marq. L. Rev.	Marquette Law Review
Med. L. Int.	Medical Law International
Mich. L. Rev.	Michigan Law Review
Modern L. Rev.	Modern Law Review
MurUEJL	Murdoch University Electronic Journal of Law
N.E.J.M	New England Journal of Medicine
Nev. L.J.	Nevada Law Journal
NHMRC	National Health and Medical Research Council
NOTA	National Organ Transplantation Act
Nova L. Rev	Nova Law Review
NSW	New South Wales
NT	Northern Territory
OPTN	Organ Procurement and Transplantation Network
OTDTAA	Organ and Tissue Donation and Transplantation Authority Act
PAR	Posthumous Assisted Reproduction
PMC	PubMed Central
PROST	Pronuclear Stage Tubal Transfer
Qld.	Queensland
Rev.	Review
Rutgers L. Rev.	Rutgers Law Review
S.J.L.S	Singapore Journal of Legal Studies
SA	South Australia
SCNT	Somatic Cell Nuclear Transfer
Seton Hall L. Rev.	Seton Hall Law Review
SSC	Somatic Stem Cell
Syd. L. Rev.	Sydney Law Review
TAA	Transplantation and Anatomy Act
Tas	Tasmania

Tenn. L. Rev.	Tennessee Law review
TET	Tubal Embryo Transfer
TGLNA	Trillium Gift of Life Act
THOA	Transplantation of Human Organs Act
THOTA	Transplantation of Human Organs and Tissues Act
TPG	German Transplantation Act
TTS	The Transplantation Society
U. of La Verne L. Rev	University of La Verne Law Review
UAGA	Uniform Anatomical Gifts Act
UCLJLJ	UCL Journal of Law and Jurisprudence
UDDA	Uniform Determination of Death Act
UDHR	Universal Declaration of Human Rights
UHTGA	Uniform Human Tissue Gift Act
UK	United Kingdom
ULCC	Uniform Law Conference of Canada
UNESCO	United Nations Educational, Scientific and Cultural Organization
UNOS	United Network for Organ Sharing
US	United States of America
Vic	Victoria
WA	Western Australia
WHO	World Health Organisation
WMA	World Health Assembly
Yale L. J.	Yale Law Journal
ZIFT	Zygote Intra fallopian Transfer

### I. THE HUMAN BODY AND BODILY MATERIALS

#### **1.1. INTRODUCTION**

The human body is a complex structure with cells<sup>1</sup> as the basic structural and functional unit. Several hundreds of cells form tissues<sup>2</sup> in the human body. Various tissues together form organs<sup>3</sup>. Various organs<sup>4</sup> working together to perform specific functions constitute the organ system and the organ systems together form the human body. In short, the human body is the sum total of its functional organs.

Materials that are procured from the human body are generally classified as 'human bodily materials' or 'human biological materials'.<sup>5</sup> Various human bodily materials such as tissues, blood, gametes, cornea, transplantable organs,

<sup>&</sup>lt;sup>1</sup> "The smallest transplantable and functional unit of living organisms", World Health Organisation, (hereinafter referred to as WHO), Global Glossary of Terms and Definitions on Donation and Transplantation, 8 (2009), (Jun. 18, 2018), http://www.who.int/transplantation/activities/GlobalGlossaryonDonationTransplantation.pdf?ua=1.

<sup>&</sup>lt;sup>2</sup> "All constituent parts of the human body formed by cells" are known as tissues, WHO, Global Glossary of Terms and Definitions on Donation and Transplantation, 14 (2009), (Jun. 18, 2018), http://www.who.int/transplantation/activities/GlobalGlossaryonDonationTransplantation.pdf? ua=1; § 2(oa) of the Transplantation of Human Organs and Tissues Act, 1994, of India, defines the term tissue as "a group of cells, except blood, performing a particular function in the human body".

<sup>&</sup>lt;sup>3</sup> "Differentiated and vital part of the human body, formed by different tissues, that maintains its structure, vascularisation and capacity to develop physiological functions with an important level of autonomy", WHO, Global Glossary of Terms and Definitions on Donation and Transplantation, 12 (2009), (Jun. 18, 2018), http://www.who.int/transplantation/activities /GlobalGlossaryonDonationTransplantation.Pdf?ua=1.

<sup>&</sup>lt;sup>4</sup> "Human Organ means any part of a human body consisting of a structured arrangement of tissues which, if wholly removed, cannot be replicated by the body", § 2 (h) of the Transplantation of Human Organs Act, 1994 of India.

<sup>&</sup>lt;sup>5</sup> Jean-Paul Pirnay et al., Access to Human Tissues for Research and Product Development: From EU Regulation to Alarming Legal Developments in Belgium, 16 EMBO Reports 557-562 (2015), For a detailed discussion, see paragraph 1.4.

foetus/embryo, pituitary gland, etc., collected from the human body<sup>6</sup> are widely used for research<sup>7</sup> and therapeutic purposes<sup>8</sup>.<sup>9</sup> Propelled by research and development in biotechnology<sup>10</sup> as well as modern medical technologies<sup>11</sup>, the use of the bodily materials are greater than that of transfusion and transplantation<sup>12</sup>, which are, to an extent regulated by laws.<sup>13</sup>

<sup>11</sup> "Medical research involves research in a wide range of fields, such as biology, chemistry, pharmacology and toxicology with the goal of developing new medicines or medical procedures or improving the application of those already available. It can be viewed as encompassing preclinical research (for example, in cellular systems and animal models) and clinical research (for example, clinical trials)", *Medical Research*, (Oct. 10, 2018), https://www.nature.com/subjects/medical-research.

<sup>&</sup>lt;sup>6</sup> "Specimens are obtained from the following four sources: (a) tissues collected prospectively for a research project; (b) excess tissue from samples taken specifically for clinical purposes, such as diagnosis or treatment, which are subsequently recognized as valuable for research; (c) cadaveric tissues; and (d) tissues with reproductive potential, including eggs, sperm, zygotes, embryos, and foetal tissues, which are also often collected for clinical purposes", Monica J. Allen et al., *Human Tissue Ownership and Use in Research: What Laboratorians and Researchers Should Know*, 56 CLINICAL CHEMISTRY, 1675 (2010).

<sup>&</sup>lt;sup>7</sup> Understanding of the human body, its ailments and potential treatments is expanding rapidly, and human tissue is vital for such research, (Oct. 10, 2017), http://www.moh.govt.nz/ notebook/nbbooks.nsf/0/3be88a08377469fdcc256e760071deac/\$FILE/HumanTissueConsulta tion.pdf

<sup>&</sup>lt;sup>8</sup> "Therapeutic purposes means systematic treatment of any disease or the measures to improve health according to any particular method or modality", § 2 (o) of the Transplantation of Human Organs Act, 1994, of India.

<sup>&</sup>lt;sup>9</sup> Nuffield Council on Bioethics, *Human Tissue, Ethical and Legal Issues*, Apr. 1995, (Aug. 17, 2015), http://nuffieldbioethics.org/wp-content/uploads/2014/07/Human-tissue.pdf.

<sup>&</sup>lt;sup>10</sup> "Biotechnology is the technological application which utilizes biological entities, living organisms or biological derivatives. The concept of biotechnology bound in a wide range of procedures for modifying living organisms based on the need of human activities". The latest developments in biotechnology are genetic engineering and biochemical engineering. "Genetic engineering technique involves the change of nature of genetic matter of a living organism and to introduce in to host organism to alter the nature of the host organism. Biochemical engineering is the technique involving the maintenance of sterile conditions of a desired microorganism in biotechnological processes to get the products like enzymes, hormones, antibiotics, vaccines and medicines", *see*, Raju, P., *World History of Modern Biotechnology and its Applications*, 12 Biotechnol. Ind. J., (Oct. 10, 2018), https://www.tsijournals.com/articles/ world-history-of-modern-biotechnology-and-its-applications.html.

<sup>&</sup>lt;sup>12</sup> "Transplantation means the grafting of any human organ from any living person or deceased person to some other living person for therapeutic purposes", § 2 (o) of the Transplantation of Human Organs Act, 1994, of India.

<sup>&</sup>lt;sup>13</sup> Nuffield Council on Bioethics, *Human Tissue, Ethical and Legal Issues*, Apr. 1995, (Aug. 17, 2015), http://nuffieldbioethics.org/wp-content/uploads/2014/07/Human-tissue.pdf.

Materials taken from the human body cannot be classified alike since the significance of material extracted and the purpose for which they are taken differs.<sup>14</sup> For example, blood, semen, liver tissues, kidney, heart, etc., are all human bodily materials. But the importance given to a vial of semen is different from that for a vial of blood. Significance attributed to blood cannot be the same as that to liver tissues. Similarly, sparing a kidney and donating the heart cannot be treated alike. Thus, there is a requirement for further classification in the case of human bodily materials based on their relative significance.

#### **1.2. HUMAN BODY: THE SIGNIFICANCE**

The law gives much significance to a person's body. This is evident from the words of the eminent jurist Salmond when he states that, "there are three things in respect of which the anxieties of living men extend beyond the period of their deaths in such manner that the law will take notice of them. They are a man's body, his reputation and his estate."<sup>15</sup>

<sup>&</sup>lt;sup>14</sup> JONATHAN HERRING, MEDICAL LAW AND ETHICS, 427 (Oxford University Press, 3<sup>rd</sup> ed.), (2010).

<sup>&</sup>lt;sup>15</sup> P. J. FITZGERALD, SALMOND ON JURISPRUDENCE, (London: Sweet & Maxwell, 12<sup>th</sup> ed., 1966, Indian Reprint, Tripathi), 301 (1996).

A dead human body <sup>16</sup> is widely used in medical schools for anatomical studies <sup>17</sup>. <sup>18</sup> The human body parts and tissues are used by biotechnology companies in the production of biomedical goods and services. It is also used in academic and commercial research. <sup>19</sup> Organs and/or tissues taken from the human body are used in transplantation operations, fertility treatments, making of artistic casts, medical education, and so on.<sup>20</sup> In certain situations, the human body and materials taken from it are used as raw materials resulting in inventions and innovations which have a commercial value. <sup>21</sup> Legal legitimacy and recognition of this commercial value attributed to the human body and bodily materials, is the subject matter of this study.

#### **1.3. LAW RELATING TO THE HUMAN BODY**

A living person is considered to possess certain value which cannot be determined in terms of money or property.<sup>22</sup> Similarly, soon after the death, the

<sup>&</sup>lt;sup>16</sup> It is also referred to as a cadaver or a corpse. 'Cadaver' refers to a dead human body that is intended to be dissected. This term is specifically used in medical science. Whereas, the term 'corpse' refers to a dead body, especially that of a human being and this word is used in common parlance, literature, law, and medicine.

<sup>&</sup>lt;sup>17</sup> Whole bodies of deceased persons are dissected and examined by the students of medicine as part of their curriculum. This allows a detailed examination of the structure of the human body and how the components relate to each other, (Oct 11, 2017), http://www.moh.govt. nz/notebook/nbbooks.nsf/0/3be88a08377469fdcc256e760071deac/\$FILE/HumanTissueCons ultation.pdf.

<sup>&</sup>lt;sup>18</sup> Henry E. Sigerist, *The Foundation of Human Anatomy in the Renaissance*, 22 Sigma Xi Quarterly, 8-12 (1934), (Dec. 22, 2018), http://www.jstor.org/stable/27824522.

<sup>&</sup>lt;sup>19</sup> For a detailed discussion, *see* chapter III.

<sup>&</sup>lt;sup>20</sup> REMIGIUS N. NWABUEZE, BIOTECHNOLOGY AND THE CHALLENGE OF PROPERTY: PROPERTY RIGHTS IN DEAD BODIES, BODY PARTS, AND GENETIC INFORMATION, (Ashgate), 1 (2007).

<sup>&</sup>lt;sup>21</sup> See, Moore v. Regents of the University of California, 51 Cal.3d 120; Greenberg v. Miami Children's Hospital, 264 F. Supp. 2d 1064, 2003., For a detailed discussion, see chapter III.

<sup>&</sup>lt;sup>22</sup> Stephanie A. Gangon, *Moral Limits of Markets: Implications for the Commodification of Oozytes*, (Dec. 21, 2014), https://philpapers.org/rec/GAGMLO.

human body is treated in the same way as that of a living human being.<sup>23</sup> The rituals associated with burial reveals the fact that the human body even after death, has possessed a value throughout its history.<sup>24</sup> Thus, the human body, whether alive or after death, is treated as something important, something which was worthy of special treatment from time immemorial.

Legal status of the human body - whether dead or alive, is hotly contested, yet the law relating to the body remains in a state of confusion and chaos. One such confusion lies around the question of commercial interest in the human body and its parts. Any commercial interest would bring in the application of the concept of property into play. Hence there is a need to re-examine the status of the human body and bodily materials in the framework of jurisprudence relating to property.

#### **1.3.1.** LAW IN RELATION TO THE DEAD HUMAN BODY

The corpse or a cadaver is the stage soon after end of life and before the stage of decomposition. Historically the dead body or corpse has been an object of peculiar fascination and concern.<sup>25</sup> Corpses were treated as the 'symbols' of the living human beings and that this symbolic presence explains the common

<sup>&</sup>lt;sup>23</sup> It is the unanimous opinion of the theologians and the jurists that the human dignity of the deceased shall not be violated, and due respect be paid to the corpse, *See*, Hans-Jürgen Kaatsch, *Legislation on Organ Transplantation in Germany*, in ETHICS IN MEDICINE, (Alfred J. Schauer, et al., eds.), (Vandenhoeck & Rupreht in Göttingen) 128 (2001).

<sup>&</sup>lt;sup>24</sup> Marcia Carteret, *Cultural Aspects of Death and Dying*, (Dec. 6, 2014), http://www. dimensionsofculture.com/2010/11/cultural-aspects-of-death-and-dying/.

<sup>&</sup>lt;sup>25</sup> Prue Vines, *The Sacred and the Profane: The Role of Property Concepts in Disputes about Post-mortem Examination*, 9 Syd. Law. Rev, 235 (2007).

intuition that the dead - like the living - deserve respect.<sup>26</sup> "Emotional attachment to the dead exists in most cultures, as is demonstrated by burial rituals".<sup>27</sup> History reveals that at every point of time, the human body was given a special status when compared to that of mere objects. Respect for the dead is often understood in terms of respect for the living beings.<sup>28</sup> Performing specific rituals over the dead,<sup>29</sup> be it for proper burial, entombment, or cremation, has been long held to be one of the central characteristics distinguishing the 'truly human' from the animal.<sup>30</sup>

At every point of time, human beings possessed value of their own and even after death, people respect the dead body of their relatives and loved ones. The dead retain their value after death and are distinguishable from another.<sup>31</sup> Even though the law does not directly respect property rights in dead human bodies, there are well established rights, as well as duties, to provide a proper disposition of the

<sup>&</sup>lt;sup>26</sup> Susan C. Lawrence, *Beyond the Grave - The Use and Meaning of Human Body Parts: A Historical Introduction*, Faculty Publications, Department of History, Paper. 37, 3 (1998), (May 20, 2014), http://digitalcommons.unl.edu/historyfacpub/37.

<sup>&</sup>lt;sup>27</sup> Cordelia Mary Thomas, *A Framework for the Collection, Retention and Use of Human Body Parts*, (2006), (Jul. 11, 2013), http://researcharchive.vuw.ac.nz/bitstream/handle/10063/297/ thesis.pdf.txt?sequence=4.

<sup>&</sup>lt;sup>28</sup> OWNERSHIP OF THE HUMAN BODY: PHILOSOPHICAL CONSIDERATIONS ON THE USE OF THE HUMAN BODY AND ITS PARTS IN HEALTHCARE, (Henk A. M. J. Ten Have & Jos V.M. Welie eds., Kluwer Academic Publishers), 19 (1988).

<sup>&</sup>lt;sup>29</sup> WILLIAM HENRY FRANCIS BASEVI, THE BURIAL OF THE DEAD, (G. Routledge & Sons), (1920), in Dahlia Lithwick, *What are the Rights of Dead People?*, Slate Magazine, Mar. 14, 2002, (Apr 18, 2018), http://www.slate.com/articles/news\_and\_politics/jurisprudence/2002/03/habeas\_corpses.html.

<sup>&</sup>lt;sup>30</sup> ROBERT F. FEIR, STORED TISSUE SAMPLES: ETHICAL, LEGAL AND PUBLIC POLICY IMPLICATIONS, (University of Iowa Press), 112 (1998).

<sup>&</sup>lt;sup>31</sup> DANIEL SPERLING, POSTHUMOUS INTERESTS: LEGAL AND ETHICAL PERSPECTIVES, (Cambridge University Press), 3 (2008).

dead remains. Showing disrespect to the human body, mutilating the dead body, etc., are considered a crime in most legal systems.<sup>32</sup>

The English law has discussed the question of property rights relating to corpse way back in the 17<sup>th</sup> Century itself.<sup>33</sup> Blackstone has stated:

"Though the heir has a property in the monuments and escutcheons of his ancestors, yet he has none in their bodies or ashes; nor can he bring any civil action against such as indecently at least, if not impiously, violate and disturb their remains, when dead and buried".<sup>34</sup>

Lord Coke has also commented in R v. Lynn,<sup>35</sup>

<sup>&</sup>lt;sup>15</sup> In India, § 297 of Indian Penal Code, 1860, prohibits irreverence to dead bodies, trespassing the burial places, etc. In the United States of America, there are state laws which forbid abuse of corpses. They vary from state to state, but in essence they all outlaw two things: treating a corpse in a way which would outrage family sensibilities and treating a corpse in a way which would outrage community sensibilities. "The cutting of and tampering with a human body amounts to mutilation and deformation of a divinely created body (*muthla*) has clearly been prohibited in Shariah. According to Islamic jurisprudence, the human body, dead or alive has great significance. It is honoured and sacred, and because of the sanctity that is attached to it, it will be unlawful to tamper with it, cut parts of it or dishonour it in any way". (Apr18, 2018), http://www.daruliftaa.com/node/5896. Under International Law, the obligation to take all possible measures to prevent the dead from being despoiled (or pillaged) was first codified in the 1907 Hague Convention. Convention (IV) Respecting the Laws and Customs of War on Land and its Annex: Regulations Concerning the Laws and Customs of War on Land (1907 Hague Convention IV), signed on 18th October 1907, (Apr. 18, 2018) https://ihl-databases. icrc.org/ihl/INTRO/195. It was later affirmed in the Geneva Conventions, 1949. It is also contained in Additional Protocol I, of the Geneva Conventions, 1949, albeit in more general terms of 'respecting' the dead, which includes the notion of preventing the remains from being despoiled. Part II, Section III, Protocol Additional to the Geneva Conventions of Aug. 12, 1949, and Relating to the Protection of Victims of International Armed Conflicts (Protocol I) of Jun. 8, 1977, https://www.icrc.org/eng/assets/files/other/icrc\_002\_0321.pdf. Further, Rule 113 of Customary International Humanitarian Law, codified by ICRC, states that each party to the conflict must take all possible measures to prevent the dead from being despoiled. Mutilation of dead bodies is prohibited. IHL Database, (Apr. 18, 2018), https://ihl-databases.icrc.org/ customary-ihl/eng/docs/v1\_rul\_rule113.

<sup>&</sup>lt;sup>33</sup> Property right in the human body was reportedly first denied in 1614 in the *Haynes*'s Case.

<sup>&</sup>lt;sup>34</sup> WILLIAM BLACKSTONE, COMMENTARIES ON THE LAWS OF ENGLAND, Book II, (University of Chicago Press), 429 (1979).

<sup>&</sup>lt;sup>35</sup> (1788) 2 TR 733; 100 ER 394. It was held that "under Common Law, it was a misdemeanour to exhume a dead body, even for honourable reasons, without the authority of a court".

"It is to be observed that in every sepulchre that hath a monument two things are to be considered, *vis.*, the monument, and the *sepulchre* or burial of the dead. The burial of the cadaver, that is *caro dato vermibus*<sup>36</sup>, is *nullius in bonis*<sup>37</sup>, [among the property of no person] and belongs to the ecclesiastical cognizance...".

In general, the Common Law did not recognise property in human corpse earlier,<sup>38</sup> though in the later centuries exceptions to this 'no property in corpse' rule has been diluted.<sup>39</sup>

The body is undeniably a 'thing', but there is a peculiar difference between a living body and a dead one: so much the same, and yet so different. Even in this 21<sup>st</sup> century, it is difficult to think that the body of a person loses its significance soon after the death. To have property right in the human body is to have power to make decisions about the fate and use of the body.<sup>40</sup> The dead body is not

<sup>&</sup>lt;sup>36</sup> "Flesh given to worms", *See*, CARL ZOLLMANN, AMERICAN CIVIL CHURCH LAW, (The Lawbook Exchange Ltd., New Jersey), 435 (2008).

<sup>&</sup>lt;sup>37</sup> "In no man's ownership", ANDREW FITZMAURICE, SOVEREIGNTY, PROPERTY AND EMPIRE, 1500-2000, (Cambridge University Press), 54 (2014).

<sup>&</sup>lt;sup>38</sup> For a detailed discussion, *See*, Chapter III.

<sup>&</sup>lt;sup>39</sup> *Quick v. Coppleton*, 83 Eng. Rep. 349 (K.B. 1803); *R. v. Cheere*, 107 Eng. Rep. 1294 (K.B. 1825), both the cases recognised a property interest in dead bodies. A creditor may arrest the body of a deceased debtor for debts owed. *Doodeward v. Spence*, (1908) 6 CLR 406, the Australian High Court held that "there is a distinction between a mere corpse awaiting burial and a body or part of a body that had, through work and skill, acquired some attributes differentiating it from the corpse". In *Doodeward*, the Court had to decide whether there was a property in the corpse of a two-headed baby that had been stored in a jar and exhibited by the plaintiff, a showman. Later in *R. v. Kelly*, [1998] All ER 741, the English Court held that "material subjected to processing acquired the attributes of property". Body parts stored in jars at the Royal College of Surgeons were held to be the property of the college and hence it could bring an action for theft.

<sup>&</sup>lt;sup>40</sup> Prue Vines, *The Sacred and the Profane: The Role of Property Concepts in Disputes about Post-mortem Examination*, 9 Syd. L. Rev., 236 (2007).

treated as a mere 'thing' and its treatment and disposal after death continue to turn on issues of human dignity and respect.

## 1.3.1.1. DEFINING 'DEATH'

Throughout history, cutting across cultures, the moment of death is held great fascination. The change in status from living person to corpse is not a mere clinical phenomenon, it has profound psychological, legal, moral, religious, and economic implications. However, the advent of medical technology has raised a new set of troublesome questions regarding the dividing line between life and death. Technology has made the determination of death more difficult and important. Even though cardiopulmonary criteria of death still hold good, the progress in medical technologies and life support systems with the capacity to prolong life has diminished the importance of the same, which was earlier used to determine the dividing line between life and death. Such a prolonging of life solely based on the life support systems has raised significant questions regarding the quality of life of a person. At the same time, it has also opened up the opportunity for procurement of the organs which could be utilized for transplantation.<sup>41</sup> Thus distinguishing between life and death has become harder in a high-tech medical society than it was in a primitive society.<sup>42</sup> The advent of the artificial respirator, along with sophisticated techniques for sustaining life in comatose patients has transformed the 'simple' process of dying. Medical

<sup>&</sup>lt;sup>41</sup> THE DEFINITION OF DEATH: CONTEMPORARY CONTROVERSIES, (Stuart J. Youngner, Robert M. Arnold, et.al., eds.), (The John Hopkins University Press), 14 (1999).

<sup>&</sup>lt;sup>42</sup> J. K. MASON & G. T. LAURIE, MASON AND MC'CALL SMITH'S LAW AND MEDICAL ETHICS, (8<sup>th</sup> edn., Oxford University Press), 521 (2011).

science has become capable of supporting the biological functions of such patients for long periods of time, even in the complete absence of brain function.<sup>43</sup>

Today, the line between death and life looks blurred and it should be drawn according to scientific criteria.<sup>44</sup> Death is no longer a natural phenomenon; for modern human beings, it is now no more than an artificial manipulation based on the market's need for body parts.<sup>45</sup>

Clinically, death is defined as the complete and permanent cessation of circulation, respiration and functions of the brain. It is the irreversible cessation of all vital functions especially as indicated by permanent stoppage of the heart, respiration, and brain activity.<sup>46</sup> Normally diagnosis of death was not difficult. But in the modern context, determination of death becomes important in the case of organ transplantation. For a successful transplant, the organs have to be procured immediately after the death of the donor.<sup>47</sup> After death, the organs will

<sup>&</sup>lt;sup>43</sup> Jay A. Friedman, *Taking the Camel by the Nose: The Anencephalic as a Source for Paediatric Organ Transplants*, in ORGAN AND TISSUE TRANSPLANTATION, (David Price, ed.), (The International Library of Medicine, Ethics and Law, Ashgate), 926 (2006).

 <sup>&</sup>lt;sup>44</sup> Tia Ghose, *Clinically Dead?: The Blurred Line Between Life and Death*, Live Science, Jun.
 19, 2014, (Aug. 17, 2018), https://www.livescience.com/46418-clinical-death-definitions.html.
 <sup>45</sup> Jongho Kim, *The Philosophical, Ethical, and Legal Challenges Toward Biopolitics on the Commercializing Human Body Parts*, (May 27, 2015), http://works.bepress.com/jongho\_kim/1/.

<sup>&</sup>lt;sup>46</sup> Robert D. Truog, *Is it Time to Abandon Brain Death?*, 27 Hastings Centre Report, in, ORGAN AND TISSUE TRANSPLANTATION, (David Price, ed.), (The International Library of Medicine, Ethics and Law, Ashgate), 29 (2006).

<sup>&</sup>lt;sup>47</sup> Jean-Paul Pirnay, et al., *Access to Human Tissues for Research and Product Development: From EU Regulation to Alarming Legal Developments in Belgium*, 16 EMBO Reports, 557-562 (2015), (Apr. 17, 2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4428037/pdf/ embr0016-0557.pdf.

undergo molecular changes and the viability will be lost immediately, except in the case of some tissues like the cornea.<sup>48</sup> In other words, organs can be retrieved productively only from a 'beating heart donor'.<sup>49</sup>

The definition of death consists of not only the biological and the medical but also the legal and ethical elements; especially when it comes to organ or tissue procurement and transplantation. <sup>50</sup> The current definitions of death is not comprehensive enough to answer all legal and ethical questions with regard to procurement of organs and tissues from the dead human body.<sup>51</sup> The need for defining death by revisiting the question of when death occurs came with the desire to procure transplantable organs or tissues before the decay of the 'dead body'.<sup>52</sup>

<sup>&</sup>lt;sup>48</sup> "In corneal transplantation, the storage time for transplantation limited to 1–4 weeks". *See*, Jean-Paul Pirnay, et al., *Access to Human Tissues for Research and Product Development: From EU Regulation to Alarming Legal Developments in Belgium*, 16 EMBO Reports, 557-562 (2015), (Apr. 17, 2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4428037/pdf/embr00 16-0557.pdf.

<sup>&</sup>lt;sup>49</sup> D. W. McKeown, R. S. Bonser, et al., *Management of the Heart Beating Brain-Dead Organ Donor*, 108 BJA, 96 (2012), (Jul. 13, 2015), https://doi.org/10.1093/bja/aer351.

<sup>&</sup>lt;sup>50</sup> Medical-Ethical Guidelines approved by the Senate of the Swiss Academy of Medical Sciences on the Determination of Death in the Context of Organ Transplantation, May 2011, (Jan. 14, 2016), https://www.samw.ch/dam/jcr.../guidelines\_sams\_determination\_death\_ 2011 .pdf.

<sup>.</sup>pdf. <sup>51</sup> JONATHAN HERRING, MEDICAL LAW AND ETHICS, (Oxford University Press, 3<sup>rd</sup> edn.), 464 (2010).

<sup>&</sup>lt;sup>52</sup> Alan Rubenstein, Eric Cohen, et al., *The Definition of Death and the Ethics of Organ Procurement from the Deceased*, (2006), (May. 12, 2016), https://bioethicsarchive.George town.edu/pcbe/background/rubenstein.html.

The purpose of defining brain-stem death<sup>53</sup> itself is for the procurement of organs and tissues for transplantation.<sup>54</sup> The concept of 'brain death'<sup>55</sup> was proposed as one means by which all of the requirements for a definition of death could be reconciled for the purpose of facilitating organ/tissue procurement. In the case of brain death, though there is a complete and irreversible loss of all brain function, the heart will be still beating thus making it the right time to procure organs from the deceased's body.<sup>56</sup> Therefore, today, it is an accepted notion that even if a person's heart is beating, he may be declared as 'brain-stem dead'.<sup>57</sup> In simple words, a person is brain dead when all the functions of the brain cease. So, determination of death is really important as the status of the human body 'just before' and 'soon after' are different.

<sup>&</sup>lt;sup>53</sup> "Irreversible cessation of cerebral and brain stem function; characterized by absence of electrical activity in the brain, blood flow to the brain, and brain function as determined by clinical assessment of responses. A brain dead person is dead, although his or her cardiopulmonary functioning may be artificially maintained for some time.", WHO, Global Glossary of Terms and Definitions on Donation and Transplantation, 8 (2009), (Jun. 18, 2018), http://www.who.int/transplantation/activities/GlobalGlossaryonDonationTransplantat ion.pdf? ua=1. They are also known as 'beating-heart cadavers'. "Their hearts are still beating. They urinate. Their bodies don't decompose and they are warm to the touch; their stomachs rumble, their wounds heal and their guts can digest food. They can have heart attacks, catch a fever and suffer from bedsores. They can blush and sweat – they can even have babies", Zaria Gorvett, *The Macabre Fate of 'Beating Heart Corpses'*, (Nov. 04, 2016), BBC Future, (Jul. 14, 2017), http://www.bbc.com/future/story/20161103-the-macabre-fate-of-beating-heart-corpses.

<sup>&</sup>lt;sup>54</sup> Alan Rubenstein, Eric Cohen, et al., *The Definition of Death and the Ethics of Organ Procurement from the Deceased*, (2006), (May. 12, 2016), https://bioethicsarchive.George town.edu/pcbe/background/rubenstein.html.

<sup>&</sup>lt;sup>55</sup> § 2 (d) of the Transplantation of Human Organs Act, 1994, of India defines "brain-stem death as the stage at which all functions of the brain-stem have permanently and irreversibly ceased" and is so certified under § 3 (6) of the Act.

<sup>&</sup>lt;sup>56</sup> JONATHAN HERRING, MEDICAL LAW AND ETHICS, (3<sup>rd</sup> edn., Oxford University Press), 464 (2010).

<sup>&</sup>lt;sup>57</sup> Though the term 'brain-stem death' is defined by various statutes, the definition given by the Uniform Determination of Death Act, 1980, of the United States of America seems to be the most appropriate. § 1 explains 'determination of death' as "an individual who has sustained either (1) irreversible cessation of respiratory and circulatory functions, or (2) irreversible cessation of all functions of the entire brain, including the brain stem, is dead".

## 1.3.2. LAW IN RELATION TO A LIVING HUMAN BODY

Advancements in medical science and biotechnological research has given rise to new definitions and uses for the human body and the bodily materials in the recent years. The human body and the materials that are procured from it have become potentially valuable commodities. Therefore, the ownership of the human body and body parts is a recurring subject in contemporary bioethical debates. The law concerning property in the human body and its parts is complex and at present under the state of evolution.<sup>58</sup> Whether a live human body and the materials procured from a living human body can be treated as subject of property is a legal and ethical question of significance in the present scenario.

There was a time when human beings were considered as an 'object' which could be 'owned, possessed, alienated and used for enjoyment' just like any other property.<sup>59</sup> Slavery is a classic ownership model for regarding live human beings as property.<sup>60</sup> Modern world abolished this trade in human beings<sup>61</sup> because it was agreed that the degradation of individual rights is unacceptable.<sup>62</sup> Though

<sup>&</sup>lt;sup>58</sup> PRINCIPLES OF MEDICAL LAW, (Andrew Grubb, Judith Laing, et al., eds.), (Oxford University Press), 1036 (2010).

<sup>&</sup>lt;sup>59</sup> In ancient and medieval society, human beings were traded just like livestock.

<sup>&</sup>lt;sup>60</sup> For long centuries, human beings were treated as slaves. The abolition of slavery in the Western world was not brought about until the 19<sup>th</sup> century.

<sup>&</sup>lt;sup>61</sup> Article 4 of the Universal Declaration of Human Rights, 1948, New York: United Nations, (Sept. 30, 2014), http://www.un.org/en/universal-declaration-human-rights/.

<sup>&</sup>lt;sup>62</sup> REMIGIUS N. NWABUEZE, BIOTECHNOLOGY AND THE CHALLENGE OF PROPERTY: PROPERTY RIGHTS IN DEAD BODIES, BODY PARTS, AND GENETIC INFORMATION, (Ashgate), 14 (2007).

slavery has been abolished in almost all parts of the world,<sup>63</sup> slavery exists in the modern world in new forms.<sup>64</sup>

Human beings are trafficked and traded in markets for monetary consideration.<sup>65</sup> Market developments in recent years has brought up the question whether the human body and its parts are to be given the status of property. The status of property would allow the commercial transactions of human beings again, this time perhaps not the human being as a whole, but various parts of the human body.

Within the past several decades, medicine and biotechnology have revolutionized the uses of the human body.<sup>66</sup> Today, each and every part of the human body have a distinct and important status in the market. "The true reason for the unique worth which the body now has is the newly discovered capacity

<sup>&</sup>lt;sup>63</sup> "Slavery was abolished by most countries 150 years ago, but bonded and forced labour, trafficking and exploitation persist". *See, Modern Day Slavery: An Explainer*, The Guardian, Apr. 03, 2013, (Feb. 12, 2018), https://www.theguardian.com/global-development/2013/apr/03/modern-day-slavery-explainer.

<sup>&</sup>lt;sup>64</sup> United Nations, in the Protocol to Prevent, Suppress and Punish Trafficking in Persons, Especially Women and Children, (Palermo Protocol), Supplementing the United Nations Convention against Transnational Organized Crime, 2000, defines 'human trafficking' as "exploitation with the purpose of the prostitution of others or other forms of sexual exploitation, forced labour or services, slavery or practices similar to slavery, servitude or the removal of organs", (Apr. 06, 2018), http://www.ohchr.org/EN/ProfessionalInterest/Pages/Protocol TraffickingInPersons.aspx.

<sup>&</sup>lt;sup>65</sup> Namitha Bhandare, *Trafficking is the Fastest Growing Black Market Trade and it's all Around Us*, Hindustan Times, Dec 02, 2016, (May 02, 2018), https://www.hindustantimes. com/columns/trafficking-is-the-fastest-growing-black-market-trade-and-it-s-all-around-us/sto ry-lfLzW7pRpmEwqrU7RPjuPJ.html.

<sup>&</sup>lt;sup>66</sup> Kaan Sheung Hung Terry, *Rights, Ethics and Commercialisation of Human Body*, S.J.L.S, 483 (2000).

of its tissues and organs to cure disease and repair defective bodies."<sup>67</sup> Thus, the commercial exploitation of the human body enabled through technology raises questions on its legal status as property.

The demand for the human body and its parts has increased, and the supply shortage has grown more severe.<sup>68</sup> Therefore, people seek out measures to alleviate this shortage. A set of people essentially challenging those with traditional views about human bodies are making efforts to commercialize human bodies so as to efficiently reap the benefits of bioengineering and to satisfy the market demand. Notwithstanding the efforts to protect the body and its parts as a sacrosanct realm, markets have evolved in tissue, organs, and other body parts, as these human parts constitute the raw material for multiple industries.<sup>69</sup>

Multidimensional biomedical uses of the human body, driven by progress in organ and tissue transplantation, assisted reproductive technologies (hereinafter referred to as ART), research involving human stem cells (hereinafter referred as hSC) and human embryonic stem cells (hereinafter referred to as hESC), cloning, gene therapy, etc., necessitates the examination of the scope of property

<sup>&</sup>lt;sup>67</sup> Remigius N. Nwabueze, *Legal Paradigms of Human Tissues*, in HUMAN TISSUE RESEARCH: A EUROPEAN PERSPECTIVE ON THE ETHICAL AND LEGAL CHALLENGES, (Christian Lenk, Nils Hoppe et al., eds.), (Oxford), 88 (2011).

<sup>&</sup>lt;sup>68</sup> Organ Donors Still Scarce, WHO, (Mar. 24, 2018), http://www.who.int/mediacentre /multimedia/podcasts/2010/organ\_transplants\_20100806/en/, See, Simon Bramhall, Presumed Consent for Organ Donation: A Case Against, 93 Ann. R. Coll. Surg. Engl., 270 (2011), (Oct. 26, 2016), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3363073/.

<sup>&</sup>lt;sup>69</sup> Elizabeth E. Appel Blue, *Redefining Stewardship Over Body Parts*, 21 J. of Law & Health, 75, 77 (2008).

rights in the human body and bodily materials.<sup>70</sup> "Developments in medical science now require a re-analysis of the Common Law's treatment of and approach to the issue of ownership of parts or products of a living human body..."<sup>71</sup>

Therefore, sometimes "the body is treated as an object of property, sometimes it is dealt with under the rubric of contract, and sometimes it is not conceived as property at all, but rather as the subject of privacy rights".<sup>72</sup> But it can be seen that law is slowly recognising that the source<sup>73</sup> may have some legal rights regarding their own bodily material. The ensuing chapters analyses the growing legislative framework and judicial pronouncements across the world while deciding questions relating to property rights in the human body and its parts.

## **1.4. DEFINING HUMAN BODILY MATERIAL**

Human bodily material<sup>74</sup> includes, but are not limited to, blood, urine, saliva, or other bodily fluids; tissues; hair or nails; sperm, oocytes, and products of

<sup>&</sup>lt;sup>70</sup> Richard Taylor, *Human Property: Threat or Saviour?*, 9 MurUEJL, 44 (2012), (Sep. 12, 2015), http://www5.austlii.edu.au/au/journals/MurUEJL/2002/44.html.

<sup>&</sup>lt;sup>71</sup> Yearworth v. NHS Trust, (2009) EWCA Civ. 37.

<sup>&</sup>lt;sup>72</sup> Radhika Rao, *Genes and Spleens: Property, Contract or the Privacy Rights in the Human Body*, 35 J. L. Med. & Ethics, 371 (2007).

<sup>&</sup>lt;sup>73</sup> A person from whose body, a biomaterial is sourced for transplantation or for research is referred to as a source person.

<sup>&</sup>lt;sup>74</sup> In Belgium, the statute on the Procurement and Use of Human Body Material Destined for Human Medical Applications or for Scientific Research Purposes, 2008 defines 'human bodily material' as "any biological body material, including human tissues and cells, gametes, embryos and foetuses, as well as substances extracted there from, whatever the degree to which they have been processed", Jean-Paul Pirnay et al., *Access to Human Tissues for Research and Product Development: From EU Regulation to Alarming Legal Developments in Belgium*, 16 EMBO Reports 557-562 (2015), (Apr. 17, 2018), https://www.ncbi.nlm.nih.gov/pmc/articles/ PMC4428037/pdf/embr0016-0557.pdf.

conception such as placenta or umbilical cord; excess pathological tissue; and waste surgical leftover.<sup>75</sup> A wide range of human bodily material may be provided by one person for the treatment of others, or for medical research that aims to improve medical treatment in the future.<sup>76</sup>

Human bodily materials including cells, biopsy specimens, organs and tissues removed during surgeries, surgical left-overs, etc., are used for various research activities. These researches mainly focus on the development of knowledge about diseases and also to develop better means of preventing, diagnosing, and treatment.<sup>77</sup>

According to the Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans,<sup>78</sup> human biological materials include "tissues, organs, blood, plasma, skin, serum, DNA, RNA, proteins, cells, hair, nail clippings, urine, saliva

<sup>&</sup>lt;sup>75</sup> Use of Human Biological Materials in Research, Office of Human Subject Research, John Hopkins Medicine, (July 12, 2014), http://www.hopkinsmedicine.org/institutional\_review\_board/guidelines policies/guidelines/bio\_mats.html.

<sup>&</sup>lt;sup>76</sup> *Human Bodies: Donation for Medicine and Research*, Nuffield Council on Bioethics, (July 12, 2017), http://nuffieldbioethics.org/wp-content/uploads/Donation\_Chapter1\_Overview1.pd f.

<sup>&</sup>lt;sup>77</sup> Research Involving Human Biological Materials: Ethical Issues and Policy Guidance Executive Summary, (July 12, 2017), https://bioethicsarchive.georgetown.edu/nbac/hbm\_ exec. pdf.

<sup>&</sup>lt;sup>78</sup> Tri-Council Policy Statement on Ethical Conduct on Research Involving Humans, by the Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, Social Sciences and Humanities Research Council of Canada, Dec., 2014, (May 27, 2015), http://www.pre.ethics.gc.ca/pdf/eng/tcps2-2014/TCPS\_2\_FINAL\_Web.pdf.

and other body fluids".<sup>79</sup> As per this policy, human biological materials are classified as:

- 1. Identified human biological materials,<sup>80</sup>
- 2. Coded human biological materials,<sup>81</sup>
- 3. Anonymized human biological materials,<sup>82</sup> and
- 4. Anonymous human biological materials.<sup>83</sup>

Section 53 (1) of the United Kingdom Human Tissues Act, 2004 (hereinafter referred as HTA) states that the statute is concerned with "material, other than gametes, which consists of, or includes human cells". In HTA, references to relevant material from a human body do not include embryos outside the human body, or hair and nail from the body of a living person.<sup>84</sup> The Human Tissue Authority constituted under the HTA classifies bodily materials as follows:<sup>85</sup>

1. Specifically identified relevant material,<sup>86</sup>

<sup>&</sup>lt;sup>79</sup> Panel on Research Ethics, Government of Canada, *Human Biological Material*, Chapter 12, (July 7, 2015), http://www.pre.ethics.gc.ca/eng/policypolitique/initiatives/tcps2-eptc2/chapter 12-chapitre12/.

<sup>&</sup>lt;sup>80</sup> The materials are labelled with a direct identifier (e.g., name, personal health number). Materials and any associated information are directly traceable back to a specific individual.

<sup>&</sup>lt;sup>81</sup> Direct identifiers are removed from the materials and replaced with a code. Depending on access to the code, it may be possible to re-identify specific individuals (e.g., a principal investigator retains a key that links the coded material with a specific individual if re-linkage is necessary).

<sup>&</sup>lt;sup>82</sup> The materials are irrevocably stripped of direct identifiers, a code is not kept to allow future re-linkage, and risk of re-identification of individuals from remaining indirect identifiers is low or very low.

<sup>&</sup>lt;sup>83</sup> The materials never had identifiers attached to them and risk of identification of individuals is low or very low.

<sup>&</sup>lt;sup>84</sup> § 53 (2) of HTA.

<sup>&</sup>lt;sup>85</sup> Human Tissue Authority, *Relevant Material Under the Human Tissue Act, 2004*, (Apr. 18, 2016), https://www.hta.gov.uk/policies/relevant-material-under-human-tissue-act-2004.

<sup>&</sup>lt;sup>86</sup> This includes material such as bodies, organs and tissues, consisting largely or entirely of cells, and are clearly identifiable.

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- 2. Processed material,<sup>87</sup>
- 3. Bodily waste products (including excretions and secretions)<sup>88</sup>, and
- 4. Cell deposits and tissue sections on microscope slides.<sup>89</sup>

According to the Human Tissue Authority, bile, blood, bone marrow, breast milk, saliva, puss, mucus, platelets, human organs; products of conception other than foetus; hair and nails from deceased persons, etc. are considered to be human materials which are relevant for the purpose of the HTA.<sup>90</sup> Thus, "if a sample is known to contain even a single cell that has come from a human body", then the sample is to be classified as relevant material under the HTA.<sup>91</sup>

In India, under the Transplantation of Human Organs Act, 1994 (hereinafter referred as THOA), the term human biological material has not been defined. But Section 2 (oa) of THOA<sup>92</sup> has defined the term 'tissue' as a "group of cells, except blood, performing a particular function in the human body".

<sup>&</sup>lt;sup>87</sup> Material made as a result of a process.

<sup>&</sup>lt;sup>88</sup> The HTA considers that bodily waste should normally be regarded as relevant material.

<sup>&</sup>lt;sup>89</sup> In general, cell deposits or tissue sections on microscope slides are considered to constitute relevant material. This is because such deposits or sections are likely to contain whole cells or are intended to be representative of whole cells. Human Tissue Authority, *Relevant Material under HTA*, 2004, (Mar. 14, 2016), https://www.hta.gov.uk/policies/relevant-material-under-human-tissue-act-2004.

<sup>&</sup>lt;sup>90</sup> To supplement the HTA's information about relevant material, a list has been produced to provide stakeholders with further guidance on whether specific materials fall within the definition of relevant material under the HTA. Human Tissue Authority, *Relevant Materials under HTA*, 2004, (Mar. 14, 2016), https://www.hta.gov.uk/policies/relevant-material-under-human-tissue-act-2004.

<sup>&</sup>lt;sup>91</sup> Subject to the exception mentioned in § 53 (2).

<sup>&</sup>lt;sup>92</sup> Inserted by the Transplantation of Human Organs (Amendment) Act, 2011.

In United States of America, amendment made in 2006 to the Uniform Anatomical Gift Act, 1987<sup>93</sup> (hereinafter referred to as UAGA) defines the term 'part' as "an organ, an eye, or tissue of a human being. The term does not include the whole body."<sup>94</sup> Further Clause 30 of the Section 2 defines the term 'tissue'. It means, "a portion of the human body other than an organ or an eye. The term does not include blood unless the blood is donated for the purpose of research or education".

For the purpose of this study, 'human bodily material' is the term used to denote all human materials including human organs, tissues, cells or fluids taken from the human body, which is either regenerative or non-regenerative. It therefore refers to both regenerative substances such as blood, bone marrow, hair, urine, perspiration, saliva, semen, etc., and non-regenerative substances such as organs or oocytes.

## **1.5.** CLASSIFICATION OF HUMAN BODILY MATERIALS

Human bodily materials can be divided and classified on various basis. It can be on the basis of source from which a human material is procured, i.e., a cadaver, a living person or a brain-stem dead person. It can be classified on the basis of the nature of the material taken, purpose for which it is extracted, etc.

<sup>&</sup>lt;sup>93</sup> § 1 (7) of the Uniform Anatomical Gift Act, 1987 defined the term 'part' as "an organ, tissue, eye, bone, artery, blood, fluid or other portion of a human body."
<sup>94</sup> § 2 (18) of the UAGA Amendment Act, 2006.

Various human tissues are obtained for various purposes in a variety of ways. Blood, skin, hair, organs, corneal tissue, gametes, etc., are often taken for various purposes.

"Blood may be donated or sold by living persons for use in transfusion or for research. Hair may be sold by living persons for wig makers, or placental tissue collected after childbirth for cosmetics manufacturers. Surgical procedures may result in pathological samples taken both for diagnostic purposes and for long storage for both clinical uses related to the patient and research uses going far beyond the patient's lifetime. These tissues may also be manipulated to create replicating cell lines that have characteristics resulting both from the underlying tissue and from the laboratory manipulation. Gametes (sperm and eggs) and foetal tissue from abortions and miscarriages are also collected from donors and transferred to others".<sup>95</sup>

## **1.5.1.** CLASSIFICATION ON THE BASIS OF SOURCE

Human bodily materials can be classified firstly on the basis of the source from which such material is procured. That is, materials, tissues, organs, etc., can be collected from living human beings, brain stem dead persons, from cadavers and even from aborted foetuses. The ethical implications of procuring materials from these four categories of sources, differs.

<sup>&</sup>lt;sup>95</sup> R. Alta Charo, *Skin and Bones: Post-Mortem Markets in Human Tissue*, 26 Nova L. Rev., 421, 423 (2002).

### 1.5.1.1. CADAVER AS A SOURCE OF HUMAN MATERIAL

The cadaver is used in medical colleges for anatomical studies.<sup>96</sup> Apart from that, cadaver can be a potential donor of various bodily materials including heart, liver, kidney, corneal tissue, etc.<sup>97</sup> Several human organs/ tissues can be taken for transplantation from a cadaver. But in recent years there has been a drop in the number of dead donors, largely due to better medical treatment preventing early deaths and fewer fatal road accidents.<sup>98</sup> This has intensified the need to consider the legal changes and the option of alternative systems of acquisition.<sup>99</sup> The main legal and ethical issue relating to the organ/tissue transplants from the dead circulates around the issues of consent to donate the human organs.<sup>100</sup>

## 1.5.1.2. BRAIN-STEM DEAD PERSONS AS A SOURCE OF HUMAN MATERIALS

Apart from the conventional type of death,<sup>101</sup> medical science has recognised the concept of 'brain- death' or more precisely, 'brain-stem death' in order to facilitate organ procurement. They are also known as heart-beating cadavers.<sup>102</sup>

<sup>&</sup>lt;sup>96</sup> Erich Brenner, *Human Body Preservation - Old and New Techniques*, 224 J. Anat., 316 (2014), (Jan. 31, 2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3931544/.

<sup>&</sup>lt;sup>97</sup> "Tissues from a deceased donor may be transplanted into as many as 100 people", *Human Tissues and Cells for Transplantation*, European Directorate for the Quality of Medicines and Health, Council of Europe, (Jul. 18, 2018), https://www.edqm.eu/en/human-tissues-and-cells-1522.html.

<sup>&</sup>lt;sup>98</sup> J. K. MASON & G. T. LAURIE, MASON AND MCCALL SMITH'S LAW AND MEDICAL ETHICS, (8<sup>th</sup> edn., Oxford University Press), 550 (2011).

<sup>&</sup>lt;sup>99</sup> SHAUN D. PATTINSON, MEDICAL LAW AND ETHICS, (3<sup>rd</sup> edn., Sweet & Maxwell, South Asian Edition), 467 (2013).

<sup>&</sup>lt;sup>100</sup> For a detailed discussion, *see* Chapter VII.

<sup>&</sup>lt;sup>101</sup> Death is defined as "complete cessation of respiration and circulation", THE DEFINITION OF DEATH: CONTEMPORARY CONTROVERSIES, (Stuart J. Youngner, Robert M. Arnold, et al., eds.), (The John Hopkins University Press), 14 (1999).

<sup>&</sup>lt;sup>102</sup> SHAUN D. PATTINSON, MEDICAL LAW AND ETHICS, (3<sup>rd</sup> edn., Sweet & Maxwell, South Asian Edition), 467 (2013).

Today, through artificial means, a patient's oxygen supply and heartbeat can be maintained even after his brain is dead. Once brain stem cells are damaged, the brain function cannot be replaced by current medical or mechanical devices. Thus, a patient suffering from irreversible cessation of brain-stem function, is termed as 'brain-stem dead'.

The re-usable potential of body parts progressively deteriorates during the dying process and some organs are not transplantable unless they are removed from a body with a beating heart.<sup>103</sup> Hence, a brain-stem dead person is a potential source of all transplantable human organs and tissues. Organs and tissues can be taken from such a person because they continue to live<sup>104</sup> even after the brain is dead.<sup>105</sup>

#### **1.5.1.3.** LIVING HUMAN BEING AS A SOURCE OF HUMAN MATERIALS

A living human being can also donate various bodily materials and organs, except the vital organs. A live donor can donate certain body parts such as a kidney, liver lobes, lung lobes, pancreas segments, bone marrow, blood, sperms,

<sup>&</sup>lt;sup>103</sup> J. Savulescu, *Death, Us and Our Bodies: Personal Reflections*, 29 J. Med. Ethics, 127 (2003), (Mar. 20, 2014) http://jme.bmj.com/content/29/3/127.full.

<sup>&</sup>lt;sup>104</sup> "In multicellular organisms, death is a gradual process at the cellular level with tissues varying in their ability to withstand deprivation of oxygen. Thus the individual cells of the body are not dead; depending on their specialized needs or characteristics, they will continue to function until their residual oxygen is exhausted", *See*, J. K. MASON & G. T. LAURIE, MASON AND MCCALL SMITH'S LAW AND MEDICAL ETHICS, (8<sup>th</sup> edn., Oxford University Press), 522 (2011).

<sup>&</sup>lt;sup>105</sup> J. Savulescu, *Death, Us and Our Bodies: Personal Reflections*, 29 J. Med. Ethics, 127 (2003), (Mar. 20, 2014) http://jme.bmj.com/content/29/3/127.full.

ovum, skin, etc.<sup>106</sup> Removal of blood and certain other bodily materials are easy and less risky when compared to that of removal of whole or parts of solid organs. In addition to the inevitable pain and scarring, having a solid organ removed carries the risk of mortality, morbidity, psychological harm, and long term complications.<sup>107</sup> The important ethical and legal issues that revolves around a living organ/tissue donation is the questions of 'bodily autonomy' and 'appropriate consent' of the person concerned.

#### 1.5.1.4. ABORTED FOETUSES AS A SOURCE OF HUMAN MATERIALS

Human tissues and cells for various research activities can be procured even from the aborted foetuses.<sup>108</sup> The legal status of the human foetus becomes important in the context of considering it as a potential donor of human materials for research. The ethical and legal questions arising out of the use of foetal tissues are entirely different from that of adult beings, either living or dead. Aborted foetus can be a potential source of tissues for transplantation. The female foetuses can be used for the procurement of female gametes for using it for Assisted Reproductive Techniques. In such situations, mother of that child who is born using such artificial methods will be an unborn foetus!<sup>109</sup>

<sup>&</sup>lt;sup>106</sup> *The Living Donation Process*, U.S. Government Information on Organ Donation and Transplantation, (Sep. 1, 2016), https://www.organdonor.gov/about/process/living-donation. html.

<sup>&</sup>lt;sup>107</sup> SHAUN D. PATTINSON, MEDICAL LAW AND ETHICS, (3<sup>rd</sup> edn., Sweet & Maxwell, South Asian Edition), 468 (2013).

<sup>&</sup>lt;sup>108</sup> For a detailed discussion, *see* chapter V.

<sup>&</sup>lt;sup>109</sup> Stephanie A. Gangon, *Moral Limits of Markets: Implications for the Commodification of Oozytes*, (Dec. 21, 2014) https://philpapers.org/rec/GAGMLO.

"Tissue transplants from aborted foetus may restore functions in person suffering from degenerative neurological diseases, from diabetes and from a variety of blood and immune system disorders. Although still highly experimental, the clinical potential of foetal tissue warrants further investigation."<sup>110</sup> The pro-life activists fear that it will legitimise and encourage abortion. Others foresee women becoming pregnant and aborting to produce foetal tissue, probably creating a market for abortion.<sup>111</sup>

#### 1.5.2. CLASSIFICATION ON THE BASIS OF NATURE OF THE BODILY MATERIAL

Another classification of bodily materials can be made on the basis of the nature of the bodily material collected. Bodily materials may be collected from a source person either for biomedical research or for transplantation. Certain tissues like blood, gametes, liver lobes, etc., are regenerative. Whereas, certain other tissues like kidney, heart, corneal tissue, etc., are non-regenerative. The legal and ethical issues concerning the regenerative tissues are simple when compared to that of non-regenerative vital organs such as a heart or a kidney.<sup>112</sup> The reason is that the loss of a kidney can have potential long-term health impact which would not be analogous to the loss of a pint of blood.<sup>113</sup>

<sup>&</sup>lt;sup>110</sup> John A. Robertson, *Fetal Tissue Transplants*, in ORGAN AND TISSUE TRANSPLANTATION, (David Price, ed.), The International Library of Medicine, Ethics and Law, (Ashgate), 391 (2006).

<sup>&</sup>lt;sup>111</sup> John A. Robertson, *Fetal Tissue Transplants*, in ORGAN AND TISSUE TRANSPLANTATION, (David Price, ed.), The International Library of Medicine, Ethics and Law, (Ashgate), 391 (2006).

<sup>&</sup>lt;sup>112</sup> JONATHAN HERRING, MEDICAL LAW AND ETHICS, (4<sup>th</sup> edn., Oxford University Press), 439 (2012).

<sup>&</sup>lt;sup>113</sup> JONATHAN HERRING, MEDICAL LAW AND ETHICS, (4<sup>th</sup> edn., Oxford University Press), 439 (2012).

#### **1.5.2.1. HUMAN GAMETES AND EMBRYOS**

Though the human gametes are regenerative, the ethical and legal issues relating to them are also to be treated differently. With the advancement of reproductive technologies, human gametes have now entered the marketplace as goods, allowing infertile couples to have babies, and providing another source of money for those with excess viable eggs.<sup>114</sup> Human gametes, though considered as a human bodily material, should be treated differently from other bodily materials as it has the potential to give birth to a child who is genetically related to the person providing the material.<sup>115</sup> Therefore, though eggs, sperm and embryos are also treated as human materials, they are treated in a different category from other forms of human body tissues.<sup>116</sup>

#### 1.5.2.2. MATERIALS LIKE HAIR, NAIL, UMBILICAL CORD, PLACENTA, ETC.

The status of certain other bodily materials like blood, bone marrow, hair, nails, umbilical cord, placenta, breast milk, etc., has to be analysed separately. The significance of these bodily materials is, that even if they are removed, there

<sup>&</sup>lt;sup>114</sup> Stephanie A. Gangon, *Moral Limits of Markets: Implications for the Commodification of Oozytes*, (Dec. 21, 2014), https://philpapers.org/rec/GAGMLO.

<sup>&</sup>lt;sup>115</sup> "An organ, be it a kidney or a cornea, is integrated into the body of the transplant recipient, whereas an egg or a sperm will essentially be half of the recipient. Human gametes represents the qualities that define the donor's personhood, and also embodies the essence of the child", Stephanie A. Gangon, *Moral Limits of Markets: Implications for the Commodification of Oozytes*, (Dec. 21, 2014), https://philpapers.org/rec/GAGMLO.

<sup>&</sup>lt;sup>116</sup> The Human Tissue Act, 2004, clearly excludes the use of embryos and gametes from its purview. The control of use of embryos and gametes are covered by the Human Fertilization and Embryology Act, 1990. For detailed discussion, *See* chapters IV & V.

won't be any impact on the human body as such.<sup>117</sup> Human nails and human hair has to be treated differently in cases where it is derived from a live person or from a deceased person. They are also treated as human bodily materials as it is derived from the human body, but they cannot be compared to a kidney or a liver, but still has a commercial value. The umbilical cord, placenta and other products of conception other than the foetus, etc., possess significant commercial value.<sup>118</sup>

"Cord blood<sup>119</sup> is donated for altruistic purposes to be transplanted into persons suffering from diseases that can be cured through transplant of cord blood stem cells."<sup>120</sup> There are certain ethical and legal issues arising in situations wherein the cord blood which is not suitable for transplantation may be discarded as waste, or used for research or may be even used to make blood derived medicines.<sup>121</sup>

Not every 'bodily materials' generate controversy. Therefore assumptions cannot be made that all bodily materials hold some inherent, universal, and

<sup>&</sup>lt;sup>117</sup> "The donation of an organ which will automatically be replaced is much less controversial than the donation of an organ which is not replenished", JONATHAN HERRING, PRINCIPLES OF MEDICAL LAW AND ETHICS, (4<sup>th</sup> edn., Oxford University Press), 427 (2010).

<sup>&</sup>lt;sup>118</sup> Dorothy Nelkin & Lori Andrews, *Homo Economicus: Commercialization of Body Tissue in the Age of Biotechnology*, 28 The Hastings Center Report, 30 (1998), (Jul.12, 2016), http://www.jstor.org/stable/3528230.

<sup>&</sup>lt;sup>119</sup> The umbilical cord is cut soon after the childbirth. The remaining blood is seen in the blood vessels of the placenta and the portion of the umbilical cord that remains attached to it. This blood is called placental blood or umbilical cord blood or in short, 'cord blood'. Cord blood is rich in stem cells, similar to those found in bone marrow and are used for transplantation as an alternative to bone marrow., (Sep. 01, 2018), http://www.national.cordbloodprogram.org/qa/.

<sup>&</sup>lt;sup>120</sup> Carlo Petrini, *Ethical and Legal Considerations Regarding the Ownership and Commercial Use of Human Biological Materials and their Derivatives*, 3 J. Blood Med., 87 (2012), (Apr. 16, 2016), www.ncbi.nlm.nih.gov/pmc/articles/PMC3440234/.

<sup>&</sup>lt;sup>121</sup> Carlo Petrini, *Ethical and Legal Considerations Regarding the Ownership and Commercial Use of Human Biological Materials and their Derivatives*, 3 J. Blood Med., 87 (2012), (Apr. 16, 2016), www.ncbi.nlm.nih.gov/pmc/articles/PMC3440234/.

undeniable moral quality.<sup>122</sup> The most controversial situation arises when "the human biological material that has been donated for altruistic purposes is used to develop products that can potentially be exploited commercially".

## **1.5.3.** CLASSIFICATION ON THE BASIS OF QUANTITY OF MATERIAL TAKEN FROM THE BODY

Classification is also made on the basis of the amount or quantity of material removed from the body. Generally, samples are small portion of tissues collected for research purposes. Organs, which are large portion of tissues are generally collected for transplantation purposes. Another important point which requires attention is the matter of claims which arises in surgical left overs and left over samples in the pathological labs. "During diagnostic procedures larger samples of body fluids and tissues are usually collected than strictly necessary for primary testing, 'just in case'."<sup>123</sup> These excess samples collected and preserved is generally used for the benefit of the source person itself, if any requirements for the same arises in the future. In addition, this leftover material is a rich source of raw material for further research and learning.<sup>124</sup>

<sup>&</sup>lt;sup>122</sup> KLAUS HOEYER, EXCHANGING HUMAN BODILY MATERIAL: RETHINKING BODIES AND MARKETS, (Sept. 13, 2014), http://link.springer.com/chapter/10.1007/978-94-007-5264-1\_5. <sup>123</sup> Paul J. Van Diest, *No Consent Should Be Needed for Using Leftover Body Material for Scientific Purposes*, 21 BMJ, 648 (2002), (Oct. 05, 2012), http://www.ncbi.nlm.nih. gov/pmc/articles/PMC1124166/.

<sup>&</sup>lt;sup>124</sup> Paul J. Van Diest, *No Consent Should Be Needed for Using Leftover Body Material for Scientific Purposes*, 21 BMJ, 648 (2002), (Oct. 05, 2012), http://www.ncbi.nlm.nih. gov/pmc/articles/PMC1124166/.

## **1.5.4.** CLASSIFICATION BASED ON THE PURPOSE OF THE PROCUREMENT OF BODILY MATERIAL

Human materials are donated for the purposes of treatment as well as for research.<sup>125</sup> Sometimes these tissues or organs are extracted specifically for the purposes of treating someone close. Whereas, in certain other cases, the human tissues and organs are just donated without knowing who the recipient would be (if possible) on voluntary donation of human tissue.<sup>126</sup> Most often the human materials removed/ collected during the treatments or surgeries are later used for research purposes with or without the knowledge of the source persons.<sup>127</sup>

Thus, these recent developments involving transplant surgeries and biotechnological researches necessitate a re-examination of the concept of property in the context of the human body and its parts.

<sup>&</sup>lt;sup>125</sup> Carlo Petrini, *Ethical and Legal Considerations Regarding the Ownership and Commercial Use of Human Biological Materials and their Derivatives*, 3 J. Blood Med., 87 (2012), (Apr. 16, 2016), www.ncbi.nlm.nih.gov/pmc/articles/PMC3440234/.

<sup>&</sup>lt;sup>126</sup> Principle 18 of the Directive 2004/23/EC of the European Parliament and of the Council, 2004 states thus: "tissue and cell application programmes should be founded on the philosophy of voluntary and unpaid donation, anonymity of both donor and recipient, altruism of the donor and solidarity between donor and recipient", (Oct. 13, 2017), https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:102:0048:0058:en:PDF.

<sup>&</sup>lt;sup>127</sup> Carlo Petrini, *Ethical and Legal Considerations Regarding the Ownership and Commercial Use of Human Biological Materials and their Derivatives*, 3 J. Blood Med., 87 (2012), (Apr. 16, 2016), www.ncbi.nlm.nih.gov/pmc/articles/PMC3440234/.

## **II. DEFINING PROPERTY**

## **2.1. INTRODUCTION**

The inter relationship between law and property was expressed by Bentham as "Property and law are born together, and die together. Before laws were made, there was no property; take away laws, and property ceases."<sup>1</sup> Society may not exist without property. It would be well-nigh impossible for any society to regulate property relations without a legal system.<sup>2</sup> Concept of property existed throughout history in some or other form. However, different meanings were given to property during different periods and different places. The meaning of property, like forms of property, is not constant and changes from time to time in response to changes in the socio-economic<sup>3</sup> circumstances of a particular society.<sup>4</sup>

During the ancient period when human beings were leading a nomadic life, life of a hunter and a gatherer, the notion of property had simple components. They took whatever resource they wanted from nature and individual property claims focused on weapons, tools, and other personal effects. Livestock was being

<sup>&</sup>lt;sup>1</sup> JEREMY BENTHAM, THEORY OF LEGISLATION, (English Trans. by R. Hildreth, London: Trubner & Co.), 113 (1931).

<sup>&</sup>lt;sup>2</sup> N. S. GOPALAKRISHNAN, INTELLECTUAL PROPERTY AND CRIMINAL LAW, (National Law School of India University), 1 (1994).

<sup>&</sup>lt;sup>3</sup> A fine reading on socio-economic changes reveals that the alleged attributes of many socioeconomic aspects is a creation of the legal systems' fascination for property.

<sup>&</sup>lt;sup>4</sup> REMIGIUS N. NWABUEZE, BIOTECHNOLOGY AND THE CHALLENGE OF PROPERTY: PROPERTY RIGHTS IN DEAD BODIES, BODY PARTS AND GENETIC INFORMATION, (Ashgate), 24 (2007).

treated as property. With gradual shift to settled life centered on agriculture, property rights devolved on household.<sup>5</sup> Then onwards, land was considered to be a form of wealth. The first person who enclosed a piece of land and said - 'this is mine'- is said to be the originator of the notion of property and founder of the real society.<sup>6</sup>

During the medieval period, land became the main form of wealth and probably the most significant item on the contemporary property list of the medieval world. Land was the prevailing property model and it is partly attributable to the feudal system in England and the agrarian economy that characterized many production systems in the past.<sup>7</sup> Industrial revolution changed the production systems of a significant part of the Western world with the result that new forms of property emerged to diminish the value of land.<sup>8</sup> Even then land enjoys an important status and value as property today.<sup>9</sup>

In the modern period, technology has brought in changes to the form of wealth and property. Developments in medicine and related sciences had an impact on

<sup>&</sup>lt;sup>5</sup> RICHARD PIPES, PROPERTY AND FREEDOM, (Random House *e* Books, First Published in Harvil Press, London), (1999).

<sup>&</sup>lt;sup>6</sup> NICHOLAS HUMPHREY, A HISTORY OF THE MIND: EVOLUTION AND THE BIRTH OF CONSCIOUSNESS, (Copernicus), 143 (1992).

<sup>&</sup>lt;sup>7</sup> REMIGIUS N. NWABUEZE, BIOTECHNOLOGY AND THE CHALLENGE OF PROPERTY: PROPERTY RIGHTS IN DEAD BODIES, BODY PARTS AND GENETIC INFORMATION, (Ashgate), 14 (2007).

<sup>&</sup>lt;sup>8</sup> REMIGIUS N. NWABUEZE, BIOTECHNOLOGY AND THE CHALLENGE OF PROPERTY: PROPERTY RIGHTS IN DEAD BODIES, BODY PARTS AND GENETIC INFORMATION, (Ashgate), 14 (2007).

<sup>&</sup>lt;sup>9</sup> GUILFORD L. MOLESWORTH, LAND AS PROPERTY, (E. & F. N. Spon, 125, Strand, London) (1885).

the use of concept of property in the context of the human body.<sup>10</sup> Social innovations has also broadened the scope and ambit of the concept of property. Today, the term 'property' applies also to incorporeal assets such as credits, patents and copy rights.<sup>11</sup>

## 2.2. DEFINING THE CONCEPT OF PROPERTY

'Property' as a term or as a concept, is part and parcel of the legal systems. But it is not easy to define a dynamic and purposeful concept like property.<sup>12</sup> The word 'property' is derived from Latin word *proprius*, with meaning, 'one's own'.<sup>13</sup> In normal English usage, property is 'an object of legal rights'.<sup>14</sup> In simple words, property is anything that is owned by an individual or jointly by a group of individuals. Legally speaking, it is the right and interest which a man has in land and chattels to the exclusion of others.<sup>15</sup> However even after exhausting all these attributes from different perspectives, it can be seen that the term is having a wider meaning and is still expanding.

<sup>&</sup>lt;sup>10</sup> See, Meredith Render, *The Law of the Body*, 62 Emory L.J. 549 (2013). See also, REMIGIUS N. NWABUEZE, BIOTECHNOLOGY AND THE CHALLENGE OF PROPERTY: PROPERTY RIGHTS IN DEAD BODIES, BODY PARTS AND GENETIC INFORMATION, (Ashgate), 18 (2007).

<sup>&</sup>lt;sup>11</sup> RICHARD PIPES, PROPERTY AND FREEDOM, (Random House *e* Books, First Published in Harvil Press, London), (1999).

<sup>&</sup>lt;sup>12</sup> PROPERTY: MAINSTREAM AND CRITICAL POSITIONS, (C. B. Macpherson, ed., University of Toronto Press), 2 (1978).

<sup>&</sup>lt;sup>13</sup> George P. Costigan, A Plea for a Modern Definition and Classification of Real Property, 12 The Yale L. J., 425, 425 (1903).

<sup>&</sup>lt;sup>14</sup> Encyclopedia Britannica, (Apr. 16, 2013), http://www.britannica.com/EBchecked/topic/ 479008/property.

<sup>&</sup>lt;sup>15</sup> George P. Costigan, A Plea for a Modern Definition and Classification of Real Property, 12 The Yale L. J., 425, 426 (1903).

As per John W. Preston J., in *Yuba River Power Co. v. Nevada Irr. Dist.*<sup>16</sup>, "The term 'property' is sufficiently comprehensive to include every species of estate, real and personal, and everything which one person can own and transfer to another. It extends to every species of right and interest capable of being enjoyed as such upon which it is practicable to place a money value."<sup>17</sup>

Rights relating to a property is the right to enjoy and to dispose of a property in the most absolute manner as one pleases. Provided, it is not used for a purpose prohibited by law.<sup>18</sup> An owner of the property has certain rights attached to that property. Depending on the nature of the property, an owner has the right to sell, rent, mortgage, transfer, gift, exchange or destroy the property, and/or to exclude others from doing these things.<sup>19</sup> A person can also enjoy rights such as, possession, enjoyment, use, etc., without owning the property. A property right is the right to make decisions about the 'things' one possesses.<sup>20</sup> Thus, the '*thing*' should be called property, and the right to, or interest in it, should be called a right of property is a right to the exclusive enjoyment of any property, or to the exclusive enjoyment of some part of, or undivided interest in such property.<sup>21</sup>

<sup>&</sup>lt;sup>16</sup> (1929) 207 Cal. 521.

<sup>&</sup>lt;sup>17</sup> (1929) 207 Cal. 521, at 523.

<sup>&</sup>lt;sup>18</sup> JAMES W. ELY, PROPERTY RIGHTS IN AMERICAN HISTORY: FROM THE COLONIAL ERA TO THE PRESENT, (Garland Publishing, Inc.), 255 (1997).

<sup>&</sup>lt;sup>19</sup> Monica J. Allen et al., *Human Tissue Ownership and Use in Research: What Laboratorians and Researchers Should Know*, 56 Clinical Chemistry, 1675-1682, 1677 (2010).

<sup>&</sup>lt;sup>20</sup> Bjorkman, et al., *Bodily Rights and Property Rights*, 32 J.M.E., 209-214, (2006).

<sup>&</sup>lt;sup>21</sup> George P. Costigan, A Plea for a Modern Definition and Classification of Real Property, 12 The Yale L. J., 425, 425 (1903).

Law of property is that branch of law by which legal system regulates the interactions between people and 'things'.<sup>22</sup> The possibility that more than one person might interact with a thing creates a potential for conflict. It is the law of property that identifies who is subject to which legal relations with respect to a 'thing' at any given moment and how these can be enforced.<sup>23</sup> "Before a right or an interest can be admitted into the category of property, or of a right affecting property, it must be definable, identifiable by third parties, capable in its nature of assumption by third parties, and have some degree of permanence or stability."<sup>24</sup> Thus, right to a property equates to the right to make decisions about matters such as the right to use, right to sell, and right to destroy the 'thing' in question.

Property is best understood as the complex of *jural* relationships between persons with respect to 'things'.<sup>25</sup> It regulates the relationship between external objects or things and individuals. It deals with the allocation, use and transfer of wealth and objects of wealth. The basic features associated with the property rights are the control over the use of the property, right to take any benefit from the property, right to transfer or sell the property, etc. Thus the owner of the

<sup>&</sup>lt;sup>22</sup> Lyria Bennatt Moses, *The Applicability of Property Law in New Contexts: From Cells to Cyberspace*, 30 Syd. L. Rev., 639-662, 639 (2008), (Apr 22, 2016), http://www.austlii.edu.au/au/journals/SydLRev/2008/30.pdf.

<sup>&</sup>lt;sup>23</sup> Paul Kohler, *The Death of Ownership and the Demise of Property*, 53 Current Legal Problems, 237, 282 (2000); Cited in Lyria Bennatt Moses, *The Applicability of Property Law in New Contexts: From Cells to Cyberspace*, 30 Syd. Law Rev., 639-662, 639 (2008), (Apr. 22, 2016), http://www.austlii.edu.au/au/journals/SydLRev/2008/30.pdf.

<sup>&</sup>lt;sup>24</sup> National Provincial Bank Ltd. v. Ainsworth [1965] AC.1175, 1247-8.

<sup>&</sup>lt;sup>25</sup> PROPERTY THEORY: LEGAL AND POLITICAL PERSPECTIVES, (James Penner & Michael Otsuka, eds.), (Cambridge University Press), 32 (2018).

property can do whatever he wishes with his property and can exclude everyone from affecting it. He can simply sell it, misuse it, give it away, change it, use it or destroy it.<sup>26</sup>

To say that a person has property in a thing means he has the exclusive right to own it and to exclude others from interfering with it.<sup>27</sup> On a much wider perspective, property regulates the relationship between external objects or things and individuals. It regulates the relationship of individuals with respect to the ownership and possession of 'things'.<sup>28</sup> It is a right or an enforceable claim to some use or benefit of something.<sup>29</sup> Analysis of the general and legal meanings of the term 'property' reveals the fact that no single definition of property has produced a universal or general meaning and apart from the idea that property rights are rights of control over objects, there appears to be little consensus about what constitutes having an object as one's property.<sup>30</sup> A way out of this complexity is achieved by classifying the concept of property into different streams and sub-streams.

<sup>&</sup>lt;sup>26</sup> IMMANUEL KANT, METAPHYSICAL ELEMENTS OF JUSTICE, THE COMPLETE TEXT OF METAPHYSICS OF MORALS, PART I, (Translation by John Ladd), (2<sup>nd</sup> edn., Hackett Publishing Co.), xxxiii, (1999).

<sup>&</sup>lt;sup>27</sup> N. S. GOPALAKRISHNAN, INTELLECTUAL PROPERTY AND CRIMINAL LAW, (National Law School of India University), 7 (1994).

<sup>&</sup>lt;sup>28</sup> ALAN GEWIRTH, THE COMMUNITY OF RIGHTS, (The University of Chicago Press), 166 (1996).

<sup>&</sup>lt;sup>29</sup> PROPERTY: MAINSTREAM AND CRITICAL POSITIONS, (C. B. Macpherson, ed.), University of Toronto Press,) 3 (1978).

<sup>&</sup>lt;sup>30</sup> Cordelia Mary Thomas, *A Framework for the Collection, Retention and Use of Human Body Parts*, (2006), (Jul. 11, 2013), http://researcharchive.vuw.ac.nz/bitstream/handle/10063/297/ thesis.pdf.txt?sequence=4.

#### **2.2.1. CLASSIFICATION OF PROPERTY**

Throughout history, though different meanings and definitions were given to the concept of property, the classification of the same as common property or private property always existed. The scholars who have discussed about property has either argued in favour of common property or of private property.<sup>31</sup>

The English law classifies the property as 'real property' and 'personal property'.<sup>32</sup> Real property includes land and all the things that are attached to it.<sup>33</sup> Therefore, real property consists of lands, tenements and hereditaments.<sup>34</sup> Anything that is not real property is personal property and personal property is anything that isn't nailed down, dug into or built onto the land.<sup>35</sup>

<sup>&</sup>lt;sup>31</sup> For example, traversing through the time line, one can find that different scholars have conceived the notion of property either as common property or as private property. For example, Plato conceived of his ideal *Republic* as based on common property arguments. While Aristotle promoted private property as a better way of organizing social relations. The Biblical teachings are based on the concept of common property. At a later stage, the naturalists considered that the conception of property arises from the laws of nature, rather than from the laws of man. Locke believed that in the state of nature, God gave the world for all to use. It became private property because of the rational convenience and protection. According to Samuel Pufendorf, in the beginning, people lived in a state of communism. But after a time, this was found inconvenient. People then agreed to divide certain things and tracts of land, leaving the rest free for occupation. In this way, private right of property, *dominium*, was introduced. Karl Marx saw private property is the tool for the capitalist class to exploit the proletariat by extracting the surplus value of their labour.

<sup>&</sup>lt;sup>32</sup> George P. Costigan, A Plea for a Modern Definition and Classification of Real Property, 12 The Yale L. J., 425, 426 (1903).

<sup>&</sup>lt;sup>33</sup> George P. Costigan, A Plea for a Modern Definition and Classification of Real Property, 12 The Yale L. J., 425, 427 (1903).

<sup>&</sup>lt;sup>34</sup> George P. Costigan, A Plea for a Modern Definition and Classification of Real Property, 12 The Yale L. J., 425, 427 (1903).

<sup>&</sup>lt;sup>35</sup> David Lametti, *The Concept of Property: Relations through Objects of Social Wealth*, 53 The University of Toronto L. J., 325-378, (2003).

The term 'property' also covers both material and abstract things. It not only includes money and other tangible things of value, but also includes any intangible right considered as a source or element of income or wealth. The word 'property' thus means either, (1) anything corporeal or incorporeal<sup>36</sup> which a person may acquire, own and dispose of to the exclusion of some other person, or, (2) any legal or equitable incorporeal right to or interest in such corporeal or incorporeal thing, which right a person may acquire, own and dispose of to the exclusion of others.<sup>37</sup>

#### 2.3. CONCEPTUAL ANALYSIS OF PROPERTY

The meaning given to the concept of property was different during different periods and different places. Even then, history of all societies, from the most primitive to the most advanced, reveals the universality of property claims and failure of every attempt to found a property less community, whether voluntarily or by force.<sup>38</sup> "Property never has been abolished and never will be abolished. It is simply a question of who has it".<sup>39</sup> "Writings in political philosophy dealing with property do not always refer to the same thing. Sometimes property is envisioned as a simple relation between a person and a thing, and explored in

<sup>&</sup>lt;sup>36</sup> "Corporeal property is tangible or physical in nature, while incorporeal property exists only as a legal right", Randy W. Marusyk & Margaret S. Swain, *A Question of Property Rights in Human Body*, 21 Ottawa L. Rev., 359 (1989).

<sup>&</sup>lt;sup>37</sup> George P. Costigan, A Plea for a Modern Definition and Classification of Real Property, 12 The Yale L. J., 425, 425 (1903).

<sup>&</sup>lt;sup>38</sup> RICHARD PIPES, PROPERTY AND FREEDOM, (Random House e Books, First Published in Harvil Press, London), (1999).

<sup>&</sup>lt;sup>39</sup> A. N. WILSON, TOLSTOY, (Atlantic Books, e-book Edition), (2015).

terms of justifications that exist for someone to have absolute dominion over a thing of the external world".<sup>40</sup>

According to Fred D. Miller,

"A theory of property rights should provide answers to certain questions like what sort of individuals can hold property rights, to what sort of objects can they have property rights, the circumstances under which the individuals justly acquire property and the circumstances in which they possess them unjustly, what specific public policies are implied by property rights - that is, in what way should property rights be protected, and, if at all individual property rights be restricted or regulated by government?, etc."<sup>41</sup>

A study of various theories of property reveals how the concept of property has changed across the world and the times. The classical theories in relation to the basis of property are analysed in order to check whether the existing framework of property is suitable while discussing the legal status of the dead human body and excised bodily materials.

Even though many legal scholars and philosophers have tried to conceptualise the idea of property, very few have succeeded in their attempt. Discussions on property from the time of Plato to the present have revolved around four principal

<sup>&</sup>lt;sup>40</sup> J. Martin Pedersen, *Properties of Property: A Jurisprudential Analysis*, 14 The Commoner, (2010), http://www.commoner.org.uk.

<sup>&</sup>lt;sup>41</sup> Fred D. Miller, *Aristotle on Property Rights*, in JOHN PETER ANTON, GEORGE L. KUSTAS & ANTHONY PREUS, ESSAYS IN ANCIENT GREEK PHILOSOPHY IV: ARISTOTLE'S ETHICS, (State University of New York Press, Albany), 277 (1991).

themes: its relation to politics, ethics, economics and psychology.<sup>42</sup> These four approaches fairly exhaust the range of arguments for and against property articulated during the past three thousand years.<sup>43</sup>

Discussions relating to property pertaining to the time when land and livestock alone were treated as property may not be appropriate for the time when ideas and inventions are treated as property. Now the idea of property has traversed much from its initial framework to include even human body and bodily materials in limited ways. This evolution of the theories of property needs to be analysed critically to find whether the existing definitions can accommodate such changes.

# 2.3.1. DEVELOPMENT OF THE CONCEPT OF PROPERTY DURING ANCIENT PERIOD

Throughout history the institution of property was construed and interpreted to suit the needs of the times. In almost every period of its development property

<sup>&</sup>lt;sup>42</sup> "The political argument in favour of property holds that (unless distributed in a grossly unfair manner) it promotes stability and constrains the power of government. Against property it is claimed that the inequality which necessarily accompanies it generates social unrest. From the moral point of view, it is said that property is legitimate because everyone is entitled to the fruits of his labour. To which critics respond that many owners exert no effort to acquire what they own and that the same logic requires everyone to have an equal opportunity to acquire property. The economic line of reasoning of property holds that it is the most efficient means of producing wealth, whereas opponents of this argument hold that economic activity driven by the pursuit of private gain leads to wasteful competition. The psychological defence of property maintains that it enhances the individual's sense of identity and self-esteem. Critics of this theory assert that it corrupts the personality by infecting it with greed.", RICHARD PIPES, PROPERTY AND FREEDOM, (Random House *e* Books, First Published in Harvil Press, London), (1999).

<sup>&</sup>lt;sup>43</sup> RICHARD PIPES, PROPERTY AND FREEDOM, (Random House *e* Books, First Published in Harvil Press, London), (1999).

has played a central role in the society. It was always adapted to fit the social, economic, political and cultural needs of the society.<sup>44</sup>

"Ancient Greeks recognise a distinction which is fundamental to the conception of property right: the distinction between the mere possession of an object and the ownership of it. Greek law provides elaborate procedures through which property owners could seek protection and compensation."<sup>45</sup> One of the ancient classifications of the property is the classification into private property and common property. The concept of common property leads to the concept of communal property in the context of a community and the same is vested jointly in all its members; nevertheless, the community is incapable of disposing it, neither does it have any collective rights upon it. On the other hand, private property belongs to an individual, a kinship group, or an association of individuals.<sup>46</sup> Thus, as mentioned above, throughout history it can be seen that the theories of property propounded by various scholars either argue that private property is better than common property or vice versa.

<sup>&</sup>lt;sup>44</sup> Johannes Erasmus, *The Interaction Between Property Rights and Land Reform in the New Constitutional Order in South Africa*, University of South Africa, 5 (1998), (May, 23, 2018), uir.unisa.ac.za/bitstream/handle/10500/18032/thesis\_erasmus\_j.pdf; sequence=1.

<sup>&</sup>lt;sup>45</sup> Fred D. Miller, *Aristotle on Property Rights*, in JOHN PETER ANTON, GEORGE L. KUSTAS & ANTHONY PREUS, ESSAYS IN ANCIENT GREEK PHILOSOPHY IV: ARISTOTLE'S ETHICS, (State University of New York Press, Albany), 228 (1991).

<sup>&</sup>lt;sup>46</sup> RICHARD PIPES, PROPERTY AND FREEDOM, (Random House *e* Books, First Published in Harvil Press, London), (1999).

Plato conceived of his ideal republic as based on common property.<sup>47</sup> In his work, '*The Republic*' he suggests that the goal of the rulers in conducting the law suits will be that individuals should neither have another's things nor be deprived of their own things.<sup>48</sup>

Aristotle promoted forms of private property as a better way of organizing social relations.<sup>49</sup> In his '*Politics*' Aristotle remarks, "How immeasurably greater is the pleasure, when a man feels a thing to be his own."<sup>50</sup> He discussed property in several different contexts throughout the *Politics* as well as in other works, most notably the *Rhetoric* and *Nicomachean* Ethics. Aristotle's discussions on property "begins with an enumeration of the parts of wealth: plenty of money; possession of land and estates; possession of movable objects, animals and slaves."<sup>51</sup> He recognises a number of different ways in which property can be

<sup>&</sup>lt;sup>47</sup> Plato's *Republic* and the *Laws* seek ways to eliminate property as the cause of the social strife. Plato outlined his utopian communism in Books 5-7 of the *Republic*. His objective was to devise a social order in which the ruling elite would not be driven by selfishness but dedicate itself wholly to the public good. "The ideal Platonic state consisted of two castes: the rulers, called 'Guardians' made up of the oldest and the wisest members of the community, and the rest. The Guardians, who ran the state, acquired their status after passing rigorous tests. They owned no property - neither houses nor land - so that they would not "tear the city in pieces by differing about "mine" and "not mine". Plato saw property and virtue as incompatible: for the money and virtue are like the two scales of a balance. As one goes up, the other goes down", *See* Fred D. Miller, *Aristotle on Property Rights*, in JOHN PETER ANTON, GEORGE L. KUSTAS & ANTHONY PREUS, ESSAYS IN ANCIENT GREEK PHILOSOPHY IV: ARISTOTLE'S ETHICS, (State University of New York Press, Albany), 227 (1991).

<sup>&</sup>lt;sup>48</sup> Fred D. Miller, *Aristotle on Property Rights*, in JOHN PETER ANTON, GEORGE L. KUSTAS & ANTHONY PREUS, ESSAYS IN ANCIENT GREEK PHILOSOPHY IV: ARISTOTLE'S ETHICS, (State University of New York Press, Albany), 228 (1991).

<sup>&</sup>lt;sup>49</sup> J. Martin Pedersen, *Properties of Property: A Jurisprudential Analysis*, 14 The Commoner, 158 (2010).

<sup>&</sup>lt;sup>50</sup> ARISTOTLE, POLITICS, (Translated to English by Benjamin Jowett), Book 2, Part 5, (Altenmünster Jazzybee Verlag), (2015).

<sup>&</sup>lt;sup>51</sup> Fred D. Miller, *Aristotle on Property Rights*, in JOHN PETER ANTON, GEORGE L. KUSTAS & ANTHONY PREUS, ESSAYS IN ANCIENT GREEK PHILOSOPHY IV: ARISTOTLE'S ETHICS, (State University of New York Press, Albany), 229 (1991).

justly acquired: original acquisition from nature like hunting, farming etc., barter, cash exchange, gifts, inheritance, and distribution by government.<sup>52</sup> According to him, property is a part of the household, and the art of acquiring property is therefore a part of household management, for, without these necessary things, living and living well are impossible.<sup>53</sup> Therefore an article of property, including a slave, which is a live article of property, is to be understood as a tool.<sup>54</sup>

Aristotle believed that extreme inequalities in the distribution of wealth will lead to social strife. He opposed the common ownership of property based on utilitarian grounds. His view is that; it is impractical because no one takes proper care of objects that are not his. But unlike Aristotle, Plato regarded the institution of property as indestructible and ultimately a positive force. Property in fact, is an attribute of the household and not of the community or the state. According to Plato, "States require property, but property... is no part of a state."<sup>55</sup>

<sup>&</sup>lt;sup>52</sup> ARISTOTLE'S POLITICS: CRITICAL ESSAYS, (Richard Kraut & Steven Skultety, eds.), Rowman & Littlefield Publishers, Inc.), 138 (2005).

<sup>&</sup>lt;sup>53</sup> ARISTOTLE, POLITICS, (Translated to English by Benjamin Jowett), Book 2, Part 5, (Altenmünster Jazzybee Verlag), (2015).

<sup>&</sup>lt;sup>54</sup> William Mathie, *Property in the Political Science of Aristotle*, in THEORIES OF PROPERTY-ARISTOTLE TO PRESENT, (Anthony Parel & Thomas Flanagen eds.), (The Calgary Institute for the Humanities, Wilfred Laurier University Press, Canada), 18 (1979).

<sup>&</sup>lt;sup>55</sup> ARISTOTLE, POLITICS, (Translated to English by Benjamin Jowett), Book 2, Part 5, (Altenmünster Jazzybee Verlag), (2015).

The classical Roman concept of '*dominion ex jure quiritium*'<sup>56</sup> is often described as conferring absolute rights over the object of ownership to the owner.<sup>57</sup> Roman law defines property as the right to use and abuse a thing within the limits of the law, which is expressed in Latin as, *Jus utendi et abutendi re sua, quatenus iuris ratio patitur*. <sup>58</sup> Abuse of property is really indistinguishable from use of property. One way or another, the proprietor<sup>59</sup> can do what he likes with his land.

He can "let the crops rot underfoot, sow his field with salt, milk his cow on the sand, turn his vineyard into a desert, and use his vegetable garden as a park".<sup>60</sup>

Under Roman Law, *res* is considered as an element of wealth or an asset.<sup>61</sup> It has many meanings as 'thing', but, used technically, always connotes a right, though not necessarily all rights, or, in early law, all rights having a money value come within that notion. The *res* can be classified into two. They are, the rights

<sup>&</sup>lt;sup>56</sup> "Dominium derived from the verb domo, meaning to conquer. Ex iure Quiritium means 'according to the law of the Quirites'. The term Quirites originally denoted the inhabitants of the Sabine town of Cures. Around the middle of seventh century BC, the Romans and the Sabines merged to form a single nation and this nation was termed Populous Romans Quiritium. The words Romanus and Quiritium finally came to be used interchangeably and thus ownership by Roman title was referred to as dominium ex iure Quiritrium", GEORGE MOUSOURAKIS, ROMAN LAW AND THE ORIGINS OF THE CIVIL LAW TRADITION, (Springer), 115 (2015).

<sup>&</sup>lt;sup>57</sup> Johannes Erasmus, *The Interaction Between Property Rights and Land Reform in the New Constitutional Order in South Africa*, University of South Africa, Preface, xvii, (1998) (May, 23, 2018), uir.unisa.ac.za/bitstream/handle/10500/18032/thesis\_erasmus\_j.pdf; sequence=1.

<sup>&</sup>lt;sup>58</sup> PETER GARNSEY, THINKING ABOUT PROPERTY, FROM ANTIQUITY TO THE AGE OF REVOLUTION, (Cambridge University Press), 177 (2007).

<sup>&</sup>lt;sup>59</sup> "A proprietor is one who has the legal right or exclusive title to anything", Wharton's Concise Law Dictionary, (Universal Law Publishing Co. Ltd., 15<sup>th</sup> edn.), 836 (2011 Reprint).

<sup>&</sup>lt;sup>60</sup> PIERRE-JOSEPH PROUDHON, WHAT IS PROPERTY?, CAMBRIDGE TEXTS IN THE HISTORY OF POLITICAL THOUGHT, (Donald R. Kelley & Bonnie G. Smith, eds.), (Cambridge University Press), 35 (1993).

<sup>&</sup>lt;sup>61</sup> W. W. BUCKLAND, A TEXTBOOK OF ROMAN LAW: FROM AUGUSTUS TO JUSTINIAN, (Cambridge at the University Press, 3<sup>rd</sup> edn., revised by Peter Stein), 182 (1963).

available generally (*iura in rem*) and the obligations available only against specific persons (*iura in personam*).<sup>62</sup>

The right of private property was asserted by the Romans and was elaborated in their law. The individualistic element in Roman property law can be seen in the principles of Roman jurisprudence which referred the right of property to "first possession, labour, succession, and donation".<sup>63</sup>

#### **2.3.2.** CONCEPT OF PROPERTY DURING THE MIDDLE AGES

Many of the medieval philosophers like Grotius, Pufendorf, Locke, etc., are strongly influenced by Biblical conception of property.<sup>64</sup> Bible was an important component which determined the outlook of most of the naturalists including John Locke.<sup>65</sup> In the Biblical version of conception of property, in the beginning, property was common to all human species, and later to a people or family.<sup>66</sup> This view is based on the Biblical words that "God has created the world and He gave everything to man for his enjoyment".<sup>67</sup> The Biblical interpretations points to the assertion that, God has possession over all things in a primary sense.

<sup>&</sup>lt;sup>62</sup> W. W. BUCKLAND, A TEXTBOOK OF ROMAN LAW: FROM AUGUSTUS TO JUSTINIAN, (Cambridge at the University Press, 3<sup>rd</sup> edn., revised by Peter Stein), 182 (1963).

<sup>&</sup>lt;sup>63</sup> George B. Newcomb, *Theories of Property*, 1 Political Science Quarterly, 595-611, 597 (1886), (Sep. 06, 2018), https://www.jstor.org/stable/pdf/2139069.pdf.

<sup>&</sup>lt;sup>64</sup> Karl Olivecrona, *Locke's Theory of Appropriation*, in LOCKE'S MORAL, POLITICAL AND LEGAL PHILOSOPHY, (J. R. Milton, ed.), (Ashgate), 265 (1999).

<sup>&</sup>lt;sup>65</sup> See, KIM IAN PARKER, THE BIBLICAL POLITICS OF JOHN LOCKE, (Wilfred Laurier University Press), (2004).

<sup>&</sup>lt;sup>66</sup> Luigi Miraglia, *Comparative Legal Philosophy*; (Augustus M. Kelley Publishers, New York), 385 (1968).

<sup>&</sup>lt;sup>67</sup> Old Testament, Genesis I: 28-30, (King James), "And God blessed them, and God said unto them, be fruitful, and multiply, and replenish the earth, and subdue it: and have dominion over the fish of the sea, and over the fowl of the air, and over every living thing that moveth upon the earth. And God said, Behold, I have given you every herb bearing seed, which is upon the

"Things by their nature obey God, since their nature comes from God himself. Man's ownership of things is over the use of things. Man can use things for his own good. Lower things are for the sake of higher things, and so the things of nature are for the sake of man to use for his own good."<sup>68</sup>

Reliance of natural law school of thought is the integrating factor of the Middle Age philosophers. The principal subject matter of natural law doctrine covered the relations between free and equal individuals in the state of nature.<sup>69</sup> These relations were supposed to be governed by the law of nature and conventions between the individuals.<sup>70</sup>

"The principal subject matter of natural law doctrine covered the relations between free and equal individuals in the state of nature. These relations were supposed to be governed by the law of nature and conventions between the individuals. 'My own' [*meum, tuum, or suum*] and 'to each his own' or 'to each what he deserves' [*Suum cuique tribure*] are the two fundamental principles of law of nature which means, according to everybody, his own."<sup>71</sup>

face of all the earth, and every tree, in the which is the fruit of a tree yielding seed; to you it shall be for meat.<sup>30</sup> And to every beast of the earth, and to every fowl of the air, and to everything that creepeth upon the earth, wherein there is life, I have given every green herb for meat: and it was so".

<sup>&</sup>lt;sup>68</sup> Thomas Aquinas on Property, Property in General: Do Human Beings have the Right to Use the Natural World in Any Way?, (Jun. 16, 2013), http://www.Hyoomik.com/Aquinas/ property. html.

<sup>&</sup>lt;sup>69</sup> JOHN DUNN & IAN HARRIS, LOCKE, (Edward Elgar Publications), 336 (1997).

<sup>&</sup>lt;sup>70</sup> Karl Olivecrona, *Locke's Theory of Appropriation*, in LOCKE'S MORAL, POLITICAL AND LEGAL PHILOSOPHY, (J. R. Milton, ed.), (Ashgate), 267 (1999).

<sup>&</sup>lt;sup>71</sup> Karl Olivecrona, *Locke's Theory of Appropriation*, in LOCKE'S MORAL, POLITICAL AND LEGAL PHILOSOPHY, (J. R. Milton, ed.), (Ashgate), 267 (1999).

For naturalists, the conception of property arises from the laws of nature, rather than from the laws of man, since individuality is of natural origin. Property, which is expressed in terms of ownership, is an extension of the concept of personal identity to relations between persons with respect to objects.<sup>72</sup> Natural rights theory of property argues that every person has property in his own body and that the person's individuality, created by nature, is innate and cannot be separated from the person.<sup>73</sup>

As the time passes by, the notions relating to the property underwent great changes. Hugo Grotius, one of the pioneering proponents of natural law holds that,

"By nature, life, body, limbs, reputation, honour and our own actions belongs to ourselves. These goods constitute the original *suum* [that which belongs] of the individual existing independently of the human will. Things to which an individual had acquired *dominium* belonged to himself in the same way as his life, honour, *actions propriae*, etc. To rob the owner of an object was to deprive his personality of an item included in it".<sup>74</sup>

<sup>&</sup>lt;sup>72</sup> THOMAS HODGSKIN, THE NATURAL AND ARTIFICIAL RIGHT OF PROPERTY CONTRASTED, (B. Steil, London), (1832); Cited in Cordelia Mary Thomas, *A Framework for the Collection, Retention and Use of Human Body Parts*, (2006), (Oct. 2, 2013), http://researcharchive.vuw.ac.nz/ bitstream/handle/10063/297/thesis. pdf. txt?sequence=4.

<sup>&</sup>lt;sup>73</sup> THOMAS HODGSKIN, THE NATURAL AND ARTIFICIAL RIGHT OF PROPERTY CONTRASTED, (B. Steil, London), (1832); Cited in Cordelia Mary Thomas, *A Framework for the Collection, Retention and Use of Human Body Parts*, (2006), (Oct. 2, 2013), http://researcharchive.vuw.ac.nz/bitstream/handle/0063/297/thesis.pdf.txt?sequence=4.

<sup>&</sup>lt;sup>74</sup> Karl Olivecrona, *Locke's Theory of Appropriation*, in LOCKE'S MORAL, POLITICAL AND LEGAL PHILOSOPHY, (J. R. Milton, ed.), (Ashgate), 268 (1999).

According to Thomas Hobbes, in the state of nature, "Every man has a right to everything; even to one another's body."<sup>75</sup> In the state of nature, he says, property did not exist. People might agree to divide a certain field between them, but without a coercive power, either side could renege on the bargain whenever it was convenient. To him, property came into existence only after the creation of a sovereign power capable of enforcing contracts.<sup>76</sup>

John Locke's labour theory which he details in his *Two Treatises of Government* is one of the most discussed theoretical explanations to the concept of property. Like other naturalists, Locke also started with the point that earth had been given to mankind in common; the state of nature, where the world is owned by all.<sup>77</sup> In the state of nature, Locke believed that God gave the world for all to use, and that private property only became such because of the rational convenience.<sup>78</sup> But later he struck a different path for himself from others by proposing that property is an integral basis for politics. That a thing 'in my own' means, in the opinion of Locke, that it is part of myself. For that reason, nobody else can have any right to it.

<sup>&</sup>lt;sup>75</sup> THOMAS HOBBES, LEVIATHAN, (W.G. Pogson Smith, ed.), (Oxford: Clarendon Press), 99 (1909), Cited in STEPHEN MUNZER, A THEORY OF PROPERTY, (Cambridge Studies in Philosophy and Law, Cambridge University Press), 41 (1990).

<sup>&</sup>lt;sup>76</sup> STEPHEN MUNZER, A THEORY OF PROPERTY, (Cambridge Studies in Philosophy and Law, Cambridge University Press), 41 (1990).

<sup>&</sup>lt;sup>77</sup> JOHN LOCKE, TWO TREATISES OF GOVERNMENT, (Whitmore & Fenn, London), 208 (1821). <sup>78</sup> "God, who hath given the world to men in common, hath also given them reason to make use of it to the best advantage of life, and convenience. The earth, and all that is therein, is given to men for the support and comfort of their being.", JOHN LOCKE, TWO TREATISES OF GOVERNMENT, (Whitmore & Fenn, London), 209 (1821).

"The fruit or venison, which nourishes the wild *Indian*, who knows no inclosure, and is still a tenant in common, must be his, and so his, *i.e.* a part of him, that another can no longer have any right to it, before it can do him any good for the support of his life."<sup>79</sup>

According to Locke, every individual has originally the duty and right to work, and as means for the fulfillment of his duty and the exercise of his right, has the power of occupancy.<sup>80</sup> Property came into existence only after work has been applied.<sup>81</sup> His theory proposes that property and labour are inter related. If man invests himself, through his labour, into a piece of property, he may then own it because he owns himself.<sup>82</sup> "…for it is *labour* indeed that *puts the difference of value* on everything…"<sup>83</sup>

<sup>&</sup>lt;sup>79</sup> Chapter V, *Of Property*, § 26, JOHN LOCKE, TWO TREATISES OF GOVERNMENT, (Whitmore & Fenn, London), 209 (1821).

<sup>&</sup>lt;sup>80</sup> Chapter V, *Of Property*, JOHN LOCKE, TWO TREATISES OF GOVERNMENT, (Whitmore & Fenn, London), 209 (1821). § 27 explores this labour theory: "Though the earth, and all inferior creatures, be common to all men, yet every man has a *property* in his own *person*: this nobody has any right to but himself. The *labour* of his body, and the *work* of his hands, we may say, are properly his. Whatsoever then he removes out of the state that nature hath provided, and left it in, he hath mixed his *labour* with, and joined to it something that is his own, and thereby makes it his *property*. It being by him removed from the common state nature hath placed it in, it hath by his *labour* something annexed to it, that excludes the common right of other men: for this *labour* being the unquestionable property of the labourer, no man but he can have a right to what that is once joined to, at least where there is enough, and as good left in common for others", JOHN LOCKE, TWO TREATISES OF GOVERNMENT, (Whitmore & Fenn, London), 209-10, (1821).

<sup>&</sup>lt;sup>81</sup> LUIGI MIRAGLIA; COMPARATIVE LEGAL PHILOSOPHY; (Augustus M. Kelley Publishers, New York), 386 (1968).

<sup>&</sup>lt;sup>82</sup> See, Chapter V, Of Property, § 28, JOHN LOCKE, TWO TREATISES OF GOVERNMENT, (Whitmore & Fenn, London), 210 (1821). See also, Traci Lynne Timmons, Earth Jurisprudence and Lockean Theory: Rethinking the American Perception of Private Property, 103 (Apr. 21, 2014), https://lawpublications.barry.edu/cgi/viewcontent.cgi?article=1004&cont ext=ejejj.

<sup>&</sup>lt;sup>83</sup> Chapter V, *Of Property*, § 40, JOHN LOCKE, TWO TREATISES OF GOVERNMENT, (Whitmore & Fenn, London), 221 (1821).

According to Locke, every man has a property in his own person.<sup>84</sup> His "labour theory of property asserts that each person is entitled to the ownership of whatever they acquire or create through their own labour".<sup>85</sup> Thus, "Locke asserted that each individual has a 'property in his own person' and that no one other than that individual has a claim to that property".<sup>86</sup> What gives someone a right to a thing is not simply his seizing of the object but rather the fact that he has mixed his labour with the thing in making it his own.

Like Locke, for Samuel Pufendorf also, people lived in a state of communism in the beginning. But after a time, this was found inconvenient. People then agreed to divide certain things and tracts of land, leaving the rest free for occupation. In this way, private right of property, *dominium*, was introduced. During the era before the introduction of *dominium*, it was permitted for everybody to take from the common such things as were needed for the support of life. What a man took for his use and could consume became 'his own'.<sup>87</sup>

<sup>&</sup>lt;sup>84</sup> "Though the earth, and all inferior creatures, be common to men, yet every man has a *property* in his own *person*: this no body has any right to but himself. The *labour* of his body, and the *work* of his hands, we may say, are properly his. Whatsoever then he removes out of the state that nature hath provided, and left it in, he hath mixed his *labour* with, and joined to it something that is his own, and thereby makes it his *property*." JOHN LOCKE, TWO TREATISES ON GOVERNMENT, (Whitmore & Fenn, London), 209 (1821).

<sup>&</sup>lt;sup>85</sup> Cordelia Mary Thomas, *A Framework for the Collection, Retention and Use of Human Body Parts*, (2006), (Jul. 11, 2013), http://researcharchive.vuw.ac.nz/bitstream/handle/10063/297/ thesis.pdf.txt?sequence=4.

<sup>&</sup>lt;sup>86</sup> Cordelia Mary Thomas, A Framework for the Collection, Retention and Use of Human Body Parts, (2006), (Jul. 11, 2013), http://researcharchive.vuw.ac.nz/bitstream/handle/10063/297/ thesis.pdf. txt?sequence=4.

<sup>&</sup>lt;sup>87</sup> Karl Olivecrona, *Locke's Theory of Appropriation*, in LOCKE'S MORAL, POLITICAL AND LEGAL PHILOSOPHY, (J. R. Milton, ed.) (Ashgate), 266 (1999).

Pufendorf thought it to be an *injuria* against all others to take anything from the common without their consent.<sup>88</sup> According to Pufendorf, only things to which one had a right could be made of use to oneself. But private rights to objects that were common property could only be established by general agreement. He therefore concluded that people at a very early time had made a compact to the effect that each is entitled to collect as much of the fruits of earth as is needed for his existence, thus becoming the owner of these objects. The substance of things remained common property. But the fruits became the property of those who collected them.<sup>89</sup> Pufendorf holds that the property is founded in the physical power manifested in seizing the object of property i.e., occupation. However, in order to convert the fact of physical power into a right, the sanction of the state is necessary. But the state cannot, make a property right where physical possession is not present. Thus, both occupation and state sanction are necessary conditions for the legitimacy of property.<sup>90</sup>

Friedrich Hegel suggested that protection of property is intimately connected with protection of the human will. He proposed that, when someone extends his will to a thing, he makes that thing a part of himself. Protection of property is thus immediately connected with protection of the human will.<sup>91</sup> According to

<sup>&</sup>lt;sup>88</sup> Karl Olivecrona, *Locke's Theory of Appropriation*, in LOCKE'S MORAL, POLITICAL AND LEGAL PHILOSOPHY, (J. R. Milton, ed.) (Ashgate), 266 (1999).

<sup>&</sup>lt;sup>89</sup> JOHN R. MILTON, LOCKE'S MORAL, POLITICAL AND LEGAL PHILOSOPHY, (Ashgate), 266 (1999).

<sup>&</sup>lt;sup>90</sup> THE IDEAS THAT MADE THE MODERN WORLD: THE PEOPLE, PHILOSOPHY AND HISTORY OF THE ENLIGHTENMENT, (Constable and Robinson Ltd.), 167 (2008).

<sup>&</sup>lt;sup>91</sup> FRIEDRICH HEGEL, PHILOSOPHY OF RIGHT, (Translated by T. M. Knox), (Clarendon Press), (1942).

Hegel, property should have been regarded as a condition for the realisation of human essence.

"... To have power over a thing *ab extra* constitutes possession. The particular aspect of the matter, the fact that I make something my own as a result of my natural need, impulse, and caprice, is the particular interest satisfied by possession. But I as free will am an object to myself in what I possess and thereby also for the first time am an actual will, and this is the aspect which constitutes the category of property, the true and right factor in possession. If emphasis is placed on my needs, then the possession of property appears as a means to their satisfaction, but the true position is that, from the standpoint of freedom, property is the first embodiment of freedom and so is in itself a substantive end."<sup>92</sup>

Thus, "If emphasis is placed on my needs, then the possession of property appears as means to their satisfaction, but the true position is that, from the standpoint of freedom, property is the first embodiment of freedom and so is in itself a substantive end."<sup>93</sup> Hegel's idea of property appears to be that the "possession, as power over the thing, simply aims at satisfying human needs is the intermediate point for the realisation of the individual as free agent. Power over the thing is therefore a means for the development of the individual's will.

<sup>&</sup>lt;sup>92</sup> Part 1, Sub-section 1, Property, § 45, FRIEDRICH HEGEL, PHILOSOPHY OF RIGHT, (Translated by T. M. Knox), (Clarendon Press), (1942).

<sup>&</sup>lt;sup>93</sup> MEROLD WESTPHAL, HEGEL, FREEDOM AND MODERNITY, (State University of New York Press), 22 (1992).

The things, which are contained in the real world, become property only as an externalisation of the individual's will".<sup>94</sup>

For John Stuart Mill, property is associated with the concept of 'liberty' and proposed that security of property is essential for humankind to maximize its potential for liberty.<sup>95</sup> For Mill, property comprised the rights to things that human beings produce by their own labour because those who are excluded have not lost anything if they cannot share in a thing that otherwise would not have existed at all.<sup>96</sup>

Metaphysical theories of property are part of the general movement that replaced the 17<sup>th</sup> and 18<sup>th</sup> century natural law conception of property. They begin with Immanuel Kant, who is the proponent of the inviolability of the individual human personality.<sup>97</sup> For Kant, "property is an external thing - something other than my own powers - is simply the right to have that thing at my disposal with which to set and pursue ends."<sup>98</sup> According to Kant, the structural reason for protecting person and property is the same, i.e., to ensure freedom. Much of the structure of rights to property applies in just the same way to the rights with respect to

<sup>&</sup>lt;sup>94</sup> WOLFGANG FABER, BRIGITTA LURGER, PRINCIPLES OF EUROPEAN LAW: ACQUISITION AND LOSS OF OWNERSHIP OF GOODS, (European Law Publishers), 263 (2011).

<sup>&</sup>lt;sup>95</sup> JOHN START MILL, ON LIBERTY, (Boston: Ticknor and Fields, 2<sup>nd</sup> edn.), (1863).

<sup>&</sup>lt;sup>96</sup> Cordelia Mary Thomas, *A Framework for the Collection, Retention and Use of Human Body Parts*, (2006), (Sep. 5, 2013), http://researcharchive.vuw.ac.nz/bitstream/handle/10063/297/ thesis.pdf.txt?sequence=4.

<sup>&</sup>lt;sup>97</sup> ROSCOE POUND, AN INTRODUCTION TO THE PHILOSOPHY OF LAW, (Transaction Publishers, 1999, originally published by Yale University Press), 198 (1922).

<sup>&</sup>lt;sup>98</sup> IMMANUEL KANT, (Arthur Ripstein, ed.), (Routledge: International Essays in the History of Social and Political Thought), (2016).

one's own person. Strictly speaking, "I do not have property in my own person: there are some inherent limits on my possessary rights, so that, for example, I may not alienate my own person. But I have rights in my person like those I have in external things."<sup>99</sup> He asserted, "a thing is rightfully mine when I am so connected with it that anyone who uses it without my consent does me an injury and where there is an actual physical relation to the object, any interference therewith, is an aggression upon personality".<sup>100</sup> In his opinion, just as property can be both injured and trespassed against, so can one's person too be injured and trespassed against. Kant holds that trespass against one person is like using such person for some purposes that is not anticipated by the person concerned. Thus, for Kant, property must be understood broadly, to include one's right over one's own person.<sup>101</sup>

Kant defines the universal principle of right in the following way:

"Any action is right if it can coexist with everyone's freedom in accordance with a universal law. The freedom of choice of each can coexist with everyone's freedom in accordance with a universal law. By this, Kant means that each person is entitled to be his or her own master, not in the sense of enjoying some special self-relation, but in the

<sup>&</sup>lt;sup>99</sup> IMMANUEL KANT, (Arthur Ripstein, ed.), (Routledge: International Essays in the History of Social and Political Thought), (2016).

<sup>&</sup>lt;sup>100</sup> IMMANUEL KANT, (Arthur Ripstein, ed.), (Routledge: International Essays in the History of Social and Political Thought), (2016).

<sup>&</sup>lt;sup>101</sup> IMMANUEL KANT, (Arthur Ripstein, ed.), (Routledge: International Essays in the History of Social and Political Thought), (2016).

contrastive sense of not being subordinated to the choice of any other particular person."<sup>102</sup>

Metaphysical theories of property were further developed by Hegal, for whom property is simply the realization of the idea of liberty. He discarded the notion of occupation. And in giving expression to this idea of liberty, Hegal speaks of the right of an individual to exercise or direct his will upon an external object and so claim it as his own. For him, property was an essential instrument of the human personality.<sup>103</sup>

#### **2.3.3.** CONCEPT OF PROPERTY IN THE MODERN PERIOD

Law relating to property became more developed and crystallized so as to include a wide variety of factors during the second half of 19<sup>th</sup> and 20<sup>th</sup> century. Property law became much more than the law relating to 'things' in relation to a person. The meaning of property is changing; the actual institution as well as the way people see it are also changing, and hence the meaning given to the word 'property' has also changed over time.<sup>104</sup> There are various factors which contributed to the changes in different forms of property. Transitions in

<sup>&</sup>lt;sup>102</sup> GREGORY S. ALEXANDER & EDUARDO M. PENALVER, AN INTRODUCTION TO PROPERTY THEORY, (Cambridge University Press), 71 (2012).

<sup>&</sup>lt;sup>103</sup> John Lurye, *The Evolution and Philosophy of Property*, (1946), (Sep. 06, 2018), http:// classic.austlii.edu.au/au/journals/ResJud/1947/45.pdf.

<sup>&</sup>lt;sup>104</sup> PROPERTY: MAINSTREAM AND CRITICAL POSITIONS, (C. B. Macpherson, ed., University of Toronto Press), 1 (1978).

economic pattern, societal organization and technological change, all contributed to the change in the notion of property.<sup>105</sup>

A marked shift in approach to the concept of property was pointed out by Karl Marx and Fredric Engels. Such a new approach towards the concept of property and its repercussions on the society, though not in a legalistic perspective, was attempted in their work *Communist Manifesto*. Marx and Engels saw private property as the tool for the capitalist class to exploit the proletariat by extracting the surplus value of their labour.<sup>106</sup> According to Marx and Engels, 'reform' would not come until the bourgeois property is abolished.<sup>107</sup> In Marx's terms, it is not what you possess that counts because you do not own that. Rather, it belongs to the State, or if the State determines, to someone else in need.<sup>108</sup>

Marx and Engels hypothesized a 'prehistory of society' that included 'common ownership of land' and the 'primitive form of society everywhere'. They claimed that these early societies, characterized by common ownership of all property and by economic classlessness, were, in fact, the ideal 'primitive communistic society' towards which all naturalistic historical forces were directed. Marx

<sup>&</sup>lt;sup>105</sup> REMIGIUS N. NWABUEZE, BIOTECHNOLOGY AND THE CHALLENGE OF PROPERTY: PROPERTY RIGHTS IN DEAD BODIES, BODY PARTS AND GENETIC INFORMATION, (Ashgate), 7 (2007).

<sup>&</sup>lt;sup>106</sup> PETER CANE & JOANNE CONAGHAN, THE NEW OXFORD COMPANION TO LAW, (Oxford University Press), 947 (2008).

<sup>&</sup>lt;sup>107</sup> KARL MARX & FREDERICK ENGELS, ECONOMIC AND PHILOSOPHICAL MANUSCRIPTS OF 1844 AND THE COMMUNIST MANIFESTO, (Translated by Martin Milligan), Prometheus Books, 223 (2009).

<sup>&</sup>lt;sup>108</sup> Guido Calabresi; *Do We Own Our Bodies?*, Yale Law School Legal Scholarship Repository; Faculty Scholarship Series, Paper 2011, (Apr. 25, 2013), http://digital commons.law.yale.edu/fss\_papers/2011.

called in his *Communist Manifesto* for a return to that ideal state by urging the destruction of the artificial 'bourgeois society' and the 'abolition of bourgeois property'. Thus, he summarized the major programme of any new communist society to be 'the abolition of private property'.<sup>109</sup>

A reversion, based on an economic perspective, mooted by Karl Marx and Frederick Engels, as mentioned above, was in drastic contradiction to the chronological and systematic development in the conception of property. This shift in approach to the concept of property took place in the second half of the 19<sup>th</sup> century. Changes in technology, economic system, social and political patterns are some of the reasons that instigated changes in forms of property or concepts of property in the 20<sup>th</sup> century.<sup>110</sup>

Latest studies on the theories of property points to the fact that "property... is no longer coherent or crucial category in our conceptual scheme, and that in fact, property ceases to be an important category in legal and political theory".<sup>111</sup> Till recently, wealth was primarily tangible. Wealth resided in material objects like food, shelter and tradable commodities. But in the modern era, wealth resides in promises and claims backed by the force of law such as trusts, bonds, insurance

<sup>&</sup>lt;sup>109</sup> Herbert W. Titus, *Biblical Principles of Law*, (Oct. 19, 2013), http://www.lonang.com/ curriculum/2/s23.htm.

<sup>&</sup>lt;sup>110</sup> REMIGIUS N. NWABUEZE, BIOTECHNOLOGY AND THE CHALLENGE OF PROPERTY: PROPERTY RIGHTS IN DEAD BODIES, BODY PARTS AND GENETIC INFORMATION, (Ashgate), 18 (2007).

<sup>&</sup>lt;sup>111</sup> Meredith Render, *The Law of the Body*, 62 Emory L.J. 549, 560 (2013).

and securities.<sup>112</sup> Thus the traditional concept of property has undergone a vast change.

Recent developments in science and technology also have had its impact on the meaning of property. Apart from the traditional notions of tangible property, property can even exist in intangible form such as ideas, inventions and other intellectual property rights also. With advancements in medical science and biotechnology, the human body once considered to be special, sacred and sacrosanct has been subjected to property interests in the recent years. The new situation thus calls for a re-examination of concept of the property for the purpose of affording protection to the various novel forms of property.<sup>113</sup>

### 2.4. 'CONCEPT OF PROPERTY' IN ANCIENT INDIA

Ancient Indian legal system is rich in philosophy and concepts, among which 'property' enjoyed prime position. "Property is not '*bhog*' (enjoyment or possession) but in its essence, it is one's '*Mamatva*' or '*Savatva*' (mine-ness, own-ness) which is conceptualised in ownership. The concept of 'own-ness' transmutes matter and idea into property. To be able to say '*memedam*' (this is mine) about something constitutes the very soul of owning or appropriation."<sup>114</sup>

<sup>&</sup>lt;sup>112</sup> Meredith Render, *The Law of the Body*, 62 Emory L.J. 549, 561 (2013).

<sup>&</sup>lt;sup>113</sup> N. S. GOPALAKRISHNAN, INTELLECTUAL PROPERTY AND CRIMINAL LAW, (National University of India University, 1), (1994).

<sup>&</sup>lt;sup>114</sup> S. K. PUROHIT, ANCIENT INDIAN LEGAL PHILOSOPHY: ITS RELEVANCE TO CONTEMPORARY JURISPRUDENTIAL THOUGHT, (Deep & Deep Publications Pvt. Ltd.), 206 (1994).

According to the ancient texts, property or wealth was considered the God's gift which should be enjoyed with '*tyag*', i.e., without the sense of ownership.<sup>115</sup> Due to the expectation of the people for a better life in the other world, 'property' during those days, had no tendency to remain concentrated in the hands of the rich. It had the tendency to perform the task of social welfare. A regular distribution of property by way of '*daana*' (placating with gifts) and '*punya*' was prescribed in *Shastras*. Property-oriented ideologies and materialistic approaches of life and its aims never loomed large on the mental horizon of Indians those days.<sup>116</sup> Ancient Indians never viewed property as the end in itself but a means to social welfare. Moreover, as a general rule, people in ancient India obeyed the laws of reason and nature, and respected one another's person and property.

According to '*Mahabharata*', proprietary consciousness is created only by the existence of state. State by its sanction '*danda*' (punishment) ensures property. It is because of 'danda' alone that the world observes the laws of 'dharma' (law, justice, duty, righteousness) and each individual is able to enjoy his life and property.<sup>117</sup> "For it enjoins that vehicles, apparels, ornaments, jewels, be enjoyed

<sup>&</sup>lt;sup>115</sup> "Whatever there is changeful in this ephemeral world, all that must be enveloped by the Lord. By this renunciation, support yourself. Do not covet the wealth of anyone. O fool, give up excessive desire for wealth; yoke your mind to the good and the true, and cultivate detachment. Whatever wealth you obtain by your own honest labour, with that learn to delight your mind and heart." Mantra 1, Verse 1 of *Isha Upanishad*, (Oct. 11, 2018), https://www. wisdomlib.org/hinduism/book/isha-upanishad/d/oc122460.html.

<sup>&</sup>lt;sup>116</sup> S. K. PUROHIT, ANCIENT INDIAN LEGAL PHILOSOPHY: ITS RELEVANCE TO CONTEMPORARY JURISPRUDENTIAL THOUGHT, (Deep & Deep Publications Pvt. Ltd.), 208 (1994).

<sup>&</sup>lt;sup>117</sup> The philosophies of '*dharma*' and '*danda*' runs through the ancient texts of Hindu political theory such as Mahabharata, Manu Samhitha, Shookra-Neeti and so on. *See*, Benot Kumar

by those to whom they belong, and that one's wife, children and food must not be encroached upon by others. And it is only through '*bhaya*' or fear of the state that people are prevented from encroaching upon others..."<sup>118</sup>

In the 'varna' <sup>119</sup> society which existed in India, 'Brahmins' could not accumulate property, as they were to be occupied with learning and teaching of religion. The 'Kshathriyas' were to be fighters and rulers. They were to hold only political power. 'Vaishyas' were traders, and they alone, were functionally suitable as holders of property. The 'Sudras' were servants rendering service to all the higher varnas and due to social status, and low remuneration, they could not accumulate property. As there was harmony in the functioning of varnas and their mutual dependence, 'property' only performed its appropriate social function of integration. It never attained the status of political power.<sup>120</sup> Thus no other caste in the 'varna' system except 'vysya' could accumulate wealth. Even vysyas are not allowed to accumulate wealth in 'ashrams'<sup>121</sup> of 'brahmacharya', 'vanaprastha' and 'sannyasa'.

Sarkar, *The Theory of Property, Law, and Social Order in Hindu Political Philosophy*, (Oct.11, 2018), https://archive.org/stream/jstor-2377667/2377667\_djvu.txt.

<sup>&</sup>lt;sup>118</sup> S. K. PUROHIT, ANCIENT INDIAN LEGAL PHILOSOPHY: ITS RELEVANCE TO CONTEMPORARY JURISPRUDENTIAL THOUGHT, (Deep & Deep Publications Pvt. Ltd.), 206 (1994).

<sup>&</sup>lt;sup>119</sup> 'Chathurvarna' is Sanskrit word – 'Chatur' means four and 'Varna' means groups'. 'Chathurvarna' means four groups. There were four groups of people Brahmins, Kshatriyas, Vaishyas, and Sudras – the producers. CHATURVARNA...real meaning...its misunderstanding, misuse leading to injustice & divide in society, (Oct. 11, 2018), https://www.strategicfront.org/ forums/threads/chaturvarna-real-meaning-its-misunderstanding-misuse-leading-to-injustice-divide-in-society.964/.

<sup>&</sup>lt;sup>120</sup> S. K. PUROHIT, ANCIENT INDIAN LEGAL PHILOSOPHY: ITS RELEVANCE TO CONTEMPORARY JURISPRUDENTIAL THOUGHT, (Deep & Deep Publications Pvt. Ltd.), 208 (1994).

<sup>&</sup>lt;sup>121</sup> 'Ashramas' according to the ancient Hindu philosophy, are the stages of life which provide training and environment for realising the ideal of one's life. There are four ashramas. 'Brahmacharya' or the student life, 'Garhasthya' or the family life, 'Vanaprastha' or the retired life, and 'Sannyasa' or the life of renunciation. The first two provides the training and

Ancient Indians thus gave a proper position for the concept of property in the society. Property was never permitted to grow abnormally. Indian culture, through its social system of *varnas*, struck a balance in such a way that no one would covet other people's wealth nor could one accumulate property out of greed beyond one's need. Any abuse of property makes it liable to confiscation. It was clearly understood that private property is nothing but an extension of man's ego and his love of 'self'.

Kautilya's '*Arthasasthra*'<sup>122</sup> explains clearly about the concept of property and legal relations arising out of the same. It explains the rules for partitioning of inheritance, <sup>123</sup> on immovable property<sup>124</sup> and classifies what all constitutes immovable property<sup>125</sup>. It also discusses the sale of immovable property<sup>126</sup>, deals with the disputes concerning boundaries, fixing borders, on impairment and

environment for the '*Pravrtti Marg*' and the last two for the '*Nivrtti Marg*' of an individual's development. Puja Mondal, *Four Ashramas of Vedic Life: Stages of Life in Realising the Hindu Ideal of Life!*, (Oct. 11, 2018), http://www.yourarticlelibrary.com/society/indian-society/four-ashramas-of-vedic-life-stages-of-life-in-realising-the-hindu-ideal-of-life/39153.

<sup>&</sup>lt;sup>122</sup> Kautilya, also known as Vishnugupta or Chanakya, is credited for having played an important role in the establishment of the Mauryan Empire. He served as the chief advisor to both emperors Chandragupta and his son Bindusara. *Arthashastra* written by Kautilya is an ancient Indian treatise on statecraft, economic policy and military strategy, written in Sanskrit. The title 'Arthashastra' is translated as 'the science of politics'. (Oct. 11, 2018), https://en.wikipedia.org/wiki/Arthashastra.

<sup>&</sup>lt;sup>123</sup> KING, GOVERNANCE AND LAW IN ANCIENT INDIA: *KAUTILYA'S ARTHASASTHRA*, (Translated to English by Patrick Olivelle), (Oxford University Press) 190 (2013).

<sup>&</sup>lt;sup>124</sup> KING, GOVERNANCE AND LAW IN ANCIENT INDIA: *KAUTILYA'S ARTHASASTHRA*, (Translated to English by Patrick Olivelle), (Oxford University Press) 195 (2013).

<sup>&</sup>lt;sup>125</sup> KING, GOVERNANCE AND LAW IN ANCIENT INDIA: *KAUTILYA'S ARTHASASTHRA*, (Translated to English by Patrick Olivelle), (Oxford University Press) 196 (2013).

<sup>&</sup>lt;sup>126</sup> KING, GOVERNANCE AND LAW IN ANCIENT INDIA: *KAUTILYA'S ARTHASASTHRA*, (Translated to English by Patrick Olivelle), (Oxford University Press) 196 (2013).

encroachment. Arthasasthra also explains the relationship between the owner and his 'property'.<sup>127</sup>

During the medieval period, property rights were concentrated on patriarchal lineage. As soon as the son is born, he acquires a vested interest in his father's property.<sup>128</sup> As a fact, however, a division rarely takes place even at the death of the father, and the property constantly remains undivided for several generations, though every member of every generation has a legal right to an undivided share in it.<sup>129</sup> The domain thus held in common is sometimes administered by an elected manager. The subject of the common property is neither divided in practice nor considered in theory as divisible. The entire land is cultivated by the combined labour of all the members of the undivided family, and the produce is annually distributed among the households. The co-owners have their rights distinct, and this separation of rights is complete and continues indefinitely.<sup>130</sup> Thus the notion of private property in land and soil was quite unknown to Indians during those days. They recognized only common property.

The concept of 'property' is not clearly defined in modern Indian Law. The framers of the Constitution of India, 1950 regarded the 'right to acquire and hold property' as a fundamental right under Part III. As it was enacted, the

<sup>&</sup>lt;sup>127</sup> KING, GOVERNANCE AND LAW IN ANCIENT INDIA: *KAUTILYA'S ARTHASASTHRA*, (Translated to English by Patrick Olivelle), (Oxford University Press) 215 (2013).

<sup>&</sup>lt;sup>128</sup> HENRY MAINE, ANCIENT LAW: ITS CONNECTION WITH THE EARLY HISTORY OF SOCIETY, AND ITS RELATION TO MODERN IDEAS, (Cambridge University Press) 261 (2012).

<sup>&</sup>lt;sup>129</sup> HENRY MAINE, ANCIENT LAW, (Cosimo Classics, New York), 154 (2005).

<sup>&</sup>lt;sup>130</sup> HENRY MAINE, ANCIENT LAW: ITS CONNECTION WITH THE EARLY HISTORY OF SOCIETY, AND ITS RELATION TO MODERN IDEAS, (Cambridge University Press) 267 (2012).

Constitution of India contained the provision which guaranteed the right of the citizens to acquire hold and dispose of property.<sup>131</sup> This right was subjected to Article 19 (5) which says nothing in Art.19 (1) (f) shall affect the operation of any existing law in so far as it imposes, or prevents the state from making any law imposing, reasonable restrictions on the exercise of any of the rights conferred by the said sub-clause either in 'the interest of the general public' or for 'the protection of the interests of any scheduled tribe.' Further, Article 31(1) of the Constitution stated that, no person shall be deprived of his property save by authority of law. Art.31(2) stated thus: "no property, movable or immovable, including any interest in.... shall be taken possession or acquired for public purpose..."

"Art.19(1)(f) applies to concrete and abstract rights of property, and the word 'property' in that article should be given liberal and wide meaning, and so interpreted, should be extended to those well-recognised types of interest which have an insignia or characteristic of proprietary right." <sup>132</sup> The expression contained in Article 19(1)(f) should therefore be liberally interpreted to include any interest capable of achieving certain value. And as regards the future, the law can certainly create new property rights, and once they are created, they automatically acquire the Constitutional protection.<sup>133</sup>

<sup>&</sup>lt;sup>131</sup> Article 19(1) (f) of the Constitution.

<sup>&</sup>lt;sup>132</sup> H. M. SEERVAI, CONSTITUTIONAL LAW OF INDIA, (4<sup>th</sup> edn., vol. I, Universal Book Traders), 839 (2002).

<sup>&</sup>lt;sup>133</sup> K. Subba Rao, *Property Rights under the Constitution*, (1969) 2 SCC (Jour) 1, (Dec. 02, 2012), http://www.ebc-india.com/lawyer/articles/69v2a1.htm.

The expression property is a term of wide connotation.<sup>134</sup> The term 'property' was indicative or descriptive of every possible interest which a person can have. 'Property' is a generic term with extensive application. It may mean a 'thing' or a 'right' which a person has in relation to that 'thing'.<sup>135</sup> The expression 'property' in the Constitution of India was also used with the same intention, with this wide meaning and implications. The right of property preserved by the Constitution is the right not only to possess and enjoy it, but also to acquire it in any lawful mode, or by following any lawful pursuit, which the citizen in the exercise of the liberty guaranteed may choose to adopt. The right to property therefore consists of three elements (1) to acquire (2) to own and possess and (3) to dispose of the same.<sup>136</sup> Thus, property consists of a bundle of rights, some of which the law treat themselves capable of separate acquisition and possession and enjoyment.<sup>137</sup>

Later, Article 19 (1) (f) has been deleted from part III of the Constitution by Constitution 44<sup>th</sup> Amendment Act, 1976 and has been inserted as Article 300A which states that: "No person shall be deprived of his property save by authority of law". Thus, even though the wordings of the article have not changed, the right to property has deprived of its status of a fundamental right to that of a legal

<sup>&</sup>lt;sup>134</sup> Mathew, J., in Kesavananda Bharati v. State of Kerala, (1973)4 SCC 225, 884-85.

<sup>&</sup>lt;sup>135</sup> K. Subba Rao, *Property Rights under the Constitution*, (1969) 2 SCC (Jour) 1, (Dec. 02, 2012), http://www.ebc-india.com/lawyer/articles/69v2a1.htm.

<sup>&</sup>lt;sup>136</sup> K. Subba Rao, *Property Rights under the Constitution*, (1969) 2 SCC (Jour) 1, (Dec. 02, 2012), http://www.ebc-india.com/lawyer/articles/69v2a1.htm.

<sup>&</sup>lt;sup>137</sup> H. M. SEERVAI, CONSTITUTIONAL LAW OF INDIA, (4<sup>th</sup> edn., vol. I, Universal Book Traders), 823 (2002).

right. That is, the right will be available against the executive interference, but not against the legislative interference.

Indian law classifies 'property' as 'movable property' and 'immovable property' under the Transfer of Property Act, 1882, which deals with the transfer of immovable property. The transfer of movable property is dealt under the Sale of Goods Act, 1930. Even then, none of the above mentioned statutes seems to have given a proper definition for the term 'property'. The General Clauses Act<sup>138</sup> defines 'immovable property' as "including land, benefits to arise out of land and things attached to the earth or permanently fastened to anything attached to the earth". 'Movable property' is defined as the "property of every description except immovable property".<sup>139</sup>

Section 3 of the Transfer of Property Act also defines 'immovable Property'. It states, "immovable property does not include standing timber, growing crops or grass". Further, the Benami Transactions (Prohibition) Act, 1988, defines property as, "Property means property of any kind, whether movable or immovable, tangible or intangible, and includes any right or interest in such property".<sup>140</sup> The general inferences that can be drawn from reading these definitions is that property can be anything which is either movable or

<sup>&</sup>lt;sup>138</sup> § 3 (26) of General Clauses Act, 1897.

<sup>&</sup>lt;sup>139</sup> § 3 (36) of General Clauses Act, 1897.

<sup>&</sup>lt;sup>140</sup> § 2 (c) of the Benami Transactions (Prohibition) Act, 1988.

immovable, tangible or intangible.<sup>141</sup> It can also include any interest arising out of it and can be anything which is a source or element of wealth.

#### 2.5. THEORETICAL ANALYSIS OF PROPERTY INTERESTS IN THE HUMAN BODY

Acknowledgement of the immense value of the human body and bodily materials in the field of research and transplantation surgeries<sup>142</sup> as well as the evolution of laws for the protection of intellectual property <sup>143</sup> were the greatest developments in jurisprudence relating to property during the latter half of the 20<sup>th</sup> century. Questions relating to property interests in the human body and bodily materials have become more and more complex with the development of medical science and biotechnology.

According to the analysis of Wesley Hohfeld, all legal regulation consists of interrelated rights and obligations and their opposites. Hohfeld's fundamental legal conceptions are four entitlements and four disentitlements. Four entitlements are rights, liberties, powers and immunities. Four disentitlements according to him are duties, no-rights, liabilities and disabilities.<sup>144</sup> Arranged in sets of correlatives and opposites these eight concepts describe, for Hohfeld, all possible legal regulation.<sup>145</sup> His important contribution to jurisprudence was a

<sup>&</sup>lt;sup>141</sup> Property that has physical substance and can be touched is treated as tangible property and the property that lacks this physical quality is termed as intangible property.

<sup>&</sup>lt;sup>142</sup> C. J. E. Watson & J. H. Dark, *Organ Transplantation: Historical Perspective and Current Practice*, 108 BJA, i29–i42, (May 25, 2018), https://doi.org/10.1093/bja/ aer384.

<sup>&</sup>lt;sup>143</sup> P. A. David, *The Evolution of Intellectual Property Institutions*, (May 12, 2018), https://www.merit.unu.edu/publications/rmpdf/1993/rm1993-009.pdf.

<sup>&</sup>lt;sup>144</sup> Wesley Newcomb Hohfeld, *Fundamental Legal Conceptions as Applied in Judicial Reasoning*, 26 The Yale L. J., 710-770 (1917).

<sup>&</sup>lt;sup>145</sup> Pavlos Eleftheriadis, *An Analysis of Property Rights*, 16 Oxford Journal of Legal Studies, 31-54, 31 (1996).

variety of systematizing components of legal reasoning. His analysis applies to property as one of the sub-systems of law.<sup>146</sup>

The commonly accepted 'bundle of rights'<sup>147</sup> theory of property was derived from a combination of Hohfeld's 'framework of legal relations'<sup>148</sup> and Honoré's concept of 'full ownership'<sup>149</sup>.<sup>150</sup> These incidents of ownership are right to possess, right to use, right to manage, right to the income of the thing, right to the capital, right to security, right of transmissibility, right of absence of term, duty to prevent harm, liability to execution and the incident of residuary.<sup>151</sup> According to Honoré, in order to recognize 'full ownership in a thing', an

<sup>&</sup>lt;sup>146</sup> J. Martin Pedersen, *Properties of Property: A Jurisprudential Analysis*, 14 The Commoner, 155 (2010).

<sup>&</sup>lt;sup>146</sup> Walter W. Cook, *Hohfeld's Contributions to the Science of Law*, 28 Yale L.J. (1919), (May 25, 2018), http://digitalcommons.law.yale.edu/ylj/vol28/iss8/1.

<sup>&</sup>lt;sup>147</sup> 'Bundle of rights' is an abstract notion that describes property as a collection of rights visà-vis others, rather than rights to a 'thing'. It describes the rights as well as the responsibilities upon the 'thing' owned. The 'bundle of rights' also demonstrates the ways in which ownership can be divided. Denise R. Johnson, *Reflections on the Bundle of Rights*, 32 Vermont L. Rev., 247-272, 247 (2007).

<sup>&</sup>lt;sup>148</sup> In his articles published in 1913 and 1917, Hohfeld offered a systematic and precise vocabulary to describe the range of functional relations created by legal rights. He tried to reorient legal thought away from the abstract notions of entitlement. Hohfeld presented with an analytical scheme which categorises rights into *jural* relationships, between the concerned persons, which is referred to as 'framework of legal relations'. Moreover, it is a description of the legal positions which are connected with each other by means of logical relations of entailment and negation.

<sup>&</sup>lt;sup>149</sup> Through a review and analysis of the jurisprudence relating to property, Honoré arrived at a set of eleven rights, duties and other elements which, taken together, give an account of ownership. Muireann Quigley, *Property and the Body: Applying Honoré*, 33 J. Med. Ethics, 631 (2007), (Apr. 24, 2013), http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2598107/.

<sup>&</sup>lt;sup>150</sup> Cordelia Mary Thomas, A Framework for the Collection, retention and Use of Human Body Parts, (2006), (May 12, 2014), http://researcharchive.vuw.ac.nz/bitstream /handle/10063/297/ thesis.pdf.txt?sequence=4.

<sup>&</sup>lt;sup>151</sup> J. W. HARRIS, PROPERTY AND JUSTICE, (Oxford University Press), 126 (1996).

individual must hold most (but not necessarily all) of these elements regarding that thing.<sup>152</sup>

Honoré's conception of property, however, is rarely applied to the realm of the human body and that of human biological materials. Indeed, Honoré has claimed that "a person does not either 'own' or 'have' his body or liberty"<sup>153</sup> and that in the case of 'self', the parallel with ownership is not convincing. However, when he wrote the original paper in 1960, transplant surgery was in its infancy, stem cells had only just been discovered and a multitude of medical technologies and applications utilising the body and its parts and products were decades away. The development of these and the commercial and quasi-commercial activities surrounding them requires that we necessarily have to think about and treat the body in a manner different from that envisaged by Honoré.<sup>154</sup>

Many contemporary theories of property have included the human body and its parts as the subject matter of property rights. Malleability is an important feature of property which makes its framework suitable for analysis of some aspects of legal challenges posed by claims relating to human bodies and bodily materials.<sup>155</sup>

<sup>&</sup>lt;sup>152</sup> Muireann Quigley, *Property and the Body: Applying Honoré*, 33 J. Med. Ethics, 631 (2007), (Apr. 24, 2013), http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2598107/.

<sup>&</sup>lt;sup>153</sup> Muireann Quigley, *Property and the Body: Applying Honoré*, 33 J. Med. Ethics, 631 (2007), (Apr. 24, 2013), http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2598107/.

<sup>&</sup>lt;sup>154</sup> Muireann Quigley, *Property and the Body: Applying Honoré*, 33 J. Med. Ethics, 631 (2007), (Apr. 24, 2013), http://www.ncbi.nlm.nih.gov/pmc/articles/ PMC2598107/.

<sup>&</sup>lt;sup>155</sup> REMIGIUS N. NWABUEZE, BIOTECHNOLOGY AND THE CHALLENGE OF PROPERTY: PROPERTY RIGHTS IN DEAD BODIES, BODY PARTS AND GENETIC INFORMATION, (Ashgate), 7 (2007).

Stephen Munzer studied on the variants of property rights drawing on sources as diverse as Hohfeld, Hegel, Locke, Marx and so on. His theory of property which was published in 1990, also analyses the significance of property rights in the context of the human body. According to Munzer, body rights as a whole amount to limited property rights rather than ownership, and only some of the body rights qualify as property rights<sup>156</sup> and the criterion for classifying those body rights as property rights is the aspect of transferability.<sup>157</sup>

Munzer clarifies that "too many incidents are lacking to say that persons own their bodies. Restriction on transfer and the absence of a liberty to consume or destroy<sup>158</sup> indicate that persons do not own their bodies in the way that they own automobiles or desks". Even then there are various things which the law permits or enables people to do with their bodies. It would be a mistake to say that they have no property rights in them at all. Hence one can draw the immediate conclusion that they have limited property rights in their bodies.<sup>159</sup>

<sup>&</sup>lt;sup>156</sup> STEPHEN R. MUNZER, A THEORY OF PROPERTY, Cambridge Studies in Philosophy and Law, (Cambridge University Press), 38 (1990).

<sup>&</sup>lt;sup>157</sup> STEPHEN R. MUNZER, A THEORY OF PROPERTY, Cambridge Studies in Philosophy and Law, (Cambridge University Press), 47 (1990).

<sup>&</sup>lt;sup>158</sup> STEPHEN R. MUNZER, A THEORY OF PROPERTY, Cambridge Studies in Philosophy and Law, (Cambridge University Press), 47 (1990).

<sup>&</sup>lt;sup>159</sup> STEPHEN R. MUNZER, A THEORY OF PROPERTY, Cambridge Studies in Philosophy and Law, (Cambridge University Press), 43 (1990).

### III. PROPERTY INTERESTS IN RELATION TO THE HUMAN BODY AND BODILY MATERIALS

#### **3.1. INTRODUCTION**

Interest in the human body, of a proprietary nature, arose as a result of people's curiosity in knowing the intricacies of the human body thereby understanding its structure and functioning. Rudimentary form of the branch of anatomy in medical science is considered to be the reason for the increased demand for the cadavers (dead human bodies) in early times.

Historically speaking, literature attributes Egypt and Greece as the civilisations that first attempted anatomical exercises.<sup>1</sup> The utilisation of this branch of medical science continued during the period of the Roman Empire also.<sup>2</sup> However, after the fall of the Roman Empire, anatomical studies came to a near standstill and in many places the use of cadavers became illegal.<sup>3</sup> For many years researchers were prosecuted for post-mortem dissections and it wasn't until the 15<sup>th</sup> century that researchers at medical schools in Europe were able to study the human body and its tissues without the fear of prosecution.<sup>4</sup> Studies using the human body and bodily materials have come a long way since then, and human

<sup>&</sup>lt;sup>1</sup> Monica J. Allen et al., *Human Tissue Ownership and Use in Research: What Laboratorians and Researchers Should Know*, 56 CLINICAL CHEMISTRY, 1675 (2010), (Jun. 13, 2015), http://www.clinchem.org/content/56/11/1675.full.

<sup>&</sup>lt;sup>2</sup> *Roman Medicine*, (Jun. 09, 2017), https://www.bbc.com/bitesize/guides/zcyj9qt/revision/2.

<sup>&</sup>lt;sup>3</sup> See, HELEN MACDONALD, HUMAN REMAINS: DISSECTION AND ITS HISTORIES, (Yale University Press) (2006).

<sup>&</sup>lt;sup>4</sup> Monica J. Allen et al., *Human Tissue Ownership and Use in Research: What Laboratorians and Researchers Should Know*, 56 CLINICAL CHEMISTRY, 1675 (2010), (Jun. 13, 2015), http://www.clinchem.org/content/56/11/1675.full.

bodily materials have become critical to the research enterprise. In other words, the human body as a whole and almost every part of it, including every cell is very much in demand in this modern era of biotechnology.

Whether to treat the human body and its parts as property or not has been a consistent controversy since bioethics<sup>5</sup> arose as an academic field in the late 1950's and early 1960's.<sup>6</sup> There has been an exponential rise in the use of human bodily materials for medical purposes and in scientific researches. Coupled with this, commercially inclined activities of the pharmaceutical companies and biotechnology industries has also accelerated the utility for human bodily materials.<sup>7</sup> Unprecedented advancements in biotechnology in the last few decades have complicated this question of ownership of the ownership by producing an extraordinary array of uses for the human body.<sup>8</sup> The human body and bodily materials have been used widely today for various research activities and for transplantation surgeries<sup>9</sup> and have acquired a value that is different from a value based traditional conception of the human body.<sup>10</sup>

Requirement and use of the human body and bodily materials right from the ancient Greece has progressed only arithematically till the 20<sup>th</sup> century and

<sup>&</sup>lt;sup>5</sup> Carlo Petrini, *Ethical and Legal Considerations Regarding the Ownership and Commercial Use of Human Biological Materials and their Derivatives*, 3 J. Blood Med., 87 (2012), (Apr. 16, 2016), www.ncbi.nlm.nih.gov/pmc/articles/PMC3440234/.

<sup>&</sup>lt;sup>6</sup> Meredith Render, *The Law of the Body*, 62 Emory L. J. 549, 551 (2013).

<sup>&</sup>lt;sup>7</sup> OWNERSHIP OF HUMAN TISSUES AND CELLS: NEW DEVELOPMENTS IN BIOTECHNOLOGY, Office of Technology Assessment, United States Congress, (Books for Business), 7 (2002).

<sup>&</sup>lt;sup>8</sup> Meredith Render, *The Law of the Body*, 62 Emory L. J., 549, 551 (2013).

<sup>&</sup>lt;sup>9</sup> C. J. E. Watson & J. H. Dark; Organ Transplantation: Historical Perspective and Current Practice, 108 BJA, i29–i42, (2012), (Jun. 06, 2018), https://doi.org/10.1093/bja/aer384.

<sup>&</sup>lt;sup>10</sup> Muireann Quigley, *Property and the Body: Applying Honoré*, 33 J. Med. Ethics, 631 (2007), (Jul.12, 2016), http://www.jstor.org/stable/27719970.

thereafter it has taken a geometric progression. These advances in science, technology and research have brought the question of property rights in human bodies and bodily materials to the forefront. These issues are thus important to the researchers and the society in general.<sup>11</sup>

Whether there is any property interest in the human body was a question which was discussed on various occasions in various contexts during the past.<sup>12</sup> However, the question has achieved greater significance in the present day due to above said reasons.<sup>13</sup> Recent and rapid development in biotechnology has radically altered the utility and potential value of parts of the body formerly considered waste products fit for disposal only.<sup>14</sup> Many human tissues are used for biotechnological research in which the results are very significant and yield monetary benefits and thus have become potentially valuable commodities.<sup>15</sup>

"For better or for worse, we have irretrievably entered an age that requires examination of our understanding of the legal rights and relationships in the human body and the human cell."<sup>16</sup> Law concerning property in the human body

<sup>&</sup>lt;sup>11</sup> Remigius N. Nwabueze, *Biotechnology and the New Property Regime in Human Body and Body Parts*, 24 LOY. L.A. INT'L & COMP. L. REV., 19, 21 (2002).

<sup>&</sup>lt;sup>12</sup> *See* paragraphs 3.3. & 3.4.

<sup>&</sup>lt;sup>13</sup> ROHAN HARDCASTLE, LAW AND THE HUMAN BODY: PROPERTY RIGHTS, OWNERSHIP AND CONTROL, (Hart Publishing, Oxford and Portland, Oregon), 3 (2007).

<sup>&</sup>lt;sup>14</sup> Neil Maddox, *Property Rights in the (Fragmented) Human Body: Property, Control and Separated Human Biomaterials*, 23, Eur. J. Health Law, (2016), (May 05, 2018), http://books andjournals.brillonline.com/content/journals/10.1163/15718093-12341411.

<sup>&</sup>lt;sup>15</sup> Margaret S. Swain & Randy W. Marusyk, *An Alternative to Property Rights in Human Tissue*, in ORGAN AND TISSUE TRANSPLANTATION, (David Price, ed.), (The International Library of Medicine, Ethics & Law, Routledge), (2016).

<sup>&</sup>lt;sup>16</sup> *Moore v. Regents of the University of California*, California 2<sup>nd</sup> District Court of Appeals, 249 Cal. Rptr. 494 at 504 as per Rothman, J. (1988).

and its parts is complex and at present is under a state of evolution.<sup>17</sup> One of the aftereffects of these activities is, today, more than ever, people are concerned about questions of what can and cannot be done with human bodies and bodily materials.<sup>18</sup> Whether or not the human body and the materials procured from the human body should be given property rights remains an unsettled question to a large extent.

#### **3.2. PROPERTY RIGHTS IN THE HUMAN BODY**

Property rights over the human body and bodily materials would mean the rights over the fate of the human body and its parts, and the use of them. The question whether the human body and bodily materials should be treated as property or not has to be analysed from different dimensions. Discussions about the human body should begin with the human body as a whole. Logically speaking, living human body and the dead human body has to be treated differently. Answer to the question whether a whole living human body can be attributed with property rights will be different from the answer to the question whether a human corpse can be the subject of property rights. Apart from this, the status of excised human tissues and human bodily materials has to be treated differently. The importance of surgical leftovers, specimen collected post mortem, specimen collected for future unspecified use, etc., has to be analysed differently.

<sup>&</sup>lt;sup>17</sup> PRINCIPLES OF MEDICAL LAW, (Andrew Grubb, Judith Laing, et al., eds.), (Oxford University Press), 1036 (2010).

<sup>&</sup>lt;sup>18</sup> Muireann Quigley, *Property and the Body: Applying Honoré*, 33 J. Med. Ethics, 631 (2007), (Jul. 12, 2016), http://www.jstor.org/stable/27719970.

Common Law did not initially recognise property rights in human corpse, but it did recognize property rights in human beings.<sup>19</sup> Property rights with respect to human persons first arose in the context of slavery, whereby slaves were treated as chattels and not legal persons.<sup>20</sup> Perusal of the history of the United States of America will show that prior to the abolition of slavery in the 19<sup>th</sup> century, the Courts accepted that "... a portion of our fellow creatures may become the subject of property."<sup>21</sup> Thus, under the Common Law, although a dead human

The practice of slavery is condemned<sup>22</sup> by the modern world<sup>23</sup> and any reliance on the said practice even from an analytical purpose does not have any significance. So the question relating to property rights over the human body excludes slavery in its traditional and strict meaning.

body could not be owned, a living body could apparently be owned as a slave.

The twenty first century is witnessing an explosion of research in biotechnology where the human bodily materials are subject matter of research as well as controversies. The most important question relating to the use, storage and

<sup>&</sup>lt;sup>19</sup> It can be observed that English Law in its various decisions has categorically denied property rights in the dead human body. More or less at the same time, systems following the Common Law practiced slavery.

<sup>&</sup>lt;sup>20</sup> Richard Taylor, *Human Property: Threat or Saviour?*, 44 MurUEJL, (2012), (Jun. 12, 2014), http://www. murdoch.edu.au/elaw/issues/ v9n4/taylor94\_text.html#Notes\_C.

<sup>&</sup>lt;sup>21</sup> Gregson v. Gilbert (1783) 99 ER 629, Cited in Taiwo A. Oriola, Genes for Sale: Ethical Reflections on Donor's Proprietary Rights in Human Genetic Derivatives, (Jun. 20, 2014), http://www.ccels.cf.ac.uk/archives/publications/2006/oriolapaper.pdf.

<sup>&</sup>lt;sup>22</sup> Supplementary Convention on the Abolition of Slavery, the Slave Trade, and Institutions and Practices Similar to Slavery, 1956, United Nations, *Treaty Series*, vol. 266, 3, (Oct. 15, 2017), https://treaties.un.org/pages/ViewDetailsIII.aspx?src=TREATY&mtdsg\_no=XVIII-4& chapter=18&Temp=mtdsg3&clang=\_en.

<sup>&</sup>lt;sup>23</sup> JENNY S. MARTINUS, SLAVE TRADE AND THE ORIGINS OF INTERNATIONAL HUMAN RIGHTS LAW, (Oxford University Press), Introduction, 13 (2012).

retention of the body tissue revolves around questions relating to property jurisprudence. From the age where man treated land, cattle and wife as property, humanity has travelled a long way and presently the human bodily materials such as blood, kidney, eyes, gametes, etc., are treated as sources of income.<sup>24</sup>

#### **3.3. PROPERTY RIGHTS IN A DEAD HUMAN BODY**

Body of a dead person, referred to as corpse<sup>25</sup> is the stage soon after life exits and before the stage of decomposition. Historically, corpse has been an object of peculiar interest and concern. The body itself is undeniably a 'thing', but there is a peculiar difference between a living body and a dead one, so much the same, and yet so different.<sup>26</sup>

Before anatomy emerged as a recognised branch of medical practice, corpses had no medical or commercial value and, as such, disputes concerning their ownership hardly arose. With the emergence of anatomy as a separate and recognised branch of medicine, physicians needed corpses to practice dissection and perfect the art of surgery. Initial supply, in Europe, came from a class of infamous men known as the 'resurrectionists' or 'body snatchers'.<sup>27</sup> This group

<sup>&</sup>lt;sup>24</sup> For a detailed discussion, *see* chapter VI.

<sup>&</sup>lt;sup>25</sup> Corpse is also referred to as cadaver.

<sup>&</sup>lt;sup>26</sup> See, Hans Jonas, *Life, Death, and the Body in the Theory of Being,* 19 The Review of Metaphysics, 3-23 (1965), (Oct. 03, 2018), www.jstor.org/stable/20124095.

<sup>&</sup>lt;sup>27</sup> CHRIS HABLES GRAY, CYBORG CITIZEN: POLITICS IN THE POSTHUMAN AGE, (Routledge), 83 (2001), *See* also, REMIGIUS N. NWABUEZE, BIOTECHNOLOGY AND THE CHALLENGE OF PROPERTY: PROPERTY RIGHTS IN DEAD BODIES, BODY PARTS AND GENETIC INFORMATION, (Ashgate), 17 (2007).

specialised in stealing newly buried corpses from their graves and selling the same to physicians.<sup>28</sup>

In post Renaissance period, with the increasing interest in anatomical studies, the commercial value of corpses also increased.<sup>29</sup> It sustained the activities of the resurrectionists for many years.<sup>30</sup> Body snatchers prevailed during the period when the Common Law did not recognise a property right in corpses. The Common Law's non consideration of corpses as property made it difficult to prosecute body snatchers. Public concern regarding the inhuman activities of the resurrectionists and the urgent medical demand for corpses for the purpose of dissection inspired the development of a legal governance regime.<sup>31</sup> With that, the interferences with corpses were considered as meddling with property rights.<sup>32</sup>

More recently, with the emergence of biotechnology, the raw materials used for research are compounds commonly found in the human body or are components of the human body itself. The advent of modern biotechnology and the claims of

<sup>&</sup>lt;sup>28</sup> See in general, SUZIE LENNOX, BODY SNATCHERS, (Pen & Sword Books Ltd.), (2016), See also, REMIGIUS N. NWABUEZE, BIOTECHNOLOGY AND THE CHALLENGE OF PROPERTY: PROPERTY RIGHTS IN DEAD BODIES, BODY PARTS AND GENETIC INFORMATION, (Ashgate), 17 (2007).

<sup>&</sup>lt;sup>29</sup> MARY ROACH, STIFF: THE CURIOUS LIVES OF HUMAN CADAVERS, (Penguin Books), (2012).

<sup>&</sup>lt;sup>30</sup> The supply from 'body-snatchers' or 'resurrectionists' was objected to by the local inhabitants and led to an attack on the Cambridge anatomical school in 1833. Cited in, O. Dearlove, *Rights of Possession in Human Corpses*, 50 J. Clin. Pathol., 90-91 (1997), (Jun. 06, 2018), http://jcp. bmj.com/content/jclinpath/50/2/90.full.pdf.

<sup>&</sup>lt;sup>31</sup> REMIGIUS N. NWABUEZE, BIOTECHNOLOGY AND THE CHALLENGE OF PROPERTY: PROPERTY RIGHTS IN DEAD BODIES, BODY PARTS AND GENETIC INFORMATION, (Ashgate), 17 (2007).

<sup>&</sup>lt;sup>32</sup> REMIGIUS N. NWABUEZE, BIOTECHNOLOGY AND THE CHALLENGE OF PROPERTY: PROPERTY RIGHTS IN DEAD BODIES, BODY PARTS AND GENETIC INFORMATION, (Ashgate), 17 (2007).

the researchers who practice it, for the first time since the abolition of slavery, necessitated deciding whether the human body and its components ought again to be the subject matter of the property discourse.<sup>33</sup> New developments in biotechnology have thus radically altered the human being's relationship with the human bodies.

To have a property right in the body or to a component of the body is to have the power to make decisions about the fate and use of the body and its components.<sup>34</sup> "While modern Westerners are far more likely to think the body is no longer of significance after the person has died, the body continues to be thought of as far more than a simple 'thing' and disputes about it, its disposal and its treatment after death continue to turn on issues of human dignity and respect".<sup>35</sup>

# 3.3.1. THE COMMON LAW DEVELOPMENT: PROPERTY IN RELATION TO CORPSE

The English Law has discussed the issue of property rights relating to corpse earlier in the 17<sup>th</sup> century itself.<sup>36</sup> Under the Common Law, the general proposition is that, there are no property interests in the human corpse.<sup>37</sup>

<sup>&</sup>lt;sup>33</sup> RICHARD E. GOLD, BODY PARTS: PROPERTY RIGHTS AND OWNERSHIP OF HUMAN BIOLOGICAL MATERIALS, (Georgetown University Press, Washington, D.C), 20 (2007).

<sup>&</sup>lt;sup>34</sup> Prue Vines, *The Sacred and the Profane: The Role of Property Concepts in Disputes about Post-mortem Examination*, 9 Syd. L. Rev., 235 (2007), (Nov. 15, 2012), http://sydney.edu. au/law/slr/slr29\_2/Vines.pdf.

<sup>&</sup>lt;sup>35</sup> Prue Vines, *The Sacred and the Profane: The Role of Property Concepts in Disputes about Post-mortem Examination*, 9 Syd. L. Rev., 235 (2007), (Nov. 15, 2012), http://sydney.edu. au/law/slr/slr29\_2/Vines.pdf.

<sup>&</sup>lt;sup>36</sup> Haynes's Case (1614) 12 Co. REP. 113.

<sup>&</sup>lt;sup>37</sup> Richard Taylor, *Human Property: Threat or Saviour?*, 9 MurUEJL, 44 (2002), (Oct. 09, 2016), http://www5.austlii.edu.au/au/journals/MurUEJL/2002/44.html#Origins%20of%20the %20Rule\_T.

Property right in the human body was reportedly first denied earlier in 1614 in the *Haynes's* case<sup>38</sup>. The proposition that a body cannot own property was laid down in this case<sup>39</sup> although the facts of the case do not appear to provide a basis for the 'no property in human body rule', as there was no actual theft of the human body. Rather, Haynes was charged with the theft of winding sheets used to wrap up four corpses in a graveyard.

The old Common Law principle relating to the ownership of the human corpse can be strongly based on *Williams v. Williams*<sup>40</sup>. In this case, the Court laid down that there is no property in the corpse; and therefore a person could not dispose of his body by will. Kay, J., stated that "accordingly the law in this country is clear, after the death of a man, his executors have a right to the custody and

<sup>&</sup>lt;sup>38</sup> Mr. Haynes was charged with stealing, from a graveyard, the winding sheets that bound the bodies of four corpses. He was whipped for petty larceny. The first point to note is that the case does not involve theft of a body, though always quoted in the context of property jurisprudence in relation to the human body. The apparent lack of a nexus between the facts of the case and the proposition has generated the view by analysts that the Haynes case did not actually establish the 'no property in human body rule', PERSONS, PARTS AND PROPERTY: HOW SHOULD WE REGULATE HUMAN TISSUES IN THE 21<sup>ST</sup> CENTURY?, (Imoogen Gold et.al., (eds.),(Hart Publishing), 237 (2014).

<sup>&</sup>lt;sup>39</sup> Richard Taylor, *Human Property: Threat or Saviour?*, 9 MurUEJL, 44 (2002), (Jun. 12, 2014), http://www.murdoch.edu.au/elaw/issues/v9n4/taylor94\_text.html#Notes\_C.

<sup>&</sup>lt;sup>40</sup> [1882] 20 Ch. D 659, The deceased had directed that his executors should give his body to Miss Williams; and by letter he requested her to cremate his body under a pile of wood, to place the ashes into a specified Wedgwood vase and to claim her expenses from his executors. After the body had been buried at the direction of the executors, Miss Williams therefore caused it to be dug up, sent to Milan and cremated; and she caused the ashes to be placed in the vase. Then she claimed her expenses from the executors. The Court dismissed her claim. The Court of Chancery held that since "there is no property in the dead body of a human being", the deceased was unable to dispose of his body through his will; and that Miss Williams therefore had no right to cause it to be dug up and taken abroad for cremation. JESSEY WALL, BEING AND OWNING: THE BODY, BODILY MATERIAL AND THE LAW, (Oxford), 1-2 (2015).

possession of his body (although they have no property in it) until it is properly buried"<sup>41</sup>.<sup>42</sup>

The Common Law also offered some criminal law protection for the buried and even the unburied bodies. In *R. v. Lynn*<sup>43</sup>, it was held to be a misdemeanour to exhume a dead body, even for honourable reasons, without the authority of a Court. Further in *R. v. Sharpe*,<sup>44</sup> the Court referred to the fact that there could be no property in a corpse - "neither does our law recognise the right of any one child to the corpse of its parent as claimed by the defendant. Our law recognizes no property in a corpse…"<sup>45</sup> In *Foster v Dodd*,<sup>46</sup> Mr Justice Byles stated: "A dead body by law belongs to no one, and is, therefore, under the protection of

<sup>&</sup>lt;sup>41</sup> [1882] 20 Ch. D 659, 665.

<sup>&</sup>lt;sup>42</sup> A similar position can be seen in the US decisions as well as Canadian decisions. In *Enos v Snyder* 63, 170, (Cal. 1900). The California Supreme Court held that, in the absence of statutory provisions, there is no property in a dead body, that it is not part of the estate of the deceased person, and that a man cannot by will dispose of that which after his death will be his corpse. In *Davidson v. Garreth*, [1899] C.C.C. 200, 203; the plaintiff brought an action for damages against some practicing physicians for conducting an unauthorised dissection on his deceased wife's body. The Court held that "there is no property in a dead body, and a trespass cannot be committed in respect of it". In *Edmonds v. Amstrong Funeral Home Ltd.*, [1931] D.L.R. 676, the Alberta Supreme Court referred to the British decisions and upheld the no-property rule.

<sup>&</sup>lt;sup>43</sup> (1788) 2 TR 733, 100 ER 395. This was the first reported conviction for taking a body, but it was done on the basis of criminal law, and not on the basis of property rights. *Cited* in, Prue Vines, *The Sacred and the Profane: The Role of Property Concepts in Disputes about Post-mortem Examination*, 9 Syd. L. Rev., 235 (2007), (Nov. 15, 2012), http://sydney.edu.au/law/slr/slr29\_2/Vines.pdf.

<sup>&</sup>lt;sup>44</sup> *R v. Sharpe* (1857) Dears & B 160. In this case, a son removed his mother's remains from a graveyard. The Court upheld the 'no property' rule and the defendant was charged for trespass to land. The man removed his mother's body from the burial ground of a dissenting church in order to bury it with his father's. It was held, that although his motive was good, yet as he removed it without consent of the congregation or its officers, the indictment should be sustained. The Court said that under the English law, the only protection of a grave, independent of ecclesiastical authority, was by indictment. Cited in O. Dearlove, *Rights of Possession in Human Corpses*, 50 J. Clin. Pathol., 90-91 (1997), (Jun. 06, 2018), http://jcp.bmj.com/content/jclinpath/50/2/90.full.pdf.

<sup>&</sup>lt;sup>45</sup> Cited in, Prue Vines, *The Sacred and the Profane: The Role of Property Concepts in Disputes about Post-mortem Examination*, 9 Syd. L. Rev., 235, (2007), (Nov. 15, 2012), http://sydney. edu.au/law/slr/slr29\_2/Vines.pdf.

<sup>&</sup>lt;sup>46</sup> (1867) LR 3 QB 67.

the public. If it lies in consecrated ground, the ecclesiastical law will interpose for its protection..."<sup>47</sup>

Though the traditional view considers that the dead body is not property,<sup>48</sup> recent trend in the cases and statutes which are warranted by the advancement in medical technologies points to the fact that there can be property rights, though limited, in the human body and bodily materials. Therefore, the two possibilities are, either the body is not property, or the body is a property. If it is property, someone must own it. It further raises the question of who could legitimately own it.

## **3.3.1.1. 'APPLICATION OF WORK AND SKILL' AS AN EXCEPTION TO THE 'NO PROPERTY RULE'**

The general rule is that there is no property in the human corpse. However, an examination of cases concerning the human corpse demonstrate that Courts of law have carved out certain exceptions. Many of these attempts do not hold precedential value.

Certain old English cases had held that a creditor may arrest the body of a deceased debtor for debts he owed, thereby regarding corpses as property in

<sup>&</sup>lt;sup>47</sup> Gallaghar S. & Cosgrove Gibson, *Exhuming Justice*, New Law Journal, (2008), (Jun. 06, 2018), https://www.newlawjournal. co.uk/content/exhuming-justice.

<sup>&</sup>lt;sup>48</sup> Prue Vines, *The Sacred and the Profane: The Role of Property Concepts in Disputes about Post-mortem Examination*, 9 Syd. L. Rev., 235, (2007), (Nov. 15, 2012), http://sydney.edu.au/law/slr/slr29\_2/Vines.pdf.

certain circumstances. <sup>49</sup> However, in *Jones v. Ashburnham*, <sup>50</sup> the Court condemned the practice as being "contrary to every principle of law and moral feeling".<sup>51</sup> Finally by the mid-nineteenth century, it was reasonably settled that a dead human body was not property that could be arrested in execution of a debt or judgment.<sup>52</sup>

Later, during the second half of the 20<sup>th</sup> century, English Courts started accepting property rights in certain body materials such as hair,<sup>53</sup> urine,<sup>54</sup> blood,<sup>55</sup> etc. These cases generally laid down the principle that certain body materials are capable of theft.<sup>56</sup> Other instances where property interests are granted to the human body are when it is possessed by medical colleges for the purpose of anatomical studies or display.

<sup>&</sup>lt;sup>49</sup> *Quick v. Coppleton*, 83 Eng. Rep. 349 (K.B. 1803); *R. v. Cheere*, 107 Eng. Rep. 1294 (K.B. 1825). *Cited* in, Remigius N. Nwabueze, *Biotechnology and the New Property Regime in Human Bodies and Body Parts*, 24 Loy. L.A. INT'L & COMP. L. Rev., 19, 20 (2002), (Jun 24, 2014), http://digitalcommons.lmu.edu/ilr/vol24/iss1/2/.

<sup>&</sup>lt;sup>50</sup> 102 Eng. Rep. 905 (K.B. 1804).

<sup>&</sup>lt;sup>51</sup> (1804) 102 E.R. 905.

<sup>&</sup>lt;sup>52</sup> Remigius N. Nwabueze, *Biotechnology and the New Property Regime in Human Bodies and Body Parts*, 24 Loy. L.A. INT'L & COMP. L. Rev., 19, 20 (2002), (Jun 24, 2014), http://digital commons.lmu.edu/ilr/vol24/iss1/2/.

<sup>&</sup>lt;sup>53</sup> *R v. Herbert* (1961) 25 JCL 163, a lock of Byron's hair was sold at Sotheby's Auction House in 1970 for £320.

<sup>&</sup>lt;sup>54</sup> *R v. Welsh* [1974] RTR 478, a man was taken to a police station under suspicion of being in charge of driving a motor vehicle under the influence of alcohol. He provided a urine sample but then when the constable left the room he emptied it into a sink. He was convicted of attempting to defeat the course of justice and theft of the urine sample. He appealed, but only in respect of the severity of the sentences imposed. The conviction for theft was not questioned. <sup>55</sup> In *R v Rothery* (1976) 63 Cr App R 231, a man in similar circumstances to those in *Welsh* was required to provide a specimen of blood. The specimen was provided, but was stolen later. He was charged with theft and with failing to provide a specimen for laboratory testing. He pleaded guilty to both offences yet appealed against his conviction, but only in respect of the latter offence. The appeal was upheld. Again, the conviction for theft was not questioned. <sup>56</sup> PRINCIPLES OF MEDICAL LAW, (Andrew Grubb, Judith Laing, et al., eds.), (3<sup>rd</sup> edn., Oxford University Press, Oxford), 1037 (2010).

Such cases were instances wherein Courts tried to carve out exceptions from the 'no property rule' to provide a remedy to the litigant. These decisions were not successful enough in laying down a general principle of law. However, *Doodeward v. Spence*<sup>57</sup> which came up before the High Court of the Commonwealth of Australia in the beginning of 20<sup>th</sup> century later became a trend setter.

As an exception to the 'no property rule', certain property rights are recognised in body parts, generally excised, if there is any 'application of work and skill' on that said part by a person other than the source person. Griffith C. J., in *Doodeward v. Spence*<sup>58</sup> observed,

"When a person has by the lawful exercise of work or skill so dealt with a human body or part of a human body in his lawful possession that it has acquired some attributes differentiating it from a mere corpse awaiting burial, he acquires a right to retain possession of it..."

The case, for the first time, thus created an exception where the 'application of work and skill' could transform the human body and body parts into property. This is akin to applying the Roman law concept of '*specificatio*'<sup>59</sup> to

<sup>&</sup>lt;sup>57</sup> (1908) 6 CLR 406.

<sup>&</sup>lt;sup>58</sup> (1908) 6 CLR 406. The body of a still-born two-headed baby was preserved in spirits for 40 years by the doctor who had been attending its mother; upon the doctor's death it was sold as part of the doctor's estate to the appellant. The appellant exhibited it for profit until the police officer seized it with a view to its burial. An action was brought by the plaintiff/ appellant for recovery of the foetus. Cited in, Richard Taylor, *Human Property: Threat or Saviour?*, 9 MurUEJL, 44 (2002), (Jun. 12, 2014), http://www.murdoch.edu.au/elaw/issues/v9n4/taylor 94\_text.html#Notes\_C.

<sup>&</sup>lt;sup>59</sup> It is the doctrine whereby the creator of the new thing takes property in it if the materials are incapable of separation as a result of the separation. For example, the painter owns the cloth on which he paints. W. J. STEWART, COLLINS DICTIONARY OF LAW, (2006), (Oct. 03, 2018), https://legal-dictionary.thefreedictionary.com/specificatio. *See* also, W.W. BUCKLAND, A

human tissue, the consequence being that the new 'product' not only acquires an individual property status but also that the property is vested in the person who performed the work.<sup>60</sup>

This exception of 'application of work and skill' to the 'no property rule' even though devised in 1908 is not seen used for a long time. In 1996, English Court in *Dobson v. North Tyneside Health Authority*, <sup>61</sup> referred to *Doodeward v. Spence* and concluded that the said exception cannot be applied in that case for the reason that the applied work and skill was not sufficient enough. In this case, the relatives of a woman who died from brain tumour brought action against the hospital alleging that it had converted the 'property' to which the relatives were entitled.<sup>62</sup> The Court of Appeal held that there was no right of possession or ownership of the brain, or indeed of the corpse, vested in relatives. Further it was held that the minimal work or skill that was applied to the bodily material, i.e., the preservation of the brain in fluid, was insufficient for claiming the exception of the 'application of work and skill'.<sup>63</sup>

TEXT-BOOK OF ROMAN LAW: FROM AUGUSTUS TO JUSTINIAN, (3<sup>rd</sup> edn., Cambridge University Press) (1968).

<sup>&</sup>lt;sup>60</sup> Kenyon Mason & Graeme Laurie, *Consent or Property? Dealing with the Body and Its Parts in the Shadow of Bristol and Alder Hey*, 64 The Modern L. Rev., 710-729, 721 (2001).
<sup>61</sup> [1006] 4 All EP 474

<sup>&</sup>lt;sup>61</sup> [1996] 4 All ER 474.

<sup>&</sup>lt;sup>62</sup> In order to establish the claim of the relatives of the deceased, it has to be ascertained whether the tumours were malignant. That could be done only by examining the deceased's brain. Brain had been removed and preserved by the hospital during autopsy as directed by the coroner, but disposed of later.

<sup>&</sup>lt;sup>63</sup> [1996] 4 All ER 474, 479.

It is to be noted that the Court in  $Dobson^{64}$  is not discarding the far-reaching wisdom of the Court in  $Doodeward^{65}$  but is only of the opinion that the case in hand was not having the sufficient attributes for the application of the said exception. Thus, even though not applied, the ratio in *Doodeward v. Spence* came into prominence and it could be seen in a few later cases.

Later in *R. v. Kelly*,<sup>66</sup> the Court of Appeal recognised property rights in body parts where they had been subjected to dissection, preservation or had otherwise acquired different attributes by the application of skill.<sup>67</sup> Following this the English Courts have built up the exception of application of work and skill, to the rule that there can be no ownership in human corpse. Thus the exception of 'application of work and skill' to the 'no property rule' in relation to human corpse was affirmed in *R. v. Kelly*.<sup>68</sup> The Court of Appeal observed: "parts of a corpse are capable of being property... if they have acquired different attributes by virtue of the application of skill, such as dissection or preservation techniques, for exhibition or teaching purposes".<sup>69</sup> That is, certain property rights can be

<sup>&</sup>lt;sup>64</sup> [1996] 4 All ER 474.

<sup>&</sup>lt;sup>65</sup> (1908) 6 CLR 406.

<sup>&</sup>lt;sup>66</sup> [1998] All ER 741.

<sup>&</sup>lt;sup>67</sup> The question in this case was, whether it was 'theft' for a junior technician of the Royal College of Surgeons to remove body parts for use, and ultimate disposal, by an artist who was interested in employing them as moulds for his sculptures. Kelly and Lindsay, who were artist and technician respectively, were charged with the theft of up to forty anatomical specimens. The Court of Appeal held that "body parts do not constitute property within § 4 of the Theft Act, 1968, is subject to an exception where those parts have acquired different attributes by virtue of application of skill, such as dissection or preservation techniques, for exhibition or teaching purposes", as per Rose L.J., at 749.

<sup>&</sup>lt;sup>68</sup> [1998] All ER 741.

<sup>&</sup>lt;sup>69</sup> [1998] All ER 741, at 749-750.

attributed to the body and bodily materials if somebody had applied his skill to it.

In *AB* v *Leeds Teaching Hospital NHS Trust*,<sup>70</sup> the Court reiterated the exception accepted in *R* v. *Kelly*.<sup>71</sup> It was held that the slides and blocks produced with the retained paediatric parts were the property of the defendants due to the skill and work required for their preparation.

According to Gage, J.,

"...the part of a body may acquire the character of property which can be the subject of rights of possession and ownership is now part of our law... to dissect and fix an organ from a child's body requires work and a great deal of skill. The subsequent production of blocks and slides is also a skilful operation requiring work and expertise of trained scientists".<sup>72</sup>

This series of decisions spread across the last decade of the 20<sup>th</sup> century and the first decade of 21<sup>st</sup> century is basically relying on a decision of the 1<sup>st</sup> decade of the 20<sup>th</sup> century and has invariably settled the exception of 'work and skill' to the 'no property rule' in relation to corpse. Thus, contrary to the long history of jurisprudence which was not favourable for attributing property interest in dead

<sup>&</sup>lt;sup>70</sup> [2004] All ER (D) 506; (2004) EWHC 644 (QB). This case is also known as *Re, Organ Retention Group Litigation*. Action was initiated by the parents of the deceased children, whose organs were removed, retained and finally disposed of after post mortem. Although the parents consented to post mortem, they allegedly did not consent to the removal and retention of their children's organs. With respect to the claim for unlawful interference with the body, Gage, J., held that it was in the nature of conversion of paediatric organs and the conversion of the human body is not a recognised cause of action in England.

<sup>&</sup>lt;sup>71</sup> [1998] All ER 741.

<sup>&</sup>lt;sup>72</sup> [2004] All ER (D) 506; according to Gage, J.

human bodies, the recent legal philosophy favours recognition of property rights.<sup>73</sup>

# 3.4. PROPERTY RIGHTS IN A LIVING HUMAN BODY

Whether living human body<sup>74</sup> and excised bodily materials therefrom can be treated as subject of property is a legal and ethical issue of significance in the present scenario. The progress in medical science and biotechnology, has given rise to unanticipated uses of the human body and bodily materials. As long as the individual's parts remain within the person, they serve the function of the person, but once it is severed from the body of the person, the question of property rights arises in such excised body part.

## 3.4.1. STATUS OF EXCISED HUMAN BODY PARTS

In a short span of time, advancements in science of biotechnology have made it possible to derive new medicines from human tissue. The potential profitability of these medicines has sparked a great debate over whether the donors of these tissues must be informed that a commercial product may be developed using their cells and whether they have any right to compensation for such use.<sup>75</sup>

<sup>&</sup>lt;sup>73</sup> Remigius N. Nwabueze, *Biotechnology and the New Property Regime in Human Bodies and Body Parts*, 24 LOY. L.A. INT'L & COMP. L. Rev., 19, 20 (2002), (Jun 24, 2014), http://digital commons.lmu.edu/ilr/vol24/iss1/2/.

<sup>&</sup>lt;sup>74</sup> Property interests in living human body arises in various situations where the human body is put to use for various purposes including slavery, prostitution, commercial surrogacy, etc., which is strictly speaking commercialisation of bodily services, and is outside the scope of this present work, which deals only with the commercialisation of human body and bodily materials in its abstract sense.

<sup>&</sup>lt;sup>75</sup> Maureen S. Dorney, *Moore v. The Regents of the University of California: Balancing the Need for Biotechnology Innovation against the Right of Informed Consent*, 5 Berkeley Tech. L.J. 333 (1990), (Jun. 06, 2018), http://scholarship.law.berkeley.edu/btlj/vol5/iss2/4.

The bodily materials can be obtained through various means. It can be donated, it can be procured from surgical leftovers, or specimens left for some diagnostic purposes.<sup>76</sup> Courts now face multiple controversies concerning the use of bits and pieces of human bodies and their derivatives that lie scattered in pathology laboratories, state museums, archives, sperm banks, fertility clinics, and forensic DNA collections.<sup>77</sup>

Excised human tissues have a special status apart from the originator and has to be looked upon from a different perspective. Once it is removed from the source person, it cannot be treated as part of that body. Even then, it cannot be treated as a tangible property, like any other, which can have its own existence. Thus excised tissues can neither be treated in the same way as part of a living human body nor any other tangible property of commercial value.

"Once a body part is reintegrated into the body of another, the source's rights would be extinguished and the part become part of the recipient's body and thus, included in that person's personal rights. Thus, an excised kidney in a dish awaiting transplantation is a different entity and has a use or significance beyond its mere existence, when compared with a kidney forming part of a complex entire living body."<sup>78</sup>

Discussions relating to the property rights in excised human tissues has to be further analysed from two perspectives. 1) excised tissues from a living person,

<sup>&</sup>lt;sup>76</sup> OWNERSHIP OF HUMAN TISSUES AND CELLS: NEW DEVELOPMENTS IN BIOTECHNOLOGY, Office of Technology Assessment, United States Congress, (Books for Business), 7 (2002).

<sup>&</sup>lt;sup>77</sup> R. Alta Charo, *Body of Research - Ownership and Use of Human Tissue*, 355 N.E.J.M., 1517 (2006).

<sup>&</sup>lt;sup>78</sup> Cordelia Mary Thomas, *A Framework for the Collection, Retention and Use of Human Body Parts*, (2006), (Jun. 06, 2018), http://researcharchive.vuw.ac.nz/xmlui/bitstream/handle/10063/297/thesis.pdf?sequence=2.

2) excised tissues from a cadaver. The use of excised tissues from a living person is mostly governed by the consent of the source person. If the originator of the tissue consents to the same, anything can be done with the excised tissues is one way of looking at the status of the same. Mostly the surgical left overs are put to research with a blanket consent obtained from the source person prior to the surgery in question. A totally different question can arise when researchers use tissue obtained post-mortem. That is, the question whether family members have an ownership interest in the deceased's body.<sup>79</sup>

Another major question arises in this area is the specimens collected for future unspecified use. The potential value of human material depends on a number of different factors. These include the circumstances in which the material is removed from the body, whether and how it is retained or used and, if so, the form in which it is retained or used.<sup>80</sup>

# 3.4.1.1. PROPERTY INTERESTS IN EXCISED HUMAN TISSUES: JUDICIAL ATTITUDE

Perusal of law reports of Common Law systems shows that the first instance where a court examined rights over excised human tissues was with regard to the question relating to property rights in excised human tissues. The same question was discussed by the Californian Supreme Court in *Moore v. Regents of the* 

<sup>&</sup>lt;sup>79</sup> Monica J. Allen, et al., *Human Tissue Ownership and Use in Research: What Laboratorians and Researchers Should Know*, 56 CLINICAL CHEMISTRY 1680 (2010).

<sup>&</sup>lt;sup>80</sup> Kenyon Mason & Graeme Laurie, *Consent or Property? Dealing with the Body and its Parts in the Shadow of Bristol and Alder Hey*, 64 The Modern L. Rev., 710, 712 (2001).

*University of California*<sup>81</sup>. It can be observed that the US case reports is comparatively rich in dealing with these legal issues more than any other Common Law jurisdictions. In *Moore's* Case, the Court held that Moore's spleen was not his property.<sup>82</sup> The Court found that the 'Mo cell line' - which had been created from Moore's spleen cells and, ironically, named after him - was the property of the researchers who had been granted a patent upon it. The Court also held that individuals do not retain rights of ownership in excised tissues when the tissues are used for research purposes. It was observed that "even if human cells initially belonged to an individual, the excised cells were legally and factually distinct from the resulting research product."<sup>83</sup>

In the case of *Greenberg v. Miami Children's Hospital*,<sup>84</sup> a lawsuit was initiated against the researchers who developed and patented a test for a rare disease called Canavan disease, using samples donated by the families of the affected children. When the gene was identified, the researchers sought a patent over it and a related test. They restricted access to the invention and controlled it through exclusive licences. The plaintiffs objected and sought action against the researchers on grounds like lack of informed consent, unjust enrichment, breach

<sup>&</sup>lt;sup>81</sup> 51 Cal.3d 120. The plaintiff Moore initiated a cause of action against his physician and other defendants for using his cells in potentially lucrative medical research without his permission. Plaintiff alleges that his physician failed to disclose pre-existing research and economic interests in the cells before obtaining consent to the medical procedures by which they were extracted.

<sup>&</sup>lt;sup>82</sup> The crux of this case revolved around the question of whether the plaintiff held personal property rights in the tissue and substances of his body and, if so, whether these rights were breached when the defendants converted his tissue for commercial profit.

<sup>&</sup>lt;sup>83</sup> 51 Cal.3d 120, 141.

<sup>&</sup>lt;sup>84</sup> 264 F. Supp. 2d 1062 (S.D. Fla.2003).

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of fiduciary duty and conversion. The plaintiffs claimed a property interest in their samples.<sup>85</sup> The Court rejected the property claim, but suggested that argument based on unjust enrichment may succeed.<sup>86</sup>

According to the Court, property rights in the body are limited and "the property right in blood and tissue samples evaporates once the sample is voluntarily given to a third party."<sup>87</sup> It refused to recognize a claim of conversion because the blood and body tissue were 'voluntary donations to medical research' and were donated 'without any contemporaneous expectations of return'.<sup>88</sup>

Further, in *Washington University v. Catalona*,<sup>89</sup> the question raised was whether after making voluntary donations of biological materials for medical research to a research institution, the research participants retain ownership rights in such materials in that they can direct the said materials' use and transfer to third parties.<sup>90</sup> The Court held that not just intellectual property in the body but also tangible physical parts of the body, example, blood, DNA, and tissue samples, were owned by the University that stored them in its repository rather

<sup>&</sup>lt;sup>85</sup> The families wanted information about the disease and the test to be freely available. But the case was abandoned after a primary hearing.

<sup>&</sup>lt;sup>86</sup> 264 F. Supp. 2d 1062 (S.D. Fla.2003) at 1073.

<sup>&</sup>lt;sup>87</sup> 264 F. Supp. 2d 1062 (S.D. Fla.2003) at 1075.

<sup>&</sup>lt;sup>88</sup> 264 F. Supp. 2d 1062 (S.D. Fla.2003) at 1075-76.

<sup>&</sup>lt;sup>89</sup> 437 F. Supp. 2d 985 (2006).

<sup>&</sup>lt;sup>90</sup> The University argued that the research participants made voluntary donations; i.e. gifts, of biological materials. Once these 'gifts' were delivered to the University it became the sole owner with control as to use and storage, pursuant to the applicable federal and state regulations. Dr. Catalona and the research participants argued that the research participants had donated their biological materials with the 'intent' that such materials stay with Dr. Catalona for his research. The research participants claimed that they have retained ownership rights in their donated biological materials. Since they have retained the ownership rights, they can withdraw their biological materials and can transfer it to Dr. Catalona via their discontinuation of participation in any research at Washington University and their signing of Dr. Catalona's consent form.

than the patients from whose bodies these biological materials had been derived. The Court found that the "research participants are 'donors' and the subject biological materials constitute an *inter vivos* gift".<sup>91</sup> Thus the Court made it clear that neither the researcher nor any research participant in connection with any research protocol conducted under the auspices of Washington University has any ownership or proprietary interest in the biological samples housed in the biorepository.<sup>92</sup> Thus the research participants retain no ownership of biological materials they contribute for medical research as it is given in the nature of a 'gift'.

In *Havasupai Tribe of Havasupai Reservation v. Arizona Board of Regents*,<sup>93</sup> the plaintiffs brought claims against the Arizona Board of Regents and others arising out of the alleged misuse of blood samples. The samples were taken from members of the Havasupai Tribe in the early 1990's for research into the cause of diabetes, which was common among the tribe members.

The claim was that Havasupai blood collected by Arizona State University has been distributed to others for research, and that research may have been conducted on Havasupai blood, for purposes unrelated to diabetes or any other medical disorder, all in violation of the consent given by Havasupai members. The researchers misused their blood samples for unauthorized purposes causing them severe harm, extreme distress, and emotional trauma. The Arizona Court

<sup>&</sup>lt;sup>91</sup> 437 F. Supp. 2d 985 (2006), at 997.

<sup>&</sup>lt;sup>92</sup> 437 F. Supp. 2d 985 (2006) at 1002.

<sup>&</sup>lt;sup>93</sup> 204 P 3d 1063 (Ariz. Ct. App. 2008).

of Appeals held that "we do not agree that a notice of claim alleging general damages fails... if it does not describe physical manifestations of emotional distress suffered by the tribe members".<sup>94</sup>

*Baleno v. Texas Department of State Health Services*,<sup>95</sup> involved more than 5 million leftover dried blood-spot samples collected for screening of the new born babies by the Texas Department of State Health Services. According to the plaintiffs, the State had been retaining these samples since 2002 for use in research. The plaintiffs claimed that defendants had violated plaintiffs' rights under the US Constitution to be free of unreasonable searches and seizures. They also claimed that the blood spots contained deeply private medical and genetic information, and defendants' retention and use of the samples violated plaintiffs' rights to privacy. Moreover, consent was not obtained for indefinite storage and undisclosed research, and the defendants had effectively made the samples their own property.<sup>96</sup>

In *Hecht v. Kane*,<sup>97</sup> the question discussed was, whether sperm is a sort of thing that could be donated, bought, sold or bequeathed by will? The Californian Court of Appeal held that a deceased man who had previously deposited sperm for the

<sup>&</sup>lt;sup>94</sup> Amy Harmon, *Indian Tribe Wins Fight to Limit Research of Its DNA*, Apr. 21, 2010, NY Times, (Jun. 05, 2018), https://www.nytimes.com/2010/04/22/us/22dna.html.

 <sup>&</sup>lt;sup>95</sup> Beleno v. Texas Dept. of State Health Serv. Case, Case no: 5:2009cv00188, San Antonio:
 U.S. District Court for the Western District of Texas; [March 3, 2009].

<sup>&</sup>lt;sup>96</sup> In response to the lawsuit, the Texas legislature enacted a law governing the collection of new born blood samples. The law states that the Texas DSHS may retain the leftover material for research as long as parents are given an opportunity to 'opt out' by filling out a 'destruction directive'. Monica J. Allen et al., *Human Tissue Ownership and Use in Research: What Laboratorians and Researchers Should Know*, 56 CLINICAL CHEMISTRY 1680 (2010).
<sup>97</sup> 16 Cal. App 4th 836 (1993).

use of his partner had an interest 'in the nature of ownership' of the samples such as to render them 'property' and, accordingly, disposable property on his death.

As mentioned earlier, compared to the volume of American decisions, English decisions in the area are limited. *Yearworth v. North Bristol NHS Trust*,<sup>98</sup> was concerned with the materials produced by a living human body and the claim related to the products of a living body intended for use by the persons whose bodies generated them. England and Wales Court of Appeal considered the question whether sperm can be treated as property of men who had given it for storage before undergoing chemotherapy on fear of becoming infertile subsequently. The Court observed that, "by their bodies, they alone generated and ejaculated the sperm and concluded that the men had the ownership of the sperm".<sup>99</sup> The Court further observed that it would have had no difficulty in finding that the preserved sperm had been subjected to a process involving work and skill which had changed its character. Thus, recent cases are moving steadily towards a general recognition of human material as 'property capable of ownership'<sup>100</sup> in Common Law.<sup>101</sup>

Taken together, these judicial decisions suggest that patients and other human research participants do not retain ownership interests in their excised tissue. The

<sup>&</sup>lt;sup>98</sup> [2009] EWCA Civ. 37; [2009] 2 All ER 986, Six men had given their sperm to be stored in the hospital for future use, before starting treatment for cancer, which may adversely affect their fertility. But due to the negligence of the hospital, the sperms were destroyed.

<sup>&</sup>lt;sup>99</sup> [2009] 2 All ER 986 at 1002.

<sup>&</sup>lt;sup>100</sup> In tune with the judicial reasoning, the English Parliament inserted clause 9 to Section 32 of the Human Tissue Act, 2004, thereby accepting that the human material becomes a subject of property by application of human skill.

<sup>&</sup>lt;sup>101</sup> Shawn H. E. Harmon & Graeme T. Laurie, *Yearworth v. North Bristol NHS Trust: Property, Principles, Precedents and Paradigms,* 69 The Cambridge L. J., 476, 2010.

tissue donors cannot benefit economically from research performed on that tissue and they cannot require the receiving institution to transfer the tissue to a site of their choice.<sup>102</sup> Courts have been reluctant to burden medical research in these ways. Thus, in the above cases, the courts refused to accord property rights to those who supply body parts for medical research, although the same courts were willing to recognize the property rights of other persons in the body parts themselves and in the resulting products.<sup>103</sup>

At the same time, it is clear that the tissue donor does retain certain rights in the tissue. For example, depending on how the informed consent documents are structured, some donor 'property-like' rights may be reserved, such as the ability to direct destruction of the donated tissue after the specified use is through.<sup>104</sup>

#### 3.5. IMPACT OF TECHNOLOGIES AND RESEARCH ON THE HUMAN BODY AND

## **BODILY MATERIALS**

Society is experiencing a period of unprecedented technological innovation, especially in the related fields of medicine and biotechnology. Due to these advances, doctors can now keep alive, and often restore to full health, patients who not that long ago might have been doomed.<sup>105</sup> Transplantation of human organs, preservation of body products such as blood, ova, semen, etc., for later use, are the

<sup>&</sup>lt;sup>102</sup> Monica J. Allen, et al., *Human Tissue Ownership and Use in Research: What Laboratorians and Researchers Should Know*, 56 CLINICAL CHEMISTRY 1679 (2010).

<sup>&</sup>lt;sup>103</sup> Radhika Rao, *Property, Privacy, and the Human Body*, 80 B. U. L. Rev., 359-460, 359 (2000).

<sup>&</sup>lt;sup>104</sup> Monica J. Allen et al., *Human Tissue Ownership and Use in Research: What Laboratorians and Researchers Should Know*, 56 CLINICAL CHEMISTRY 1679 (2010).

<sup>&</sup>lt;sup>105</sup> William Boulier, Sperm, Spleens and Other Valuables: The Need to Recognize Property Rights in Human Body Parts, 23 Hofstra L. Rev., 693-731, 693 (1995).

result of biotechnological developments. Scientists and researchers make use of body parts and tissues, which were once considered to be useless and discarded, to develop lifesaving medicines and therapies. Human tissues have attained a commercial value beyond imagination some time ago.

In the tissue industry, for example, donated skin becomes a commodity and is often applied to higher dollar value cosmetic products instead of what might have been envisioned by the donor as the most need driven purpose of, for example, aiding a burn victim.<sup>106</sup> Blood which one give for a routine blood check-up may be used for some other research purposes, which one may not even come to know of. Organs of the deceased relatives may be taken for research purposes during an autopsy, without knowledge or consent.

Thus, in the modern era, the commercial value of the human body as it is and bodily materials derived therefrom cannot be undermined since the same is a subject matter of various branches of science and technology having high commercial implications. As mentioned above, medical men and researchers may use discarded, donated, or disembodied body parts. Thus commercial utilisation of the human body per se is very much evident in various developments in those technologies using the human body and bodily materials as a raw material.

<sup>&</sup>lt;sup>106</sup> Michele Goodwin, *Altruism's Limits: Law, Capacity, and Organ Commodification,* 56 Rutgers L. Rev., 305, 382 (2004), "While many uses of tissue are legitimate and may be foreseen, the fact that cadaver skin is used to "enhance penis size, puff up lips, or erase laugh lines" and that "plastic surgeons have not reported trouble obtaining skin for plastic surgery, but burn centres across the country are struggling to find skin to treat burn victims, may not be envisioned by most donors." *See* also, Elizabeth E. Appel Blue, *Redefining Stewardship over Body Parts*, 21 J. of Law and Health, 75-121, 78 (2008).

An analysis of the cases resulting from the utilisation of technology by the parties involved wherein the human bodily parts are alleged to be stolen, <sup>107</sup> misappropriated, subjected to tort of conversion,<sup>108</sup> etc., are in turn compelling the courts to verify the claims of proprietary nature about the same by the litigants and further discussion and conclusion are based on the said determination.

#### **3.5.2.** COMMERCIAL VALUE OF THE HUMAN BODY AND BODILY MATERIALS

There are situations where Courts may have to determine whether or not something is property. Only when that matter is settled, certain particular legal consequences follow. By attributing commercial value to the human body, it supports treating the human body and bodily materials as objects with commercial value. There are quite a number of scholars who support this approach.<sup>109</sup>

Today, it can be seen that most of the terms used in commerce and trade has been used to denote the transactions in the human body and bodily materials. Terms such as commodity, trade, market, sale, etc., are frequently used in transactions involving the human body also. Though the term 'donation' is popular, monetary considerations are also attached to these types of donations. There are a few countries which supports this idea and has not banned commercial transactions in the human body and bodily materials.<sup>110</sup> It is evident that human biological

<sup>&</sup>lt;sup>107</sup> *R v. Kelly* [1998] 3 ALL ER 741.

<sup>&</sup>lt;sup>108</sup> Moore v. Regents of University of California, (1990) 793 P.2d. 479 (Cal SC).

<sup>&</sup>lt;sup>109</sup> See Carlo Petrini, Between Altruism and Commercialisation: Some Ethical Aspects of Blood Donation, 49 Ann 1<sup>st</sup> Super Sanita 2013, 412-416, (April 16, 2016), www.iss.it/binary/ publ/cont/ ANN\_13\_04\_16.pdf.

<sup>&</sup>lt;sup>110</sup> Belgium Statute of 2009, "*Arrete' ministerial fixant le prix du mater'ielcorporelhumain*" contains a detailed list of the cost (in euros) of different parts of the human body. In Germany, biological materials taken from the human body can be subject of ownership and there are no laws or guidelines that prohibit trade in it. As a result, sales of human biological material stored

material is treated in many countries as property and that property rights are granted.<sup>111</sup>

Advantages of treating the human body and human tissues as property once it is removed from a person's body is evidenced by the frequency with which the courts turn to property law to resolve disputes. While inside a person's body, the law of battery, assault and privacy rights provide sufficient protection to the human body and bodily materials.<sup>112</sup> But once the body part is severed from a person's body and made available for transactions, the question of ownership, possession, etc., is attracted.

Those who argue for granting property rights in human bodily materials suggests that creating a market in human organs and tissues would actually help reduce the chronic shortage of the same for transplantation as well as research.<sup>113</sup> If the poor can actually sell their tissue, monetary gains could make them wealthy. The poor should not be unfairly exploited, but would profit handsomely from their contribution. According to Stephen Munzer, body parts are potentially a highly

in hospital biobanks are legally held, even without the consent of the persons from whom the material was taken. Although Spanish law bans trade in the human body and its parts, the 'commercial donation' of gametes for the purpose of medically assisted procreation or for research is allowed in Spain, and the precise rates are specified. Cited in Carlo Petrini, *Between Altruism and Commercialisation: Some Ethical Aspects of Blood Donation*, 49 Ann 1<sup>st</sup> Super Sanita, 412-16, (2013), (Apr. 16, 2016), www.iss.it/binary/publ/cont/ANN\_13\_04\_16.pdf.

<sup>&</sup>lt;sup>111</sup> Carlo Petrini, *Between Altruism and Commercialisation: Some Ethical Aspects of Blood Donation*, 49 Ann 1<sup>st</sup> Super Sanita, 412-16, 413 (2013), (Apr. 16, 2016), www.iss.it/binary/publ/cont/ANN\_13\_04\_16.pdf.

<sup>&</sup>lt;sup>112</sup> Lyra Bennet Moses, *The Applicability of Property Law in New Contexts: From Cells to Cyberspace*, 30 Syd. L. Rev., 639-662, 645 (2008).

<sup>&</sup>lt;sup>113</sup> Margaret S. Swain & Randy W. Marusyk, *An Alternative to Property Rights in Human Tissue*, in ORGAN AND TISSUE TRANSPLANTATION, (\David Price, ed.), (The International Library of Medicine, Ethics & Law, Routledge), (2016).

valuable medical resource and therefore, they should not be allowed to be wasted. One way to prevent `such wastage is to establish and protect property rights in them.<sup>114</sup>

Biotechnology holds great promise for both the advancement of scientific knowledge and the improvement of human health, and this eventually requires the use of human tissue in research. Private industry will participate in research only if it can generate profit and that is possible only if they can claim property rights in their research products.<sup>115</sup> If property rights are not granted in human materials, research in biotechnology using human tissues will not progress.

# 3.5.3. THE HUMAN BODY AND BODILY MATERIALS: A NON-COMMERCIAL TREATMENT

The view that is conflicting with the grant of proprietary rights upon human bodily material also exists and this school of thought does not support the idea of treating the human body as well as its parts as objects which can be treated as property or valuable commodities in the market. Many arguments arise against recognizing any form of property rights in the context of human tissue and bodily materials. It is basically evolved from a 'paternalistic approach of the State' which tends to protect its subjects from exploitation. Major criticism against treating the human

<sup>&</sup>lt;sup>114</sup> Stephen R. Munzer, *The Special Case of Property Rights in Umbilical Cord Blood for Transplantation*?, 51 Rutgers L. Rev., 568 (1999).

<sup>&</sup>lt;sup>115</sup> Margaret S. Swain & Randy W. Marusyk, *An Alternative to Property Rights in Human Tissue*, in ORGAN AND TISSUE TRANSPLANTATION, (David Price, ed.), (The International Library of Medicine, Ethics & Law, Routledge), (2016).

body parts as property is that, the dignity of a human being is diminished if the body is treated like a commodity that can be traded in exchange for money.<sup>116</sup>

In fact, the possibility of a market opening up for the human body parts could be one major reasoning behind the public policies to ban statutorily all sales of human tissue.<sup>117</sup> It is feared that should a market arise for the human body parts, their availability will become subject to the typical market pressures of supply and demand. This consideration raises feelings of discomfort and uneasiness especially given that the socially and economically deprived people could physically suffer as a result of scientific and medical advances.

# 3.6. LEGAL STATUS OF THE HUMAN BODY AND BODILY MATERIALS: AN

## **OPEN ENDED QUESTION**

From the age old Common Law principle of 'no property in human corpse', the law have moved ahead and has recognised property rights in various human materials such as hair<sup>118</sup>, blood<sup>119</sup>, urine<sup>120</sup>, sperm<sup>121</sup>, etc. Recent decisions favour

<sup>&</sup>lt;sup>116</sup> Principle No.5, *WHO's Guiding Principles on Human Cell, Tissue and Organ Transplantation*, Res. WHA 63.22, 21 May 2010.

<sup>&</sup>lt;sup>117</sup> Randy W. Marusyk & Margaret S. Swain, *A Question of Property Rights in Human Body*, 21 Ottawa L. Rev., 359 (1989).

<sup>&</sup>lt;sup>118</sup> *R. v. Herbert* (1961) 25 JCL 163.

<sup>&</sup>lt;sup>119</sup> *R v. Rothery* [1976] Crim LR 691.

 $<sup>^{120}</sup>$  *R v. Welsh* [1974] RTR 478. In this case, a person provided the police with a urine sample. He then dropped it down the sink. He was convicted of theft of urine from the police.

<sup>&</sup>lt;sup>121</sup> Hetch v. Superior Court (Kane) [1993] 16 Cal App 4<sup>th</sup> 836. In this case, the Californian Court held that the donor had an ownership interest in his ejaculated sperm that was sufficient to give the Probate Court jurisdiction, *Yearworth v. North Bristol NHS Trust* (2009) EWCA Civ. 37., wherein the focus was on the destruction of the sperm specimens from six men who claimed that they had suffered mental harm as a result of this destruction. The Court held that this was compensable through gratuitous bailment on the basis that the donor retained ownership rights because the sperm was being held for future use by them. See also Bazley v. Wesley Monash IVF, [2010] QSC 118, where the Australian Court held that property continued to subsist in sperm and that the ownership resided in the donor's personal representative following his death.

granting property rights in human bodily materials and to products derived from the same. Though a lot of criticisms are levelled against treating the human body as a whole as property, much acceptance is given to the proposition of treating certain bodily materials as property.

Legal status of the human body is hotly contested, yet the law of the body remains in a state of confusion and chaos. Sometimes the body is treated as an object of property, sometimes it is dealt with under the rubric of contract, and sometimes it is not conceived as property at all.<sup>122</sup> Developments in medicine and biotechnology have brought about different dimensions to individual autonomy.<sup>123</sup> As a result of technological advancements, human body parts have taken on a new value above and beyond the sentimental, dignitary or the elemental. The newly acquired economic value of a human body, is adding novel aspects to the confrontation between man and society. On the one hand now there is technology to make people healthier, and on the other hand, it has also created a demand for each and every organ and tissue of the human body, and thus a reason to take it out of people and to sell them. Therefore, it can be considered as a novel form of slavery re-surfacing in the name of a market in human body.<sup>124</sup>

'things' of property interest, even then, there are certain aspects which cannot be

<sup>&</sup>lt;sup>122</sup> Radhika Rao, *Property, Privacy, and the Human Body*, 80 Boston U. L. Rev. 359-460, 359 (2000).

<sup>&</sup>lt;sup>123</sup> For further discussion, *see* chapter VII.

<sup>&</sup>lt;sup>124</sup> OWNERSHIP OF THE HUMAN BODY: PHILOSOPHICAL CONSIDERATIONS ON THE USE OF THE HUMAN BODY AND ITS PARTS IN HEALTHCARE, (Henk A. M. J. Ten Have & Jos V.M Welie eds., Kluwer Academic Publishers, 19) (1988).

considered as objects of property rights because they necessarily pertain to an individual. For example, a person's self-consciousness, emotions, perceptions, etc., all part of his 'persona', cannot be treated as property. One could take this requirement further, and insist that only things physically external to a person can be property. It is on this basis that many scholars draw a distinction between human tissue integrated in a human body, which is not property, and excised tissue or tissues intended to be excised.<sup>125</sup>

Today, the human body and its parts have been treated more or like a property by the ordinary person. The developments in science and technology have definitely had its impact on the meaning of property. Biotechnology has become one of the most important developments on the horizons of research, health care, and business. Society is on the verge of commercializing the human body itself and its parts by separating and breaking it up and the law is lagging much behind medical and technological advancements. The rights of cell and tissue donors, researchers, and biotechnology companies must be negotiated, either through innovative approaches to property law or through new concepts outside of the property law. The new situation thus calls for a re-examination of the legal status of the human body and bodily materials, which includes a cadaver as well as the excised body parts and tissues.

<sup>&</sup>lt;sup>125</sup> Lyria Bennett Moses, *The Applicability of Property Law in New Contexts: From Cells to Cyberspace*, 30 Syd. L. Rev., 639-662, 649.

We live in a time in which we cannot, at any point in our lives 'own' our own bodies (or its constituent parts), but other people can and do.<sup>126</sup> We may not be able to completely ignore the theory of property in relation to the human body. Even then, we cannot reduce the value of the human body to that of any other commodity available in the market.

<sup>&</sup>lt;sup>126</sup> Meredith Render, *The Law of the Body*, 62 Emory L.J. 549, 551 (2013).

# **IV. SPECIAL STATUS OF HUMAN GAMETES**

#### **4.1. INTRODUCTION**

With the development of transplantation surgery all over the world, commercial transactions in transplantable human organs has been legally regulated in most countries.<sup>1</sup> An area of confusion lies in the special treatment of human gametes.<sup>2</sup> Even though human gametes are also materials collected from the human body, the law tends to give gametes separate status when compared to other bodily materials.<sup>3</sup>

<sup>&</sup>lt;sup>1</sup> In India, the Transplantation of Human Organs Act, 1994 (hereinafter referred to as THOA), regulates the commercial transactions relating to organ transplantation. In the United Kingdom, the legislation that prohibits commercial dealings in human material for transplantation is the Human Tissue Act, 2004 (hereinafter referred to as HTA). The National Organ Transplantation Act, 1984 (hereinafter referred to as NOTA), of the United States prohibits sale of organs within the United States. South Africa enacted the Human Tissue Act, 1983, which outlaws the transfer of tissues in exchange for payment. In 2007, China adopted the Human Transplantation Act, banning organ sale. Except for Iran, almost all the countries across the world have regulated commercial dealings in human organs and tissues. For a detailed discussion, *see* chapter VIII.

<sup>&</sup>lt;sup>2</sup> Human gametes or the human reproductive cells are spermatozoa produced by the males (also known as sperm cells) and oocytes produced by the females (commonly known as ova or egg cells), KERRY L. HULL, STUDY GUIDE TO ACCOMPANY HUMAN FORM, HUMAN FUNCTION, ESSENTIALS OF ANATOMY AND PHYSIOLOGY, (Wolters Kluwer, 457 (2011).

<sup>&</sup>lt;sup>3</sup> Human gametes and the embryos are treated differently. For eg., the United Kingdom HTA regulates the removal, storage and use of human tissue. 'Human material' is defined as "material that has come from a human body and consists of, or includes, human cells". Section 53 of the said statute defines the term 'relevant material'. 'Relevant material' means "material, other than gametes, which consists of or includes human cells". Live gametes and embryos are excluded from the ambit of the HTA and is covered by the Human Fertilisation and Embryology Act, 1990 (hereinafter referred to as HFEA). In India, THOA regulates "the removal, storage and transplantation of human organs and tissues for therapeutic purposes and for the prevention of commercial dealings in the human organs." The term 'tissue' is defined as "a group of cells, except blood, performing a particular function in the body". THOA is totally silent about the human reproductive materials, though it has not excluded human gametes under the definition of the term 'tissue'. The Assisted Reproductive Technologies (Regulations) Bill, 2017, is proposed which exclusively deals with the collection, use and retention of human gametes in India. (Apr. 06, 2018), https://dhr.gov.in/circulars/assisted-reproductive-technology-regulati on-bill-2017.

In the past few decades, due to unparalleled growth in reproductive medicine and related technologies<sup>4</sup>, transactions involving human gametes have increased.<sup>5</sup> Advances are also seen in the areas of preservation of human reproductive materials for later use.<sup>6</sup> The sperm cells as well as embryos<sup>7</sup> ready for implantation are frozen <sup>8</sup> and preserved even for years for future use.<sup>9</sup>

<sup>&</sup>lt;sup>4</sup> Assisted Reproductive Technologies (hereinafter referred to as ART), also known as medically assisted reproduction or artificial reproduction is a procedure which has developed over the last few decades where medicine and technology assists the infertile couples to have their offspring. RENE ALMELING, SEX CELLS: THE MEDICAL MARKET FOR EGGS AND SPERM, (University of California Press), Introduction, 4 (2011). ART means, "all treatments or procedures that include the in vitro handling of both human oocytes and sperm or of embryos for the purpose of establishing a pregnancy. This includes, but is not limited to, *in vitro* fertilization and embryo transfer, gamete intrafallopian transfer, zygote intrafallopian transfer, tubal embryo transfer, gamete and embryo cryopreservation, oocyte and embryo donation, and gestational surrogacy", F. Zegers-Hochschild, G. D. Adamson, et al., *International Committee for Monitoring Assisted Reproductive Technology (ICMART) and the World Health Organization (WHO) revised glossary of ART terminology, 2009*, (Sep. 23, 2018), http://www. who.int/reproductivehealth/publications/infertility/art\_terminology2.pdf.

<sup>&</sup>lt;sup>5</sup> BABY MARKETS: MONEY AND THE NEW POLITICS OF CREATING FAMILIES, (Michele Goodwin, ed.), (Cambridge University Press), 258 (2010).

<sup>&</sup>lt;sup>6</sup> Karin Hammarberg et al., Cryopreservation of Reproductive Material before Cancer Treatment: A Qualitative Study of Health Care Professionals' Views about Ways to Enhance Clinical Care, 17 BMC Health Services Research, 343 (2017), (Jun. 07, 2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5424377/., See also, Waseem Ashgar et al., Preserving Human Cells for Regenerative, Reproductive, and Transfusion Medicine, 9 Biotechnol. J., 895-903, (2014) (Jun. 07, 2018), https://www.ncbi.nlm.nih.gov/pmc/articles/ PMC41 45864/.

<sup>&</sup>lt;sup>7</sup> An embryo is "the product of the division of the zygote to the end of the embryonic stage, 8 weeks after fertilization", F. Zegers-Hochschild, G. D. Adamson et al., International Committee for Monitoring Assisted Reproductive Technology (ICMART) and the World Health Organization (WHO) revised glossary of ART terminology, 2009, (Sep. 23, 2018), http://www.who.int/reproductivehealth/publications/infertility/art\_terminology 2.pdf.

<sup>&</sup>lt;sup>8</sup> Cryopreservation is a process where cells, whole tissues, or any other substances susceptible to damage caused by chemical reactivity or time are preserved by cooling to sub-zero temperatures. The technique of cryopreservation is used to store the semen and embryos. It is not recommended that unfertilized eggs be frozen for later use as the freezing of an egg produces problems. The egg is larger with a high water content and is prone to ice crystal damage. *See, Embryo Cryopreservation*, (Jun. 04, 2018), https://www.sciencedirect.com/ topics/biochemistry-genetics-and-molecular-biology/embryo-cryopreservation.

<sup>&</sup>lt;sup>9</sup> Unfertilized oocytes are not frozen since freezing results in deleterious effects on the chromosomes at that particular stage. *See* Simon Fishel, *Assisted Conception in the Human* - *The Embryological View*, in, CONCEIVING THE EMBRYO: ETHICS, LAW AND PRACTICE IN HUMAN EMBRYOLOGY, (Donald Evans, ed., Martinus Nijhoff Publishers), 21 (1996).

Procurement, use, storage and destruction of the same has given rise to complex legal questions.<sup>10</sup>

Though law regulates commercial transactions in human gametes, paid donations in human reproductive materials are common in practice.<sup>11</sup> Moreover, due to the increasing transfer of gamete donors in developed countries, recent years have also seen an increasing transactions in the sperm and oocytes across the national borders.<sup>12</sup> In this chapter, an attempt is made to examine the reasons for giving special status for human gametes, i.e., the sperm cells and the ova.

## 4.2. SIGNIFICANCE OF HUMAN GAMETES

Human gametes are reproductive cells of a male and a female, and they combine

to form a new cell known as the zygote.<sup>13</sup> Human reproduction involves union

<sup>&</sup>lt;sup>10</sup> Recent years have witnessed questions involving 'interests in the nature of property' in human gametes in various cases. *See* paragraph 4.7.2. of this chapter for the discussions on property rights in the human gametes.

<sup>&</sup>lt;sup>11</sup> See, David B. Resnik, *The Commodification of Human Reproductive Materials*, 24 J.M.E., 388-393 (1998), (Jul. 25, 2016), http://www.ncbi.nlm.nih.gov/pmc/articles/PMC479139/pdf/jmedeth00001-0026.pdf.; *See* also, Stephanie A. Gagnon, *Moral Limits of Markets: Implications for the Commodification of Oocytes*, (Mar. 31, 2016), http://philpapers.org/archive/GAGMLO.

<sup>&</sup>lt;sup>12</sup> Boon Chin Heng, *Legal and Ethical Issues in the International Transaction of Donor Sperm and Eggs*, 24 J. Assist. Reprod. Genet., 107-109 (2007), (May 10, 2016), http://www.ncbi. nlm.nih.gov/pmc/articles/PMC3455062/.

<sup>&</sup>lt;sup>13</sup> "Zygote is a fertilized egg cell that results from the union of a female gamete (egg, or ovum) with a male gamete (sperm). This single cell represents the first stage in the development of a genetically unique organism. The zygote is endowed with genes from two parents". (June. 12, 2018), https://www.britannica.com/science/zygote.

of reproductive cells from each parent with half the number of chromosomes<sup>14</sup>, to make a zygote<sup>15</sup> containing both their genetic characteristics.<sup>16</sup>

In discussions relating to the legal status of the human body and bodily materials, human gametes are given a distinct and unique status when compared to the other human bodily materials. Though sperms and ova are also bodily materials, law is inclined to treat the same under a different category, perhaps for the reason that, only gametes have the reproductive capacity to make a new human life, and in doing so, carries an individual's lineage to the next generation.<sup>17</sup>

## 4.2.1. NEED FOR SPECIAL TREATMENT OF HUMAN GAMETES

Transactions involved in the human gametes are not treated like transactions in the other body tissues and organs. <sup>18</sup> Even when reproductive cells are regenerative and easily procured when compared to other human organs, many find it more easy to part with one of their kidneys or liver tissues than donating their reproductive cells. Unlike other human tissues, sperm cells and oocytes

<sup>&</sup>lt;sup>14</sup> "DNA molecule is packaged into thread-like structures in the nucleus of each cell. These thread-like structures are known as chromosomes. They carry genetic information in the form of genes". *What is a Chromosome?*, (Jun. 12, 2018), https://ghr.nlm.nih.gov/primer/basics/ chromosome.

<sup>&</sup>lt;sup>15</sup> Both human sperm and eggs contain 23 chromosomes each and the resultant zygote contain 46 chromosomes., D. A. LOUW, HUMAN DEVELOPMENT, (Kagiso Tertiary, 2<sup>nd</sup> edn.,), (1998).

<sup>&</sup>lt;sup>16</sup> Robert P. S. Jansen, *Sperm and Ova as Property*, 11 J. Med. Ethics, 123-126, 123 (1985), (May 16, 2016), http://jme.bmj.com/content/medethics/11/3/123.full.pdf., *Formation of Sex Cells*, (Apr. 24, 2016), http://www.bbc.co.uk/schools/gcsebitesize/science/add\_edexcel/cells/ mitosisrev2.shtml.

<sup>&</sup>lt;sup>17</sup> *Human Embryos and Gametes*, (Apr. 20, 2016), http://www.bioethics.org.au/ Resources/Resource%20Topics/ Human%20Embryos%20and%20Gametes.html.

<sup>&</sup>lt;sup>18</sup> Julie L. Sauer, *Competing interests and Gamete Donation: The Case for Anonymity*, 39 Seton Hall Rev., 919-954, 929 (2009), (Apr. 16, 2016), http://scholarship.shu.edu/cgi/view content.cgi?article=1023&context=shlr.

contain half a human genome each, which can unite to form a zygote, which may result in a potential human being.<sup>19</sup> Certain authors even go to the extent of describing sale of gametes as dangerously close to selling persons, since gametes can become potential persons.<sup>20</sup>

An ovum or a sperm cell is an integral part of the human body, hence a bodily material. But there is a subtle distinction between other human organs, tissues or materials and the gametes. Reproductive cells can result in the creation of a potential human being and the purpose for which it is extracted makes it distinct and different. Moreover, an organ, be it a kidney or a cornea, is integrated into the body of the transplant recipient. However, with respect to gametes, it still continues to retain half of the traits of the donor. This unique feature of the gamete *vis-a-vis* other human bodily material is conveyed very clearly by Stephaine A. Gagnon, thus:

"A donor receives organs, body tissue, etc., indiscriminately as long as it is compatible with their body. To put it simply, patients with renal failure are not concerned if their donor is black, white, funny or serious. When kidney is a part of someone, it is more analogous to a machine<sup>21</sup> and we do not attribute an organ the same value as a human being. Conversely, a human egg or a sperm cell contains a genetic code, i.e., the information

<sup>&</sup>lt;sup>19</sup> A zygote can become a child if it implants in a uterus and develops normally. *See*, RAYMOND D. DEVETTERE, PRACTICAL DECISION MAKING IN HEALTH CARE ETHICS: CASES, CONCEPTS AND THE VIRTUE OF PRUDENCE, (Georgetown University Press, 4<sup>th</sup> edn.), 168 (2016).

<sup>&</sup>lt;sup>20</sup> David B. Resnik, *The Commodification of Human Reproductive Materials*, 24 J.M.E., 388-393, 391 (1998), (Jul. 25, 2016), http://www.ncbi.nlm.nih.gov/pmc/ articles/PMC479139/pdf/ jmedeth00001-0026.pdf.

<sup>&</sup>lt;sup>21</sup> Stephaine A. Gagnon, *Moral Limits of Markets: Implications for Commodification of Oozytes*, (Aug. 13, 2015), http://philpapers.org/archive/GAGMLO.

about the eye colour, height, skin colour and aspects of the donor's personality - all of which are unique to one person. Though the egg or a sperm is not a person in itself, it is intimately connected with the donor, and is an integral part of the resulting child".<sup>22</sup>

#### 4.3. MARKET FOR HUMAN GAMETES

Human gametes have become an object of demand for infertility treatments and an invaluable training resource for scientists and technicians working in the field of assisted reproduction. It is also very important for research relating to the identification of causes of genetic and congenital anomalies<sup>23</sup>, miscarriage, and for increasing knowledge about the treatment of serious diseases.<sup>24</sup>

In *in vitro* fertilization,<sup>25</sup> (hereinafter referred to as IVF), fertilization of the egg and the sperm takes place outside the human body and the resultant embryo is placed in the uterus of the commissioning mother or the surrogate.<sup>26</sup> The number of individuals who opts for ART are increasing constantly.<sup>27</sup> Human gametes are

<sup>&</sup>lt;sup>22</sup> Stephaine A. Gagnon, *Moral Limits of Markets: Implications for Commodification of Oozytes*, (Aug. 13, 2015), http://philpapers.org/archive/GAGMLO.

<sup>&</sup>lt;sup>23</sup> It means, "all structural, functional, and genetic anomalies diagnosed in aborted fetuses, at birth, or in the neonatal period", F. Zegers-Hochschild, G. D. Adamson, et al., *International Committee for Monitoring Assisted Reproductive Technology (ICMART) and the World Health Organization (WHO) revised glossary of ART terminology*, 2009, (Sep. 23, 2018), http://www.who.int/reproductivehealth/ publications/infertility/art\_terminology 2.pdf.

<sup>&</sup>lt;sup>24</sup> Waseem Ashgar et al., *Preserving Human Cells for Regenerative, Reproductive, and Transfusion Medicine*, 9 Biotechnol. J., 895-903, (2014), (Jun. 07, 2018), https://www.ncbi. nlm.nih.gov/pmc/articles/PMC4145864/.

<sup>&</sup>lt;sup>25</sup> *In vitro* fertilization literally means, "fertilization in glass". GEOFFREY SHER et al., IN VITRO FERTILIZATION: THE A.R.T. OF MAKING BABIES, (Skyhorse Publishing, 4<sup>th</sup> edn.,) 18 (2013).

<sup>&</sup>lt;sup>26</sup> Patrick Präg & Melinda C. Mills, *Assisted Reproductive Technology in Europe: Usage and Regulation in the Context of Cross-Border Reproductive Care*, 289-309, 289, in CHILDLESSNESS IN EUROPE: CONTEXTS, CAUSES, AND CONSEQUENCES, (Michaela Kreyenfeld & Dirk Konietzka, eds.), (Springer Open), (2017).

<sup>&</sup>lt;sup>27</sup> It is estimated that more than 186 million ever-married women of reproductive age in developing countries were maintaining a 'child wish', translating into one in every four couples. *Infecundity, Infertility, and Childlessness in Developing Countries,* (Jun. 04, 2018),

in high demand for these treatments and with the increasing demand, prices of semen and ovum also rises.<sup>28</sup> Large-scale market for human tissue lies in the area of reproductive medicine, where sperm and ova are routinely obtained from donors.<sup>29</sup> Today, human gametes have entered the marketplace as goods,<sup>30</sup> and it seems all the market norms are practically applicable in the case of human reproductive materials also.<sup>31</sup>

There is difference between the extraction of male and female gametes. Semen can be obtained easily and the absence of external intervention favour the free availability. The process of egg donation is not easy<sup>32</sup> when compared to the

http://www.who.int/reproductivehealth/topics/infertility/DHS-CR9.pdf., *See* also, Patrick Präg & Melinda C. Mills, *Assisted Reproductive Technology in Europe: Usage and Regulation in the Context of Cross-Border Reproductive Care*, 289-309, 289, in CHILDLESSNESS IN EUROPE: CONTEXTS, CAUSES, AND CONSEQUENCES, (Michaela Kreyenfeld & Dirk Konietzka, eds.), (Springer Open), (2017).

<sup>&</sup>lt;sup>28</sup> "In India, there is an increase of 50%-100% in the prices of donor sperm in the past five years. A single vial of sperm now costs Rs.2000/- to Rs.5000/-. Depending on the specifications, (depending on the colour of the eyes, educational background, etc., it may go up to Rs.6000/- and for the couples who want Caucasian sperm have to pay between Rs.20,000/- to Rs.40,000/- per vial", *Rising Infertility & Rigorous Testing Push up Sperm Prices*, Times of India, (Jan. 25, 2016). "A regular donor gets about Rs.30,000 to 35,000 per procedure here, while those in the premium list draw Rs.50,000-60,000", *The Great Indian Egg Bazaar*, The Indian Express, (Feb. 9, 2014), https://indianexpress.com/article/india/india-others/the-great-indian-egg-bazaar/, *See* also, *U.S. Public Policy and the Biotechnologies that Touch the Beginnings of Human Life: A Detailed Overview*, (May 12, 2016) https://bioethicsarchive.georgetown.edu/pcbe/background/biotechnology.html#initiate.

<sup>&</sup>lt;sup>29</sup> R. Alta Charo, *Skin and Bones: Post-Mortem Markets in Human Tissue*, 26 Nova L. Rev., 421-450, 432 (2002).

<sup>&</sup>lt;sup>30</sup> RENE ALMELING, SEX CELLS: THE MEDICAL MARKET FOR EGGS AND SPERM, (University of California Press), introduction 4 (2011).

<sup>&</sup>lt;sup>31</sup> See, K. R. Daniels, *To Give or Sell Human Gametes - the Interplay Between Pragmatics, Policy and Ethics,* 26 J. of Med. Ethics, 206-211 (2000).

<sup>&</sup>lt;sup>32</sup> The procedure involves taking medication to stop the ovaries' normal functioning, followed by hormone injections, which stimulate the ovaries to produce a greater number of eggs than a normal cycle. During the administration of medication, a donor must have regular blood tests and ultrasound examinations to allow doctors to monitor the number of ovulated eggs and determine how the donor is responding to the hormones. Once the eggs are harvested, they are removed from the donor's ovaries, *See*, BABIES FOR SALE? TRANSNATIONAL SURROGACY, HUMAN RIGHTS AND THE POLITICS OF REPRODUCTION, (Miranda Davies, ed.), (Zed Books Ltd.), (2017).

donation of the sperms. External intervention is necessary to extract oocytes by abdominal incision.<sup>33</sup> In addition, semen may be obtained during most of the male's life, whereas oocytes represent a kind of 'limited resource'.<sup>34</sup> Thus, "sperm is abundant, easily obtainable and inexpensive. Whereas egg cells are a scarce resource and their procurement entails risky and invasive intervention into the woman's body".<sup>35</sup>

Sperm donation has been in practice since 1945, but egg donation is a comparatively new practice<sup>36</sup> which entered the market place recently as a source of money.<sup>37</sup> There is a growing international market in human gametes and there is a shortage of human reproductive materials, especially, the egg cells. This shortage is met by the donors from developing countries.<sup>38</sup>

 <sup>&</sup>lt;sup>33</sup> Eggs can be harvested by a minor surgical procedure called transvaginal ovarian aspiration, PRINCIPLES OF OOCYTE AND EMBRYO DONATION, (Mark V. Sauer, ed.), (Spinger), 12 (2013).
 <sup>34</sup> Eduardo Osuna et al., *What's wrong with Gamete Donation? Legal and Ethical Status of Gametes in Assisted Reproduction Techniques*, 2 J. Fert. In Vitro, (2012), (Apr. 14, 2016), http://www.vda.pt/xms/files/Publicacoes/Artigo\_VLR\_-\_What\_s\_wrong\_with\_Gamete\_Don ation.pdf.

<sup>&</sup>lt;sup>35</sup> Carmel Shalev & Gabriele Werner-Felmayer, *Patterns of Globalized Reproduction: Egg Cells Regulation in Israel and Austria*, 1 Israel Journal of Health Policy Research, (2012), (Apr. 22, 2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3424961//, *See* also, GEOFFREY SHER et al., IN VITRO FERTILIZATION: THE A.R.T. OF MAKING BABIES, (Skyhorse Publishing, 4<sup>th</sup> edn.,) 64 (2013).

<sup>&</sup>lt;sup>36</sup> "The practice of egg donation began in the early 1980s", Michelle Sargent, *Regulating Egg Donation: A Comparative Analysis of Reproductive Technologies in the United States and United Kingdom*, 4 Michigan J. of Public Affairs, 2 (2007), (Oct. 16, 2018), http://mjpa.umich. edu/files/2014/06/2007-Sargent-EggDonation.pdf.

<sup>&</sup>lt;sup>37</sup> Carmel Shalev & Gabriele Werner-Felmayer, *Patterns of Globalized Reproduction: Egg Cells Regulation in Israel and Austria*, 1 Isr. J. Health Policy Res., 15 (2012), (Jun. 08, 2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC 3424961/.

<sup>&</sup>lt;sup>38</sup> In most of the developed countries, legislations have regulated commercial transactions in gametes. "Donors, have to face much hassle and inconvenience in gamete donation, especially women donors. They are not even compensated for their time and effort as well as the risk of medical complications from super ovulatory drugs in the case of oocyte donation. The situation is made worse by abolishing donor anonymity in some countries. Additionally, the shortage of oocyte donors is further increased by the rising trend of age-related female infertility in

#### 4.4. HUMAN GAMETES OUTSIDE THE HUMAN BODY

The progress made in medical science now enables human bodily materials including reproductive cells to be severed from a persons' body. The ever expanding artificial reproductive techniques have increased demand for sperm cells and the egg cells. Once they are severed from the human body, they cannot be treated as part of that body. Reproductive cells used for infertility treatments are obtained from various sources. Embryological research<sup>39</sup> and research in assisted reproductive technologies exert a huge demand for human reproductive cells.

Infertility clinics generally use the 'donated'<sup>40</sup> gametes for infertility treatments and research.<sup>41</sup> Infertile couple who are incapable of procreation by natural coitus or by artificial methods using their own gametes may have to depend upon

developed countries, due to increasing numbers of highly-educated urban women choosing to delay marriage and child-bearing in pursuit of educational and career goals. The severe shortage of gamete donors arising from these various factors has in turn led to many fertility clinics sourcing donor sperm and oocytes from abroad." *See*, Boon Chin Heng, *Legal and Ethical Issues in the International Transaction of Donor Sperm and Eggs*, 24 J. Assist. Reprod. Genet., 107-109 (2007), (Apr. 30, 2018), http://www.ncbi. nlm.nih.gov/pmc/articles/PMC3455062/.

<sup>&</sup>lt;sup>39</sup> "Research using human gametes are done in order to study fundamental science, fertility and infertility, prevention of hereditary diseases and treatment of human disease", Advisory Committee on Assisted Reproductive Technology, *Use of Gametes and Embryos in Human Reproductive Research: Determining Policy for New Zealand: A Discussion Paper*, 14 (2006), (May 12, 2016), http://www.newhealth.govt.nz/acart.

<sup>&</sup>lt;sup>40</sup> Though the term denotes an altruistic approach, transactions involving human reproductive materials involve paid transactions. Reimbursements for the service of providing gametes strongly resemble a payment for the sale of their gametes. R. Alta Charo, *Skin and Bones: Post-Mortem Markets in Human Tissue*, 26 Nova L. Rev., 421-450, 432 (2002).

<sup>&</sup>lt;sup>41</sup> "The term 'donation' is supposed to reflect the essential characteristic of being free from monetary reward. Indeed, it is supposed that the gametes cannot be sold or be the subject of any other onerous contract because of the imperative nature of the gift", Eduardo Osuna et al., *What's Wrong with Gamete Donation? (Legal and Ethical Status of Gametes in Assisted Reproduction Techniques)*, 2 J. Fert. In Vitro, (2012), (May 14, 2018), https://www.omics online.org/open-access/whats-wrong-with-gamete-donation-legal-and-ethical-status-of-gamet es-in-assisted-reproduction-techniques-2165-7491.1000115.php?aid=9917.

the donated gametes. In treatments like IVF, extracted eggs are fertilized with sperm from either the recipient's partner or another donor whose sperms are collected and stored in a laboratory.<sup>42</sup> Majority of the human gametes used for these assisted reproductive technologies comes through donation. <sup>43</sup> These volunteer gamete donors are not themselves trying to conceive, but undergo the procedures of retrieval solely in order to donate these eggs to others.<sup>44</sup>

Another way of getting access to human reproductive materials is by making use of the unused excess gametes stored in the infertility clinics after the infertility treatment. The fertility centres routinely ask for permission to use non-viable or unused gametes and embryos for research purposes. Stored gametes may be used by the surviving spouse for creating offspring after the death of the source person. Human gametes can be procured even from dead persons,<sup>45</sup> immediately upon the death of the person, and it is practiced occasionally by partners and parents of the deceased.<sup>46</sup>

<sup>&</sup>lt;sup>42</sup> Though sperm donation is less invasive compared to that of egg donation, it also involves a series of appointments for health screening and blood and semen tests before the potential donor is accepted, EMILY JACKSON, MEDICAL LAW: TEXTS, CASES AND MATERIALS, (Oxford University Press, 4<sup>th</sup> edn.), 829 (2013).

<sup>&</sup>lt;sup>43</sup> Stephanie A. Gagnon, *Moral Limits of Markets: Implications for the Commodification of Oocytes*, (Mar. 31, 2016), http://philpapers.org/archive/GAGMLO.

<sup>&</sup>lt;sup>44</sup> Nuffield Council on Bioethics, *Human Bodies: Donation for Medicine and Research*, Para 1.17, 39 (2011), (Jun. 29, 2016), http://nuffieldbioethics.org/wp-content/uploads/2014/07/ Donation\_full\_ report.pdf.

<sup>&</sup>lt;sup>45</sup> It is also known as Posthumous Assisted Reproduction (PAR), G. Bahadur, *Death and Conception*, 17 Human Reproduction, 2769–2775 (2002), (Jun. 12, 2018), https://academic.oup.com/humrep/article/17/10/2769/607780.

<sup>&</sup>lt;sup>46</sup> PRINCIPLES OF OOCYTE AND EMBRYO DONATION, (Mark V. Sauer, ed.), (Spinger), 401 (2013).

The aborted female foetal ovary is a rich source of oocytes.<sup>47</sup> It may be used for

research and donation. <sup>48</sup> The shortage of donated oocytes for assisted reproduction could be met with by extracting egg from aborted female foetuses.<sup>49</sup> Thus embryonic research<sup>50</sup> has even gone to the extent of giving birth from a dead foetus.<sup>51</sup> "Biologically, the foetus could herself become a mother, of sorts, even in her own death throes".<sup>52</sup> Ultimately, the biological mother of these embryos would be an unborn, dead foetus.<sup>53</sup>

<sup>&</sup>lt;sup>47</sup> "Egg follicles can be retrieved from aborted female foetuses. Egg follicles appears as early as the sixteenth week of foetal development. Researchers have discovered that there are a large number of follicles in the foetal ovary. The entire pool of immature egg cells is built up prenatally, peaking at the 20<sup>th</sup> week of foetal development. Foetal ovary consists of somewhere in the region of 4 million oocytes which decline in number to approximately 2 million at birth. By the time the female reaches puberty, the actual number of oocytes for potential conception range from a few thousand to a few hundred thousand. After a natural abortion, the dead foetus' eggs could be extracted, matured, and then fertilized with donor sperm, and then the resulting embryos could be implanted", Simon Fishel, *Assisted Conception in the Human-The Embryological View*, cited in, CONCEIVING THE EMBRYO: ETHICS, LAW AND PRACTICE IN HUMAN EMBRYOLOGY, (Donald Evans, ed.), (Martinus Nijhoff Publishers), 24 (1996).

<sup>&</sup>lt;sup>48</sup> Prospect of Babies from Unborn Mothers, The Guardian, Jul. 1, 2003, (Jun. 11, 2016), https://www.theguardian.com/world/2003/jul/01/health.healthandwellbeing. See also, Stephanie A. Gagnon, Moral Limits of Markets: Implications for the Commodification of Oocytes, (Mar. 31, 2016), http://philpapers.org/archive/GAG MLO.

<sup>&</sup>lt;sup>49</sup> Martin Hutchinson, *Aborted Foetus Could Provide Eggs*, BBC News, Jul. 16, 2003, (May 04, 2016), http://news.bbc.co.uk/2/hi/health/3031800.stm.

<sup>&</sup>lt;sup>50</sup> In India, § 49 (7) of the Draft ART Bill, 2014, proposes that no assisted reproductive technology clinic is permitted to use ova that are derived from a foetus, in any process of *in vitro* fertilisation.

<sup>&</sup>lt;sup>51</sup> Stephanie A. Gagnon, *Moral Limits of Markets: Implications for the Commodification of Oocytes*, (Mar. 31, 2016), http://phil papers.org/archive/GAG MLO.

<sup>&</sup>lt;sup>52</sup> Angela Kennedy, *Great Britain's Debate over the Utilization of Foetal Ova*, (May 05, 2016), http://www.fnsa.org/v1n3/kennedy.html.

<sup>&</sup>lt;sup>53</sup> Asher Shushan & Josef G. Schenker, *The Use of Oocytes Obtained from Aborted Foetuses in Egg Donation Programs*, 62 Fertility and Sterility, 449-451 (1994), (Oct. 19, 2018), https://www.fertstert.org/article/S0015-0282(16)56929-5/pdf. *See* also, Stephanie A. Gagnon, *Moral Limits of Markets: Implications for the Commodification of Oocytes*, (Mar. 31, 2016), http://philpapers.org/archive/GAG MLO.

#### 4.5. COMMERCIALISATION OF HUMAN REPRODUCTIVE MATERIALS

Rapid innovations in reproductive technology have expanded into new markets and shattered many biological barriers.<sup>54</sup> With advancements in embryological research and increase in infertility treatments, human reproductive materials are of much need throughout the world.<sup>55</sup> People are ready to pay any amount and to undergo any difficult treatment to beget a child.<sup>56</sup> Over dependence on the assisted reproductive technologies by individuals,<sup>57</sup> including fertile couples have resulted in establishing a market for the gametes, which has ultimately lead 58 commercialisation the human reproductive materials. the of to

<sup>&</sup>lt;sup>54</sup> G. Bahadur, *Death and Conception*, 17 Human Reproduction, 2769-2775 (2002), (Jun. 12, 2018), https://academic.oup.com/humrep/article/17/10/2769/607780.

<sup>&</sup>lt;sup>55</sup> K. R. Daniels, *To Give or Sell Human Gametes - the Interplay Between Pragmatics, Policy and Ethics,* 26 J. of Med. Ethics, 206-211 (2000).

<sup>&</sup>lt;sup>56</sup> Parents with infertility problems are willing to pay up to \$50,000 for a human egg they hope will produce a smart, attractive child. The American Society for Reproductive Medicine (ASRM) ethics committee recommends limits on the amount of money egg donors should be paid, saying "sums of \$5,000 or more require justification and sums above \$10,000 are not appropriate", Exorbitant Fees Offered to Human Egg Donors, Study Finds, Livescience, (May 10, 2016), http://www.live science.com/8171-exorbitant-fees-offered-human-egg-donorsstudy-finds.html#sthash.NK8lszgB.dpuf. "In India, there is an increase of 50%-100% in the prices of donor sperm in the past five years. A single vial of sperm now costs Rs.2000/- to Rs.5000/-. Depending on the specifications, (colour of the eves, educational background, etc.,) it may go up to Rs.6000/- and for the couples who want Caucasian sperm have to pay between Rs.20,000/- to Rs.40,000/- per vial", Rising Infertility & Rigorous Testing Push up Sperm Prices, Times of India, (Jan. 25, 2016). In the case of egg donation, "a regular donor gets about Rs.30,000 to 35,000 per procedure here, while those in the premium list draw Rs.50,000-60,000", The Great Indian Egg Bazaar, The Indian Express, (Feb. 9, 2014), https://indian express.com/article/india/india-others/the-great-indian-egg-bazaar/, See also, U.S. Public Policy and the Biotechnologies that Touch the Beginnings of Human Life: A Detailed Overview, (May 12, 2016) https://bioethicsarchive. georgetown.edu/pcbe/background/biotech nology.html#initiate.

<sup>&</sup>lt;sup>57</sup> ART procedures are used not only by infertile couples alone. But it also used by homosexual couples, single parents as well transsexuals who wish to beget a child and start a family. *See, Medically Assisted Reproduction in Singles, Lesbian and Gay Couples, and Transsexual People,* 29 Human Reproduction 1859-65, (Jun. 17, 2018), https://www.eshre.eu/.../ESHRE-TF-EL-23-Medically-assisted-reproduction-in-singles.

<sup>&</sup>lt;sup>58</sup> "A collection of oocyte donor recruitment ads published in college newspapers across the country suggests that certain advertisements offered \$35,000, up to \$50,000 to 'an extraordinary egg donor'." Aaron D. Levine, *Self-Regulation, Compensation, and the Ethical Recruitment of Oocyte Donors*, Hastings Center Report, 25-36, March-April 2010, (May 10,

Commercialisation leads to exploitation, especially of the needy and the vulnerable sections in the society.<sup>59</sup>

Commerce in human gametes has resulted in unprecedented legal, ethical and social dilemmas.<sup>60</sup> It has led to the commodification of human reproductive materials, <sup>61</sup> whereby the market value of human material, including cells, tissues, and cellular tissue can be lucrative, creating a potential conflict for physicians and others between economic interests and professional ethical obligations.<sup>62</sup>

Like any other commercial framework, there can be two sides of arguments for commodification of reproductive cells also. On the one hand, it can be argued that it is not morally wrong to donate reproductive materials to the infertile couples in return for money. Many do not essentially see commercialisation of reproductive materials as a bad thing and argues that monetary incentives may be given for the 'donation' of gametes.<sup>63</sup> The one's who argue for this 'paid

<sup>2016),</sup> http://www.thehastingscenter.org/Publications/HCR/Detail.aspx?id=4549#ixzz48D0K PMvI, *See*, the statistical data published in http://www.thehastingscenter.org/uploadedFiles/ Publications/HCR/Articles/2010\_March-April/levine%20figures%20and%20tables.pdf.

<sup>&</sup>lt;sup>59</sup> JO SAMANTA & ASH SAMANTA, MEDICAL LAW, (Palgrave Law Masters, 2<sup>nd</sup> edn.,) 343 (2015).

<sup>&</sup>lt;sup>60</sup> Aaron D. Levine, *Self-Regulation, Compensation, and the Ethical Recruitment of Oocyte Donors*, Hastings Center Report, 25-36, March-April 2010, (May 10, 2016), http://www.the hastingscenter.org/Publications/HCR/Detail.aspx?id=4549#ixzz48D0KPMvI.

<sup>&</sup>lt;sup>61</sup> Commodification is a practice of treating things or objects of value as commodities, i.e., properties that can be bought, sold, leased, etc. Commodification of gametes, just like any other object, has created a market for the same, and all the words associated with market and commerce such as sale, donation, gift, etc., are associated with the transactions involving human reproductive materials also., For a detailed discussion, *see*, chapter VI.

<sup>&</sup>lt;sup>62</sup> WMA Resolution on the Non-Commercialisation of Human Reproductive Material, (Apr.12, 2016), http://www.wma.net/en/30publications/10policies/r1/index.html.

<sup>&</sup>lt;sup>63</sup> "Commerce in human gametes is no different from commerce in other meaningful activities (like paying one's doctor) or commerce in articles of special significance (like religious text or

donation' of human reproductive materials poses a question that if a person has the right to sell blood or hair, then should not that person have a right to sell their gametes? On the contrary, there is a group which thinks donating gametes for monetary consideration would amount to commodification, which may in turn leads to exploitation, which should be prevented.<sup>64</sup>

"By putting human reproductive tissue - the seeds of the next generation - up for sale in the marketplace, it is argued that we stand to introduce a commercial character into human reproduction, and to introduce commercial concerns into the coming-to-be of the next generation. If the essential materials of human procreation are regularly bought, sold, and esteemed in accordance with market valuations (and indeed valued differently based on the desirability of certain traits, as in ads in college newspapers that offer premium prices for donors with particular characteristics), the human meaning of bringing forward the next generation may be obscured or undermined."<sup>65</sup>

To put a 'value' on a person's body for its physical strength, intellectual capacity, aesthetic or physical beauty, seems to be unacceptable both under law and ethics. Commodification and commercialisation of human gametes, which have the

a wedding ring). The clinics and laboratories are making money from assisting reproduction, and suggests that it is unfair that only the donor is excluded from financial benefits". *Reproduction and Responsibility: The Regulation of New Biotechnologies*, A Report on the President's Council on Bioethics, Washington D.C., 150 (2004).

<sup>&</sup>lt;sup>64</sup> Stephanie A. Gagnon, *Moral Limits of Markets: Implications for the Commodification of Oocytes*, (Mar. 31, 2016), http://philpapers.org/archive/GAGMLO.

<sup>&</sup>lt;sup>65</sup> *Reproduction and Responsibility: The Regulation of New Biotechnologies*, A Report on the President's Council on Bioethics, Washington D.C., 150 (2004).

potential to become human beings, threatens human dignity and other established moral values.

One major problem in commercialisation of human gametes is that, unlike other bodily materials, gametes are transporters of a person's genetic code to the next generation. The sperm cells and the egg cells contain the genetic code which will be transmitted to the child born out of the fertilization of such gametes. Gametes of the biological parents determine the factors such as height, stature, colour of the eyes, colour of the skin, hair, intellectual quotient, etc., of the child. Hence there is a high demand for gametes from the educated and physically well-built persons.

There are other important ethical questions which arises in the commercial framework of human gametes, most importantly, what could be the value of an egg or a vial of semen? How can the value of the same be expressed in terms of money? If the value of gametes can be expressed in terms of money, the next important question arises as to who determines the 'value' of any person's reproductive material? If it is donated by a celebrity, may it be a super model or a famous cricket player or a well-known athlete, can they demand for more money claiming that they are more qualified to be sources of genetic material for a future child? Can a person or an infertility clinic advertise claiming high price for such gametes? If the market could set a price for gametes, can those people with the so called 'best' qualities demand the highest prices for their reproductive materials?

#### 4.6. REGULATION OF COMMERCIAL TRANSACTIONS IN HUMAN GAMETES

There is a constant increase in the demand and supply of the human reproductive materials.<sup>66</sup> Whether the market in human gametes can be controlled, how it can be controlled and how such control can be enforced are very important questions. In many countries, there exists clear laws and regulations for the use and storage of human reproductive materials. Whereas in certain other countries, there exists a legal vacuum in the area of regulation of research and commerce in human reproductive materials.<sup>67</sup>

On a detailed analysis of the legal framework of various jurisdictions, one can see that there are debates surrounding the use, retention, storage, etc., of human gametes. The most pivotal question in this regard is with respect to the protection of human dignity as well as regulating the practice of commercialisation of human reproductive materials. The topic of human reproduction invokes a discussion of fundamental values and ethics and therefore the research and practice of new reproductive technologies has to be done in a very cautious manner.

<sup>&</sup>lt;sup>66</sup> ISSUES IN LAW AND MEDICINE, (Q. Ashton Acton, ed.,), Scholarly Editions, 18 (2013).

<sup>&</sup>lt;sup>67</sup> As of now, in India, there is no legislation prohibiting commercial transactions in reproductive materials except a Draft Bill which has been modified from time to time. If the said Bill is passed by the Parliament, India would be one among the very few countries which would legalise commercial transactions in human gametes. § 52 (6) of the same states thus: "An assisted reproductive technology bank may advertise for gamete donors and surrogates, who may be compensated financially by the bank". But § 55(2) prohibits the sale of gametes, except for use by an assisted reproductive technology clinic for treating infertility; the sale of zygotes and embryos, or of any information related to gametes, zygotes or embryos, within India is prohibited.

#### 4.6.1. INTERNATIONAL SCENARIO

At the international level, Preamble to the Convention on Human Rights and Biomedicine, 1997<sup>68</sup>, declares that there is a "need to respect the human being both as an individual and as a member of the human species, recognising the importance of ensuring dignity of the human being". Preamble to the Convention reminds that the misuse of biology and medicine may lead to acts endangering human dignity and it also affirms that "progress in biology and medicine should be used for the benefit of the present and future generations". Most importantly, Article 21 of the Convention<sup>69</sup> specifically prohibits financial gain from the human body and its parts.

Article 12<sup>70</sup> of the European Union's 'Tissues and Cells Directive'<sup>71</sup> requires that gametes should only be supplied on a 'not for profit' basis. The Directive also provides that, "donors may receive compensation which is strictly limited to making good the expenses and inconveniences related to the donation."<sup>72</sup> It

<sup>&</sup>lt;sup>68</sup> Council of Europe, Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, Oviedo, 4. IV. 1997, European Treaty Series-No.164, (Apr. 22, 2016), https://rm.coe.int/168007cf98.

<sup>&</sup>lt;sup>69</sup> Article 21 states: "The human body and its parts shall not, as such, give rise to financial gain".

 $<sup>^{70}</sup>$  Article 12 states: "Member States shall endeavour to ensure voluntary and unpaid donations of tissues and cells". Moreover, it also requires the Member States to "endeavour to ensure that the procurement of tissues and cells as such is carried out on a non-profit basis".

<sup>&</sup>lt;sup>71</sup> Directive 2004/23/EC of the European Parliament and of the Council on Setting Standards of Quality and Safety for the Donation, Procurement, Testing, Processing, Preservation, Storage and Distribution of Human Tissues and Cells, 2004, (Apr. 22, 2016), https://www.hta.gov.uk/sites/default/files/European\_Directive\_2004-23-EC\_ (Parent\_Directive).pdf.

<sup>&</sup>lt;sup>72</sup> Article 12 (1), Directive 2004/23/EC of the European Parliament.

also casts the duty on the Member States of the European Union to ensure voluntary and unpaid donations of tissues and cells.<sup>73</sup>

The World Medical Association's <sup>74</sup> Statement on Assisted Reproductive Technologies, 2006<sup>75</sup>, states that it is inappropriate to offer financial benefits to encourage donation of human reproductive material. <sup>76</sup> Moreover, monetary compensation given to individuals for economic losses, expenses or inconveniences associated with the retrieval of donated reproductive materials should be distinguished from payment for the purchase of reproductive materials.<sup>77</sup>

## 4.6.2. LEGAL FRAMEWORK IN THE UNITED KINGDOM

Section 12 of the United Kingdom Human Fertilization and Embryology Act, 1990 (as amended in 2008, hereinafter referred to as HFEA), provides for the conditions of licence granted under HFEA. Clause (e) of Section 12 specifically mandates that "no money or other benefit shall be given or received in respect of

<sup>&</sup>lt;sup>73</sup> Article 12 (1), Directive 2004/23/EC of the European Parliament.

<sup>&</sup>lt;sup>74</sup> Founded in 1947, the World Medical Association is an international and independent confederation of free professional medical associations, representing physicians worldwide., (Jul. 25, 2018), https://www.wma.net/.

<sup>&</sup>lt;sup>75</sup> Adopted by the 57th WMA General Assembly, Pilanesberg, South Africa, October 2006, (Jun. 12, 2016), https://www.wma.net/policies-post/wma-statement-on-assisted-reproductive-technologies/.

<sup>&</sup>lt;sup>76</sup> WMA Statement on Assisted Reproductive Technologies, adopted by the 57<sup>th</sup> WMA General Assembly, Pilanesberg, South Africa, October 2006, (Aug.12, 2016), https://www.wma.net/policies-post/wma-statement-on-assisted-reproductive-technologies/

<sup>&</sup>lt;sup>77</sup> WMA Resolution on the Non-Commercialisation of Human Reproductive Material, adopted by the 54<sup>th</sup> WMA General Assembly, Helsinki, Finland, September 2003, and revised by 65th WMA General Assembly, Durban, South Africa 2014, (Apr. 28, 2016), http://www.wma.net/ en/30publications/10policies/r1/index.html.

any supply of gametes or embryos unless authorised by Directions".<sup>78</sup> Section 41 of HFEA lays down offences and consequential stringent penalties. Section 41 (8) provides: "Where a person to whom a licence applies or the holder of the licence gives or receives any money or other benefit, not authorised by directions, in respect of any supply of gametes, embryos or human admixed embryos<sup>79</sup>, he is guilty of an offence." Section 41 (9) of the same further prescribes the punishment for the contravention.<sup>80</sup>

Directions on the Gamete and Embryo Donation, 2015<sup>81</sup> under HFEA specifies that the infertility centres "must not accept an individual as a donor who is known, or is reasonably suspected, by that centre to have received or to be about to receive money or other benefits not in line with these Directions."<sup>82</sup> Moreover,

<sup>&</sup>lt;sup>78</sup> Under the Human Fertilisation and Embryology Act, 1990, the HFEA has the power to issue Directions - or rules, (May 22, 2016), http://www.hfea.gov.uk/188.html.

<sup>&</sup>lt;sup>79</sup> § 4 A (6) of HEFA defines the term admixed embryo as, "(a) an embryo created by replacing the nucleus of an animal egg or of an animal cell, or two animal pronuclei, with—(i) two human pronuclei, (ii) one nucleus of a human gamete or of any other human cell, or (iii) one human gamete or other human cell, (b) any other embryo created by using—(i) human gametes and animal gametes, or (ii) one human pronucleus and one animal pronucleus, (c) a human embryo that has been altered by the introduction of any sequence of nuclear or mitochondrial DNA of an animal into one or more cells of the embryo, (d) a human embryo that has been altered by the introduction of one or more animal cells, or (e) any embryo not falling within paragraphs (a) to (d) which contains both nuclear or mitochondrial DNA of a human and nuclear or mitochondrial DNA of an animal ("animal DNA") but in which the animal DNA is not predominant".

<sup>&</sup>lt;sup>80</sup> A person guilty of an offence under subsection (8) above is "liable on summary conviction to imprisonment for a term not exceeding six months or a fine not exceeding level five on the standard scale or both".

<sup>&</sup>lt;sup>81</sup> (May 22, 2016), http://www.hfea.gov.uk/docs/2015-10-29\_-\_General\_Directions \_0001\_-\_Gamete\_and\_embryo\_donation\_-\_Website\_version\_-\_\_FINAL\_PDF.pdf.

<sup>&</sup>lt;sup>82</sup> Directives 5-9 provides that the "Centres may compensate sperm donors a fixed sum of up to £35 per clinic visit and the egg donors a fixed sum of up to £750 per cycle of donation. Where a prospective egg donor does not complete the cycle, the centre may compensate the egg donor on a 'per clinic visit' basis. Where a person has stored gametes or embryos for use in their own treatment but then consents to donate them, a centre may compensate the donor for subsequent visits on a 'per clinic visit' basis. The Centres may also compensate donors an excess amount in cases where expenses (such as for travel, accommodation or childcare) exceed the amounts

Section 25 of HFEA requires that the Human Fertilization and Embryology Authority<sup>83</sup> "shall maintain a code of practice giving guidance about the proper conduct of activities carried on in pursuance of a licence under this Act and the proper discharge of the functions of the person responsible and other persons to whom the licence applies". The Code of Practice, Guidance Note 13 details about the aspect of payment for donors.<sup>84</sup>

Reading together, HFEA along with Directions on the Gamete and Embryo Donation, 2015 and the HFEA Code of Practice makes it clear that in the United Kingdom, payments for the use or transfer of human reproductive materials are prohibited. Only compensation for the pain, suffering as well as the time lost for the procedure is allowed under the same. HFEA does not give status of property to the human gametes. The Authority has recommended that donors can receive payment in kind in the form of discounts for assisted reproductive services.<sup>85</sup>

specified above. Centres may only provide excess expenses which: (a) are reasonable; (b) do not include loss of earnings; (c) have been incurred by the donor in connection with the donation of gametes provided to that centre; and (d) have been incurred by the donor solely within the United Kingdom. Donors who are not permanent residents of the UK should be compensated in the same way as UK donors without an excess for overseas travel expenses. Centres must not directly or indirectly pay the overseas travel of a non-UK donor."

<sup>&</sup>lt;sup>83</sup> The Human Fertilisation and Embryology Authority is constituted under § 5 of the HFEA and it oversees the use of gametes and embryos in fertility treatment and research. It licenses fertility clinics and centres carrying out IVF, other assisted conception procedures and human embryo research. The Authority is an executive non-departmental public body, sponsored by the Department of Health and Social Care, (Jul. 09, 2016), https://www.gov.uk/government/ organisations/ human-fertilisation-and-embryo logy-authority.

<sup>&</sup>lt;sup>84</sup> Human Fertilization and Embryology Authority, Code of Practice, 8<sup>th</sup> Edition, 2008, (Sep. 14, 2018), http://ifqtesting.blob.core.windows.net/umbraco-website/1561 /2017-05-02-code-of-practice-update-may-2017-final.pdf.

<sup>&</sup>lt;sup>85</sup> PETER R. BRINSDEN, A TEXTBOOK ON IN VITRO FERTILIZATION AND ASSISTED REPRODUCTION, (The Bourn Hall Guide to Clinical and Laboratory Practice, The Parthenon Publishing Group, 2<sup>nd</sup> edn.), 409 (1999).

## 4.6.3. POSITION IN AUSTRALIA

In Australia<sup>86</sup>, gamete and embryo donation and surrogacy are permitted within the regulatory framework set out by federal and state governments.<sup>87</sup> Although subtle differences exists between states, third-party reproduction is by and large a socially acceptable and legally permissible way to form a family throughout Australia.<sup>88</sup>

The Australian Federal Government, through the National Health and Medical Research Council (hereinafter referred to as NHMRC), has issued Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research, 2017.<sup>89</sup> Principle 5.4. states that "the gamete donation must be altruistic, and that commercial trading in human gametes or the use of direct or indirect inducements is prohibited". In addition, four of the six Australian states have legislations<sup>90</sup> which regulates ART.

<sup>&</sup>lt;sup>86</sup> Australia comprises of six states: New South Wales (NSW), Queensland (Qld), South Australia (SA), Tasmania (Tas), Victoria (Vic) and Western Australia (WA) and two Territories: Australian Capital Territory (ACT) and the Northern Territory (NT). Legislation relating to health, including ART, is a matter for individual states.

<sup>&</sup>lt;sup>87</sup> Karin Hammarberg, et al., *Gamete and Embryo Donation and Surrogacy in Australia: The Social Context and Regulatory Framework*, 4 Int. J. Fertil. Steril., 176-183 (2011), (Apr. 04, 2016), http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4023505/.

<sup>&</sup>lt;sup>88</sup> Karin Hammarberg, et al., *Gamete and Embryo Donation and Surrogacy in Australia: The Social Context and Regulatory Framework*, 4 Int. J. Fertil. Steril., 176-183, (2011), (Apr. 04, 2016), http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4023 505/.

<sup>&</sup>lt;sup>89</sup> Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research, 2017, by the National Health and Medical Research Council, (Sep. 11, 2018), www.nhmrc.gov.au/ guidelines/publications/e79.

<sup>&</sup>lt;sup>90</sup> In New South Wales, the Assisted Reproductive Technology Act, 2007, (NSW) and the associated Assisted Reproductive Technology Regulation, 2009, governs the realm of ART. The Assisted Reproductive Treatment Act, 1988, is applicable in South Australia and the same is also adopted by the Northern Territory. In Victoria, the Assisted Reproductive Treatment Act, 2008, and the associated Assisted Reproductive Treatment Regulations, 2009, governs the law relating to the use of assisted reproductive techniques. In Western Australia, The Human

Chapter V of the Human Tissue and Transplant Act, 1982 of Western Australia prohibits trading in human tissue. <sup>91</sup> The subsequent sections prohibit the advertisements relating to buying human tissue. The main object of the Assisted Reproductive Technology Act, 2007, of New South Wales as detailed in Section 3 is "to prevent the commercialisation of human reproduction." Section 5 of the Assisted Reproductive Treatment Act, 2008 of Victoria, lays down the guiding principles of the statute, and most importantly, that at no time treatment procedures should be used for the purpose of exploiting, in trade or otherwise.

In broad terms, the state laws and the NHMRC Ethical Guidelines stipulate that only altruistic gamete and embryo donation is permissible in Australia. It also makes it clear that these legislations though do not expressly create property rights in respect of donated gametes, relies upon 'property-like interests' in reproductive materials.<sup>92</sup> "Apart from compensation for expenses incurred as a result of donating gametes or embryos, a donor cannot receive any payment or other inducement."<sup>93</sup> Analysing the legal provisions prevalent in Australia regarding the procurement, use and retention of human gametes gives an

Reproductive Technology Act, 1991 and the associated Human Reproductive Technology (Licences and Registers) Regulations, 1993 governs the regulation of ART.

<sup>&</sup>lt;sup>91</sup> Under § 3 of the Act, "tissue" includes an organ or part of the human body or a substance extracted from, or from a part of, the human body. This includes human reproductive materials as well.

<sup>&</sup>lt;sup>92</sup> ROHAN HANDCASTLE, LAW AND THE HUMAN BODY: PROPERTY RIGHTS, OWNERSHIP AND CONTROL, (Bloomsbury Publishing), 91 (2007).

<sup>&</sup>lt;sup>93</sup> Karin Hammarberg, et al., *Gamete and Embryo Donation and Surrogacy in Australia: The Social Context and Regulatory Framework*, 4 Int. J. Fertil. Steril., 176-183, (2011), (Apr. 20, 2016), http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4023505/.

impression that consent from gamete providers is the governing principle in all transactions involving human gametes.<sup>94</sup>

# 4.6.4. POSITION IN THE UNITED STATES OF AMERICA

The Uniform Anatomical Gift Act, 1987, (hereinafter referred to as UAGA) of the United States of America authorises the donation of body parts for transplantation or medical research. The UAGA has been thoroughly revised in 2006. It provides the framework for uniform laws governing cadaveric organ and tissue donation in the United States. An important highlight of the UAGA is that it allows the posthumous retrieval of gametes for ART use.<sup>95</sup> Section 16 of the UAGA prohibits sale or purchase of 'parts'.<sup>96</sup> But Section 16 (b) excludes a reasonable amount for the removal, processing, preservation, quality control, storage, transportation, implantation, or disposal of a part. This statutory recognition of body part as 'gift' itself can be regarded as an example that the society currently treats body parts as property. The concept of 'donation' itself is related to property.<sup>97</sup>

There are no other federal statutes regulating the transfer or control of gametes in the United States. Many state legislatures in the United States have chosen to

<sup>&</sup>lt;sup>94</sup> ROHAN HANDCASTLE, LAW AND THE HUMAN BODY: PROPERTY RIGHTS, OWNERSHIP AND CONTROL, (Bloomsbury Publishing), 91 (2007).

<sup>&</sup>lt;sup>95</sup> ETHICAL DILEMMAS IN ASSISTED REPRODUCTIVE TECHNOLOGIES, (Joseph G. Schenker, ed.), Walter de Gryter GmbH & Co. KG, Berlin/Boston, 289 (2011).

 $<sup>^{96}</sup>$  'Part' is defined under § 2 (18). 'Part' means an organ, an eye, or tissue of a human being. The term does not include the whole body.

<sup>&</sup>lt;sup>97</sup> William Boulier, Sperm, Spleens, and other Valuables: The Need to Recognize Property Rights in Human Body Parts, 23 Hofstra L. Rev., 693-731, 712 (1995).

make gamete transfers in the nature of 'donation'. These enactments basically focus on removing from gamete providers all rights, obligations, or interests with respect to children born as a result of artificial insemination. They neither classify donated gametes as property nor confer on gamete providers any property rights.<sup>98</sup> "A number of states like Florida, Illinois, Louisiana, Michigan, South Dakota, and Utah imposes a ban or restrict the sale of embryos. Only Louisiana explicitly bans the sale of ova. Virginia, on the other hand, explicitly exempts ova from its prohibition on the sale of body parts. California bans the sale of ova for use in attempts at cloning-to produce children."<sup>99</sup>

The National Organ Transplantation Act, 1984 (hereinafter referred to as NOTA) makes it unlawful for "any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce."<sup>100</sup> However NOTA has limited scope as it does not deal with dispositions of organs for purposes other than for transplantation.

## 4.6.5. POSITION IN CANADA

In Canada, the Federal Government prohibited the purchase of sperm under

<sup>&</sup>lt;sup>98</sup> Rohan Handcastle, *Law and the Human Body: Property Rights, Ownership and Control*, Bloomsbury Publishing, 91 (2007).

 <sup>&</sup>lt;sup>99</sup> Reproduction and Responsibility: The Regulation of New Biotechnologies, The President's Council on Bioethics, Washington, D.C, (May 06, 2016), https://bioethicsarchive.georgetown.
 edu/pcbe/reports/reproductionandresponsibility/chapter6.html.
 <sup>100</sup> § 301 (a) of NOTA; 42 U.S. Code § 274e.

Section 7(1) of the Assisted Human Reproduction Act, 2004.<sup>101</sup> Section 2 (f) of the same provides: "trade in the reproductive capabilities of women and men and the exploitation of children, women and men for commercial ends raise health and ethical concerns that justify their prohibition." Section 9 further prohibits any person from obtaining any sperm or ovum "from a donor under 18 years of age, or use of any sperm or ovum so obtained, except for the purpose of preserving the sperm or ovum or for the purpose of creating a human being that the person reasonably believes will be raised by the donor".

Despite the fact that many countries have laws prohibiting commercial transactions of reproductive material, most have not been successful in preventing the sale of human ova, sperm and embryos on the internet and elsewhere.<sup>102</sup>

# 4.6.6. POSITION IN INDIA

There is no specific legislation in India to deal with the commercialisation of human gametes. Section 45(1) of the Assisted Reproductive Technology (Regulation) Bill, 2017, prohibits commercial transactions thus: "the sale, transfer or use of gametes, zygotes and embryos, or any part thereof or information related thereto, directly or indirectly to any party within and outside

<sup>&</sup>lt;sup>101</sup> § 7 (1) No person shall purchase, offer to purchase or advertise for the purchase of sperm or ova from a donor or a person acting on behalf of a donor.

<sup>&</sup>lt;sup>102</sup> See, Katarina Lee M.A. Laura Gotti Tedeschi, *Worldwide Human Eggs Laws: Comment* on *Reproductive Ethics*, (Oct. 16, 2018), https://corethics.org/wp-content/uploads/Human-Eggs-Laws.pdf, *See* also, WMA Resolution on the Non-Commercialisation of Human Reproductive Material, (Apr.12, 2016), http://www.wma.net/en/30publications/10policies/r1/ index.html.

India is prohibited except in the case of transfer of own gametes and embryos for personal use with the permission of the National Registry".<sup>103</sup> Further, Section 49(2)(b) of the same Bill provides punishment for the sale of human embryo or gametes with a penalty of minimum five lakh rupees extendable up to ten lakh rupees for the first instance. Subsequent offence shall be punishable with imprisonment for a term which shall not be less than ten years and with fine not less than ten lakhs and which may be extended up to twenty lakh rupees.

## 4.7. PROPERTY INTERESTS IN THE HUMAN GAMETES

If egg or sperm is treated as a subject matter of property, it would follow that it could be treated as any other 'thing' which could be bought, sold, inherited, etc. Courts have approved property interests in human reproductive materials in various cases,<sup>104</sup> after looking into various aspects including the intention of the source person.

When the cases over last few decades are analysed, one can see that it concentrates on the question of either 'property' or 'no property' in human corpse, the human body or human bodily materials. The property approach in the human body basically recognises that bodily materials can constitute items of

<sup>&</sup>lt;sup>103</sup> Assisted Reproductive Technology (Regulation) Bill, 2017 (Sep. 17, 2018), https://dhr. gov.in/sites/default/files/Asssited%20Reproductive%20Technology%20%28Regulation%29 %20Bill%2C2017.pdf.

<sup>&</sup>lt;sup>104</sup> For a detailed discussion, *see* paragraph 4.7.1.

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property in law, and hence individuals can exercise property rights in relation to them.<sup>105</sup>

A few recent cases have upheld the existence of property in human reproductive materials. The cases which discussed the property interests in human gametes can be broadly classified into two groups. There are a set of cases where the extraction, storage and use of sperm after the death of the originator was in question.<sup>106</sup> Another set of cases focused on the point of negligence in the handling of sperms by the storage banks, resulting in their destruction.<sup>107</sup>

# 4.7.1. PROPERTY INTERESTS OVER STORED SPERM

Sperm and egg retrieval, storage and disposition raises most crucial questions of use and possession rights as well as the right to dispose of the same in cases of unanticipated events. *Hecht v. Kane*<sup>108</sup> was one among the early cases which

<sup>&</sup>lt;sup>105</sup> PERSONS, PARTS AND PROPERTY: HOW SHOULD WE REGULATE HUMAN TISSUE IN THE TWENTY FIRST CENTURY, (Imogen Goold et.al, eds.), (Bloomsbury Publishing), 4 (2014).

<sup>&</sup>lt;sup>106</sup> Hetch v. Kane, 16 Cal. App 4<sup>th</sup> 836 (1993), Bazley v. Wesley Monash IVF Pty Ltd., [2010] QSC 118, Re, the Estate of the Late Mark Edwards, [2011] NSWSC 478, Estate of Joseph M. Kievernagel v. Patsy Kievernagel, Parpalaix c. Centre d'' etude et de Conservation du Sperme, T.G.I. Creteil, Aug. 1, 1984, Gaz. du PaL 1984, 2, pan. jurisp., 560.

<sup>&</sup>lt;sup>107</sup> Kurchner v. State Farm Fire & Cas. Co., 858. So.2d. 1220, (2003), Yearworth v. North Bristol NHS Trust, [2009] EWCA Civ. 37.

<sup>&</sup>lt;sup>108</sup> 16 Cal. App 4<sup>th</sup> 836 (1993). In his will, Kane directed that his sperm, which he had stored in a sperm bank, was to be given to Deborah Hecht, his girlfriend. Kane had been 'assiduously generating' this sperm, probably in contemplation of his death at his own hand. About a month after he executed this will, Kane committed suicide. Kane's will was filed with the Probate Court and a special administrator was appointed to deal with the estate. Kane's children filed a statement expressing their wish that the sperm be destroyed. They argued that such a disposition would further good public policy by preventing both the birth of fatherless children and the disruption of the family by after-born children. The Probate Court ordered that Kane's sperm be destroyed. Hecht sought a writ of prohibition from the California Court of Appeals to prevent execution of the destruction order. The Court of Appeals held that "Kane had an ownership interest in his sperm to the extent that he had a decision making authority over the sperm's disposition after his death".

discussed about the property interests in human reproductive materials. The question discussed was, whether sperm can be treated as a 'thing' or 'property' that could be 'donated, bought, sold or bequeathed by will'. The Californian Court of Appeal held that "a deceased man who had previously deposited sperm for the use of his partner had an interest 'in the nature of ownership' in the samples such as to render them 'property' within the meaning of the Probate Code and, accordingly, disposable property on his death."<sup>109</sup>

More recently, in *Bazley v. Wesley Monash IVF Pty Ltd.*,<sup>110</sup> the question before the Supreme Court of Queensland, Australia, was to determine whether sperm extracted and stored can be described as 'property' and thus form part of Bazley's estate.<sup>111</sup> If it is property, then certain rights may attach and vest in his personal representatives. The Court took a 'property-based approach' to determine how semen sample stored shortly before death should be dealt with. The Court held that "...both in law and in common sense, must be that the straws <sup>112</sup> of semen currently stored with the respondent are property, the ownership of which vested in the deceased while alive and in his personal representatives after his death" and that the co-executors of the estate had sufficient proprietary interests in the semen to legally demand its return from the

<sup>&</sup>lt;sup>109</sup> 16 Cal. App 4<sup>th</sup> 836 (1993), at 850.

<sup>&</sup>lt;sup>110</sup> [2010] QSC 118. In this case, Warren Bazley stored sperm samples prior to undergoing treatment for cancer, and subsequently died of the disease. Though he had prepared a detailed will, he failed to make any written direction about the use of his sperm post-mortem. Following his death, the storage facility took the position that, in accordance with their written contract and national guidelines, they could not facilitate the use of the gametes and were required to dispose of them.

<sup>&</sup>lt;sup>111</sup> [2010] QSC 118, at para 16.

<sup>&</sup>lt;sup>112</sup> Vials of donated semen.

laboratory where it was held.<sup>113</sup> The Court also held that the storage facility stood in the position of a bailee, as it agreed to store the straws so long as the fee was paid and the contract with the deceased was maintained.

In 2011, in *Re, the Estate of the Late Mark Edwards*,<sup>114</sup> the New South Wales Supreme Court, Australia held that the widow of a recently deceased man had a right to possession of his semen. The Court held that the straws of semen are property, the ownership of which vested in the deceased while alive and in his personal representatives after his death.<sup>115</sup>

In the *Estate of Joseph M. Kievernagel v. Patsy Kievernagel*, <sup>116</sup> the question before the Court of Appeal, Third District, California, was whether a widow has the right to use her late husband's frozen sperm to attempt to conceive a child.<sup>117</sup> The Court concluded that in determining the disposition of gamete material, to which no other party has contributed and thus another party's right to procreative autonomy is not implicated, the intent of the donor must have control. Accordingly, the decedent's intent was to have his frozen sperm discarded upon his death and therefore the distribution of the frozen sperms to the widow was denied. Court further observed that the deceased had "an interest, in the nature

<sup>&</sup>lt;sup>113</sup> [2010] QSC 118, at para 33.

<sup>&</sup>lt;sup>114</sup> [2011] NSWSC 478.

<sup>&</sup>lt;sup>115</sup> [2011] NSWSC 478, at para 91.

<sup>&</sup>lt;sup>116</sup> 83 Cal. Rptr. 3d 311, decided on September 11, 2008.

<sup>&</sup>lt;sup>117</sup> Her late husband signed an agreement with the company storing the frozen sperm providing that the frozen sperm was to be discarded upon his death.

of ownership, to the extent that he had decision making authority as to the use of his sperm for reproduction."<sup>118</sup>

Furthermore, in a recent decision of the Supreme Court of British Columbia, Canada,<sup>119</sup> the question was, whether the sperm straws were to be treated as 'property' for the purpose of dividing them between two separating spouses upon the dissolution of their spousal relationship. The Court found that the sperm was property. Since the parties had the intent to divide the assets fairly, Court ordered that the remaining gametes were to be divided between the parties.

In *Parpalaix c. Centre d'' etude et de Conservation du Sperme*,<sup>120</sup> a French Court faced the question of who owned the sperm of a man who had deposited his reproductive cells to a sperm bank and subsequently passed away. He did not state his intentions regarding the frozen sperm in the event of his death.<sup>121</sup> Instead

<sup>&</sup>lt;sup>118</sup> 83 Cal. Rptr. 3d 311.

<sup>&</sup>lt;sup>119</sup> J.C.M. v. A.N.A., 2012 BCSC 584, the parties were a lesbian couple and they commenced a spousal relationship in 1998, and had two children using sperm provided by a single sperm donor. A.N.A. gave birth to their first child, and J.C.M. gave birth to their second. The couple got separated in 2006, and entered into a separation agreement in 2007. The agreement divided the property between them, but the question of the sperm straws was not addressed in the agreement. J.C.M. wanted to have a child with her new spouse, but A.N.A. expressed her preference that the sperm straws be destroyed, and refused to consent to the release of the sperm straws from the bank in which they were being stored. J.C.M. commenced an application for an order declaring the sperm straws to be her sole property, while A.N.A. opposed and requested that the sperm straws be destroyed. (May 09, 2016), http://www.canlii.org/ en/bc/bcsc/doc/2012/2012bcsc584/2012bcsc584.pdf.

<sup>&</sup>lt;sup>120</sup> (1984) JCP 1984.11.20321. This was a decision of the *Tribunaux de Grande Instance* in 1984.

<sup>&</sup>lt;sup>121</sup> Alain Parpalaix was undergoing chemotherapy for testicular cancer. Warned by his doctors that the treatments could render him sterile, and at their suggestion, he deposited sperm in the *Centre d'etude et de Conservation du Sperme* (CECOS), a research centre and sperm bank. At the time of the sperm deposit, Alain had been living with his girlfriend, Corinne. They got married and he died two days after their marriage. Following his death, his wife Corinne requested the sperm for use in artificial insemination, this was refused. Alain's wife and parents claimed that they were his heirs and the owners of the sperm. They argued that Alain's intent

of viewing sperm as ordinary property that could be alienated at will, the Court chose to decide the use of sperm based on the intent of the donor. The Court found that "the human sperm was not inheritable property within the meaning of the French Civil Code and that Alain's intent was the determining factor".<sup>122</sup> As he had not specified his intent in writing, his parents and wife were best able to articulate it. The Tribunal ordered CECOS, the sperm bank where it has been stored, to return the sperm over to his wife and her doctor for insemination. Thus, the Court held that sperm is not movable, inheritable property in the first case to determine the property rights in the sperm.<sup>123</sup>

# 4.7.2. CLAIM FOR DAMAGE FOR DESTRUCTION OF CRYOPRESERVED <sup>124</sup> GAMETES

In Leigh & Sullivan Ltd. v Aliakmon Shipping Co. Ltd., <sup>125</sup> Lord Brandon stated:

"In order to enable a person to claim in negligence for loss caused to him by

was for Corinne to use the sperm to conceive a child after his death. The sperm bank argued that they did not have any obligations to Corinne, as their agreement was with Alain and that the sperm was not divisible from the body in the absence of specific instructions from Alain, and so was not inheritable. Since Alain and Corinne were not married at the time of deposit and Alain did not provide any written directives, the sperm should not be given to Corinne. They argued that the deposit was for therapeutic purposes, to psychologically aid Alain, T.G.I. Creteil, Aug. 1, 1984, Gaz. du PaL 1984, 2, pan. jurisp., 560., Gail A. Katz, *Papalaix C. CECOS: Protecting Intent in Reproductive Technology*, 11 Harvard J. Law & Techn., 683-698 (1998).

<sup>&</sup>lt;sup>122</sup> Gail A. Katz, *Papalaix C. CECOS: Protecting Intent in Reproductive Technology*, 11 Harvard J. Law & Techn., 683-698 (1998).

<sup>&</sup>lt;sup>123</sup> Gail A. Katz, *Papalaix C. CECOS: Protecting Intent in Reproductive Technology*, 11 Harvard J. Law & Techn., 683-698 (1998).

<sup>&</sup>lt;sup>124</sup> It is the "freezing or vitrification and storage of gametes, zygotes, embryos, or gonadal tissue". F. Zegers-Hochschild, G. D. Adamson, et al., *International Committee for Monitoring Assisted Reproductive Technology (ICMART) and the World Health Organization (WHO) revised glossary of ART terminology*, 2009, (Sep. 23, 2018), http://www.who.int/reproductive health/publications/infertility/art\_terminology 2.pdf. <sup>125</sup> [1986] AC 785.

reason of loss of or damage to property, he must have had either the legal ownership of or a possessory title to the property concerned at the time when the loss or damage occurred."<sup>126</sup> The same principle is discussed in almost every case relating to the question of damage caused to a person by the reason of loss or damage caused to the sperm preserved for him.<sup>127</sup>

In *Kurchner v. State Farm Fire & Cas. Co.*,<sup>128</sup> the District Court of Appeal of Florida, in a claim for destruction of cryopreserved sperms held that the "sperm outside the body is property."<sup>129</sup>

Further, in *Yearworth v North Bristol NHS Trust*, <sup>130</sup> the England and Wales Court of Appeal held that the sperm was the property of the men who produced it. In this case, the Court observed that, "by their bodies, they alone generated and ejaculated the sperm and that the men had the ownership of the sperm".<sup>131</sup> The Court's finding of sperm as property, and that the men had ownership of sperm which they ejaculated was based on the following reasoning:

<sup>&</sup>lt;sup>126</sup> [1986] AC 785, at 809.

<sup>&</sup>lt;sup>127</sup> See the cases discussed in subsequent paragraphs.

<sup>&</sup>lt;sup>128</sup> 858. So.2d. 1220, (2003). The Appellant, before starting his chemotherapy treatment, cryopreserved his five sperm samples with the South Florida Institute for Reproductive Medicine (SFIRM). Due to the negligence of the SFIRM, the sperms were destroyed. The SFIRM had a comprehensive business liability insurance coverage with an insurance company. But the insurance company refused to indemnify SFIRM for their liability towards the appellant on the ground that the insurance policy provides coverage only for 'bodily injury' and since the sperm is not a part of the body, the destruction of which will not amount to 'bodily injury'. The Appellate Court found that the sperm outside the body is property.

<sup>&</sup>lt;sup>129</sup> 858. So.2d. 1220, 1221 (2003).

 <sup>&</sup>lt;sup>130</sup> [2009] EWCA Civ. 37. Six men had given their sperm to be stored in the hospital for future use, before starting treatment for cancer, which may adversely affect their fertility. But due to the negligence of the hospital, the sperms were destroyed.
 <sup>131</sup> [2009] EWCA Civ. 37, Para 45 (f).

"Firstly, by their bodies, they alone generated and ejaculated the sperm.<sup>132</sup> Secondly, the sole object of their ejaculation of the sperm was that, in certain events, it might later be used for their benefit in future."<sup>133</sup> The Court of Appeal held that "the sperm did amount to property that was legally owned by the men who supplied it even after it had left their body".<sup>134</sup>

In 1993, the German Federal Supreme Court<sup>135</sup> considered the case of a man whose sperm had been negligently destroyed by the sperm bank where he had deposited it for reasons of illness.<sup>136</sup> German Supreme Court recognised the question as a violation of the right to reproduce. They considered the body as integral part of the person's legal personality and the Court observed that at the point of separation, the severed body parts lose all links to the protected entity of the 'body' and become 'objects' in the legal sense. Therefore, the frozen sperm, which the owner intended to use for future procreation, represents a special case. Moreover, the sperm has permanently been separated from the body and it is intended to fulfil a bodily function, i.e., procreation. In any case when

<sup>&</sup>lt;sup>132</sup> [2009] EWCA Civ. 37, Para 45 (f).

<sup>&</sup>lt;sup>133</sup> [2009] EWCA Civ. 37, Para 45 (f).

<sup>&</sup>lt;sup>134</sup> [2009] EWCA Civ. 37, Para 45 (f).

<sup>&</sup>lt;sup>135</sup> BGHZ 124, 52 VI, Civil enate, and VI ZR 62/93.

<sup>&</sup>lt;sup>136</sup> "Before undergoing an operation which would leave him sterile, the 31 year's old plaintiff had some of his sperm frozen in order to have children later. Because of the fault of the clinic, this sperm was lost. The plaintiff demanded damages from the clinic. Both lower courts rejected his claim. The defendants, while recognising the violation of their duty to take care of the sperm, only offered to compensate the amount the plaintiff had paid to store the sperm". *See*, BGHZ 124, 52 VI. Civil Senate (VI ZR 62/93), 09 November 1993, Translated German Cases and Materials under the direction of Professors P. Schlechtriem, B. Markesinis and S. Lorenz, (May 08, 2016), https://law.utexas.edu/transnational/foreign-lawtranslations/german/case.php?id=7 60.

the preservation of sperm was meant as a substitute to the lost capability of procreation, it is no less valuable than a woman's egg cell or other bodily parts.<sup>137</sup>

In *Hall v Fertility Institute of New Orleans*,<sup>138</sup> Hall was diagnosed with cancer. He deposited vials of sperm with a fertility institute and executed a formal will, by which he transferred his interest in the sperm to his girlfriend. Following Hall's death, his executor sought to have the vials destroyed or transferred to Hall's son, because of the son's discomfort at the prospect of posthumous siblings. The Louisiana Court of Appeal concluded that sperm is not traditional property. The Court stressed that the consequences of using sperm are so enormous that transfer must not be taken lightly, and the consequences of transfer must concur with the donor's intent.<sup>139</sup>

In *Re, Matter of Daniel Thomas Christy*,<sup>140</sup> Judge Martha Beckelman of the 6<sup>th</sup> District Court of Iowa decided in favour of Daniel Christy's parents, ruling that the UAGA applies to sperm as well. The Court held that under the Act, an anatomical gift, including the gift of sperm, can be made by the donor, or, if the

<sup>&</sup>lt;sup>137</sup> See, BGHZ 124, 52 VI. Civil Senate (VI ZR 62/93), 09 November 1993, Translated German Cases and Materials under the direction of Professors P. Schlechtriem, B. Markesinis and S. Lorenz, (May 08, 2016), https://law.utexas.edu /transnational/foreign-lawtranslations/german/ case.php? id=760.

<sup>&</sup>lt;sup>138</sup> Hall v. Fertility Institute of New Orleans (1994) 647 So 2d 1348 (La Ct App).

<sup>&</sup>lt;sup>139</sup> Gail A. Katz, "PARPLAIX C. CECOS: Protecting Intent in Reproductive Technology", 11 Harvard J. Law & Techn., 683- 698, 687 (1998).

<sup>&</sup>lt;sup>140</sup> In re Daniel Thomas Christy, Johnson County Case No. EQVO68545 (Sept. 14, 2007). 23 year-old Daniel Christy suffered severe head trauma in a motorcycle accident. He was listed as an organ donor. His fiancée wanted a baby from him and considered the possibility of having the sperm retrieved and saved. The Court ordered the post mortem sperm retrieval, finding that the decedent's consent to be an organ donor under the UAGA extended to posthumous sperm retrieval also. Ellen Trachman & William E. Trachman, *The Walking Dead: Reproductive Rights for the Dead*, 3 Savannah L. Rev., 91-116, 105 (2015).

donor did not refuse to make the gift, by the donor's parents following the donor's death.

Therefore, the recent treatment of reproductive material as 'property' is to be borne in mind by anyone who have stored such material, while writing a will. If the will doesn't specify one's wish with regard to the gametes in which one have an 'ownership interest', it could form part of the residue of one's general estate, and the legal heirs may quarrel over its possession. This is likely to happen particularly in families where there are ex- and current spouses, and children from past marriages. Special consideration should be given to the disposition of this special kind of 'property'.<sup>141</sup>

Thus, ART have proved to be a boon to infertile couples, allowing them to beget their own offspring, genetically related to at least one of them. With the increase in the number of couples seeking these procedures, a market has been formed for human gametes. Human gametes are used in infertility treatments and research centres. Moreover, "it has become possible to retrieve, freeze and store sperm, embryos, and even oocytes or ovarian tissue for years, thereby creating new possibilities and new markets for this technology".<sup>142</sup>

<sup>&</sup>lt;sup>141</sup> Genetic Material as Property: Rethinking the Common Law View, (May 20, 2016), http://www.weirfoulds.com/genetic-material-as-property-rethinking-the-common-law.

<sup>&</sup>lt;sup>142</sup> G. Bahadur, Death and Conception, 17 Human Reproduction, 2769–2775 (2002), (Jun. 12, 2018), https://academic.oup.com/humrep/article/17/10/2769/607780.

The commercialisation of reproductive medicine has given rise to scarcity and consequent demand for human gametes. Giving property status to the gametes is an available alternative to solve this. Gametes are treated as property in almost all respects, which is evidence from the cases, yet there is a reluctance to acknowledge this. It also indicates the challenge to the established social structures imposed by the latest technologies and the effect they may have on traditional views of inheritance and the family. It also demonstrates the conceptual incoherence of the law.<sup>143</sup>

The status of gametes is an indication of the conceptually unsatisfactory state of the law regarding bodily materials. In this area, law has not kept up with the changes in science.<sup>144</sup> Many unanswered questions remain regarding the legal status of gametes. Therefore, the preservation, use, or destruction of gametes warrant the need for a well-defined and uniform legal framework, which clearly lays down the nature and status of the reproductive materials. In its absence there will not be uniformity as to whether it can be treated as property.

<sup>&</sup>lt;sup>143</sup> Cordelia Mary Thomas, *A Framework for the Collection, Retention and Use of Human Body Parts*, 129 (2006), (Jun. 06, 2018), http://researcharchive.vuw.ac.nz/xmlui/bitstream/handle/ 10063/297/thesis.pdf?sequence=2.

<sup>&</sup>lt;sup>144</sup> Melinda Troeger, *The Legal Status of Frozen Pre-Embryos when a Dispute Arises During Divorce*, 18 J. of the American Academy of Matrimonial Lawyers, 563-587, 563 (2003).

# V. LEGAL STATUS OF HUMAN EMBRYOS

#### **5.1. INTRODUCTION**

Biological facts concerning the beginning of life<sup>1</sup> have come to light during the past decades and it forces us to reconsider our assumptions about the early stages of the development of human life. <sup>2</sup> With the development in artificial reproductive procedures<sup>3</sup> and embryology<sup>4</sup>, it is now possible to create human embryos outside the body. An egg and a sperm can be fertilized in a *petri* dish and the resultant embryo can be frozen and stored for many years for future use.<sup>5</sup> From the time since embryos are created artificially, an array of questions which

2018

<sup>&</sup>lt;sup>1</sup> "It's a miracle that happens hundreds of thousands of times each day. Sperm meets egg. There, chromosomes begin intertwining, forming a unique genetic combination. The mysterious, awe-inspiring process of rapid cell division begins. Within a short time, if all conditions are right, the growing embryo will find a cozy spot on the uterine wall and attach, securing a life-giving bond with its mother.", *See* ELIZABETH PRICE FOLEY, THE LAW OF LIFE AND DEATH, (Harvard University Press), 1 (2011).

<sup>&</sup>lt;sup>2</sup> See in general, HUMAN GAMETES AND PREIMPLANTATION EMBRYOS: ASSESSMENT AND DIAGNOSIS, (David K. Gardner, Denny Sakkas et al., eds.), (Springer), 2013.

<sup>&</sup>lt;sup>3</sup> Also known as Assisted Reproductive Techniques, ART is defined by the American Society for Reproductive Medicine as: "All treatments which include the handling of eggs and/or embryos. Some examples of ART are in vitro fertilization (IVF), gamete intrafallopian transfer (GIFT), pronuclear stage tubal transfer (PROST), tubal embryo transfer (TET), and zygote intrafallopian transfer (ZIFT)", *Assisted Reproductive Technology: A Guide for Patients*, American Society for Reproductive Medicine, Revised Edition, 23 (2015), (Jun. 16, 2016), https://www.asrm.org/uploadedFiles/ASRM\_Content/Resources/Patient\_Resources/Fact\_She ets \_and\_Info\_Booklets/ART.pdf.

<sup>&</sup>lt;sup>4</sup> Embryology is the branch of biology that studies the development of gametes, fertilization, and development of embryos and foetuses.

<sup>&</sup>lt;sup>5</sup> If more embryos are produced for IVF than are transferred, a couple may choose the option of cryopreservation. The cryopreservation process consists of freezing the embryos in liquid nitrogen at -196 degree Celsius. *See* Melinda Troeger, *The Legal Status of Frozen Pre-Embryos When a Dispute Arises During Divorce*, 18 J.A.A.M.L., 563-87, 565 (2003). *See* also, *Assisted Reproductive Technology: A Guide for Patients*, American Society for Reproductive Medicine, Revised Edition, 23 (2015), (Jun. 16, 2016), https://www.asrm.org/uploadedFiles/ASRM\_ Content/Resources/Patient\_Resources/Fact\_Sheets\_and\_Info\_Booklets/ART.pdf. *See* also, PRACTICAL MANUAL OF IN VITRO FERTILIZATION: ADVANCED METHODS AND NOVEL DEVICES, (Zsolt Peter Nagy, Alex C. Varghese, et al., eds.), Springer, 536 (2012).

one couldn't have imagined a few decades back have also arisen. Among which, the basic and most important question is the legal status of a human embryo created outside the  $body^6$ .

Human life begins from a single cell, which then divides many thousand times to form all the different types of cells and tissues that make up the human body.<sup>7</sup> The single celled egg is fertilized by a sperm and the result is called the 'zygote'. This zygote eventually develops into the embryo and later, into the foetus. The term 'embryo' refers to the product of conception from the point of fertilisation up to the eighth week of gestation, after which it is known as 'foetus'.<sup>8</sup> A foetus is considered to be structurally complete in that all its organs have begun to form. The initial eight-week period can be further divided into the pre-embryonic stage, <sup>9</sup> and the embryo proper. The pre-embryonic stage, also known as early

<sup>&</sup>lt;sup>6</sup> It is also termed as the '*in vitro* embryo' or 'pre-implantation embryo'.

 <sup>&</sup>lt;sup>7</sup> Advisory Committee on Assisted Reproductive Technology, Use of Gametes and Embryos in Human Reproductive Research: Determining Policy for New Zealand: A Discussion Paper, 3 (Mar. 05, 2016), www.newhealth.govt.nz/acart.

<sup>&</sup>lt;sup>8</sup> ICMR *Ethical Guidelines for Biomedical Research on Human Subjects*, 82, 90 (2006), (Mar. 06, 2016), http://www.icmr.nic.in/ethical\_guidelines.pdf. For a clearer distinction between embryo and zygote, *See*, § 3 of Assisted Human Reproduction Act, 2004, Canada which defines embryo as: "a human organism during the first fifty-six days of its development following fertilization or creation, excluding any time during which its development has been suspended, and includes any cell derived from such an organism during the period of its development beginning on the fifty-seventh day following fertilization or creation, excluding any time during which its development which its development beginning on the fifty-seventh day following fertilization or creation, excluding any time during which its development has been suspended, and ending at birth."

<sup>&</sup>lt;sup>9</sup> A pre-embryo is "the very early, free-floating embryo, from the time the egg is fertilized until implantation in the mother's womb is complete, about 12 to 14 days after fertilization. It covers stages of development up to the appearance of primitive streak until 15<sup>th</sup> day after fertilization which marks the development of foetal body plan", ICMR *Ethical Guidelines for Biomedical Research on Human Subjects*, 90 (2006), (Mar. 06, 2016), http://www.icmr.nic.in/ethical\_guidelines.pdf.

embryo, is the first 14 days after fertilisation, and after that, two to eight weeks after fertilisation, it is called as the embryo proper.<sup>10</sup>

A human embryo is strictly the combination of the reproductive cells of two persons, a man and a woman, which itself gives it significance when compared to the other human materials. Moreover, human bodily materials such as blood or organs are derived from the body of a person, whereas an embryo is considered itself to constitute a person.<sup>11</sup> Legal status of the embryo becomes important in the context of expansion of assisted reproductive technologies (hereinafter referred to as ART), and related research in the early stages of fertilization. Human embryos are created artificially for the ART<sup>12</sup> and such

<sup>&</sup>lt;sup>10</sup> Advisory Committee on Assisted Reproductive Technology, *Use of Gametes and Embryos in Human Reproductive Research: Determining Policy for New Zealand*: A Discussion Paper, 3 (Mar. 05, 2016), www.newhealth.govt.nz/acart.

<sup>&</sup>lt;sup>11</sup> H. GOTTWEIS, et al., THE GLOBAL POLITICS OF HUMAN EMBRYONIC STEM CELL SCIENCE: REGENERATIVE MEDICINE IN TRANSITION, Health, Technology and Society Series, (Springer), 4 (2009).

<sup>12</sup> "In vitro fertilization (IVF) is one among the important Artificial Reproductive Technologies. It involves obtaining immature ova from a woman, placing them in a culture medium and then fertilizing them with the sperm. Within several days after the conceptus has reached the blastocyst stage of development, it is transplanted into the gestational mother. Fertilization of multiple ova allows implantation of more than one fertilized egg at a time to increase the chance of pregnancy, or the additional embryos may be frozen and stored for future use, thereby eliminating the need for additional surgery. Technicians may preserve embryos not immediately implanted by using cryopreservation, freezing the embryos in liquid nitrogen. The frozen embryos may then be stored for future attempts at pregnancy. Cryopreservation allows participants in IVF to minimize the burdens of the process and maximize the chances of successful pregnancy." See Stephanie J. Owen, Davis v. Davis: Establishing Guidelines for Resolving Disputes over Frozen Embryos, 10 J. Contemp. Health Law Pol., 493-511, 495 (1994), "In vitro fertilization includes the processes of ovulation induction, egg retrieval, fertilization, and embryo transfer. Drugs that manipulate hormones to promote ovulation are injected into the female. After an appropriate interval to allow oocyte maturation, eggs are typically retrieved with ultra sound-guided aspiration through the vagina and cervix, and are incubated with 50,000 to 1,000,000 sperm for 14-18 hours. Following transfer to a new growth medium, the eggs are examined for the presence of two pronuclei, an indicator that normal fertilization has occurred. Approximately three days later, the embryos are morphologically assessed for quality, and two to four embryos chosen by the embryologist are flushed into the uterus through a catheter." See Emilie W. Clemmens, Creating Human Embryos for Research:

creation of embryos attracts a bundle of legal, ethical, social and religious questions. Embryos warrant a special status which is distinct from other bodily materials. It cannot be treated as part of the body of its progenitors, nor can it be treated as a separate entity.

"The advent of *in vitro* fertilization<sup>13</sup> (hereinafter referred to as IVF) and ART have introduced a novel moral dilemma and legal challenge regarding the significance and rights of an embryo conceived by the union of sperm and egg in a *petri* dish that is not yet implanted into a woman's uterus and as such cannot become a human being."<sup>14</sup> Though the creation and use of human embryos *ex utero* would undoubtedly advance scientific achievements on multiple fronts, ethical and legal questions temper our rush to pursue this path.<sup>15</sup> Embryo is not a part or product of a single human body. It is a combination of products of two persons' bodies.<sup>16</sup> In the case of natural reproduction, the question of separate status of an embryo is irrelevant as it does not have a separate status from the mother's body. Even then, under the criminal law and the law of torts, unborn

A Scientist's Perspective on Managing the Legal and Ethical Issues, 2 Indiana Health L. Rev., 95-115, 97 (2005).

<sup>&</sup>lt;sup>13</sup> IVF involves ovulation induction, egg retrieval, fertilization, and embryo transfer. Madeline E. Guillot, *Playing God: Why The Thirteenth Amendment Protects Human Embryos from Stem Cell Research*, 14 Loy. J. Pub. Int. L., 171, 176 (2012-2013), (Jun. 22, 2016), http:heinonline. org.

<sup>&</sup>lt;sup>14</sup> Emilie W. Clemmens, *Creating Human Embryos for Research: A Scientist's Perspective on Managing the Legal and Ethical Issues*, 2 Indiana Health L. Rev., 95-115, 106 (2005).

<sup>&</sup>lt;sup>15</sup> "In addition to technical discussions, the issue of stem cell research has elicited debate on the role of science in alleviating human suffering and the relationship of science to the sanctity of life", Doe v. Obama, 631 f.3d 157 (2011). *See* also, Emilie W. Clemmens, *Creating Human Embryos for Research: A Scientist's Perspective on Managing the Legal and Ethical Issues*, 2 Indiana Health L. Rev., 95-115, 96 (2005).

<sup>&</sup>lt;sup>16</sup> An embryo is formed when the male sperm cell and female egg cell fuse together during fertilization.

persons are given a separate legal status.<sup>17</sup> But the status of artificially created *in vitro* embryos creates much more complex issues relating to its ownership, possession, storage, use, destruction, etc.

The use and creation of human embryos has generated considerable controversy for the past four decades.<sup>18</sup> This debate has recently been reenergized by embryonic stem cell (hereinafter referred to as ESC) research.<sup>19</sup> The growth in embryonic research necessitates the need for analysing the status of embryos in the framework of jurisprudence relating to property. Due to its independent existence, apart from the body of its progenitors, multiple issues<sup>20</sup> have arisen with regard to embryos since the time they were produced artificially outside the human body.<sup>21</sup>

<sup>&</sup>lt;sup>17</sup> Initially, Common Law did not recognise the unborn child as an entity capable of being wronged by another's tortious conduct. But later, the judicial thinking on this subject has changed. Under the law of torts, relief is granted to prenatal injuries without regard to the stage of pregnancy when they were inflicted. Under criminal law also, unborn persons are given special status and the intentional killing of quick, unborn child is considered as an offence. In India, causing miscarriage is a punishable offence under section 312 of the Indian Penal Code (IPC). If the child has reached the stage of 'quickening' severe punishment is prescribed under section 316 of the IPC. If the miscarriage is caused without the consent of the woman, the punishment is even severe under section 313 of the IPC. Killing of a quick, unborn child is considered to be an act amounting to culpable homicide under section 316 of the IPC. Moreover, in India, transfer of property can be made to a child in the womb under section 13 of the Transfer of Property Act, 1882.

<sup>&</sup>lt;sup>18</sup> From the time when embryos were created artificially in 1978.

<sup>&</sup>lt;sup>19</sup> Emilie W. Clemmens, *Creating Human Embryos for Research: A Scientist's Perspective on Managing the Legal and Ethical Issues*, 2 Indiana Health L. Rev., 95-115, 95 (2005).

<sup>&</sup>lt;sup>20</sup> The questions regarding the ownership, use, storage and destruction of embryos has been discussed in various cases across jurisdictions. One common thread which can be seen in almost every case pertaining to this subject is the question whether to treat human embryos as property or not. For a detailed discussion, *see*, paragraph 5.5. of this chapter.

<sup>&</sup>lt;sup>21</sup> Stephanie J. Owen, *Davis v. Davis: Establishing Guidelines for Resolving Disputes over Frozen Embryos*, 10 J. Contemp. Health Law Pol., 493-511, 493 (1994).

With the unprecedented growth in research using human embryos, the position of embryos has become particularly vulnerable. Embryos are capable of life outside of the mother's womb at earlier and earlier stages as technology advances.<sup>22</sup> Since the conception and early embryonic development is now possible outside the human body, embryos can be screened for genetic conditions,<sup>23</sup> frozen, stored or discarded,<sup>24</sup> used for training or research which may or may not result in their destruction.<sup>25</sup> The status of human embryos is the central question in determining what should or should not be done to them.<sup>26</sup> At the basic level, the question which needs an answer here is, whether an embryo is to be treated as a 'person' or as a 'property' in the contemplation of law?.<sup>27</sup>

If embryos are given the status of a person, the attribution of such 'personhood' demands a dignified treatment. On the other hand, if it is treated as 'property', then an embryo can be considered as an 'object' which can be owned, used or

<sup>&</sup>lt;sup>22</sup> Chris Macaluso, *Viability and Abortion*, 64 Ky. L.J. 146-164, 160 (1975), *Cited* in, Leanne E. Murray, *Davis v. Davis: The Embryonic Stages of Procreational Privacy*, 14 Pace L. Rev., 567-96 (1994), (May 17, 2016), http://digitalcommons.pace.edu/plr/vol14/iss2/5.

<sup>&</sup>lt;sup>23</sup> "Preimplantation Genetic Diagnosis, (hereinafter referred to as PGD), can now be used to screen for other genetically-based adult-onset diseases including Huntington's disease, Alzheimer disease, and breast cancer", Judith F. Daar, *Embryonic Genetics*, 2 St. Louis U. J. Health L. & Pol'y, 81-118, 83 (2008-2009) (Jun. 22, 2016), http:heinonline.org.

<sup>&</sup>lt;sup>24</sup> "The freezing of sperm, eggs, and embryos can also produce unintended results. When a happily married couple undergoes IVF and freezes excess embryos for future use, they likely do not intend to later divorce and squabble bitterly over the disposition of those embryos", Judith F. Daar, *Embryonic Genetics*, 2 St. Louis U. J. Health L. & Pol'y, 81-118, 89 (2008-2009) (Jun. 22, 2016), http:heinonline.org.

<sup>&</sup>lt;sup>25</sup> Another noteworthy unintended consequence of fertility treatment is its spillover into the emerging world of embryonic stem cell research, Judith F. Daar, *Embryonic Genetics*, 2 St. Louis U. J. Health L. & Pol'y, 81-118, 90 (2008-2009) (Jun. 22, 2016), http:heinonline.org.

<sup>&</sup>lt;sup>26</sup> Adelaide Centre for Bioethics and Culture, (May 05, 2016), http://www.bioethics.org.au/ Resources/Resource%20Topics/Human%20Embryos%20and%20Gametes.html.

<sup>&</sup>lt;sup>27</sup> This was the question which was discussed in almost every case related to the disposition of human embryos.

destroyed according to the decisions of the persons who have title over such property.

## 5.2. THE 'PERSON' V. 'PROPERTY' DICHOTOMY

Since embryos have turned to be subjects of disputes, the questions relating to the legal status of the embryos have come up for the consideration before various courts. When it comes to the matter of determining legal status of the human embryos, undercurrents such as ethics, culture, religion, etc. play a substantive role. There are two schools of thought - one where embryos are treated as 'persons' and the other where they are treated as 'property'. The above thesis and anti-thesis has resulted in a third school of thought which consider embryos as neither 'person' nor 'property' in its strict sense. They are considered as "special entities that have the potential to become persons and, therefore, warrant respect"<sup>28</sup>. They are to be regarded as "an intermediate category that entitles them to special respect because of their potential for human life"<sup>29</sup>.

Upon the union of an egg and a sperm, a genetically unique being is formed with a complete set of genetic instructions and a capacity to direct its own development. An embryo has its own unique genetic identity which is distinctive from its progenitors.<sup>30</sup> Hence one argument is that the embryos are to be considered as potential human beings. Those who support the 'personhood

<sup>&</sup>lt;sup>28</sup> Davis v. Davis, 842 S.W.2d 588 (Tenn., 1992).

<sup>&</sup>lt;sup>29</sup> Davis v. Davis, 842 S.W.2d 588 (Tenn., 1992).

<sup>&</sup>lt;sup>30</sup> Dianne N. Irving, *When do Human Beings Begin? Scientific Myths and Scientific Facts*, (Jun. 16, 2018), https://www.princeton.edu/~prolife/articles/wdhbb.html.

status<sup>'31</sup> of the human embryo treats embryos as potential persons. They are considered to have the same moral status as persons and are treated to be worthy of dignity and protection accorded to a human being. Therefore, as potential persons, the embryos merit special moral concern.<sup>32</sup>

The supporters of this theory argues that, from the moment of fertilisation, the embryo is entitled to the same protection status that is accorded to human beings after birth on the basis of their personhood.<sup>33</sup> The biological development of the early embryo into the foetus and then into the person demonstrates that throughout there is an involvement of human life.<sup>34</sup>

"The value that we place on human life is intimately linked with respect for personhood but what constitutes personhood is certainly not a matter of scientific fact. Rather it is an amalgam of legal expedience, cultural variation, and moral supposition; as such, it is likely to be subject to wide and varied interpretation."<sup>35</sup> Thus, the view exemplified by the Roman Catholic Church holds that

<sup>&</sup>lt;sup>31</sup> Supported by the Pro-life (anti-abortionists) activists, mostly influenced by the values supported by the Roman Catholic Church.

<sup>&</sup>lt;sup>32</sup> Callahan D., *The Puzzle of Profound Respect*, 25 Hastings Centre Report, 39-40 (1995), *Cited in* David B Resnik, *The Commodification of Human Reproductive Materials*, 388 J. of Medical Ethics, 388-393, 391 (1998).

<sup>&</sup>lt;sup>33</sup> "Insofar as the embryo has no legal status, the problem can be characterised as purely ethical and one which turns on the *nature* of the embryo. The extreme positions can be summarised as holding either that the embryo is a full human being - in accordance with rigid theological, perhaps mainly Roman Catholic, doctrine - or, as the pure scientist might claim, it is simply a product of the laboratory, comparable to a culture of human tissue", J. K. MASON & G.T. LAURIE, MASON AND MCCALL SMITH'S LAW AND MEDICAL ETHICS, (Oxford University Press, 8<sup>th</sup> edn.), 278 (2011).

<sup>&</sup>lt;sup>34</sup> CONCEIVING THE EMBRYO: ETHICS, LAW AND PRACTICE IN HUMAN EMBRYOLOGY, (Donald Evans, ed.), (Martinus Nijhoff Publishers), 5 (1996).

<sup>&</sup>lt;sup>35</sup> J. K. MASON & G.T. LAURIE, MASON AND MCCALL SMITH'S LAW AND MEDICAL ETHICS, (Oxford University Press, 8<sup>th</sup> edn.), 297 (2011).

personhood, exists from the moment of conception i.e., the zygote formed from the union of a male and a female gamete is a 'person'.<sup>36</sup>

On the other hand, the counter argument does not support the idea of treating embryos in the equal status of human beings attributing 'personhood' to the embryo.<sup>37</sup> Those who do not support giving embryos the same status of a person recognises the embryo *ex utero* as property. This position is widely accepted by experts in reproductive technology as well as the courts<sup>38</sup> while deciding about the usage and destruction of embryos. Classifying embryos as property describes the interest of the 'owners' in controlling their use.<sup>39</sup> Accordingly, the gamete providers or the progenitors are considered the owners because they decide the fate of such embryos.<sup>40</sup>

Debate about the worthiness of protection of the human embryo is characterised by certain fundamental positions. One argument is that, the embryo first needs to reach a specific stage in its development before it is entitled to the same status of protection granted to human beings after birth on the basis of their personhood.<sup>41</sup> There is not much debate over the use of 'embryo proper' for

<sup>&</sup>lt;sup>36</sup> J. K. MASON & G.T. LAURIE, MASON AND MCCALL SMITH'S LAW AND MEDICAL ETHICS, (Oxford University Press, 8<sup>th</sup> edn.), 297 (2011).

<sup>&</sup>lt;sup>37</sup> Advocates of abortion reject the notion of 'personhood' to the embryos due to the following reasons: 1) Only persons have a right to life, 2) An entity that lacks rationality, self-consciousness and desires about its future is not a person, 3) A foetus lacks all of these criteria, hence a foetus is not a person and has no right to life. But the counter argument is that, foetuses have the potential for achieving personhood in the course of normal development.

<sup>&</sup>lt;sup>38</sup> Relevant cases are discussed in the later part of this chapter.

<sup>&</sup>lt;sup>39</sup> Stephanie J. Owen, *Davis v. Davis: Establishing Guidelines for Resolving Disputes over Frozen Embryos*, 10 J. Contemp. Health Law Pol., 493-511, 499 (1994).

<sup>&</sup>lt;sup>40</sup> Stephanie J. Owen, *Davis v. Davis: Establishing Guidelines for Resolving Disputes over Frozen Embryos*, 10 J. Contemp. Health Law Pol., 493-511, 499 (1994).

<sup>&</sup>lt;sup>41</sup> (May 28, 2016), http://www.drze.de/in-focus/stem-cell-research/ethical-discussion.

research.<sup>42</sup> Countries those who have legislated on the area have banned research activities in embryos after 14 days.<sup>43</sup> Many countries do not permit creating embryos solely for research purposes.<sup>44</sup> Some countries take a liberal view, thereby allowing the creation of embryos for research,<sup>45</sup> but the embryos thus created are not allowed to grow after 14 days.

"The primary objection to creating embryos specifically for purposes of research is based on the notion that there is a qualitative difference between creating an embryo which may have a chance of implantation and creating embryos without even that chance of implantation."<sup>46</sup> According to J.K. Mason, G.T. Laurie,<sup>47</sup> "in the absence of implantation, there is no continuum and there is no human interaction; moreover, no moral value can be attributed to the embryo by virtue

<sup>&</sup>lt;sup>42</sup> For a detailed analysis, *see*, paragraph 5.2.1.

<sup>&</sup>lt;sup>43</sup> The 14-day limit was first proposed in 1979 by the Ethics Advisory Board of the US Department of Health, Education, and Welfare. It was endorsed in 1984 by the Warnock committee in the United Kingdom, and in 1994 by the US National Institutes of Health's Human Embryo Research Panel. Insoo Hyun et al., *Embryology Policy: Revisit the 14-Day Rule*, 533 Nature International Weekly Journal of Science, (2016). (May 04, 2016), http://www. nature.com/news/embryology-policy-revisit-the-14-day-rule-1.19838.

The countries specifically limiting the duration of embryonic research to 14 days includes, Canada, Iceland, Sweden, United Kingdom, Spain, South Korea, Denmark, Slovenia, New Zealand and Australia. The countries which have specified the 14 days' limit in specific guidelines includes, United States, China, Japan, Singapore and India. *See*, Insoo Hyun et al., *Embryology Policy: Revisit the 14-Day Rule*, 533 Nature International Weekly Journal of Science, (2016), (May 04, 2016), http://www.nature.com/news/embryology-policy-revisit-the-14-day-rule-1.19838.

<sup>&</sup>lt;sup>44</sup> The Witherspoon Council on Ethics and the Integrity of Science, Appendix E: *Overview of International Human Embryonic Stem Cell Laws*, 34 The New Atlantis, 126-146 (2012).

<sup>&</sup>lt;sup>45</sup> The United Kingdom is an example for the country which has liberal regulations on the human embryonic stem cell research. The Human Fertilization and Embryology Act, 2008 does not altogether prohibit making embryos solely for the purpose of research.

<sup>&</sup>lt;sup>46</sup> Lori P. Knowles, *Draft International Perspectives on Human Embryo and Fetal Tissue Research*, commissioned by The National Bioethics Advisory Commission, (Apr. 30, 2016), https://bioethicsarchive.georgetown.edu/nbac/briefings/may99/ip.pdf.

<sup>&</sup>lt;sup>47</sup> J. K. MASON & G.T. LAURIE, MASON AND MCCALL SMITH'S LAW AND MEDICAL ETHICS, (Oxford University Press, 8<sup>th</sup> edn.), 278 (2011).

of its potential for personhood - for no such potential exists in the medium of the *petri* dish".<sup>48</sup>

Therefore, at the first level of discussion, it may be concluded that, special legal status and protection given to the embryos *in utero* is different from that of an embryo *in vitro*. An embryo created artificially *in vitro* intended to be transplanted to a woman's womb, is given the status of property to some extent.<sup>49</sup> But the questions regarding the status of a 'pre-embryo' remains largely unsettled.

## 5.2.1. SPECIAL STATUS OF 'PRE-EMBRYOS'

Pre-embryonic stage, which is the first 14 days after fertilisation, has been accorded a different legal status.<sup>50</sup> During the 14-day pre-implantation period, the structure includes a relatively lesser number of cells that will later form the 'embryo proper', as well as a much larger number of cells that will form support tissues for the embryo, such as the placenta. In other words, the pre-embryo is far more than simply the precursor to the foetus.<sup>51</sup> This is in comparison to the embryo proper, whose cells are wholly committed to forming the developing foetus.

<sup>&</sup>lt;sup>48</sup> J. K. MASON & G.T. LAURIE, MASON AND MCCALL SMITH'S LAW AND MEDICAL ETHICS, (Oxford University Press, 8<sup>th</sup> edn.), 278 (2011).

<sup>&</sup>lt;sup>49</sup> See, the subsequent paragraphs for a detailed discussions relating to the legal status of embryos artificially created as a part of *in vitro* fertilization.

<sup>&</sup>lt;sup>50</sup> The Countries which permit research in human embryos limit the permission to conduct research in embryos to the first 14 days after the fertilization.

<sup>&</sup>lt;sup>51</sup> When a pre-embryo reaches the stage of an embryo proper, the cells are committed only to form the developing foetus. Before that stage, the cells of a pre-embryo can divide itself into twins, or it divides itself into the placenta and the embryo proper.

By the fourteenth day after conception, the primitive streak is formed and fuses, thereby preventing any further cleavage<sup>52</sup>. This is the stage at which the preembryo can develop, if destined to do so, into a single entity.<sup>53</sup> It has been argued that only after the initial 14 days, the embryo reaches the form of an entity which is capable of developing into a foetus and later into an infant. Day 14 is considered of such biological significance<sup>54</sup> that even in societies that allow research on human embryos, as mentioned earlier, no such research can be conducted on an embryo older than 14 days.

The significance of the status of pre-embryos was elaborately discussed in Davis

v. Davis, 55 by the Supreme Court of Tennessee. 56

"Three major ethical positions have been articulated in the debate over pre-embryo status. At one extreme is the view of the pre-embryo as a human subject after fertilization, which requires that it be accorded the rights of a person..... At the opposite extreme is the view that the pre-

<sup>&</sup>lt;sup>52</sup> The term 'cleavage' rather than 'growth' is used to illustrate the division of the single - celled oocyte into more than 100 cells at the blastocyst stage, without any increase in the mass. Up to the blastocyst stage the cells (blastomeres) are cleaving off from the parent cell and each subsequent daughter cell is smaller than its predecessor; hence the term 'cleavage', Simon Fishel, *Assisted Conception in the Human - The Embryological View, cited* in Donald Evans (ed.), CONCEIVING THE EMBRYO: ETHICS, LAW AND PRACTICE IN HUMAN EMBRYOLOGY, (Donald Evans, ed.), Martinus Nijhoff Publishers, 15 (1996).

<sup>&</sup>lt;sup>53</sup> Simon Fishel, *Assisted Conception in the Human - The Embryological View, cited* in Donald Evans (ed.), CONCEIVING THE EMBRYO: ETHICS, LAW AND PRACTICE IN HUMAN EMBRYOLOGY, (Donald Evans, ed.), Martinus Nijhoff Publishers, 21 (1996).

 <sup>&</sup>lt;sup>54</sup> Advisory Committee on Assisted Reproductive Technology, *Use of Gametes and Embryos in Human Reproductive Research*: Determining Policy for New Zealand: A Discussion Paper, 4 (Mar. 05, 2018), www.newhealth.govt.nz/acart.

<sup>&</sup>lt;sup>55</sup> 842 S.W.2d 588, 597 (Tenn. 1992).

<sup>&</sup>lt;sup>56</sup> This case was the first of its kind to address questions of personhood in the context of *in vitro* fertilization of a human embryo. It laid a foundation for future cases to work from. This case established the importance of prior written agreements for disposition of frozen embryos. This was also the first Court decision to borrow the word 'pre-embryo' from bioethics to describe the *in vitro* embryo.

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embryo has a status no different from any other human tissue. With the consent of those who have decision-making authority over the preembryo, no limits should be imposed on actions taken with pre-embryos. A third view, one that is most widely held, takes an intermediate position between the other two. It holds that the pre-embryo deserves respect greater than that accorded to human tissue but not the respect accorded to actual persons. The pre-embryo is due greater respect than other human tissue because of its potential to become a person and because of its symbolic meaning for many people. Yet, it should not be treated as a person, because it has not yet developed the features of personhood, and is not yet established as developmentally individual, and may never realize its biologic potential".<sup>57</sup>

Therefore, in contemporary debates relating to the status of human embryos, three main positions can be distinguished: the conservative, the liberal, and the moderate view.<sup>58</sup> According to the conservative view, human life begins at conception. Therefore the fertilised ovum, the zygote, is almost a human, and killing of the same is just as wrong as killing of an adult human being.<sup>59</sup> The liberal view holds that a developing foetus acquires human rights only at birth or at the stage when it reaches viability,<sup>60</sup> but before this stage neither the embryo

<sup>57</sup> Davis v. Davis, 842 S.W.2d 588, (Tenn. 1992), Martha Craig Daughtrey, J., Quoting the Ethical Standards set by the American Fertility Society, at 597.

<sup>&</sup>lt;sup>58</sup> CONCEIVING THE EMBRYO: ETHICS, LAW AND PRACTICE IN HUMAN EMBRYOLOGY, (Donald Evans, ed.), (Martinus Nijhoff Publishers), 21 (1996).

CONCEIVING THE EMBRYO: ETHICS, LAW AND PRACTICE IN HUMAN EMBRYOLOGY, (Donald Evans, ed.), (Martinus Nijhoff Publishers), 21 (1996).

<sup>&</sup>lt;sup>60</sup> The Supreme Court in *Roe v. Wade*, (410 U.S. 113, 93 S. Ct. 705, 35 L. ed. 2d 147, (1973) ruled that states cannot put the interests of a foetus ahead of the interests of the pregnant woman until the foetus is 'viable'. The Court defined 'viable' to mean capable of prolonged life outside the mother's womb.

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nor the foetus can be regarded as human from a moral point of view, although it is undoubtedly human from a biological point of view.<sup>61</sup>

# 5.3. SOURCES OF HUMAN EMBRYOS

Apart from the natural sexual method of fertilization, the research in ART have resulted in production of human embryos artificially in the lab. These *in vitro* embryos can be used in their very early stages of development for research.<sup>62</sup> The most important source of embryos are the ones artificially created during IVF procedure for implantation. It is inevitable that surplus embryos will be produced during IVF procedures.<sup>63</sup> Since extracting ovum is a difficult procedure,<sup>64</sup> women undergoing IVF procedures are given hormonal stimulant drugs, multiple ova are collected at a time and the fertilized eggs may be stored by means of cryopreservation.<sup>65</sup> But all the fertilized eggs may not be used for implantation.<sup>66</sup>

<sup>&</sup>lt;sup>61</sup> CONCEIVING THE EMBRYO: ETHICS, LAW AND PRACTICE IN HUMAN EMBRYOLOGY, (Donald Evans, ed.), Martinus Nijhoff Publishers, 21 (1996).

<sup>&</sup>lt;sup>62</sup> Sonya Norris, *Human Embryo Stem Cell Research*, (Jun. 06, 2016), http://publications. gc.ca/Collection-R/LoPBdP/EB/prb0026-e.htm.

<sup>&</sup>lt;sup>63</sup> In vitro fertilisation is the most commonly used method of assisted human reproduction. With this technique, eggs and sperm are mixed together *in vitro*; that is, in suitable chemical media in the laboratory. Embryos formed in this procedure are transferred into the uterus, usually at around the eight-cell stage. IVF is a procedure that attempts to reproduce what happens in non-assisted reproduction, the difference being that eggs and sperm are acquired and then fertilised in the laboratory rather than in a woman's fallopian tubes.

<sup>&</sup>lt;sup>64</sup> In egg retrieval procedure, the mature eggs are removed from the donor through a surgical procedure called transvaginal ultrasound aspiration.

<sup>&</sup>lt;sup>65</sup> Stephanie J. Owen, *Davis v. Davis: Establishing Guidelines for Resolving Disputes over Frozen Embryos*, 10 J. Contemp. Health Law Pol., 493-511, 495 (1994).

<sup>&</sup>lt;sup>66</sup> Overproduction of embryos is inherent in the treatment of infertility by IVF. It is impossible to guarantee receptive wombs for those which remain unused in the individual case and, in many instances there involves defective embryos also. "The management of undeveloped *in vitro* embryo presents a dilemma of which there are three major elements: first is that of the use and production of embryos for research purposes. Second concerns the pre-implantation selection of embryos. The third main problem derived from embryonic status relates to the

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spontaneous miscarriage or as a result of therapeutic abortion.<sup>67</sup> In most of the cases, the future of the discarded embryos as a result of induced abortion is not known.<sup>68</sup>

Another method of creating embryos is making use of the possibility of egg follicles of aborted female foetuses. After a natural abortion, the dead foetus' eggs could be extracted, matured, and then fertilized with donor sperm, and then the resulting embryos could be implanted either in the purchasing women's uterus or in that of a surrogate.<sup>69</sup>

Another area of embryo creation that causes the greatest public interest and concern is 'cloning'. Somatic Cell Nuclear Transfer<sup>70</sup> is used to produce a very early embryo to serve as a source of embryonic stem cells. In this case, the goal is to produce cells or tissues rather than a complete offspring, and so there is no intention of implanting the early embryo in a uterus.<sup>71</sup> "The most controversial

practical problems surrounding the disposal of those that are surplus to immediate therapeutic needs." J. K. MASON & G.T. LAURIE, MASON AND MCCALL SMITH'S LAW AND MEDICAL ETHICS, (Oxford University Press, 8<sup>th</sup> edn.), 279 (2011).

<sup>&</sup>lt;sup>67</sup> J. K. MASON & G.T. LAURIE, MASON AND MCCALL SMITH'S LAW AND MEDICAL ETHICS, (Oxford University Press, 8<sup>th</sup> edn.), 652 (2011).

<sup>&</sup>lt;sup>68</sup> What Happens to Unborn Babies After Abortion? Pathologists Share the Horrors, Lifenews.com, Washington D.C, 2013, (May 23, 2016). http://www.lifenews.com/2013/10/23/what-happens-to-unborn-babies-after-abortion-pathologists-share-the-horrors/.

<sup>&</sup>lt;sup>69</sup> Stephanie A. Gagnon, *Moral Limits of Markets: Implications for the Commodification of Oozytes*, (Mar. 23, 2015), http://philpapers.org/ archive/GAGMLO.

<sup>&</sup>lt;sup>70</sup> Somatic Cell Nuclear Transfer (SCNT) involves the production of one or more exact copies of any given cell, or a whole organism. This category can be further divided based on whether the technique produces cells and tissues (therapeutic or research cloning) or a new organism (reproductive cloning).

<sup>&</sup>lt;sup>71</sup> World Human Cloning Policies, (Apr. 16, 2016), http://www.ruf.rice.edu/~neal/stemcell/ World. pdf.

of the human embryonic stem cell<sup>72</sup> (hereinafter referred to as hESC) research is the transfer of a somatic cell - nucleus from a patient to an enucleated oocyte, i.e., an unfertilized egg, in order to produce hESC genetically identical to that patient for 'autologous' transplantation (therapeutic cloning), this may prevent tissue rejection."<sup>73</sup> Once isolated such cells can be grown in culture in the laboratory to form a human embryonic stem cell line<sup>74</sup> and used for research purposes.<sup>75</sup>

Parthenogenesis is the condition where apart from penetration of the oocyte by the sperm, the oocyte itself may be 'activated' generating its own pronucleus with a haploid (half) set of chromosomes. This situation, known as parthenogenesis, can arise *in utero* as well as *in vitro*. <sup>76</sup> Although parthenogenesis can be used to create an embryo, the technique moves further away from natural processes.<sup>77</sup>

 <sup>&</sup>lt;sup>72</sup> "Human embryonic stem cells are derived from cells from the inner cell mass of the blastocyst", ASSESSING THE MEDICAL RISKS OF OOCYTE DONATION, FOR STEM CELL RESEARCH, (Linda Giudice, Eileen Santa, et al., eds.) The National Academies Press, 8 (2007).
 <sup>73</sup> Guido de Wert & Christine Mummery, *Human Embryonic Stem Cells: Research, Ethics and Policy*, Oxford Journals, 18 Human Reproduction, 672-682, 672 (2003), (Jun. 16, 2018), http://humrep.oxfordjournals.org/content/18/4/672.full.

<sup>&</sup>lt;sup>74</sup> "A stem cell line is essentially a group of stem cells that is cultured for various purposes using *in-vitro* methods. Stem cell lines are commonly used in genetic research and regenerative medicine, and they have already led to countless breakthroughs that would not have been possible through the use of any other type of cells. Because of stem cells' unique ability to renew themselves as they divide, they can essentially multiply to an indefinite extent, which is part of why stem cell lines are so valuable", (Sep. 25, 2018), https://www.genetargeting. com/stem-cell/what-is-a-stem-cell-line/.

<sup>&</sup>lt;sup>75</sup> National Guidelines for Stem Cell Research 2013, (Jun. 13, 2016), http://icmr.nic.in/ stem\_cell/stem\_cell\_guidelines.pdf.

<sup>&</sup>lt;sup>76</sup> Simon Fishel, *Assisted Conception in the Human - The Embryological View*, cited in CONCEIVING THE EMBRYO: ETHICS, LAW AND PRACTICE IN HUMAN EMBRYOLOGY, (Donald Evans, ed.), Martinus Nijhoff Publishers, 14 (1996).

<sup>&</sup>lt;sup>77</sup> An egg is encouraged to develop without first being fertilised by sperm. Parthenogenesis occurs naturally in lower animals, but in mammals this usually leads to death of the embryo

The tendency towards this non-natural methods is accelerated by the fact that human embryos are much in demand for research activities.<sup>78</sup> To date, most embryos used for the establishment of hES cell lines have been spare embryos from IVF, but the creation of embryos specifically for deriving hESC's are also under discussion.<sup>79</sup> Although some of the alternatives can occur during non-assisted reproduction, it is the more recent attempts to produce embryos in the laboratory that have generated extensive debate. A number of methods used to create embryos artificially go beyond the well-known process of IVF by attempting either to bypass fertilisation altogether or to modify it in some way. Although they are relatively undeveloped, having generally not yet progressed to the point of being tested on human tissue, the scientific and clinical potential of such methods is considerable. In theory they could lead to the formation of a structure that is in effect an embryo, with the potential of forming a foetus and later a human being.

The creation of embryos is critical to the advancement of research relating to embryonic development. Science appears to have reached the point that studies with human embryos are necessary to acquire new information on human

within days, Darryl R. J. Macer, *Shaping Genes: Ethics, Law and Science of Using New Genetic Technology in Medicine and Agriculture*, Eubios Ethics Institute, (1990), (Sep. 25, 2018), http://www.eubios.info/SG/SG5.htm.

<sup>&</sup>lt;sup>78</sup> See in general, National Institutes of Health, Stem Cells Report, Report 3, *The Human Embryonic Stem Cell and the Human Embryonic Germ Cell*, US Department of Health Services, (Jun. 24, 2018), http://stemcells.nih.gov/info/scireport/pages/chapter3.aspx.

<sup>&</sup>lt;sup>79</sup> Guido de Wert & Christine Mummery, *Human Embryonic Stem Cells: Research, Ethics and Policy*, Oxford Journals, 18 Human Reproduction, 672-682, 672 (2003), (Jun. 16, 2018), http://humrep.oxfordjournals.org/content/18/4/672.full.

embryonic development as well as research leading to development of new regenerative medicines.

### 5.4. SIGNIFICANCE OF EMBRYONIC RESEARCH

The earliest stages of embryonic development, involving the progression from egg and sperm to zygote and then to an embryo, are of considerable scientific interest. There has been an increased interest in the use of human gametes and embryos in research including fundamental biological research, reproductive research, and as a source of stem cells.<sup>80</sup> Embryo research is a complex area, both scientifically and ethically; it also involves a number of legal issues. However, if done well, it is valuable to the human kind as a whole. The hESC's are considered to be the future relief or cure of a wide range of common disabilities, replacement of defective cells in a patient by transplantation of hESC derived equivalents would restore normal function.<sup>81</sup>

Embryos are also used for research relating to genetic diseases,<sup>82</sup> and for preimplantation genetic diagnosis.<sup>83</sup> Research on the early stages of the embryo is motivated by the possibility of understanding why serious developmental anomalies are most likely to occur during the first few weeks of development,

<sup>&</sup>lt;sup>80</sup> Advisory Committee on Assisted Reproductive Technology. Use of Gametes and Embryos in Human Reproductive Research: Determining Policy for New Zealand: A Discussion Paper, (Mar. 05, 2016), www.newhealth.govt.nz/acart.

<sup>&</sup>lt;sup>81</sup> Guido de Wert & Christine Mummery, *Human Embryonic Stem Cells: Research, Ethics and Policy*, Oxford Journals, 18 Human Reproduction, 672-682, 672 (2003), (Jun. 16, 2018), http:// humrep.oxfordjournals.org/content/18/4/672.full.

<sup>&</sup>lt;sup>82</sup> International Society for Stem Cell Research (ISSCR) *Guidelines for the Conduct of Human Embryonic Stem Cell Research*, 2006, (Jun. 19, 2016), http://www.isscr.org/docs/default-source/ hesc-guidelines/isscrhescguidelines2006.pdf.

<sup>&</sup>lt;sup>83</sup> JO SAMANTA & ASH SAMANTA, MEDICAL LAW, (Palgrave Macmillan), 225 (2011).

and thus of devising ways for treating and even preventing them.<sup>84</sup> Scientists have been engaged in research with foetal tissue for many years, but only recently has the possibility of transplanting foetal tissue to cure or alleviate symptoms in sick patients seemed feasible on a large scale.<sup>85</sup> Other potential uses of foetal tissue include treatment of diabetes, genetic retinal abnormalities, optic nerve and spinal cord injury, alzheimer's disease, aplastic anaemia, acute leukaemia/lymphoma and liver failure.<sup>86</sup>

Stem cell research holds great promises for improving human health by restoring cellular and organ function damaged by degeneration and various injuries. The significance of stem cell research is the potential to manipulate these cells to grow into any transplantable tissue or organ.<sup>87</sup> HESC technology could solve the organ shortage problem by restoring diseased or damaged tissue across a range of common conditions.<sup>88</sup> At the same time it also raises several scientific, ethical and social issues in the development of such application.<sup>89</sup>

Reproductive technologies have expanded greatly in the last few decades. As research in embryos mostly takes place for ART, discussions relating to the same

<sup>85</sup> John A. Robertson, *Fetal Tissue Transplants*, in ORGAN AND TISSUE TRANSPLANTATION, (David Price, ed.), The International Library of Medicine, Ethics and Law, Ashgate, 392 (2006).
 <sup>86</sup> ICMR Ethical Guidelines for Biomedical Research on Human Subjects, 82 (2006), (May 24, 2018), https://icmr.nic.in/ethical\_guidelines.pdf.

<sup>&</sup>lt;sup>84</sup> National Guidelines for Stem Cell Research, 2013 (May 20, 2016, https://www.ncbs.res.in/ sites/default/files/policies/NGSCR%202013.pdf.

<sup>&</sup>lt;sup>87</sup> Sonya Norris, *Human Embryo Stem Cell Research*, (Jun. 06, 2016), http://publications.gc.ca/ Collection-R/LoPBdP/EB/prb0026-e.htm.

<sup>&</sup>lt;sup>88</sup> Jason P. Lott & Julian Savulescu, *Towards a Global Human Embryonic Stem Cell Bank*, American J. of Bioethics, 37-44, (2007), (Jun. 19, 2018), http://philpapers.org/rec/LOTTAG.

<sup>&</sup>lt;sup>89</sup> The ICMR-DBT Guidelines for Stem Cell Research, 2012, (May. 20, 2016), https://icmr. nic.in/stem\_cell/Stem\_cell\_guidelines.pdf.

takes place primarily in that context. One of the areas of conflict is the permissibility and regulation of the use of human embryos in such research.

With progress in research in human embryo, the embryos are in much demand. Fertility centres routinely ask for permission to use non-viable embryos or unused gametes for training and research purposes. Thus, the demand for egg cells, sperm cells and the resultant embryos are increasing day by day.

## 5.4.1. RESEARCH IN HUMAN EMBRYONIC STEM CELLS (hESC)

Stem cells are a potential source of new cells. Embryonic stem cells are pluripotent<sup>90</sup> in nature and have the potential to develop into any of the human cell types. They have the ability to renew themselves, for an indefinite amount of time. Human stem cell research could be of use in formulating new therapies, by assisting with the development and testing of new drugs.<sup>91</sup> Additionally, differentiated derivatives of human embryo stem cells could be applied to transplantation therapies and may enable the treatment of diseases resulting from abnormal cell division and specialisation. The most efficient method of obtaining

<sup>&</sup>lt;sup>90</sup> In cell biology, pluripotency refers to a stem cell that has the potential to differentiate into any of the three germ layers. The two basic characteristics of stem pluripotent cells are their capacity for self-renewal and multi lineage differentiation, Shoukhrat Mitalipov, & Don Wolf, *Totipotency, Pluripotency and Nuclear Reprogramming*, 114 Advances in Biochemical Engineering/ Biotechnology, 185-199 (2009), (Sept. 25, 2018), https://www.ncbi.nlm.nih. gov/pmc/articles/ PMC2752493/.

<sup>&</sup>lt;sup>91</sup> The Role of stem cells in Developing New Drugs, (Apr. 11, 2018), https://www.cam.ac.uk/ research/news/the-role-of-stem-cells-in-developing-new-drugs.

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stem cells is to extract them from early human embryos, which results in the destruction of the embryo.<sup>92</sup>

Stem cells are unique and they have the potential for development of commercial products. Research in human stem cells, especially the embryonic stem cells have a lot of advantages, though it is not free from numerous ethical issues. Based on the cell type/ tissue of origin, stem cells are classified into Somatic Stem Cells (SSCs)<sup>93</sup>, and Embryonic Stem Cells (ESCs). Somatic Stem Cells have limited differentiation capacity and may be multipotent<sup>94</sup> or unipotent<sup>95</sup>. Embryonic Stem Cells on the other hand are pluripotent.

There are ethical issues related to the use of human embryos to create hESC lines which offer potential for commoditization of human tissues and cells. It has the inherent danger of exploitation of underprivileged people, and challenges related to prevention of human germline engineering<sup>96</sup> and reproductive cloning<sup>97</sup>.

<sup>&</sup>lt;sup>92</sup> Cordelia Mary Thomas, *A Framework for the Collection, Retention and Use of Human Body Parts*, 129 (2006), (Jun. 06, 2018), http://researcharchive.vuw.ac.nz/xmlui/bitstream/handle/ 10063/297/thesis.pdf?sequence=2.

<sup>&</sup>lt;sup>93</sup> Somatic Stem Cells, also known as adult stem cells, are a resident, self-renewable population of cells which are present in virtually all organs/tissues of the body.

<sup>&</sup>lt;sup>94</sup> Potency of a stem cell is the capacity to differentiate into specialized cell types. Stem cells can also be classified according to their plasticity. Different types of stem cells vary in their degree of plasticity, or developmental versatility. The categories into which they fall include: the totipotent stem cell, pluripotent stem cell, multipotent stem cell, and the adult stem cell (a certain type of multipotent stem cell), K. Kalra & P.C. Tomar, *Stem Cell: Basics, Classification and Applications*, 2 A.J.P.C.T., 919-930, (2014).

<sup>&</sup>lt;sup>95</sup> A unipotent cell is the stem cell that has the capacity to differentiate into only one cell type, K. Kalra & P.C. Tomar, Stem Cell: Basics, Classification and Applications, 2 A.J.P.C.T., 919-930, (2014).

<sup>&</sup>lt;sup>96</sup> It means, "altering the fertilized egg - the first cell of the embryo-to-be – so that the genetic changes will be copied into every cell of the future adult", ENGINEERING THE HUMAN GERMLINE, Gregory Stock & John Campbell, (Oxford University Press), 3 (2000).

<sup>&</sup>lt;sup>97</sup> "Reproductive cloning is defined as the deliberate production of genetically identical individuals. Each newly produced individual is a clone of the original", *Scientific and Medical* 

"Research in this field, therefore, needs to be regulated with special attention to these issues."<sup>98</sup> Apart from challenges of using appropriate stem cells for a particular condition, there are important issues related to the use of embryos for creating hESC lines.<sup>99</sup>

In India, the creation of a human zygote by IVF, Somatic Cell Nuclear Transfer or any other method with the specific aim of deriving Embryonic Stem cell line for any purpose is considered to be restricted area of research under principle 6.2. of the Indian Council for Medical Research (hereinafter referred to as ICMR) National Guidelines for Stem Cell Research, 2013.<sup>100</sup>

Research on human subjects involving cells and tissues derived from human embryos and foetuses must safeguard human rights, dignity, and fundamental freedom. This includes processes related to obtaining human tissues and cells for research, diagnosis and therapy. The fundamental tenets of beneficence, nonmalfeasance, justice and autonomy should be adhered to in all research involving

Aspects of Human Reproductive Cloning, National Academies Press, (2002), (Aug. 12, 2016), https://www.ncbi.nlm.nih.gov/books/NBK223962/.

<sup>&</sup>lt;sup>98</sup> The ICMR - DBT Guidelines for Stem Cell Research, 2012 provides guidelines mainly relating to the procurement of gametes, embryos and somatic cells for derivation and propagation of Pluripotent stem cell lines, their banking, distribution, etc.

<sup>&</sup>lt;sup>99</sup> Principle 8.1.10 of ICMR Draft Guidelines, 2012, Classification of human stem cells includes the following. Human embryonic stem cells (hES-cells) cells, derived from blastocysts arising from (i) surplus embryos from IVF clinics; (ii) specifically generated for research or therapy using IVF; (iii) other techniques like SCNT, etc. Human embryonic germ (hEG) cells, which are derived from primordial germ cells of the early embryo. Human somatic stem (hSS) cells, which are derived from fetal or adult tissues or organs, including umbilical cord blood/placenta. Human induced pluripotent stem cells (iPS) cells, which are derived from fetal or adult diploid somatic cells by forced expression of pluripotency inducing factors such as Sox2, c-Myc, Oct-4 and Klf-2. They are genetically reprogrammed PSCs and they exhibit properties similar to a typical ES-cell line.

<sup>&</sup>lt;sup>100</sup> The ICMR-DBT Guidelines for Stem Cell Research, 2012, (Jul. 30, 2016), http://icmr.nic. in/stem\_cell/stem\_cell\_guidelines.pdf.

human subjects.<sup>101</sup> Most importantly, the embryos designated for research should not be bought or sold with a monetary exchange or other valuable consideration.<sup>102</sup>

# 5. 5. EMBRYO AS A SUBJECT MATTER OF LEGAL DISPUTE<sup>103</sup>

With the rise in infertility treatments and ART, the disputes relating to the ownership, usage, storage and destruction of human embryos also started reaching the courts in the beginning of 1980's. The *Del Zios* were one of the first reported couples in the United States to attempt IVF.<sup>104</sup> The couple brought an action<sup>105</sup> alleging their embryo had been deliberately destroyed. They sought damages for conversion of their property and the intentional infliction of emotional distress. The Federal District Court for the Southern District of New York, rejected the plaintiff's conversion claim, but upheld their claim for their mental distress and awarded damages for the loss of their embryo.<sup>106</sup> The Court held that the *in vitro* fertilised embryo was not the property of the couple who

<sup>&</sup>lt;sup>101</sup> Principle 3, National Guidelines on Stem Cell Research, 2013 (Jun. 13, 2016), http://icmr. nic.in/stem\_cell/stem\_cell\_guidelines.pdf.

<sup>&</sup>lt;sup>102</sup> Donating Embryos for Human Embryonic Stem Cell (hESC) Research: A Committee Opinion, Ethics Committee of the American Society for Reproductive Medicine American Society for Reproductive Medicine, (May 03, 2016), https://www.asrm.org/uploadedFiles/ASRM\_Content/News\_and\_Publications/Ethics\_Committee\_Reports\_and\_Statements/donat ingspare.pdf.

<sup>&</sup>lt;sup>103</sup> The cases considered in this section are responses to the different factual situations in different jurisdictions relating to the legal status of human embryos.

<sup>&</sup>lt;sup>104</sup> Mark A. Pieper, *Frozen Embryos- Persons or Property? Davis v. Davis*, 23 Creighton L. Rev., 806-833, 816, (1990).

<sup>&</sup>lt;sup>105</sup> Del Zio v. Columbia Presbyterian Hospital of New York, Unreported US Dist. SDNY No.14 1978.

<sup>&</sup>lt;sup>106</sup> ROHAN HANDCASTLE, LAW AND THE HUMAN BODY: PROPERTY RIGHTS, OWNERSHIP AND CONTROL, (Bloomsbury Publishing), 91 (2007).

provided the sperm and the egg.<sup>107</sup> The Court found that the property approach was not a satisfactory framework within which to analyse the legal status of the embryo.<sup>108</sup>

*Davis v. Davis*,<sup>109</sup> was one of the earlier cases which involved disposition of the cryogenically preserved product of *in vitro* fertilization or 'frozen embryos'. In a divorce action, the parties were unable to agree upon the custody of the seven frozen embryos stored in a fertility clinic.<sup>110</sup> The Tennessee Circuit Court held that the embryos were 'human beings' from the moment of fertilisation and awarded custody of the same to the wife. But the Court of Appeal rejected the notion that the embryos were persons and held that the husband and wife shared

<sup>&</sup>lt;sup>107</sup> "In accordance with IVF procedure, the Del Zios' physician removed an egg from Mrs. Del Zio, fertilized it with Mr. Del Zio's sperm, and stored the mixture in an incubator. While the culture was housed in the incubator, Dr. Raymond Vande Wiele, the chairperson of the pediatrics department of Columbia Presbyterian Medical Center, learned about the attempted IVF. Because he believed the IVF process was both unethical and immoral, Vande Wiele removed the culture from the incubator and destroyed it without notice to the physician or the couple. As a result of the embryo destruction, the Del Zios filed suit against Vande Wiele and Columbia Presbyterian claiming unlawful destruction of their property and infliction of emotional distress. After a five-week trial and thirteen hours of jury deliberation, the jury returned a verdict rejecting the property claim but awarding the Del Zios damages for emotional distress.", *See* Mark A. Pieper, *Frozen Embryos - Persons or Property? Davis v. Davis*, 23 Creighton L. Rev., 806-833, 816 (1990).

<sup>&</sup>lt;sup>108</sup> Mark A. Pieper, *Frozen Embryos - Persons or Property? Davis v. Davis*, 23 Creighton L. Rev., 806-833, 817 (1990).

<sup>&</sup>lt;sup>109</sup> 842 S.W.2d 588, (Tenn. 1992), at 597.

<sup>&</sup>lt;sup>110</sup> The defendant wife sought the control of the 'frozen embryos' to attempt a post-divorce pregnancy. But the plaintiff objected. Later, both the parties remarried, and then defendant wanted to donate the embryos to a couple with no children, which was also objected by the plaintiff. The Trial Court determined that the embryos were 'human beings' from the moment of fertilization and awarded 'custody' to defendant. The Court of Appeals reversed the Trial Court's verdict and gave joint control to the parties to have an equal say regarding disposition of the embryos. The defendant again appealed and the Supreme Court of Tennessee held that "the frozen embryos are neither persons nor property but occupy an interim category, entitling them to special respect because of their potential for human life". In addition, the State's interest in potential human life is insufficient to justify an infringement on the procreational autonomy of the persons providing the gametes.

an interest in the embryos, and so both had joint control and an equal input into

their disposition.

The Court found that the essential issue in this case was whether the parties would become parents. The Court stated that "the right of procreational autonomy is composed of two rights of equal significance - the right to procreate and the right to avoid procreation."<sup>111</sup> The Court held that disputes involving the disposition of pre-embryos produced by IVF should be resolved first by looking to the preference of the progenitors.

In this most discussed judgment of the Supreme Court of Tennessee, it was observed that:

"the couple did not have property rights in the embryos, but they had an interest in the nature of ownership, to the extent that they had decision-making authority regarding their disposition. The embryos were not persons or property, but were an interim category that entitles them to special respect because of their potential for human life."<sup>112</sup>

In *York v. Jones*,<sup>113</sup> the progenitors brought suit against doctors who refused to release and transfer their pre-embryo to a hospital in California. The couple wishing to move embryos from one fertility clinic to another was able to rely on the tort of *detinue* to recover their embryos.<sup>114</sup> It is the first decision of its kind

<sup>&</sup>lt;sup>111</sup> 842 S.W.2d 588, (Tenn. 1992), at 597.

<sup>&</sup>lt;sup>112</sup> 842 S.W.2d 588, (Tenn. 1992), at 597.

<sup>&</sup>lt;sup>113</sup> 717 F. Supp. 421 (1989).

<sup>&</sup>lt;sup>114</sup> In this case, the plaintiffs sought to have the pre-zygote transferred from the defendant Institute in Norfolk, Virginia to another institute in Los Angeles, California. But the defendants refused to transfer the frozen pre-zygote. The plaintiffs alleged that the defendants acted contrary to the provisions of the Cryopreservation Agreement. The issues revolved around the

to recognize a property right in human cells and also to state that the embryo was the property of the gamete providers.<sup>115</sup> The Court found the requisite elements of a bailment present in this case<sup>116</sup> as the Institute had possession of the preembryo, recognized their duty to account for the pre-embryo in the Cryopreservation Agreement, and consistently referred to the pre-embryo as the 'property' of the Yorks' in the agreement.<sup>117</sup>

In a 2016 decision,<sup>118</sup> a Trial Court in Missouri held that the cryopreserved embryos as 'marital property'<sup>119</sup>. It observed that the embryos are unique and distinct from other types of property in that one party's decision to use the embryos for procreation could later result in the imposition of parental rights and obligations on the other party. It further ordered that any "transfer, release or use" of embryos would require both parties' signed authorization.<sup>120</sup>

questions of breach of contract, quasi-contract, detinue, etc. There was no dispute in the plaintiff's proprietary rights in the pre-zygotes stored as part of the IVF treatments.

<sup>&</sup>lt;sup>115</sup> Melinda Troeger, *The Legal Status of Frozen Pre-Embryos When a Dispute Arises During Divorce*, 18 J.A.A.M.L., 563-87, 568 (2003).

<sup>&</sup>lt;sup>116</sup> 717 F. Supp. 421 (1989), at 425.

<sup>&</sup>lt;sup>117</sup> The Court focused on the cryopreservation agreement between the parties and noted that the manner in which the agreement was written indicates that the defendants "fully recognize plaintiff's property rights in the pre-embryo and have limited their rights as bailee to exercise dominion and control over pre-embryo", 717 F. Supp. 421 (1989) at 427.

<sup>&</sup>lt;sup>118</sup> *McQueen-Gadberry v. Gadberry, Missouri Embryo Dispute on Appeal*, 507 S.W.3d 127 (Mo. Ct. App. 2016); (Dec. 03, 2016), http://www.reproductivefacts.org/Legally\_Speaking/ MO\_Embryo\_Dispute\_on\_Appeal\_Raegen\_Rasnic/.

<sup>&</sup>lt;sup>119</sup> § 4 of the Uniform Marital Property Act, 1983 explains what all categories of property can be termed as matrimonial property. In simple words, all property acquired by either spouse before the marriage is considered non-marital property. All property acquired after the marriage is considered property of the marriage or marital property.

<sup>&</sup>lt;sup>120</sup> In the instant Case, Ms. McQueen-Gadberry wanted the cryopreserved embryos awarded to her so that she could become pregnant and have additional children, whom she intended to parent alongside the now eight-year-old twins born from the same embryos during the parties' marriage. Mr. Gadberry objected to Ms. McQueen-Gadberry's use of the embryos for her own family formation, and indicated that he did not want to have more children with Ms. McQueen-Gadberry.

In another recent decision in *Findley v. Lee*, <sup>121</sup> the question was about determining the rights of a divorced couple regarding their five fertilized embryos frozen during their marriage. Lee requested to use the embryos and attempt to create a viable pregnancy. Findley denied his consent. In this case, the Court held that "it is simply not necessary in this case to categorise the embryos as 'life' or 'property'. The Court held that "the embryos in this case represent the nascent stage of five human lives. They are not property nor are they a fully formed human being. They are, in the construct of the law, *sui generis* and will be deemed as such..."<sup>122</sup>

In *Frisina v. Women and Infant Hospital*,<sup>123</sup> a claim alleging emotional distress was based on loss or destruction of irreplaceable property.<sup>124</sup>

In *Jeter v. Mayo Clinic, Arizona*, <sup>125</sup> the Court of Appeals, Arizona found that, as a matter of law, a cryopreserved, three-day old fertilized human egg is not a 'person' for purposes of Arizona's 'Wrongful Death' statute. The embryos were

<sup>&</sup>lt;sup>121</sup> Decided by the Superior Court of the State of California, on Nov. 18, 2015, (May 05, 2016), http://www.sfsuperiorcourt.org/sites/default/files/pdfs/FINDLEY\_Statement\_Of\_Decision%2 0Rev\_1.pdf.

<sup>&</sup>lt;sup>122</sup> Decided by the Superior Court of the State of California, on Nov. 18, 2015, at 82 (May 05, 2016), http://www.sfsuperiorcourt.org/sites/default/files/pdfs/FINDLEY\_Statement\_Of\_Deci sion%20Rev\_1.pdf.

<sup>&</sup>lt;sup>123</sup> In this case, before the Rhode Island Superior Court in May, 2002, out of the nine stored embryos kept for future use, the plaintiff was informed that only three were available. Those three frozen embryos were not thawed properly, rendering it to be unsuitable for transfer.

<sup>&</sup>lt;sup>124</sup> The Superior Court of Rhode Island heard three parties with the same issue in a summary proceeding. The issue was the legal status of the pre-embryos, the duties towards its progenitors and the damages which may flow from their loss or destruction. (Jun. 06, 2016), http://law. justia.com/cases/rhode-island/superior-court/2002/95-4037.html.

<sup>&</sup>lt;sup>125</sup> 121 P.3d 1256 (Ariz. App. Div. 1 2005), The Jeters sued Mayo for the alleged negligent destruction or loss of five of the Jeter's frozen human pre-implantation embryos or preembryos, which Mayo agreed to cryopreserve and store. The Superior Court held the Jeters had failed to state a claim upon which relief could be granted and dismissed their wrongful death claim because the pre-embryos were not 'persons' under Arizona's Wrongful Death statutes.

recognised as 'things' and thus litigation based on breach of bailment and breach of an undertaking to protect 'things' was allowed to proceed.<sup>126</sup>

In *Kass v. Kass*,<sup>127</sup> the issue was specifically regarding the disposition of five frozen, stored pre-embryos, created five years ago. Now divorced, appellant wanted the pre-embryos implanted, claiming this is her only chance for genetic motherhood. But the respondent objects to the burdens of unwanted fatherhood, claiming that the parties agreed at the time they embarked on the effort that in the present circumstances the pre-zygotes would be donated to the IVF program for approved research purposes. Court concluded that the parties' agreement providing for donation to the IVF program prevails in such situations.

The major legal questions discussed in various cases relating to the embryos deals with questions such as, whether embryos can be treated as potential life<sup>128</sup>, whether embryos can be treated as property<sup>129</sup>, the enforcement of contracts in which embryos are the subject matter<sup>130</sup>. Frozen embryos have become a subject matter of dispute especially in matters of matrimonial settlements. It is an alarming fact that over 5 million frozen or 'cryopreserved' embryos were maintained in ART clinics in the United States in early 2011.<sup>131</sup>

<sup>&</sup>lt;sup>126</sup> 121 P3d 1256 at 1272-5 (Ct. App. Ariz, 2005) *Cited* in Lyra Bennet Moses, *The Applicability of Property Law in New Contexts: From Cells to Cyberspace*, 30 Syd. L. Rev., 639-662, 643 (2008).

<sup>&</sup>lt;sup>127</sup> 673 N.Y.S.2d 350 (1998).

<sup>&</sup>lt;sup>128</sup> Davis v. Davis, 842 S.W.2d 588, at 597 (Tenn. 1992).

<sup>&</sup>lt;sup>129</sup> York v. Jones, 717 F.Supp. 421 (1989).

<sup>&</sup>lt;sup>130</sup> Kass v. Kass, 121 P.3d 1256 (Ariz.App. Div. 1 2005).

<sup>&</sup>lt;sup>131</sup> Petition for a Writ of Certiorari at 7 Doe v. Obama, 631 F.3d 157 (2011) (No. 10-1206), 2011, Madeline E. Guillot, *Playing God: Why The Thirteenth Amendment Protects Human* 

There is also a view that embryos should not be treated as 'property' to be settled along with the other items in divorce settlements.<sup>132</sup> The embryo's best interests, not market concerns or property rights, should play the deciding role in settling these type of cases.<sup>133</sup>

## 5.6. LEGAL REGULATION OF EMBRYONIC RESEARCH

Countries around the world have responded to the ethical problems raised by embryonic research in a number of ways. Some countries have passed laws prohibiting all research on human embryos, <sup>134</sup> while others have explicitly endorsed and funded embryonic research. Many countries, like the United States, regulate research through restrictions on government funding, <sup>135</sup> while others license researchers to ensure compliance with their national policy.<sup>136</sup>

*Embryos from Stem Cell Research*, 14 Loy. J. Pub. Int. L., 171, 177 (2012-2013), (Jun. 22, 2016), http:heinonline.org.

<sup>&</sup>lt;sup>132</sup> David B. Resnik, *The Commodification of Human Reproductive Materials*, 24 J. of Medical Ethics, 388-393, 391 (1998).

<sup>&</sup>lt;sup>133</sup> Jessica Wilen Berg, *Owning Persons: The Application of Property Theory to Embryos and Fetuses*, Faculty Publications. Paper 173, (2005) (Sep. 14, 2018), http://scholarlycommons. law.case.edu/faculty\_publications/173.

<sup>&</sup>lt;sup>134</sup> In Austria, the research on embryos, including the derivation of embryonic stem cell lines, is banned. Under the Reproductive Medicine Act, 2004, the procurement of cells from a human embryo for research purposes is prohibited. Embryos cannot be used for any purpose other than for assisted reproduction. (Jun. 25, 2016), http://www.eurostemcell.org/regulations/regulation-stem-cell-research-austria.

<sup>&</sup>lt;sup>135</sup> National Institutes of Health, US Department of Health & Human Services, (Jun. 21, 2016), http://stemcells.nih.gov/policy/Pages/Default.aspx.

<sup>&</sup>lt;sup>136</sup> United Kingdom has a comprehensive and well-established regulatory framework for stem cell research. Embryonic stem cell research is allowed subject to a licence from the Human Fertilisation and Embryology Authority (HFEA).

The Council of Europe's Convention on Human Rights and Biomedicine, 1997,<sup>137</sup> also referred to as the Oviedo Convention<sup>138</sup> places restrictions on research on embryos *in vitro*. Article 18 of the Convention states thus: "Where the law allows research on embryos *in vitro*, it shall ensure adequate protection of the embryo. The creation of human embryos for research purposes is prohibited."

The legal regulations of some countries with regard to embryonic research is examined here. The United Kingdom has a strong tradition of promoting scientific freedom, resulting in very liberal regulation of embryonic research.<sup>139</sup> It is perhaps the only country which has legislations which are in tune with scientific progress. Canada has regulated research in human embryos. But such regulations are limited to the use of ART. United States, being a country where no federal legislations are there to control embryonic research activities, it is regulated according to the changing government policies. In the United States of America, the degree of variations in legal control of the embryonic research

<sup>&</sup>lt;sup>137</sup> Council of Europe, Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, European Treaty Series-No. 164, Oviedo, 4. IV.1997, (Jul. 12, 2016), https://rm.coe.int/168007cf98.

<sup>&</sup>lt;sup>138</sup> It is the first legally binding international text designed to preserve human dignity, fundamental rights and freedoms, through a series of principles against the misuse of biological and medical applications. The Convention is inspired by the principle of the primacy of human beings over the sole interest of science or society. It lays down a series of principles applying to medical practice as well as to biomedical research, organ transplantation and genetics. *Guide to the Quality and Safety of Tissues and Cells for Human Application*, (Jul. 24, 2018), https://www.tripnet.nl/pages/nl/documents/Guidetothequalityandsafetyoftissuesandcellsfor humanapplication2ndedition.pdf.

<sup>&</sup>lt;sup>139</sup> Lori P. Knowles, *International Perspectives on Human Embryo and Fetal Tissue Research*, commissioned by the National Bioethics Advisory Commission, 6 (Jun. 20, 2016), https://bioethicsarchive.georgetown.edu/nbac/briefings/may99/ip.pdf.

oscillates between the extremes of total prohibition to state funding. "The question of whether to permit embryo research is characterized everywhere by a tension between the desire for therapeutic benefits derived from that research and the need to prevent abuses."<sup>140</sup>

### 5.6.1. LEGAL REGULATION OF EMBRYONIC RESEARCH IN INDIA

In India, at present, there is no specific legislation governing the area of research in human embryos.<sup>141</sup> Principle 3 of the Indian Council for Medical Research, (hereinafter referred to as ICMR) Guidelines for Stem Cell Research, 2013, lays down the general principle that "any research on human subjects, including human embryos and foetuses shall ensure safeguarding of human dignity, human rights and fundamental freedoms." The Guidelines also provides that "the use of human embryos shall be restricted as much as possible, and shall be resorted to where there are no other alternatives."<sup>142</sup>

<sup>&</sup>lt;sup>140</sup> Lori P. Knowles, *International Perspectives on Human Embryo and Fetal Tissue Research*, commissioned by the National Bioethics Advisory Commission, 6 (Jun. 20, 2016), https://bioethicsarchive.georgetown.edu/nbac/briefings/may99/ip.pdf.

<sup>&</sup>lt;sup>141</sup> Only regulations available in India are certain guidelines issued by the Indian Council for Medical Research.

<sup>&</sup>lt;sup>142</sup> Principle 7.7.

The National University of Advanced Legal Studies, Kochi.

The Guidelines<sup>143</sup> categorizes stem cell research into three areas viz., permissible research,<sup>144</sup> restricted research<sup>145</sup> and prohibited research,<sup>146</sup> according to the risk expected from each. It shall be understood that while there is no bar placed in carrying out experiments which may lead to benefit for humanity, this should not take them down on the slippery road to prohibited areas of research.<sup>147</sup> The most important of all prohibitions is contained in the principle 9.2.9. which states that "No *in vitro* studies on pre-implantation human embryos shall be carried out beyond 14 days of fertilization or formation of primitive streak, whichever is earlier. Similarly, no *in vitro* manipulated cells shall be implanted in human/animal uterus with the intent of developing a whole organism".

<sup>&</sup>lt;sup>143</sup> Principle 6.0.

<sup>&</sup>lt;sup>144</sup> "*In-vitro* studies on pluripotent stem cell lines for understanding their biology, *in-vivo* studies in experimental animals with established cell lines from any type of pluripotent stem cells, establishment of new human ES cell lines from spare embryos or iPS cell lines from foetal/adult somatic cells, etc., are permissible research" under Principle 6.1.

<sup>&</sup>lt;sup>145</sup> "Creation of a human zygote by IVF, SCNT or any other method with the specific aim of deriving ES cell line for any purpose, clinical trials using cells derived from the differentiation of human ES or iPS cells, or any stem cell after major manipulation shall require approval of DCGI after obtaining approval from NAC-SCRT through IC-SCR and IEC, international collaborative research projects, The imports of biological materials for research and development, research involving introduction of human ES / iPS / SS cells into animals (including primates), at embryonic or foetal stages of development for studies on pattern of differentiation and integration of human cells into non-human animal tissues, studies on chimeras etc., are research which are accompanied with various restrictions and prior approvals", Principle 6.2.

<sup>&</sup>lt;sup>146</sup> "Research related to human germ line gene therapy and reproductive cloning as well as the *in vitro* culture of intact human embryos, regardless of the method of their derivation, beyond 14 days of fertilization or formation of primitive streak, whichever is earlier, are prohibited. The Guideline also prohibits clinical trials involving transfer of xenogeneic cells into a human host, any clinical research on Xenogeneic-Human hybrids, research involving implantation of human embryos into uterus after in vitro manipulation, breeding of animals in which any type of human stem cells has been introduced, etc.," Principle 6.3.

<sup>&</sup>lt;sup>147</sup> Principle 5.10 of the Draft Guidelines on Stem Cell Research, 2012.

Embryo research is permitted in order to increase the knowledge about embryo development and causes of miscarriages and birth defects,<sup>148</sup> to develop methods to detect abnormalities in embryos before implantation,<sup>149</sup> to develop human disease models to understand pathophysiological mechanisms at cellular and molecular level <sup>150</sup>, to developing targeted therapies for genetic and developmental diseases<sup>151</sup>, to develop *in vitro* cell culture systems of stem cells and their progenitors during different stages of cell differentiation for drug discovery and toxicity screening, advancing current understanding of novel cell-based therapies by studying distribution, differentiation, integration, functioning and survival of implanted cells in experimental animals<sup>152</sup> and to understand mechanisms responsible for stemness<sup>153</sup>, role of niche, dormancy, recruitment, plasticity and the ability to repair and regenerate.<sup>154</sup>

The Directorate General of Foreign Trade *vide* Notification No. 52(RE-2013)/2009-2014 dated 2<sup>nd</sup> December, 2013 issued the Import Policy Norms for import of 'Human Embryos' and had put it into restricted category and the import was to be allowed subject to a NOC from ICMR.<sup>155</sup> The Supreme Court suggested that the government should put on hold the import of human embryos

<sup>&</sup>lt;sup>148</sup> Principle 9.2.1.

<sup>&</sup>lt;sup>149</sup> Principle 9.2.2.

<sup>&</sup>lt;sup>150</sup> Principle 9.2.3.

<sup>&</sup>lt;sup>151</sup> Principle 9.2.4.

<sup>&</sup>lt;sup>152</sup> Principle 9.2.6.

<sup>&</sup>lt;sup>153</sup> 'Stemness' refers to common molecular processes underlying the core stem cell properties of self-renewal and the generation of differentiated progeny, (Oct. 12, 2018), https://www.sciencedirect.com/science/article/pii/B9780124095038000020.

<sup>&</sup>lt;sup>154</sup> Principle 9.2.7.

<sup>&</sup>lt;sup>155</sup> Import of Human Embryo will be free subject to a 'No Objection Certificate' from Indian Council of Medical Research (ICMR).

as India had become an international hub for commercial surrogacy.<sup>156</sup> Later, the Ministry of Commerce and Industry issued a notification which revised the existing policy condition relating to the import of human embryos.<sup>157</sup> It prohibited the import of human embryos except for research purposes based on the guidelines of the Department of Health Research. Thus the latest notification was published on October 26, 2015 and it allowed the import of embryos only for research.<sup>158</sup> After the new notification, there is no possibility of anyone obtaining a no-objection certificate from the ICMR for importing embryos for commercial surrogacy.

## 5.6.1.1. EMBRYONIC RESEARCH IN INDIA IN THE CONTEXT OF ART

In India, there is no specific legislations which governs the use of embryos for assisted reproductive procedures. A proposed legislation, the Draft ART Bill, 2014 mandates the requirement of consent in writing, of the persons availing ART treatments with regard to the storage, use, donation, destruction, etc., of the embryos created during the IVF procedure.<sup>159</sup> The Draft Bill proposes the framework for consent rather than creating property interests in the embryos created artificially.

<sup>&</sup>lt;sup>156</sup> Amit Anand Choudhary, *SC Suggests Ban on Commercial Surrogacy*, The Times of India, Oct 15, 2015, (Jun. 25, 2016), http://timesofindia.indiatimes.com/india/SC-suggests-ban-on-commercial-surrogacy/ articleshow/49365734.cms, *See* also, *Put Import of Embryos on Hold: Supreme Court*, Hindustan Times, New Delhi, Oct 15, 2015, (Jun. 25, 2018), http://www.hindustantimes.com/india/put-import-of-embryos-on-hold-supreme-court/story-UzuxYUOJftDxxHngrsi7NN.html.

<sup>&</sup>lt;sup>157</sup> Notification No. 25/2015-2020, New Delhi, 26<sup>th</sup> October, 2015.

<sup>&</sup>lt;sup>158</sup> Bhadra Sinha, *Govt. Bans Import of Human Embryos for Commercial Surrogacy*, Hindustan Times, New Delhi, Oct. 28, 2015.

<sup>&</sup>lt;sup>159</sup> § 47 of the Draft ART Bill, 2014.

Section 53 (3) of the same suggests that "a human embryo may, for such appropriate fee as may be prescribed, be stored for a maximum period of five years and at the end of such period such embryo shall be allowed to perish or donated to a research organisation registered under this Act for research purposes with the consent of the patients and if during the period of five years, one of the commissioning partners dies; the surviving partner can use the embryo for herself or for her partner, provided an appropriate consent was taken earlier. Where the persons to whom such embryo relates fails to pay the fee, or both the commissioning couple die, the assisted reproductive technology clinic or assisted reproductive technology bank may, subject to such regulations as may be specified, destroy the embryo or transfer the embryo to any research organisation registered under this Act."

The Bill proposes to absolutely prohibit the sale, transfer or use of gametes, zygotes and embryos, or any part thereof or information related thereto, directly or indirectly to any party outside India.<sup>160</sup> The sale of gametes, except for use by an ART clinic for treating infertility, and the sale of zygotes and embryos, or of any information related to gametes, zygotes or embryos, within India is also prohibited. <sup>161</sup> Research using embryos shall be conducted only with the permission of the National Registry of ART Clinics and Banks in India. Most

<sup>&</sup>lt;sup>160</sup> § 56 (1) of the Draft ART Bill, 2014.

<sup>&</sup>lt;sup>161</sup> § 55 of the Draft ART Bill, 2014.

importantly, the Draft Bill also proposes to prohibit maintaining the human embryo created *in vitro* for more than fourteen days.

ICMR Guidelines on ART clinics in India, under Guideline 3.11 provides for the preservation, utilization & destruction of embryos. Further, clause 3.11.3 mandates that the "research on embryos shall be restricted to the first fourteen days only and will be conducted only with the permission of the 'owner' of the embryos". Furthermore, under clause 3.11.4, commercial transactions are prohibited for the use of embryos for research.<sup>162</sup>

Apart from these Guidelines and the Draft legislation on this subject, in India, nothing much is heard about the legal status of human embryos. The cultural intricacies, stigmas and taboos surrounding infertility in Indian culture seems more likely to promote a self-protective silence on the moral status of the human embryo rather than an open discussion.<sup>163</sup>

Thus, after the abortion debate, the human embryo has become a hot subject of discussion from the time it was developed *in vitro*, outside the body of a woman. The status of human embryos was influenced by religion in the earlier days.<sup>164</sup> Later, it was much influenced by the thoughts of women's liberty and

<sup>&</sup>lt;sup>162</sup> (Sept. 18, 2018), https://www.icmr.nic.in/sites/default/files/guidelines/b.pdf.

<sup>&</sup>lt;sup>163</sup> Sanjay Mittal, *Stem Cell Research: The India Perspective*, (May 16, 2006), http://www. ncbi.nlm.nih.gov/pmc/articles/PMC3601694/.

<sup>&</sup>lt;sup>164</sup> William Neaves, *The Status of the Human Embryo in Various Religions*, 144 The Company of Biologists Ltd., 2541-2543 (2017), (Oct. 19, 2018), http://dev.biologists.org/content/ develop/144/14/2541.full.pdf

reproductive autonomy. Now it is the biotechnology and related research, especially embryonic researches that attributes special status to human embryos.

Research in human embryos has become a matter of great scientific interest, and a concern, particularly the creation of embryonic stem cell lines. It has also emerged as one of the more controversial areas of medical science. While the medical benefits of such research look promising, the ethical dilemmas of embryonic research and subsequent destruction of the same remains. The status of gametes and embryos illustrates the conceptually unsatisfactory state of the law regarding body parts.<sup>165</sup> In this area the law has not kept pace with advancements in science.<sup>166</sup> Many unanswered questions remain regarding the legal status of gametes as well as frozen pre-embryos.

Embryonic cells and tissues cannot be viewed just like any other biological material from an ethical perspective. Many people believe that embryos are 'potential persons' and therefore research on embryos which would ultimately amount to killing one person to benefit another is against their morals and ethics. <sup>167</sup> Those who believe that life begins at conception recognize the embryo's legal status as a person and since an embryo is a human being from the

<sup>&</sup>lt;sup>165</sup> Cordelia Mary Thomas, *A Framework for the Collection, Retention and Use of Human Body Parts*, 129 (2006), (Jun. 06, 2018), http://researcharchive.vuw.ac.nz/xmlui/bitstream/handle/ 10063/297/thesis.pdf?sequence=2.

<sup>&</sup>lt;sup>166</sup> Melinda Troeger, *The Legal Status of Frozen Pre-Embryos When a Dispute Arises During Divorce*, 18 J.A.A.M.L., 563-87, 563 (2003).

<sup>&</sup>lt;sup>167</sup> Cordelia Mary Thomas, *A Framework for the Collection, Retention and Use of Human Body Parts*, 129 (2006), (Jun. 06, 2018), http://researcharchive.vuw.ac.nz/xmlui/bitstream/handle/ 10063/297/thesis.pdf?sequence=2.

time of conception, it is entitled to full legal protection as a person.<sup>168</sup> The moral status of the early embryo is thus determined on the basis of the autonomous subject into which he or she may potentially develop.<sup>169</sup>

The fact that an embryo has the potential for developing into what is indisputably a human person imposes certain limits upon what we should or should not do with it or do to it. For example, deliberate injury of the early foetus which leads to a distorted development and production of a crippled life would at the very least call for a moral justification. This reveals that there is at least some moral consideration attached to the foetus in terms of its potential.<sup>170</sup> Though full personhood cannot be accorded to the embryo, yet there may be certain moral responsibilities to it.<sup>171</sup>

The more prevalent position, advocated by the 1979 Ethics Advisory Board of the United States Department of Health, Education and Welfare, recognizes that the human embryo is entitled to 'profound respect', but not necessarily to the legal and moral rights inherent to personhood.<sup>172</sup>

<sup>&</sup>lt;sup>168</sup> TEXTBOOK OF PERINATAL MEDICINE, (Asim Kuraj & Frank A. Chervenak, eds.), (Vol. 1, Informa Healthcare), 170 (2006).

<sup>&</sup>lt;sup>169</sup> (Jun. 26, 2016), http://www.drze.de/in-focus/stem-cell-research/ethical-discussion.

<sup>&</sup>lt;sup>170</sup> CONCEIVING THE EMBRYO: ETHICS, LAW AND PRACTICE IN HUMAN EMBRYOLOGY, (Donald Evans, ed.), (Martinus Nijhoff Publishers), 7 (1996).

<sup>&</sup>lt;sup>171</sup> CONCEIVING THE EMBRYO: ETHICS, LAW AND PRACTICE IN HUMAN EMBRYOLOGY, (Donald Evans, ed.), (Martinus Nijhoff Publishers), 7 (1996).

<sup>&</sup>lt;sup>172</sup> Stephanie J. Owen, *Davis v. Davis: Establishing Guidelines for Resolving Disputes over Frozen Embryos*, 10 J. Contemp. Health Law Pol., 493-511, 495 (1994), (May 20, 2018), http://scholarship.law.edu/jchlp/vol10/iss1/30.

As laid down in *Davis v. Davis*, "the pre-embryos are not, strictly speaking, either 'persons' or 'property', but occupy an interim category"<sup>173</sup> that entitles them to special respect because of their potential for human life." Although patients receiving infertility treatment usually have rights of control over embryos they produce, treating human embryos as objects of property rights is generally perceived as inappropriate.<sup>174</sup>

<sup>&</sup>lt;sup>173</sup> Davis v. Davis, 842 S.W.2d 588 (Tenn., 1992), at 597.

<sup>&</sup>lt;sup>174</sup> Lyria Bennet Moses, *The Applicability of Property Law in New Contexts: From Cells to Cyberspace*, 30 Syd. L. Rev., 639-662, 642 (2008).

# VI. COMMODIFICATION OF THE HUMAN BODY AND BODILY MATERIALS

## **6.1. INTRODUCTION**

The human body and the materials taken from it have importance in various fields.<sup>1</sup> Starting with the anatomical studies in medical schools, for the clinical trials of newly created drugs and therapies, for the biotechnological researches using human bodily materials and tissues, etc., the human body is of much significance.<sup>2</sup> The human body, organs, tissues, and other materials derived from it possesses a substantial commercial value. In this globalised world, the "human body is becoming hot property; a resource to be mined, harvested, patented and traded commercially for profits in the market."<sup>3</sup>

Till recently, the terms 'sale, purchase, market, exploitation,' etc., were used only in relation with a 'commodity' or an 'object'. Now we can see these words are used even in relation to the transactions involving the human body and bodily materials.<sup>4</sup> A market exists whenever buyers and sellers come together to exchange things or services and the laws of supply and demand determine the

<sup>&</sup>lt;sup>1</sup> Lesley A. Sharp, *The Commodification of the Body and its Parts*, 29 Annual Review of Anthropology, 287-328, 289 (2000).

<sup>&</sup>lt;sup>2</sup> REMIGIUS N. NWABUEZE, BIOTECHNOLOGY AND THE CHALLENGE OF PROPERTY, PROPERTY RIGHTS IN DEAD BODIES, BODY PARTS, AND GENETIC INFORMATION, Ashgate, 1 (2007).

<sup>&</sup>lt;sup>3</sup> Dorothy Nelken & Lori Andrews, *Homo Economicus, Commercialisation of Body Tissue in the Age of Biotechnology*, 28 The Hastings Center Report, 30-39, 30 (1998), (Jul. 12, 2016), https://www.jstor.org/ stable/3528230.

<sup>&</sup>lt;sup>4</sup> See, B. Bjorkman, et al., Bodily Rights and Property Rights, 32 J. M. E., 209-214, (2006).

price. When there are willing buyers and willing sellers, anything and everything will be in the market, regardless of legal rules forbidding the practice.<sup>5</sup> The role of commerce and economic transactions in health care in general, and the buying and selling of human biological material in particular,<sup>6</sup> raises various ethical, social and legal questions.

### 6.2. COMMODIFICATION VIS-À-VIS COMMERCIALISATION

The terms 'commercialisation'<sup>7</sup> and 'commodification'<sup>8</sup> are seen to have used interchangeably, and the term 'commodification' has gathered more supporters in the literatures which discusses about the status of the human body in the new biotechnological era.<sup>9</sup> Commodification is a social practice for treating things as

<sup>&</sup>lt;sup>5</sup> Martha Ertman & Joan C. Williams, *Freedom, Equality, and the Many Futures of Commodification*, Legal Studies Research Papers, University of Utah, S.J. Quinny College of Law, Social Science Research Network Electronic Paper Collection, (Jul. 05, 2017), http://ssrn.com/abstracts=774944.

<sup>&</sup>lt;sup>6</sup> B. Bjorkman, et al., *Bodily Rights and Property Rights*, 32 Journal of Medical Ethics, 209-214, 209 (2006).

<sup>&</sup>lt;sup>7</sup> Commercialisation is the process of introducing a new product or production method into commerce - making it available on the market. (Jun. 10, 2017), https://en.wikipedia.org/ wiki/Commercialization.

<sup>&</sup>lt;sup>8</sup> In common parlance, *commodification* is putting a price on things that shouldn't have a price, things like friendship, knowledge, parenthood, etc. It is the transformation of goods, services, ideas and people into commodities, or objects of trade. A commodity at its most basic, is 'anything intended for exchange', or any object of economic value. *See* Arjun Appadurai, *Definitions: Commodity and Commodification - Commodities and the Politics of Value*, in RETHINKING COMMODIFICATION: CASES AND READINGS IN LAW AND CULTURE, (Martha Ertman & Joan C. Williams eds.), (New York University Press), 35 (2005).

<sup>&</sup>lt;sup>9</sup> See in general, Lesley A. Sharp, *The Commodification of the Body and its Parts*, 29 Annual Review of Anthropology, 287-328, 289 (2000), L D de Castro, *Commodification and Exploitation: Arguments in Favour of Compensated Organ Donation*, (May 31, 2017), http://jme.bmj.com, David B. Resnik, *The Commodification of Human Reproductive Materials*, 24 J.M.E, 388-393, 388 (1998), (Jul. 25, 2016), http://www.ncbi.nlm. nih.gov/pmc/articles/ PMC479139/pdf/jmedeth00001-0026.pdf, David E. Jefferies, *The Body as Commodity: The Use of Markets to Cure the Organ Deficit*, 5 Indiana Journal of Global Legal Studies, 621-658 (1998).

commodities or objects, i.e., as properties that can be brought, sold, or rented.<sup>10</sup> "The concept of commodification entails that an entity is viewed and treated as a commodity, that is, an instrumental object without subjectivity and intrinsic value which can be replaced by similar objects or money."<sup>11</sup>

The word commodity is defined as "an economic good … that is subject to ready exchange or exploitation within a market".<sup>12</sup> To 'commodify', in the relevant ethical sense, is to treat as a commodity something which should not be marketed.<sup>13</sup> 'Commodification' is the term scholars generally use to describe entry into the market realms.<sup>14</sup> Thus in general parlance, 'commodification', 'commodifisation' or 'commercialisation' means the making of a thing into a market product which is ready for exchange and exploitation. In the free market such 'thing' becomes a tradable good.<sup>15</sup>

<sup>&</sup>lt;sup>10</sup> David B. Resnik, *The Commodification of Human Reproductive Materials*, 24 J.M.E, 388-393, 388 (1998), (Jul. 25, 2016), http://www.ncbi.nlm.nih.gov/pmc/articles/PMC479139/pdf/jmedeth00001-0026.pdf.

<sup>&</sup>lt;sup>11</sup> Mark Schweda, et al., *The "Spare Parts Person"? Conceptions of the Human Body and their Implications for Public Attitudes Towards Organ Donation and Organ Sale*, (Dec. 19, 2017), http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2669094/.

<sup>&</sup>lt;sup>12</sup> STEPHEN WIKINSON, BODIES FOR SALE: ETHICS AND EXPLOITATION IN THE HUMAN BODY TRADE, (Routledge), 3 (2003).

<sup>&</sup>lt;sup>13</sup> STEPHEN WIKINSON, BODIES FOR SALE: ETHICS AND EXPLOITATION IN THE HUMAN BODY TRADE, (Routledge), 3 (2003).

<sup>&</sup>lt;sup>14</sup> Martha Ertman & Joan C. Williams, *Freedom, Equality, and the Many Futures of Commodification*, Legal Studies Research Papers, U. of Utah, S.J. Quinny College of Law, (Jul. 05, 2017), http://ssrn.com/abstracts=774944.

<sup>&</sup>lt;sup>14</sup> B. Bjorkman, Martha Ertman, et al., *Bodily Rights, Freedom, Equality, and the Many Futures of Commodification*, Legal Studies Research Papers, University of Utah, S.J. Quinny College of Law, (Jul. 05, 2017), http://ssrn.com/abstracts=774944.

<sup>&</sup>lt;sup>15</sup> *Commoditisation of the Human Body*, (Jul. 27, 2016), https://stopsextrafficking.wordpress. com/lawsg/commoditisation-of-the-human-body/.

One of the distinct features of a 'commodity' is the ability of one to have proprietary rights over it. This means, one can have ownership and control over the commodity, which implies to have the legal power to dispose of, sell and deal with the commodity in any way one wishes, including the power to destroy. The act of commoditisation creates a right of property over the thing being commoditised, for the thing now becomes a commodity. <sup>16</sup> Therefore, commodification is a social practice of treating things as commodities, i.e., as properties that can be bought, sold, or rented.<sup>17</sup>

In the contemporary world, the human body and the materials procured from the body is often treated as commodities.<sup>18</sup> But the commercial exploitation of human body is nothing new. There was a time when the human beings were traded as property.<sup>19</sup> Further, there are examples for commodification of

<sup>&</sup>lt;sup>16</sup> *Commoditisation of the Human Body*, (Jun. 27, 2016), https://stopsextrafficking.wordpress. com/lawsg/commoditisation-of-the-human-body/.

<sup>&</sup>lt;sup>17</sup> David B. Resnik, *The Commodification of Human Reproductive Materials*, 24 J.M.E, 388-393, 388 (1998), (Jul. 25, 2016), http://www.ncbi.nlm.nih.gov/pmc/articles/PMC479139/pdf/jmedeth00001-0026.pdf.

<sup>&</sup>lt;sup>18</sup> David E. Jefferies, *The Body as Commodity: The Use of markets to Cure the Organ Deficit*, 5 Indiana Journal of Global Legal Studies, 621-658 (1998).

<sup>&</sup>lt;sup>19</sup> Slavery has predated written records in almost every country in the world. In some societies, slavery existed as a form of legal institution to balance the socio-economic system. The practice of slavery has presently been condemned by the Universal Declaration of Human Rights, 1948. Earlier, the Anti-Slavery Convention, 1841 marked the beginning of the sustained movement toward international organization which has led to today's extensive network of world conferences and international agencies against slavery. The 1926 Slavery Convention or the Convention to Suppress the Slave Trade and Slavery was the first international treaty created under the auspices of the League of Nations which was designed to secure the abolition of slavery and of the slave trade. After that, the Forced Labour Convention of 1930 by the International Labour Organisation prohibited the forced or compulsory labour. Furthermore, the Supplementary Convention on the Abolition of Slavery, the Slave Trade, and Institutions and Practices Similar to Slavery, 1957 reaffirmed that the State parties shall take all practicable and necessary legislative and other measures to bring about progressively and as soon as possible the complete abolition or abandonment of the practice of slavery in all forms. Nonetheless, the practice of slavery still continues in various forms around the world and a particular form would be that of sex victims in the sex trade. See, Commoditisation of the

activities and many of them are conventionally associated with women.<sup>20</sup> Prostitution, is a form of commercial exploitation of the body of a person.<sup>21</sup> Other forms of body trafficking includes transnational trade in adoptable children, sale and purchase of athletes and sports persons by the elite clients, etc.<sup>22</sup> The human body is also commercially exploited also in the form of pornography, commercial modelling, etc. Towards the last decades of the twentieth century, surrogacy has grown to be a new form of commercial exploitation of a woman's body.<sup>23</sup>

Since the 1980s, concerns have been voiced about the new ways in which biomedical technologies allow us to use the human body for profit.<sup>24</sup> Later, the

*Human Body*, (Jun. 27, 2016), https://stopsextrafficking.wordpress.com/lawsg/commoditisat ion-of-the-human-body/.

<sup>&</sup>lt;sup>20</sup> Adrienne D. Davis, *Regulating Sex Work: Erotic Assimilationism, Erotic Exceptionalism, and the Challenge of Intimate Labor*, 103 Cal. L. Rev. 1195-1275, 1205 (2015), (Jul. 16, 2016), http://scholarship.law.berkeley.edu/californialawreview/vol103/iss5/3.

<sup>&</sup>lt;sup>21</sup> STEPHEN WIKINSON, BODIES FOR SALE: ETHICS AND EXPLOITATION IN THE HUMAN BODY TRADE, (Routledge), 1 (2003).

<sup>&</sup>lt;sup>22</sup> Lesley A. Sharp, *The Commodification of the Body and its Parts*, 29 Annual Review of Anthropology, 287-328, 293 (2000), Martha Ertman & Joan C. Williams, *Freedom, Equality, and the Many Futures of Commodification, in* RETHINKING COMMODIFICATION: CASES AND READINGS IN LAW AND CULTURE, (Martha Ertman & Joan C. Williams, eds.) New York University Press, (2005), also available in U. of Utah, S.J. Quinney College of Law Legal Studies Research Paper Series, (Jul. 26, 2016), http://ssrn.com/abstracts=774944.

<sup>&</sup>lt;sup>23</sup> According to Wikinson, the commercialisation of the human body involves various levels. "First, there is the commercialisation of physical objects. This includes, most obviously, the sale by individuals of particular body parts (such as kidneys and of bodily products (such as blood and semen). Second, there is the commercialisation of abstract objects. This category includes informational and intellectual property, as well as such things as images of individuals' bodies. Hence, interestingly, such apparently disparate practices as DNA patenting, pornography, and voyeurism might fall into the same general category. Finally, there are so called bodily services. Two of the most hotly contested practices in this category are reproductive services (especially paid surrogacy) and paid sex work. Payment for being a subject in biomedical research should also be placed in this final grouping." *See* in general, STEPHEN WIKINSON, BODIES FOR SALE: ETHICS AND EXPLOITATION IN THE HUMAN BODY TRADE, (Routledge), (2003).

<sup>&</sup>lt;sup>24</sup> STEPHEN WIKINSON, BODIES FOR SALE: ETHICS AND EXPLOITATION IN THE HUMAN BODY TRADE, (Routledge), 1 (2003).

progress in reproductive medicine, transplant surgery and biotechnology have accelerated the process of commercialisation of the human body and bodily materials.<sup>25</sup> Despite calls for banning commerce in many human materials, particularly human anatomical goods like blood, cadavers and organs, the gradual emergence of such commerce testifies to the growing reach of markets.<sup>26</sup>

The context of commodification insists upon "objectification in some form, transforming persons and their bodies from a human category into objects of economic desire".<sup>27</sup> Commodification of the human body and bodily materials thus results in various unwelcome situations. It tends to treat people and their body parts as commodifies. Thus the increased demand of human bodily materials for transplantation, research, etc., poses a se rious threat of commodification of the human body.

There is no doubt that the human body, whether dead or alive, has become an expensive good, <sup>28</sup> and a market for it of significant size, with a substantial number of transactions, has already been formed. Many bodily materials such as human organs, tissues, blood, etc., are extracted from the living human body for

<sup>&</sup>lt;sup>25</sup> Eileen H. Richardson & Brayan S. Turner, *Bodies as Property: From Slavery to DNA Maps*, in BODY LORE AND LAWS: ESSAYS ON LAW AND THE HUMAN BODY, (Andrew Bainham et al., eds.), (Hart Publishing, Oxford - Portland Oregon), (2002).

<sup>&</sup>lt;sup>26</sup> For instance, selling one's eggs, plasma, or sperm is a fairly common and legally permitted practice. *See* Michel Anteb, *Markets, Morals, and Practices of Trade: Jurisdictional Disputes in the U.S. Commerce in Cadavers*, 55 Administrative Science Quarterly, 606-638, (2010), (Jul. 03, 2017), https://papers.ssrn.com/sol3/papers.cfm?abstract\_id=1976216.

<sup>&</sup>lt;sup>27</sup> Lesley A. Sharp, *The Commodification of the Body and its Parts*, 29 Annual Review of Anthropology, 287-328, 293 (2000).

<sup>&</sup>lt;sup>28</sup> Oliver Decker, COMMODIFIED BODIES: ORGAN TRANSPLANTATION AND THE ORGAN TRADE, (Translated by Steven Rendall), (Routledge Studies in Science, Technology and Society), (2014).

research and therapeutic purposes.<sup>29</sup> The focus here is on the marketability of the human body and body materials. Whether they can or ought to be legally bought and sold in the market just like any other commodity? Can the procurement and handling of these materials taken from a human body be considered as 'commercial activity' if any kind of consideration or compensation is involved in the transaction?

### 6.2.1. INCIDENTS OF COMMERCIALISATION

The human body in its entirety or fragmented form has long been an object of economic, social, and symbolic use in a host of societies.<sup>30</sup> But the study of the 'commodified body' is hardly a new proposition. The word 'commercialisation' is always used along with and in relation to 'exploitation'. It is widely assumed that the interposition of commercial interests between the source of a valuable material and its user is unacceptable because it leads to exploitation. The main concern about allowing free trade in human material is that it could lead to exploitation of the weaker and vulnerable sections.<sup>31</sup> The terms such as 'exploitation', 'objectification', 'harm', 'coercion', etc., goes well with the commercial treatment of the human body and bodily materials. There is always

<sup>&</sup>lt;sup>29</sup> REGENERATIVE MEDICINE ETHICS: GOVERNING RESEARCH AND KNOWLEDGE PRACTICES, (Linda F. Hogle, ed.), (Spinger), (2014).

<sup>&</sup>lt;sup>30</sup> Lesley A. Sharp, *The Commodification of the Body and its Parts*, 29 Annual Review of Anthropology, 287-328, 292 (2000).

<sup>&</sup>lt;sup>31</sup> J. K. MASON & G.T. LAURIE, MASON AND MCCALL SMITH'S LAW AND MEDICAL ETHICS, (Oxford University Press, 8<sup>th</sup> edn.), 454 (2011).

a trend to exploit the poor<sup>32</sup> and the vulnerable sections of the society for the procurement of transplantable organs, making them the research subjects, trying the newly invented drugs, etc. Commodification thus implies a morally degrading transformation from something intrinsically human to an object of ownership.<sup>33</sup>

The prevailing majority view point is that human organs and tissues may be donated, but they should not be sold, despite the shortfall in organs available for transplantation and the consequent increase in human suffering and deaths.<sup>34</sup> Most of the countries across the globe has prohibited commercial transactions in 35 human promoted altruistic donation. Though organs, and has commercialisation of the human body and parts are condemned and regulated, the practice proves to be different. With the increase of monetary transactions in research and organ transplantation, the human body, its organs and other bodily materials are also treated as commodities, which could be sold and purchased in the market.

<sup>&</sup>lt;sup>32</sup> David B. Resnik, *The Commodification of Human Reproductive Materials*, 24 J.M.E, 388-393, 388 (1998), (Jul. 25, 2016), http://www.ncbi.nlm.nih.gov/pmc/articles/PMC479139/pdf/ jmedeth00001-0026.pdf.

<sup>&</sup>lt;sup>33</sup> Klaus Hoeyer, *Person, Patent and Property: A Critique of the Commodification Hypothesis*, 2 BioSocieties, 327-348 (2007), (Apr. 05, 2018) https://doi.org/10.1017/S17458 55207005777.

<sup>&</sup>lt;sup>34</sup> Mark J. Cherry, *Is it Morally Acceptable to Buy and Sell Organs for Human Transplantation*, 43-58, 49, in CONTEMPORARY DEBATES IN BIOETHICS, (Arthur L. Caplan & Robert Arp, eds.), (Wiley Blackwell) (2014).

<sup>&</sup>lt;sup>35</sup> For a detailed discussion, *see* chapter VII.

#### 6.3. MARKET FOR THE HUMAN BODY AND ITS PARTS

For centuries, human bodies have long served as work objects for anatomists and research scientists, as well as prized curios for medical collections. <sup>36</sup> 20<sup>th</sup> Century witnessed the development of transplantation surgeries, which again increased the demand for human organs and related research.<sup>37</sup> In recent years, biotechnology has transformed a variety of the human body tissues into valuable and marketable research materials and clinical products. <sup>38</sup> Late modern technologies brought in their wake new capabilities to plunder, harvest, store, and distribute human organs, tissues and reproductive materials.<sup>39</sup>

The global licit and illicit markets that thrive to supply the demands of transplant medicine, orthopaedic and orthodontic medicine, dermatology, plastic surgery, and to serve the needs of basic science and research, commercial pharmacology, and medical training is a late twentieth-century innovation.<sup>40</sup> Apart from solid organs like heart, lungs and kidneys, harvested tissues also include tendon<sup>41</sup>,

<sup>&</sup>lt;sup>36</sup> Lesley A. Sharp, *The Commodification of the Body and its Parts*, 29 Annual Review of Anthropology, 287-328, 295 (2000).

<sup>&</sup>lt;sup>37</sup> Peter Aziz, *Establishing a Free Market in Human Organs: Economic Reasoning and Perfectly Competitive Model*, 31 U. of La Verne L. Rev., 67 (2009-10).

<sup>&</sup>lt;sup>38</sup> Meredith Render, *The Law of the Body*, 62 Emory L. J. 549, 551 (2013).

<sup>&</sup>lt;sup>39</sup> Nancy Scheper-Hughes, *Neo-Cannibalism*, *Organ Theft, and Military-Biomedical Necropolitics*, (Jul. 08, 2016), http://www.endslavery.va/content/endslavery/en/publications /acta\_20/scheper\_hughes\_panel.html.

<sup>&</sup>lt;sup>40</sup> Nancy Scheper-Hughes, *Neo-Cannibalism*, *Organ Theft, and Military-Biomedical Necropolitics*, (Jul. 08, 2016), http://www.endslavery.va/content/endslavery/en/publications /acta\_20/scheper\_hughes\_panel.html.

<sup>&</sup>lt;sup>41</sup> Tendons and ligaments may be used in repairing sporting injuries.

bones<sup>42</sup>, skin snippets<sup>43</sup>, arteries and veins. From blood to skin, hair to gamete, the human body parts are of much significance and commercial use. The "tissueprocessing industry, once limited to whole organs, has evolved quickly as techniques have developed to make use of muscle, bone, tendon and skin in therapies and research."<sup>44</sup>

Tissues from a deceased donor may be transplanted into as many as 100 people.<sup>45</sup> Most of the organs and tissues can only be donated after death. Whole organs, such as the kidneys, heart, liver, lungs, pancreas and the small bowel may be donated after death either for transplantation or for research. Cadaver sourced corneas are used to restore sight, cadaver heart valves replace damaged ones and extent life. Some organs such as kidney, liver lobes, etc., and tissues such as blood, bone,<sup>46</sup> etc., may be donated by living donors also. Other organs, such as

<sup>&</sup>lt;sup>42</sup> "Bone can be stored for ages, ground into a paste and successfully used in a range of procedures on various people without regard to blood type. Various medical procedures such as knee reconstruction, spinal surgeries, hip replacements and dental works are commonly undertaken using donated tissues. Bone is incorporated into hundreds of different products and sold in a global medical market: as dust which forms a firm foundation for dental implants, putty used in spinal fusion, and pellets which are implanted as replacements of excised diseased bone", Meredith Render, *The Law of the Body*, 62 Emory L. J. 549, 551 (2013).

<sup>&</sup>lt;sup>43</sup> "Disembodied human skin is used by biotech companies to create an array of products, ranging from life-saving skin grafts to cosmetic lip fillers and anti-aging creams. Skin may be cut into conveniently sized dressings, incorporated into gels, or fashioned into slings for use in surgery. The skin used in these products is sold to biotech companies by tissue procurement agencies and hospitals", *See* Meredith Render, *The Law of the Body*, 62 Emory L. J. 549, 551 (2013).

<sup>&</sup>lt;sup>44</sup> Klaus Hoeyer, *Person, Patent and Property: A Critique of the Commodification Hypothesis*, 2 BioSocieties, 327-348 (2007), (Apr. 05, 2018), https://doi.org/10.1017/S17458 55207005777.

<sup>&</sup>lt;sup>45</sup> *Human Tissues and Cells for Transplantation*, European Directorate for the Quality of Medicines and Health, Council of Europe, (Jul. 18, 2018), https://www.edqm.eu/en/human-tissues-and-cells-1522.html.

<sup>&</sup>lt;sup>46</sup> For example, heads of femur removed during an operation to replace a hip joint are sometimes processed and 'recycled'.

brain, large intestine, bladder, etc., are not currently transplanted but may still be donated for research purposes.

The human body tissues has commercial value beyond the medical and research contexts.<sup>47</sup> Fat obtained from human corpses are used for reconstructive or cosmetic surgery.<sup>48</sup> Certain human tissues or tissue products are used for the manufacture of cosmetics. Placenta is used to enrich shampoos, cosmetics and skin care products.<sup>49</sup> Some types of human biological materials such as breast milk, plasma and plasma products as well as various tissues and cell lines are already treated as commodities in the marketplace of health and research.<sup>50</sup> Blood serves as the basis for immortalised cell lines that are available for sale.

The recent developments in biomedicine is now associated by the public with changing views of the human body. It is no longer viewed as integral to the human individual. We have learned with the evolution of modern medicine to consider the human body, both as a corpse and as a living organism, as a machine-like construct, a useful instrument, even a marketable commodity.<sup>51</sup>

<sup>&</sup>lt;sup>47</sup> Meredith Render, *The Law of the Body*, 62 Emory L. J., 549, 551 (2013).

<sup>&</sup>lt;sup>48</sup> (Jul. 15, 2015), http://edition.cnn.com/2009/WORLD/americas/11/20/fat.dead.humans.peru /index.html?\_s =PM:WORLD, CNN, Nov 21, 2009.

<sup>&</sup>lt;sup>49</sup> Between 1976 and 1993, Merieux UK collected 360 tons of placental tissue each year from 282 British hospitals and sent them to France for use in manufacturing drugs. *See*, Dorothy Nelken & Lori Andrews, *Homo Economicus, Commercialisation of Body Tissue in the Age of Biotechnology*, 28 The Hastings Center Report, 30-39, 30 (1998), (Oct. 10, 2014), https://www.jstor.org/stable/3528230.

<sup>&</sup>lt;sup>50</sup> C. Lenk & K. Beier, *Is the Commercialisation of Human Tissue and Body Material Forbidden in the Countries of the European Union?*, 38 J.M.E., 342-346, (2012), (Jun. 14, 2016), https://philpapers.org/rec/LENITC.

<sup>&</sup>lt;sup>51</sup> OWNERSHIP OF THE HUMAN BODY- PHILOSOPHICAL CONSIDERATIONS ON THE USE OF HUMAN BODY AND ITS PARTS IN HEALTH CARE, (Henk A. M. J. Ten Have & Jose V. M. Velie, eds.), (Kluwer Academic Publishers), 1 (1998).

"We purchase blood from 'donors', trade organs in a world - wide market, patent human tissues and cell lines. The body, or at least its parts, has become 'property'",<sup>52</sup> owned by both other persons and firms.<sup>53</sup> Human tissue has become so valuable that it is sometimes a target for corporate espionage and theft.<sup>54</sup> Human body and its parts are becoming the direct target of modern technologies. Bodies have thus emerged as sale-worthy economic capital.<sup>55</sup>

The increasing debate on financial incentives for organ donation and parts thus raises concerns about commodification of the human body.<sup>56</sup> As markets for human organs, tissues and reproductive body parts experience unprecedented growth, the limits of what can or should be bought and sold continue to be pushed.<sup>57</sup> In short, at the heart of the ethical debate over whether sale of human tissues is acceptable, is a fundamental disagreement over what constitutes

<sup>&</sup>lt;sup>52</sup> "In September 1999, visitors to the internet auction website eBay were presented with an unconventional offer: A human kidney, praised as 'fully functional' in the accompanying advertisement text. Bidding for the organ began at \$25,000 and soon reached \$5,750,100, but since organ trafficking constitutes a criminal offence under the US-National Organ Transplants Act, eBay stopped the auction as soon as it was informed." *See*, Mark Schweda, et al., *The "Spare Parts Person"? Conceptions of the Human Body and their Implications for Public Attitudes Towards Organ Donation and Organ Sale*, (Jun. 14, 2016), http://www.ncbi.nlm.nih. gov/pmc/articles/PMC2669094/.

<sup>&</sup>lt;sup>53</sup> OWNERSHIP OF THE HUMAN BODY - PHILOSOPHICAL CONSIDERATIONS ON THE USE OF HUMAN BODY AND ITS PARTS IN HEALTH CARE, (Henk A. M. J. Ten Have & Jose V. M. Velie, eds.), (Kluwer Academic Publishers), 1 (1998).

<sup>&</sup>lt;sup>54</sup> CAROL COLLIER & RACHEL HALIBURTON, BIOETHICS IN CANADA: A PHILOSOPHICAL INTRODUCTION, (Canadian Scholar's Press Inc., 2<sup>nd</sup> edn.), 374 (2015).

<sup>&</sup>lt;sup>55</sup> Sarojini N., Marwah V. et al., *Globalisation of Birth Markets: A Case Study of Assisted Reproductive Technologies in India*, 7 Globalisation and Health, (2011), (May 14, 2016), https://www.ncbi.nlm.nih.gov/pubmed/ 21838866.

<sup>&</sup>lt;sup>56</sup> Mark Schweda, et al., *The "Spare Parts Person"? Conceptions of the Human Body and their Implications for Public Attitudes Towards Organ Donation and Organ Sale*, (Jun. 12, 2016), http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2669094/.

<sup>&</sup>lt;sup>57</sup> Sarojini N., Marwah V. et al., *Globalisation of Birth Markets: A Case Study of Assisted Reproductive Technologies in India*, 7 Globalisation and Health, (2011), (May 14, 2016), https://www.ncbi.nlm.nih.gov/pubmed/21838866.

appropriate and inappropriate uses of the human body. <sup>58</sup> The ban on commercialisation of the human body and its parts represent a restrictive stance and seems to be motivated by the fear of exploitation, injustice and commodification.<sup>59</sup>

### 6.3.1. DEMAND FOR HUMAN CORPSES IN MEDICAL SCHOOLS

Though the anatomical dissection study of the human corpses began during the ancient Greek period,<sup>60</sup> it gained momentum only during the Renaissance.<sup>61</sup> During the early renaissance period, human dissection emerged as a popular domain for scholarly pursuits as physicians considered it an effective medium to communicate their discoveries in objective form. Hence, human dissection proved to be critical in dissemination of scientific knowledge in the field of medicine during this period of scientific revolution.<sup>62</sup>

<sup>&</sup>lt;sup>58</sup> Lori P. Knowles, *Commercialization and Stem Cell Research*, Stem Cell Network, (May 29, 2015), http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.545.3386&rep=rep&ty pe= pdf.

<sup>&</sup>lt;sup>59</sup> Kristin Solum Steinsbekk, Lars Øystein Ursin, et al., *We're Not in it for the Money—Lay People's Moral Intuitions on Commercial Use of 'their' Biobank*, 16 Medicine, Health Care and Philosophy, 151-162 (2013).

<sup>&</sup>lt;sup>60</sup> Monica J. Allen, et al., *Human Tissue Ownership and Use in Research: What Laboratorians and Researchers Should Know*, 56 CLINICAL CHEMISTRY, 1675 (2010).

<sup>&</sup>lt;sup>61</sup> Sanjib Kumar Ghosh, *Human Cadaveric Dissection: A Historical Account from Ancient Greece to the Modern Era*, 48 Anatomy and Cell Biology, 153-169, (2015) (Jul. 10, 2016), http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4582158/.

<sup>&</sup>lt;sup>62</sup> Sanjib Kumar Ghosh, *Human Cadaveric Dissection: A Historical Account from Ancient Greece to the Modern Era*, 48 Anatomy and Cell Biology, 153-169, (2015) (Jul. 10, 2016), http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4582158/.

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perhaps due to the overwhelming influence of the Catholic Church.<sup>63</sup> In 1540, a selected group of physicians and surgeons were given permission to dissect a very limited number of human cadavers. Mostly, these dissections were performed on the corpses of hanged criminals and hardly any of the bodies required for dissection were voluntarily donated for this purpose. However, the availability of corpses did not equate with the demand.<sup>64</sup> By the 17<sup>th</sup> century, upon the availability of printed books in anatomy from Italy and France, the demand for human cadavers for conducting dissection rose sharply.<sup>65</sup> During this period, in the United Kingdom, the Murder Act, 1752, legalized the dissection of the bodies of executed murderers in various medical schools for anatomical research and education.<sup>66</sup>

"Moreover, to ensure adequate supply of human bodies, the government significantly increased the number of crimes punishable by hanging". 67 However, all these measures proved insufficient due to the considerable expansion of anatomical and medical training activities in the 18<sup>th</sup> century

<sup>63</sup> Sanjib Kumar Ghosh, Human Cadaveric Dissection: A Historical Account from Ancient Greece to the Modern Era, 48 Anatomy and Cell Biology, 153-169, (2015) (Jul. 10, 2016), http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4582158/.

<sup>&</sup>lt;sup>64</sup> PRINCIPLES OF MEDICAL LAW, (Andrew Grubb, Judith Laing, et al., eds.), (3<sup>rd</sup> edn., Oxford University Press), 1011 (2010).

<sup>&</sup>lt;sup>65</sup> Sanjib Kumar Ghosh, Human Cadaveric Dissection: A Historical Account from Ancient Greece to the Modern Era, 48 Anatomy and Cell Biology, 153-169, (2015) (Jul. 10, 2016), http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4582158/.

<sup>&</sup>lt;sup>66</sup> Susan C. Lawrence, Beyond the Grave - The Use and Meaning of Human Body Parts: A Historical Introduction, Faculty Publications, Department of History, 37 (1998) (Jan. 15, 2014), http://digitalcommons.unl.edu/cgi/viewcontent.cgi?article=1036&context=historyfacp ub.

<sup>&</sup>lt;sup>67</sup> Sanjib Kumar Ghosh, Human Cadaveric Dissection: A Historical Account from Ancient Greece to the Modern Era, 48 Anatomy and Cell Biology, 153-169 (2015).

England. Consequently a sizeable percentage of the required cadavers were procured illegally by exhuming them from graveyards during the night by men referred to as 'resurrectionists'<sup>68</sup> or the 'body snatchers' and were sold to the medical schools.<sup>69</sup> It also resulted in grave robbing and in some instances, the commission of murder.<sup>70</sup> Thus the only sources of material for dissection and study during those days were the gallows or the grave and the supply from the former was limited by law.<sup>71</sup> Therefore, the latter became the source of a 'saleable commodity', and so the profession of grave robbing became

established.<sup>72</sup>

The passing of the Anatomy Act of 1832<sup>73</sup> in the United Kingdom helped bring an end to the grisly business of snatching bodies, but the supply of material for study still remained a problem.<sup>74</sup> But by the 1920s there was a change in public attitude towards dissection which resulted in an increase in the donation of

<sup>&</sup>lt;sup>68</sup> *The Rise of Body Snatchers*, (Jul. 10, 2016), http://www.history.co.uk/study-topics/history-of-death/the-rise-of-the-body-snatchers.

<sup>&</sup>lt;sup>69</sup> Magee R., *Art Macabre: Resurrectionists and Anatomists*, 71 ANZ J. Surg., 377-380, (2001), (Jul. 10, 2016), http://www.ncbi.nlm.nih.gov/pubmed/11409024.

<sup>&</sup>lt;sup>70</sup> PRINCIPLES OF MEDICAL LAW, (Andrew Grubb, Judith Laing, et.al., eds.), (3<sup>rd</sup> edn., Oxford University Press), 1011 (2010), *See* also, David E. Jefferies, *The Body as Commodity: The Use of markets to Cure the Organ Deficit*, 5 Indiana Journal of Global Legal Studies, 621-658 (1998).

<sup>&</sup>lt;sup>71</sup> Magee R., *Art Macabre: Resurrectionists and Anatomists*, 71 ANZ J. Surg., 377-380, (2001), (Jul. 10, 2016), http://www.ncbi.nlm.nih.gov/pubmed/11409024.

<sup>&</sup>lt;sup>72</sup> Magee R., *Art Macabre: Resurrectionists and Anatomists*, 71 ANZ J. Surg., 377-380, (2001), (Jul. 10, 2016), http://www.ncbi.nlm.nih.gov/pubmed/11409024

<sup>&</sup>lt;sup>73</sup> The Anatomy Act, 1832 sanctioned the use of bodies of those persons who had died without relatives or with insufficient money to pay for the funeral.

<sup>&</sup>lt;sup>74</sup> PRINCIPLES OF MEDICAL LAW, (Andrew Grubb, Judith Laing, et.al., eds.), (3<sup>rd</sup> edn., Oxford University Press), 1012 (2010).

bodies.<sup>75</sup> The markets in tissues, organs and body parts from unidentified persons, prisoners, including prisoners of war emerged to supply new biomedical and biotechnology markets in the late 20<sup>th</sup> and early 21<sup>st</sup> centuries.<sup>76</sup>

The significance of the human body and its parts increased with the development of medical science, especially, the anatomical studies and the resultant demand for human bodies from the increasing number of medical schools. "The cadavers allow doctors to practice on patients who don't feel pain. They help surgeons develop new procedures without risking lives. Dentists dissect their heads and torsos, and physical therapists study their musculoskeletal systems. Pharmaceutical companies test drugs on them, and automakers employ them as crash-test dummies. There are Forensic Anthropology Centers which are nicknamed as 'the Body Farm' where the experts learn how corpses decompose over time."<sup>77</sup> For medical students they are an indispensable learning tool. The demand of cadavers is very high compared to the number of cadavers received through donation.<sup>78</sup>

<sup>&</sup>lt;sup>75</sup> Magee R., Art Macabre: Resurrectionists and Anatomists, 71 ANZ J. Surg., 377-380 (2001), (Jul. 10, 2016), http://www.ncbi.nlm.nih.gov/pubmed/11409024.

<sup>&</sup>lt;sup>76</sup> Nancy Scheper-Hughes, *Neo-Cannibalism, Organ Theft, and Military - Biomedical Necropolitics*, (Jul. 08, 2016), http://www.endslavery.va/content/endslavery/en/publications /acta\_20/scheper\_hughes\_panel.html.

<sup>&</sup>lt;sup>77</sup> *The Secret Lives of Cadavers: How Lifeless Bodies Become Life - Saving Tools*, National Geographic, Jul. 29, 2016, (Jul. 21, 2017), http://news. nationalgeographic.com/2016/07/body-donation-cadavers-anatomy-medical-education.

<sup>&</sup>lt;sup>78</sup> Why there is Shortage of Cadavers, The Economist, Jan. 19, 2014, (Jul. 21, 2017), https://www.economist.com/blogs/economist-explains/2014/01/economist-explains-10.

#### 6.3.2. DEMAND FOR TRANSPLANTABLE HUMAN ORGANS AND BODY PARTS

Despite the great inroads medical science has made since the Renaissance, we have not yet succeeded in producing the human body parts. While the search for compatible artificial organs and other human parts goes on, the medical art of transplant surgery has become the most popular alternative choice.

Latter half of the 20<sup>th</sup> Century thus witnessed the development of transplantation surgery and of immunosuppressant drugs.<sup>79</sup> With this, the patients with damaged organs and tissues have an option to transplant their diseased organ or tissues with another one, thereby extending their lives. The first kidney transplant, using a cadaver, was performed in the Soviet Union in 1936.<sup>80</sup> By 1954, doctors in the United States had accomplished this feat using a living donor.<sup>81</sup> In the ensuing decades, advances in organ transplantation techniques evolved with increasing rapidity. The first successful heart transplant was performed in South Africa in 1967 and the first larynx transplant in Belgium in 1969. Medical science made improvements not only in the types of organs that could be transplanted, but in the survival rates of the patients as well.<sup>82</sup> Although the first recipient of a heart

<sup>80</sup> THE INTERNATIONAL TRAFFICKING OF HUMAN ORGANS: A MULTIDISCIPLINARY PERSPECTIVE, (Leonard Territo & Rande Matteson, Eds.), (CRC Press), 72 (2012).

<sup>&</sup>lt;sup>79</sup> Peter Aziz, *Establishing a Free Market in Human Organs: Economic Reasoning and Perfectly Competitive Model*, 31 U. of La Verne L. Rev., 67 (2009-10).

<sup>&</sup>lt;sup>81</sup> THE INTERNATIONAL TRAFFICKING OF HUMAN ORGANS: A MULTIDISCIPLINARY PERSPECTIVE, (Leonard Territo & Rande Matteson, Eds.), (CRC Press), 72 (2012).

<sup>&</sup>lt;sup>82</sup> "A number of transplant patients have survived well over 25 years and five years' survival rates for most organ transplant programmes are around 70%." *Organ Shortage: Current Status and Strategies for Improvement of Organ Donation - A European Consensus Document*, (Oct. 04, 2018), Para 1.1. https://www.edqm.eu/medias/fichiers/Organ\_shortagecurrent\_status\_ and \_ strategies \_ for\_improvement\_of\_organ\_donation\_A\_European\_consensus\_document.pdf.

transplant lived only for eighteen days, by 1992, eighty-five percent of heart transplant recipients survived at least one year.<sup>83</sup> Data of the registry of the International Society of Heart and Lung Transplantation, 2014 indicates a one-year survival of 84.5% and a five-year survival of 72.5%. This has significantly improved as compared to the 76.9% one-year survival and 62.7% five-year survival in the 1980's.<sup>84</sup> Thus, the "results with nearly all types of solid organ transplantation can be regarded as excellent today".<sup>85</sup>

Organ transplantation surgery requires sources for procurement of organs suitable for transplantation into patients suffering from critical organ failure. Human organs are procured either from cadavers, brain-stem dead persons or from living donors. A cadaver can be a potential donor of various bodily materials including heart, liver, kidney, corneal tissue, etc. But the problem lies in the procurement of transplantable organs and tissues. Though cadaver is a source for many solid organs, procuring organs from the cadavers has its own complications and limitations.<sup>86</sup> Moreover, in recent years there have been a drop

<sup>&</sup>lt;sup>83</sup> Much of this improvement in survival rates can be attributed to the discovery of various immunosuppressive drugs, David E. Jefferies, *The Body as Commodity: The Use of Markets to Cure the Organ Deficit*, 5 Indiana J. of Global Legal Studies, 621-658, 623 (1998).

<sup>&</sup>lt;sup>84</sup> Lund L. H., Edwards L. B., et al., *The Registry of the International Society for Heart and Lung Transplantation: Thirty-first Official Adult Heart Transplant Report -2014*; 33 J Heart Lung Transplant, 996-1008 (2014).

<sup>&</sup>lt;sup>85</sup> Trafficking in Organs, Tissues and Cells and Trafficking in Human Beings for the Purpose of the Removal of Organ, Joint Council of Europe/United Nations Study Council of Europe/United Nations, 18 (2009).

<sup>&</sup>lt;sup>86</sup> After death, the organs will undergo molecular changes and the viability will be lost immediately except in the case of some tissues like cornea. Moreover, "the success of any cadaveric transplant depends primarily on the following clinical factors: a) blood and tissue compatibility between the donor and the recipient; b) effective immunosuppression; c) limited ischaemia (both warm (where blood supply is maintained) and cold (where the organ is cooled) time. Tissue matching is of major importance to outcomes of renal and pancreatic transplants, whereas organ size has generally been a more significant factor in liver and heart

in the number of dead donors, largely due to better medical treatment preventing early deaths and fewer fatal road accidents.<sup>87</sup> This has intensified the need to consider the required legal changes and the option of alternative systems of acquisition,<sup>88</sup> which in turn has led to procuring organs in a state suitable for transplantation from patients whose brain was damaged but other critical organs were functioning normally.<sup>89</sup>

Though artificial means can maintain a patient's oxygen supply and heartbeat even after his brain is dead, the brain function cannot be replaced by current mechanical devices. The re-usable potential of body parts progressively deteriorates during the dying process and some organs are not transplantable unless they are removed from a body with a beating heart.<sup>90</sup> Hence, a brain-stem dead person is a potential source of all transplantable human organs and tissues.<sup>91</sup> A living human being can also donate various bodily materials and organs,

transplantation", *See* ETHICAL AND LEGAL ASPECTS OF ORGAN TRANSPLANTATION, (David Price, ed.), (Cambridge University Press), 23 (2010).

<sup>&</sup>lt;sup>87</sup> SHAUN D. PATTINSON, MEDICAL LAW AND ETHICS, (Sweet & Maxwell, South Asian Edition, 3<sup>rd</sup> edn.), 467 (2013).

<sup>&</sup>lt;sup>88</sup> SHAUN D. PATTINSON, MEDICAL LAW AND ETHICS, (Sweet & Maxwell, South Asian Edition, 3<sup>rd</sup> edn.), 467 (2013).

<sup>&</sup>lt;sup>89</sup> The way to address the growing need for organs led to redefining 'death' using the new criteria intended to increase the number of transplant surgeries. The concept of 'brain death' was introduced to satisfy the ethical norm of non-maleficence and to prevent the charge of homicide on the physician. Thus, apart from the conventional type of death, which is defined as irreversible cardiopulmonary failure, the medical fraternity has recognised the concept of 'brain-death' or more precisely, 'brain-stem death', in order to facilitate organ procurement. They are also known as 'beating-heart cadavers'. "Their hearts are still beating. They urinate. Their bodies don't decompose and they are warm to the touch; their stomachs rumble, their wounds heal and their guts can digest food. They can have heart attacks, catch a fever and suffer from bedsores. They can blush and sweat – they can even have babies", Zaria Gorvett, *The Macabre Fate of 'Beating Heart Corpses'*, (Nov. 04, 2016), BBC Future, (Jul. 14, 2017), http://www.bbc.com/future/story/20161103-the-macabre-fate-of-beating-heart-corpses.

<sup>&</sup>lt;sup>90</sup> J. Savulescu, Death, Us and Our Bodies: Personal Reflections, 29 J.M.E., 127-130 (2003).

<sup>&</sup>lt;sup>91</sup> For more discussions, *see* chapter 1.

except the vital organs. He can donate various body parts such as a kidney, liver lobes, lung lobes, pancreatic segments, bone marrow, blood, sperms, ovum, skin, etc. The removal of blood and certain other bodily materials are easy, less risky and less invasive when compared to that of removal of whole or parts of solid organs.<sup>92</sup>

In spite of the various sources from which the organs can be procured, in the current transplantation practice, an ever-widening gap exists between the number of organs needed for transplantation and the number of organs donated.<sup>93</sup> The number of persons who are waiting for a donor organ for transplantation surgery is very high and the organs available for transplantation is very limited when compared to the huge demand. Not everyone who needs an organ transplant receives one, and there remains a surplus of patients waiting to receive an organ. Thus the problem of organ scarcity is very real.<sup>94</sup>

<sup>&</sup>lt;sup>92</sup> For a detailed discussion, *see* chapter 1.

<sup>&</sup>lt;sup>93</sup> David E. Jefferies, *The Body as Commodity: The Use of Markets to Cure the Organ Deficit*,
5 Indiana Journal of Global Legal Studies, 621-658, 623 (1998).

<sup>&</sup>lt;sup>94</sup> Sebastian Giwa, Jedediah K. Lewis J. K., et al., *The Promise of Organ and Tissue Preservation to Transform Medicine*, 35 Nature Biotechnology, 530-542 (2017), (Oct. 04, 2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5724041/. "Although many problems still have to be resolved in the field of organ transplantation, the main challenge remains organ shortage, which prevents many patients from receiving the benefits of transplantation. The excellent results achieved with organ transplantation have led to a progressive increase in the number of patients on waiting lists." *Trafficking in Organs, Tissues and Cells and Trafficking in Human Beings for the Purpose of the Removal of Organ*, Joint Council of Europe/United Nations Study Council of Europe/United Nations, 18 (2009). According to the U.S. Government Information on Organ Donation and Transplantation, there are more than 114,000 persons on the national transplant waiting list as of August 2017, and 20 people die each day in the US waiting for a transplant. Each year, the number of people on the waiting list continues to be much larger than both the number of donors and transplants, which grow slowly. (Sep. 26, 2018), https://www.organdonor.gov/statistics-stories/statistics.html. Organ Donation and Transplantation Statistics: Graph Data which provides for the statistical data from 1991 to 2017

With every passing year, the number of dying patients waiting for the organs increases, which has led to a growth in demand for the same. With the increase in the number of transplantation surgeries, the greater demand for transplantable human organs has led to the unauthorised procurement of human organs and tissues.<sup>95</sup> Desperate patients are ready to pay any amount of money in order to procure the required tissue for transplantation. The commercial value of the human organs thus has resulted in the expansion of black markets for human organs.<sup>96</sup> An international black market thrives perfectly well in the trade of bones, blood and other body tissues.<sup>97</sup>

Although transplant surgery is saving lives to a great extent,<sup>98</sup> it has also resulted in the creation of trade in the human body parts. With greater delay in getting transplantable organ increases, the number of deaths also increases. This organ trade involves various people such as the agent who identifies potential donors,

is available at https://www.organdonor.gov/statistics-stories/statistics/data.html. "Today, 120,771 people are waiting for an organ, and 18 will die every day while waiting. Just one donor has the ability to save up to 8 lives. Where there's a demand, there's a way. And for the wealthy, money is no object when it comes to a vitally needed body part". *See* Dale Archer M.D, *Body Snatchers: Organ Harvesting for Profit*, Reading Between the (Head) Line, Nov. 13, 2013, (Jul. 16, 2017), http://www.psychologytoday.com/blog/reading-between-the-headlin es/201311/body-snatchers-organ-harvesting-profit.

<sup>&</sup>lt;sup>95</sup> SHAUN D. PATTINSON, MEDICAL LAW AND ETHICS, (Sweet & Maxwell, South Asian Edition, 3<sup>rd</sup> edn.), 467 (2013).

<sup>&</sup>lt;sup>96</sup> Study Report on Trafficking in Human Organs, European Parliament Directorate – General for External Policies Policy Department, 2015, (Nov. 24, 2016), http://www.europarl.europa .eu/RegData/etudes/STUD/2015/549055/EXPO\_STU(2015)549055\_EN.pdf., *Trafficking in Organs, Tissues and Cells and Trafficking in Human Beings for the Purpose of the Removal of Organ*, Joint Council of Europe/United Nations Study Council of Europe/United Nations, 22 (2009).

<sup>&</sup>lt;sup>97</sup> *Human Trafficking is Modern- Day Slavery*, (Jul. 21, 2016), http://fightslaverynow.org/why-fight-there-are-27-million-reasons/otherformsoftrafficking/organ-removal/.

<sup>&</sup>lt;sup>98</sup> SHAUN D. PATTINSON, MEDICAL LAW AND ETHICS, (Sweet & Maxwell, South Asian Edition, 3<sup>rd</sup> edn.), 467 (2013).

middle men, banks which store the organs, and transplant surgeons. Apart from this, most of the countries have prohibited trade and commercial transactions in human bodily materials and human organs.<sup>99</sup> This has also contributed much to the unavailability of organs for transplantation. The shortage of organs within those countries due to such legal regulations has created an international organ market. Affluent patients travel overseas to take advantage of regulatory loopholes in countries where such international black market has emerged.<sup>100</sup> Thus has developed the new vista of 'transplantation tourism' as well as human trafficking for organ procurement.<sup>101</sup>

## 6.4. MARKET FOR HUMAN TISSUES IN THE WAKE OF BIOTECHNOLOGY

Progress in science is changing the very mode of mankind's existence, and the advancement in medical technology has transformed our notions of the human body. Human organs and tissues differ in regard to their clinical and research

<sup>&</sup>lt;sup>99</sup> Iran is the only nation that allows organs to be bought and sold legally. However, it does place restrictions on the commercial organ trade in an attempt to limit transplant tourism. The market is contained within the country; that is, foreigners are not allowed to buy the organs of Iranian citizens. (Sep. 12, 2017), https://en.wikipedia.org/wiki/Organ\_trade., For a detailed discussion, *see* chapter VIII.

<sup>&</sup>lt;sup>100</sup> Trafficking in Organs, Tissues and Cells and Trafficking in Human Beings for the Purpose of the Removal of Organ, Joint Council of Europe/United Nations Study Council of Europe/ United Nations, 22 (2009).

<sup>&</sup>lt;sup>101</sup> According to the World Health Organization, approximately 7,000 kidneys are illegally harvested annually. It is facilitated by the traffickers worldwide and the prices vary widely from country to country. The inevitable result is a booming international black market of body parts that caters to affluent recipients and destitute and the helpless donors. In some countries, impoverished villagers may sell an organ for several hundred dollars. In other countries, organ harvesting is linked to human trafficking. Trafficking in children for slavery or prostitution are also used for their organs. Bulletin of the WHO, Yosuke Shimazon, *The State of the International Organ Trade: A Provisional Picture Based on Integration of Available Information*, (Jun. 12, 2018), http://www.who.int/bulletin/volumes/85/12/06-039370/en/.

uses and the regulatory legislation controlling their use.<sup>102</sup> Human tissues such as bone, skin and heart valves are usually removed from cadavers in hospitals.<sup>103</sup> Unlike solid organs, these tissues can be stored for many years in tissue banks. These tissues can be used in numerous recipients as and when they are needed.

"In the early days of human tissue banking, not-for-profit banks, mostly located in hospitals, dominated the field. The tissues they stored like heart valves and skin, for example, saved many lives. Blood that is not suitable for transplantation can be processed to get blood components, particularly, platelet gel<sup>104</sup>. Thus, body parts such as hair and teeth were objects of sale even during the 19<sup>th</sup> century. Towards the late 20<sup>th</sup> century, a clear market was established in human tissues including blood tissues and reproductive materials as well as solid organs such as kidney, heart, liver, etc." <sup>105</sup>

According to the author Meredith Render,

"If a deceased individual, or their relatives after their death has consented to the use of any part of their body for the treatment of others, much can

<sup>&</sup>lt;sup>102</sup> Jean-Paul Pirnay, Etienne Baudoux, et al., *Access to Human Tissues for Research and Product Development: From EU Regulation to Alarming Legal Developments in Belgium*, 16 EMBO Reports 557-562 (2015), 557–562. PMC. Web. (17 Apr. 2018), https://www.ncbi.nlm. nih.gov/pmc/articles/ PMC4428037 /pdf/embr0016-0557.pdf.

<sup>&</sup>lt;sup>103</sup> R. Alta Charo, *Skin and Bones: Post- Mortem Markets in Human Tissues*, 22 Nova L. Rev., 432 (2002).

<sup>&</sup>lt;sup>104</sup> "This gel is used most frequently in maxillofacial surgery, orthopedic and plastic surgeries, and in the treatment of some forms of cutaneous ulcers. Concentration of platelets has also been used in aesthetic medicine and surgery, for tissue reconstruction and to cure thinning hair, as well as for bio revitalisation and skin rejuvenation", Carlo Petrini, *Ethical and Legal Considerations Regarding the Ownership and Commercial Use of Human Biological Materials and their Derivatives*, J. Blood Medicine, 87- 96, (2012), (Aug. 16, 2017), www.ncbi. nlm.nih.gov/pmc/articles/PMC3440234/.

<sup>&</sup>lt;sup>105</sup> Jean-Paul Pirnay, Etienne Baudoux, et al., Access to Human Tissues for Research and Product Development: From EU Regulation to Alarming Legal Developments in Belgium, 16 EMBO Reports 557- 562 (2015), 557–562. PMC. Web. (17 Apr. 2018), https://www.ncbi. nlm.nih.gov/pmc/articles/ PMC4428037 /pdf/embr0016-0557.pdf.

be put to use: ligaments, cartilage, connective and adipose tissue, glands and nerves can all be used for therapeutic purposes. Composite tissue transplants, such as face and hand transplants have also received much publicity, although these remain very rare and are still essentially experimental. The source of tissue used in research may be the material 'left over' after a diagnostic procedure or operation; material donated as part of a research project accompanying medical treatment; or material provided specifically for a research project quite unconnected with medical treatment."<sup>106</sup>

Tissue provided by a living donor is usually preferable for research purposes, compared with tissue from a deceased donor. Bodily material collected in the course of health care interventions – from whole organs to blood and urine – is stored at least until the results of any required tests are available. Some samples of tissues and fluids are used up in the analysis but in the majority of cases, some tissue remains. Other samples taken during medical care may not in fact require analysis. Such 'leftover' or 'unneeded' material tends to be discarded, for example through incineration. Depending on its nature, however, such tissue may be suitable for research purposes and, usually with the consent of the patient concerned, may be used in specific research projects or stored in research tissue banks. Biotechnology has produced some of the most innovative results. In this field, scientists and researchers have been able to use once useless body products to develop life-saving medicines and therapies.<sup>107</sup>

<sup>&</sup>lt;sup>106</sup> Meredith Render, *The Law of the Body*, 62 Emory L. J. 549, 551 (2013).

<sup>&</sup>lt;sup>107</sup> William Boulier, Sperm, Spleens, and Other Valuables: The Need to Recognize Property Rights in Human Body Parts, 23 Hofstra L. Rev., 695 (1995).

With increase in the use of human tissues and biological materials for various therapeutic and research purposes, the commercial transactions involving the same has also increased. Human tissues are bought and sold in the international bio markets and the law has only recently started to address the issue of commerce in human materials.<sup>108</sup>

Apart from this, the recent developments in biotechnology raises questions regarding the means of lawfully accessing human tissues. <sup>109</sup> Once the researchers get access to human tissues on which research is conducted the determination of rights and interests of the source person in the results of the research.<sup>110</sup> The question of ownership of human materials has been discussed by the various courts over the past three decades.<sup>111</sup>

## 6.5. MARKET FOR HUMAN GAMETES AND FOETAL TISSUES

Human gametes and embryos, are of much significance in infertility treatment. Eggs, sperm and embryos are also very important for research including research into the treatment of infertility, the causes of genetic and congenital disease, miscarriage, etc. Large-scale market for human tissue lies in the area of reproductive medicine, where sperm and ova are routinely obtained from the

<sup>&</sup>lt;sup>108</sup> The United Kingdom Human Tissue Act, 2004, is considered to be one of the first legislations which addressed the issue of activities involving human tissue including the transfer of human remains.

<sup>&</sup>lt;sup>109</sup> Allen B. Wagner, *Human Tissue Research: Who Owns the Results*?, 3 Santa Clara Computer and High Tech L.J, 231-255, 248 (1987).

<sup>&</sup>lt;sup>110</sup> Allen B. Wagner, *Human Tissue Research: Who Owns the Results*?, 3 Santa Clara Computer and High Tech L.J, 231- 255, 248 (1987).

<sup>&</sup>lt;sup>111</sup> For detailed discussions, *see* chapter III.

donors whose reimbursements for the service of providing gametes strongly resemble a payment for the sale of their gametes.<sup>112</sup>

The gametes and embryos poses a different level of ethical issues and the transactions involving gametes and embryos is a very sensitive area. They cannot be treated as other human tissues used for research and transplantation.<sup>113</sup> With gamete donation or embryo donation there is donation of genetic information. This is a special attribute of the reproductive tissues. Even though tissues other than the gametes contain millions of living cells, each carrying all the genetic information needed to code for the synthesis of a person, the specific difference is that the genetic information carried by sperm and ova is usable.<sup>114</sup> It is this single fact that makes the gametes so special.<sup>115</sup>

Eggs and sperm may usually be 'donated' only by live donors, although it is technically possible to retrieve eggs and sperm after death<sup>116</sup> or from aborted foetuses<sup>117</sup>. Fertility centres routinely ask for permission to use non-viable or

<sup>&</sup>lt;sup>112</sup> R. Alta Charo, *Skin and Bones: Post- Mortem Markets in Human Tissues*, 22 Nova L. Rev., 432 (2002).

<sup>&</sup>lt;sup>113</sup> For a detailed discussion, *see* chapters IV & V.

<sup>&</sup>lt;sup>114</sup> Robert P. S. Jansen, Sperm and Ova as Property, J.M.E., 123-126, 124 (1985).

<sup>&</sup>lt;sup>115</sup> Robert P. S. Jansen, *Sperm and Ova as Property*, J.M.E., 123-126, 123 (1985).

<sup>&</sup>lt;sup>116</sup> It is also known as Posthumous Assisted Reproduction (PAR), G. Bahadur, *Death and Conception*, 17 Human Reproduction, 2769–2775 (2002), (Jun. 12, 2018), https://academic. oup.com/humrep/article/17/10/2769/607780. For a detailed discussion, *see* chapter IV.

<sup>&</sup>lt;sup>117</sup> "All the oocytes that a woman will ever produce are formed during foetal life - by four months from the time she herself was conceived. So, five months before birth the human female has all the eggs she will ever have about 7 million. Oocyte loss begins before she is born. By the time of birth 1 or 2 million eggs remain. Even before birth the process of atresia, in which oocytes start their development only to degenerate and be lost, has almost decimated the oocyte population. By puberty, at which time oocytes become candidates for ovulation and, perhaps, fertilisation, only about 300,000 are left. Then, if one of these 300,000 eggs ovulates each month for the twenty-five years, say, that constitute the reproductive years, it is clear that only

unused gametes and embryos for training and research purposes. Eggs may be donated by women undergoing IVF procedures as part of an egg-sharing arrangement whereby fees are reduced on the basis that some of the eggs retrieved during the procedure will be made available either for another woman's treatment, or for research. Volunteer egg donors, on the other hand, are not themselves trying to conceive, but undergo the procedures involved in egg stimulation and retrieval solely in order to donate these eggs to others. Though the term used is 'donation', certainly there involves commercial transactions in the gamete transfers.<sup>118</sup>

When compared to egg, sperm donation is less invasive, but involves a series of appointments for health screening and blood and semen tests before the potential donor is accepted. Sperm donations do not put the donor at risk. Ovum donations are more or less similar to a surgical operation and therefore carry no added physical risk. "Sperms and eggs contain half a human genome and can unite to form a zygote. A zygote can become a child if it implants in a uterus and develops

about 300 eggs have any chance at all of ending up as babies. Indeed, because of opportunities lost during pregnancy there is not the time for more than about 15 or 20 of the eggs to become babies. The other 299,000 or more are destined for oblivion". *See*, Robert P. S. Jansen, *Sperm and Ova as Property*, J.M.E., 123-126,123 (1985).

<sup>&</sup>lt;sup>118</sup> Bonnie Steinbock, *Payment for Egg Donation and Surrogacy*, 71 The Mount Sinai J. of Med., 255-265 (2004), (Oct. 19, 2018), https://scholarsarchive.library.albany.edu/cgi/view content.cgi?article=1002&context=cas\_philosophy\_scholar.

normally."<sup>119</sup> Thus, for a set of scholars, selling gametes is dangerously close to selling persons,<sup>120</sup> since gametes can become persons.

Embryos may be donated where a woman or couple undergoing IVF have completed their family and have spare frozen embryos that would otherwise perish. Those undergoing IVF may also be invited to consider donating spare embryos during their treatment if they choose not to freeze the embryos, or if freezing them for possible future treatment is not considered a viable option by the clinic, or where the embryos are not suitable for implantation but still have value in research. The embryo donations are usually made after fertilisation, therefore there is no added risk or physical discomfort for the donor.<sup>121</sup>

## 6.6. GROWTH OF BLACK-MARKETS IN THE HUMAN BODY PARTS

There is a wide demand for human organs and human bodily materials with the development of transplant surgery and biotechnological research. There is a huge rise in the number of transplantation surgeries taking place throughout the world.<sup>122</sup> Transplantation is becoming a victim of its own success, with demand

<sup>&</sup>lt;sup>119</sup> David B. Resnik, *The Commodification of Human Reproductive Materials*, 24 J.M.E., 388-393, 391 (1998).

<sup>&</sup>lt;sup>120</sup> "Zygotes are potential persons. Zygotes, unlike gametes, have a complete set of genetic instructions and normally also have their own genetic identity. Although human development depends on many different environmental factors and gene-environment interactions, zygotes are much more like adult human beings than gametes. As potential persons, zygotes merit special moral concern. Potential persons merit special moral concern because the way we treat these beings can have a profound effect on the way we treat actual persons". *See*, David B. Resnik, *The Commodification of Human Reproductive Materials*, 24 J.M.E., 388-393, 391 (1998).

<sup>&</sup>lt;sup>121</sup> Robert P. S. Jansen, Sperm and Ova as Property, J.M.E., 123-126, 124 (1985).

<sup>&</sup>lt;sup>122</sup> "126,670 solid organs were reported to be transplanted in 2015. There is 5.8% increase over 2014, which is less than 10% of the global needs", Global Observatory on Donation and

for organs being far higher than supply.<sup>123</sup> For every transplantation surgery, donor organs are needed to replace the diseased organ. Apart from the transplantable organs, biotechnological research institutions and the associated industries require human bodily materials as their raw materials.

With almost every country banning commercial dealings in human organs and tissues, there is an inevitable growth of black markets in the human body parts.<sup>124</sup> Today organs are bought and sold in black markets. Traffic in organs from executed Chinese prisoners or the poor and the desperate in Brazil, Bangladesh, Pakistan, India, and other less developed nations is well documented.<sup>125</sup>

Using biological materials extracted from ordinary people, researchers and biotechnological companies are deriving huge profits. This has resulted in commercialisation and exploitation of the human body, body parts, organs and tissues. Thus, the commercialisation of human corpses, organs, tissues, and other by-products is happening throughout the world.<sup>126</sup>

Transplantation, (Sep. 27, 2018), http://www.transplant-observatory.org/download/2015-activity-data/.

<sup>&</sup>lt;sup>123</sup> FREDERIKE AMBAGTSHEER, ORGAN TRADE, Erasmus University Rotterdam, 19 (2017).

<sup>&</sup>lt;sup>124</sup> Yosuke Shimazono, *The State of the International Organ Trade: A Provisional Picture Based on Integration of Available Information*, Bulletin of the World Health Organization, 955-962 (2007). Organ trade is ranked in the top 10 of most lucrative transnational organized crimes, INTERNATIONAL LAW AND TRANSNATIONAL ORGANIZED CRIME, (Pierre Hauck & Sven Peterke, eds.), (Oxford University Press), 57 (2016).

<sup>&</sup>lt;sup>125</sup> Yosuke Shimazono, *The State of the International Organ Trade: A Provisional Picture based on Integration of Available Information*, 85(12) Bulletin of the World Health Organization 901-80 (Dec. 2007), (Mar. 15, 2015), http://www.who.int/bulletin/volumes/85/12/06-039370/en/. *See also*, Elizabeth E. Appel Blue, *Redefining Stewardship over Body Parts*, 21 J. Law & Health, 75-121, 82 (2008).

<sup>&</sup>lt;sup>126</sup> Organ transplantation is an effective therapy for end-stage organ failure and is widely practised around the world. According to WHO, kidney transplants are carried out in 91

### 6.7. COMMERCIALISATION OF THE HUMAN BODY: PROS AND CONS

Embracing market-based incentives for organ procurement would save lives and reduce human suffering, while helping to contain economic costs and stretch healthcare budgets. <sup>127</sup> Financial and other valuable incentives <sup>128</sup> would encourage living persons to donate redundant organs, and to grant permission for organ harvesting after death. <sup>129</sup> Creating incentives for living-organ donation would thus multiply the availability of organs and tissues such as kidneys, bone marrow and liver segments. <sup>130</sup> Granting incentives will also increase donations by the relatives of brain-dead persons as well as of cadavers, which will increase

countries. Around 66,000 kidney transplants, 21,000 liver transplants and 6,000 heart transplants were performed globally in 2005. Patients' access to organ transplantation, however, varies according to their national situation, and is partly determined by the cost of health care, the level of technical capacity and, most importantly, the availability of organs. *See* Yosuke Shimazono, *The State of the International Organ Trade: a provisional picture based on integration of available information*, 85(12) Bulletin of the World Health Organization 901-80 (Dec. 2007), (Mar. 15, 2015), http://www.who.int/bulletin/volumes/85/ 12/06-039370/en/.

<sup>&</sup>lt;sup>127</sup> Mark J. Cherry, *Is it Morally Acceptable to Buy and Sell Organs for Human Transplantation*, 43-58, 49, in CONTEMPORARY DEBATES IN BIOETHICS, (Arthur L. Caplan & Robert Arp, Eds.), (Wiley Blackwell) (2014).

<sup>&</sup>lt;sup>128</sup> "A future contract in which people agree to sell any usable organs upon their death to an organ- procurement agency, and have the money paid as a death benefit to their survivors. Similarly, financial and other valuable incentives would enable families to sell the organs of a deceased loved one, rather than just to donate the organs. Knowing that their families would financially benefit would likely to encourage many more potential donors to state their intentions to be organ donors. Other incentives for organ donation might include organ entitlements (i.e., high priority on the waiting list for families whose members have donated organs), payment of funeral expenses, life insurance contracts and tax credits.", Mark J. Cherry, *Is it Morally Acceptable to Buy and Sell Organs for Human Transplantation*, 43-58, 49, in CONTEMPORARY DEBATES IN BIOETHICS, (Arthur L. Caplan & Robert Arp, Eds.), (Wiley Blackwell), (2014).

<sup>&</sup>lt;sup>129</sup> Mark J. Cherry, *Is it Morally Acceptable to Buy and Sell Organs for Human Transplantation*, 43-58, 49, in CONTEMPORARY DEBATES IN BIOETHICS, (Arthur L. Caplan & Robert Arp, eds.), (Wiley Blackwell) (2014).

<sup>&</sup>lt;sup>130</sup> Mark J. Cherry, *Is it Morally Acceptable to Buy and Sell Organs for Human Transplantation*, 43-58, 49, in CONTEMPORARY DEBATES IN BIOETHICS, (Arthur L. Caplan & Robert Arp, eds.), (Wiley Blackwell) (2014).

availability of organs for transplantation, thereby reducing the illegal trade in human organs.

The use of a market system in human organs would operate on the same principles as any other markets.<sup>131</sup> As such, it would increase the availability of human organs for transplantation. The biggest advantage of the free market is its ability to increase the supply of organs available for transplantation, thereby curbing the growth of black markets. Thus, offering payment for organs will increase its supply. Establishing free markets, where people can contract with each other for the procurement of organs, has been described as "an obvious and straightforward approach to solving the organ shortage."<sup>132</sup>

On the other hand, arguments against commercialisation of the human body takes the stand that the human body and its parts are an extension of the human personality. Allowing transactions by establishing property rights over them runs counter to the concept of human dignity. Problems arising from the fact that the market status of the human body is on the same level as that of other common goods. The term 'market' is deeply problematic for several reasons. When used in conjunction with 'body parts', it triggers strong moral reactions which tend to seriously impair the normal understanding of the human body and body parts.<sup>133</sup>

<sup>&</sup>lt;sup>131</sup> David E. Jeffries, *The Body as Commodity: The Use of Markets to Cure the Organ Deficit*,
5 Indiana J. of Global Studies, 621-658, 638 (1998).

<sup>&</sup>lt;sup>132</sup> David Kaserman, *Markets for Organs: Myths and Misconceptions*, Contemporary Health Law & Policy, 568 (2002).

<sup>&</sup>lt;sup>133</sup> Klaus Hoeyer, *Person, Patent and Property: A Critique of the Commodification Hypothesis*, 2 BioSocieties, 327-348 (2007), (Apr. 05, 2018) https://doi.org/10.1017/S1745 855207005777.

"Selling human organs for profit is held to be exploitative and degrading, morally analogous to slavery, as well as incompatible with basic values, such as human dignity and sanctity of life, and important social goals, such as equality and a spirit of altruism."<sup>134</sup>

Commodification of the human body and bodily materials results in various unwelcome situations. Treating people as commodities, with no voice in their own destiny is the most fundamental issue relating to bodily autonomy. The commerce in human bodily materials constitute a morally outrageous and gross exploitation of the poor, inherently coercive and obviously intolerable in any civilized society.<sup>135</sup> Moreover, the word 'commercialisation' is always used along with the word 'exploitation'. Thus, the main concern about allowing free trade in human material is that it could lead to exploitation of weaker sections.<sup>136</sup> Trade in body parts and human organs give rise to the spectre of exploitation, which is ethically questionable because it has the potential to harm those who are exploited.<sup>137</sup>

Most exploitation arguments against an organ market have largely focused on the possible exploitation of the poor and desperate vendors. There are least two

<sup>&</sup>lt;sup>134</sup> MARK J. CHERRY, KIDNEY FOR SALE BY OWNER: HUMAN ORGANS, TRANSPLANTATION, AND THE MARKET, (Georgetown University Press, Washington DC), 4 (2005).

<sup>&</sup>lt;sup>135</sup> Janet Radcliffe Richards, *Nephrarios Goings on: Kidney Sales and Moral Arguments*, in ORGAN AND TISSUE TRANSPLANTATION, (David Price, ed.), (The International Library of Medicine, Ethics and Law, Ashgate), 61 (2006).

<sup>&</sup>lt;sup>136</sup> J. K. MASON & G.T LAURIE, MASON AND MCCALL SMITH'S LAW AND MEDICAL ETHICS, (Oxford University Press, 8<sup>th</sup> edn.), 454 (2011).

<sup>&</sup>lt;sup>137</sup> J. K. MASON & G.T LAURIE, MASON AND MCCALL SMITH'S LAW AND MEDICAL ETHICS, Oxford University Press, 8th edn.), 448 (2011).

essential conditions for an exploitative transaction: it benefits the exploiter and it is unfair to the exploited party.<sup>138</sup> Trade in the human body parts also involves exploitation and poverty makes people vulnerable to such exploitation.<sup>139</sup>

The scholars who argue against the commercial exploitation of human organs rests their argument on the opinion that the human body is sacrosanct and should not be diminished to a mere commodity, capable of being traded in the market just like any other 'thing'.<sup>140</sup> The problem with markets is that they reduce everything - including human beings, their labour, and their reproductive capacity - to the status of commodities that can be bought, sold, traded, and stolen.<sup>141</sup> If the human body parts are allowed to be sold and purchased in the market as other commodities, that will definitely affect the value of the human body which may thus be lowered to the position of a 'thing' that may be traded in the market. By commodifying the body, mutual respect for all persons will slowly be eroded.

Moreover, commerce in human bodily materials implies a morally outrageous and gross exploitation of the poor, which is inherently coercive and obviously

<sup>&</sup>lt;sup>138</sup> Hui Min Loh, *Selling Organs Ethically: Disentangling Exploitation Arguments*, 1 UCLJLJ 1-22 (2012).

<sup>&</sup>lt;sup>139</sup> Janet Radcliffe Richards, *Nephrarios Goings on: Kidney Sales and Moral Arguments*, in ORGAN AND TISSUE TRANSPLANTATION, (David Price, ed.), (The International Library of Medicine, Ethics and Law, Ashgate), 77 (2006).

<sup>&</sup>lt;sup>140</sup> *Commoditisation of the Human Body*, (Jul. 27, 2016), https://stopsextrafficking.wordpress. com/lawsg/commoditisation-of-the-human-body/.

<sup>&</sup>lt;sup>141</sup> Nancy Scheper-Hughes, *The Ends of the Body: Commodity Fetishism and Global Traffic in Organs*, 22 SAIS Rev. of International Affairs, 61-80, 62, (2002).

intolerable in any civilized society.<sup>142</sup> Treating human beings as commodities, with no voice in their own destiny is the most fundamental issue relating to bodily autonomy. Thus commercialising the supply of organs would lead to the harvest of organs from the vulnerable sections and a loss of respect for persons. If the recipient of an organ pays the donor or the donor's family directly, the poor may be compelled, through economic necessity, to donate organs to the more financially advantaged.

Oftentimes the living donors supplying tissue for transplants are destitute and/or from the Third World, as their financial situation makes them particularly vulnerable to the solicitous methods of traders.<sup>143</sup> The fact that majority of the organ donors come from the poor, rather than the economically secure, demonstrates that the sole driving force for such organ donation is a desperate need for money.<sup>144</sup> Whereas, the proponents of a body parts market believe that this market would be a good means for the poor to escape their desperate situation.<sup>145</sup>

<sup>&</sup>lt;sup>142</sup> B. Bjorkman et al., *Bodily Rights and Property Rights*, 32 J.M.E., 209-214, (2006).

 <sup>&</sup>lt;sup>143</sup> Kripal S. Chugh & Vivekanand Jha, Commerce in Transplantation in Third World Countries: Perspectives in Clinical Nephrology, 49 Kidney International, 1181-1186 (1996), (Sep. 27, 2018), https://www.kidney-international.org/article/S0085-2538(15)59465-9/pdf.
 <sup>144</sup> Randy W. Marusyk & Margaret S. Swain, A Question of Property Rights in the Human

Body, 21 Ottawa L. Rev., 351-386, 372 (1989).

<sup>&</sup>lt;sup>145</sup> Randy W. Marusyk & Margaret S. Swain, A Question of Property Rights in the Human Body, 21 Ottawa L. Rev., 351-386, 372 (1989).

Commodification and exploitation of the human body has increased as a result of identification of new uses for the human body and bodily materials.<sup>146</sup> Today, the human body and bodily materials are sold, leased and purchased in the market like any other commodity. The body as an object of commodification attracts players as diverse as grave robbers, biotechnology companies, museums, the medical profession, organ traders, etc. In spite of laws in many countries banning the sale of human organs, it is a fact that a new breed of traders in human tissue is emerging.<sup>147</sup>

In law, the twin issues of commodification and exploitation which arises as a result of ownership rights in the human body and body parts tend to receive separate treatments<sup>148</sup> The human body as a whole and almost every part of it, including every cell is very significant in the modern era of biotechnology.<sup>149</sup> Human organs procured from living donors, brain-stem dead persons as well as cadavers are used for transplantation. In view of these ever increasing medical possibilities allowing intervention into the human body, as well as the use of

<sup>&</sup>lt;sup>146</sup> STEPHEN WIKINSON, BODIES FOR SALE: ETHICS AND EXPLOITATION IN THE HUMAN BODY TRADE, (Routledge), 3 (2003).

<sup>&</sup>lt;sup>147</sup> Randy W. Marusyk & Margaret S. Swain, *A Question of Property Rights in the Human Body*, 21 Ottawa L. Rev., 351-386, 371 (1989).

<sup>&</sup>lt;sup>148</sup> Taiwo A. Oriola, Genes for Sale: Ethical Reflections on Donor's Proprietary Rights in Human Genetic Derivatives, (Jul. 23, 2016), http://www.ccels.cf.ac.uk/archives/publications/2006/oriolapaper.pdf.

<sup>&</sup>lt;sup>149</sup> Each and every cell of a human body can be a potential raw material for biotechnology research.

body parts in research and commercial enterprises it is necessary to protect individuals' human body from any harmful and unwarranted interventions.<sup>150</sup>

The body itself can be compared to a mine from which we extract various raw materials as well as products. Hence it is valuable as a commodity and a lot of financial transactions are also associated with the same. Viewed from this perspective, the human body and body parts have turned to be valuable commodities in this 21<sup>st</sup> century. When value and money is so intensively associated with the human body, one cannot forget the inherent dangers of exploitation and commercialization. "Human remains can have significant commercial value, although they are not typically bought and sold like other goods.... Although remains which are used for these medical and scientific purposes are usually donated, rather than bought or sold, this does not negate their potential commercial value."<sup>151</sup>

<sup>&</sup>lt;sup>150</sup> OWNERSHIP OF THE HUMAN BODY - PHILOSOPHICAL CONSIDERATIONS ON THE USE OF HUMAN BODY AND ITS PARTS IN HEALTH CARE, (Henk A. M. J. Ten Have & Jose V. M. Velie, eds.), (Kluwer Academic Publishers), 2 (1998).

<sup>&</sup>lt;sup>151</sup> Judge Cowen of the US Court of Appeals, Third Circuit, in *Onyebuchi v. Pan Am* 952 F.2d 788, 792 (1992).

# VII. CONSENT: RELEVANCE IN TRANSACTIONS INVOLVING THE HUMAN BODY AND BODILY MATERIALS

## 7.1. INTRODUCTION

In the modern world, people are increasingly accustomed to a culture which is based on liberty. It is the freedom of individuals to act according to their choice, within the limits that usually concern the avoidance of harm to others.<sup>1</sup> Respecting oneself as person is the central aspect of the flourishing of individuals. This requires that they can successfully pursue their important plans, goals, interests, etc. In turn, others are required to respect them as persons and should not prevent them from pursuing their goals by denying them fundamental freedoms and the resources they need. "To put the point differently, a just society is one where persons respect one another as such, that is, give one another opportunities for self-respect."<sup>2</sup>

If no harm is caused to others, it is not the proper role of the State to interfere in what is done, or not done, consensually to a person. It is because of the fact that an individual is considered to be an autonomous being. The concept of consent has its basis on this principle of autonomy of individuals.<sup>3</sup> The State has a role

<sup>&</sup>lt;sup>1</sup> SHEILA A. M. MCLEAN, AUTONOMY, CONSENT AND THE LAW, (Routledge-Cavendish), 1 (2010).

<sup>&</sup>lt;sup>2</sup> CECILE FABRE, WHOSE BODY IS IT ANYWAY?, JUSTICE AND INTEGRITY OF THE PERSON, (Clarendon Press, Oxford), 12 (2006).

<sup>&</sup>lt;sup>3</sup> Martin Gunderson, Justifying a Principle of Informed Consent: A Case Study in Autonomy-Based Ethics, 4 Public Affairs Quarterly, 249-265 (1990), http://www.jstor.org/stable/ 40435751.

to intervene to protect and to promote superior moral interests, but, if no public interest exists condemning the particular action, the decision making power should be given to the individual.<sup>4</sup>

Consent is a concept that captures the moral grounding of our entire way of thinking about human action. It is a state of mind that depends on the libertarian concept of a person as a wholly independent, self-reliant decision maker<sup>5</sup> and voluntariness is considered to be the touchstone of the notion of consent.<sup>6</sup>

The term 'consent' is defined as "an agreement, approval, or permission as to some act or purpose, especially given voluntarily by a competent person".<sup>7</sup> It is a legally effective assent. Consent therefore means a voluntary, uncoerced decision, made by a sufficiently competent or autonomous person on the basis of adequate information and deliberation, to accept rather than reject some proposed course of action that will affect them.<sup>8</sup> Etymologically the word 'consent' has been derived from the Latin conjunction of *con*, meaning 'together' with *sentire*, meaning 'to feel, think or judge'.<sup>9</sup>

<sup>&</sup>lt;sup>4</sup> Cordelia Mary Thomas, *A Framework for the Collection, Retention and Use of Human Body Parts*, (2006), (Sep. 5, 2013), http://researcharchive.vuw.ac.nz/bitstream/handle/10063/297/ thesis.pdf.txt?sequence=4.4.

<sup>&</sup>lt;sup>5</sup> ALASDAIR MACLEAN, AUTONOMY, INFORMED CONSENT AND MEDICAL LAW: A RELATIONAL CHALLENGE, (Cambridge: Law, Medicine & Ethics, Cambridge University Press), 114 (2009).

<sup>&</sup>lt;sup>6</sup> Daniel R. Williams, *Misplaced Angst: Another Look at Consent-Search Jurisprudence*, 82 Ind. L. J., 67-97, 70 (2007), (Aug. 20, 2018), http://www.repository.law.indiana.edu/ilj/vol82/iss1/3.

<sup>&</sup>lt;sup>7</sup> BLACK'S LAW DICTIONARY, (Bryan A. Garner, ed. in chief, 8<sup>th</sup> edn.), 323 (2004).

<sup>&</sup>lt;sup>8</sup> RAANON GILLON, PHILOSOPHICAL MEDICAL ETHICS, (British Medical Journal),113 (1986).

<sup>&</sup>lt;sup>9</sup> ALASDAIR MACLEAN, AUTONOMY, INFORMED CONSENT AND MEDICAL LAW: A RELATIONAL CHALLENGE, (Cambridge: Law, Medicine & Ethics, Cambridge University Press), 111 (2009).

Consent is understood differently by various disciplines and professions, and also in various theoretical models.<sup>10</sup> The primary purpose of consent is normatively to transform the legitimacy of an act. Consent works in two ways. It either legitimates an otherwise forbidden act or it creates new obligations. As a creator of obligations, consent is crucial to an agreement. Consent's other role is to provide a bearer of rights with control of that right, which it does by allowing the transformation of an illegitimate act into a permitted one.<sup>11</sup>

Consent is a precondition of autonomous decision making<sup>12</sup> and a requirement of lawful interference with another person's right. Anyone who intentionally or recklessly touches a person without their consent will generally commit both a tort and a crime.<sup>13</sup> Consent is required primarily as a device to ensure that no unlawful interference takes place with the individual. Consent is thus an affirmative defense to assault, battery and related torts, as well as such torts as defamation, invasion to privacy, conversion, trespass. <sup>14</sup> Consent is a fundamental principle that the adult, who is *sui juris*, is recognised as having the fundamental human and personal right to control oneself. It is the right to self-

<sup>&</sup>lt;sup>10</sup> Priscilla Alderson, *Theories of Consent*, BMJ, 317 (1998), (Aug. 28, 2018), https://www. bmj.com/content/ 317/7168/1313.1.

<sup>&</sup>lt;sup>11</sup> ALASDAIR MACLEAN, AUTONOMY, INFORMED CONSENT AND MEDICAL LAW: A RELATIONAL CHALLENGE, (Cambridge: Law, Medicine & Ethics, Cambridge University Press), 114 (2009).

<sup>&</sup>lt;sup>12</sup> SHAUN D. PATTINSON, MEDICAL LAW AND ETHICS, (Sweet & Maxwell, South Asian Edition), 114 (2013).

<sup>&</sup>lt;sup>13</sup> Omprakash V. Nandimath, *Consent and Medical Treatment: The Legal Paradigm in India*, 25 IJU, 343-347 (2009), (Aug. 10, 2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2779959/.

<sup>&</sup>lt;sup>14</sup> BLACK'S LAW DICTIONARY, (Bryan A. Garner, ed. in chief, 8<sup>th</sup> edn.), 323 (2004).

determination or right to autonomy, i.e., the right to decide for oneself to the exclusion of others.<sup>15</sup>

## 7.2. CONSENT IN MEDICAL LAW

'Consent' is the cornerstone of medical law and it is often analysed against the background of medical treatment, surgical invasion, post-mortem examination, removal of organs for transplantation, etc.<sup>16</sup> The fast-growing field of biomedical research has given rise to a range of unresolved and contested legal issues concerning the extent and implementation of the requirement of consent.<sup>17</sup>

Under medical law, consent is applicable with regard to a doctor-patient relationship as well as researcher-human participant relationship. A doctor who treats, or a researcher who conducts any biomedical research involving human subjects, if doing it without a valid consent, will be liable under the tort and criminal laws.<sup>18</sup> Getting consent is important in the context of tissue/organ procurement from a living person or from a cadaver. Therefore, it is mandatory that the health professionals or researchers who interferes with the person of an

<sup>&</sup>lt;sup>15</sup> PRINCIPLES OF MEDICAL LAW, (Andrew Grubb, Judith Laing, et.al.,), (Oxford University Press, 3<sup>rd</sup> edn.), 491 (2010).

<sup>&</sup>lt;sup>16</sup> SHAUN D. PATTINSON, MEDICAL LAW AND ETHICS, (Sweet & Maxwell, South Asian Edition), 114 (2013).

<sup>&</sup>lt;sup>17</sup> Russell Korobkin, Autonomy and Informed Consent in Non-Therapeutic Biomedical Research, 54 UCLAL. Rev., 605 (2006-'07), (May 19, 2015), http://heinonline.org.

<sup>&</sup>lt;sup>18</sup> Omprakash V. Nandimath, *Consent and Medical Treatment: The Legal Paradigm in India*, 25 IJU, 343- 347 (2009), (Aug. 10, 2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2779959/.

individual should obtain a valid<sup>19</sup> consent.<sup>20</sup> Justice Cardozo in *Schloendorff v*. *Soc'y of N.Y. Hospital*<sup>21</sup>, opined that "every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without the patient's consent commits an assault".<sup>22</sup>

Adequately informing patients or the affected persons and obtaining consent in regard to an operation, procedure or treatment is both a specific legal requirement and an accepted part of good medical practice. Therefore, consent is sought as the ultimate expression of self-determination.

Under medical law, consent is a prerequisite in the following aspects in relation to a living person. 1) Any medical treatment or medical procedure<sup>23</sup>, 2) Any medical intervention, including invasive procedures like blood transfusion,

<sup>&</sup>lt;sup>19</sup> In law, a valid consent can be obtained only from a person who is competent to give consent. To be competent to give a legally effective consent means, the person must be endowed with the ability to weigh the risks and benefits of the proposed action. The capacity of a person can be decided by his majority age and soundness of mind, and the person must also give the consent voluntarily. *See*, paragraph 7.4. of chapter VII.

<sup>&</sup>lt;sup>20</sup> SHAUN D. PATTINSON, MEDICAL LAW AND ETHICS, (Sweet & Maxwell, South Asian Edition), 114 (2013).

<sup>&</sup>lt;sup>21</sup> 105 N.E. 92 (N.Y. 1914).

<sup>&</sup>lt;sup>22</sup> Plaintiff was suffering from some disorder of stomach. Her physician discovered a lump, which proved to be a fibroid tumour. He consulted the visiting surgeon, who advised an operation. The plaintiff's testimony is that she was informed that the character of the lump could not be determined without another examination. She consented to such an examination, but notified that there must be no operation. She was taken at night from the medical to the surgical ward and prepared for an operation by a nurse. On the following day ether was administered, and while she was unconscious, the tumour was removed. Her testimony is that this was done without her consent or knowledge.105 N.E. 92 (N.Y. 1914).

<sup>&</sup>lt;sup>23</sup> Daniel E. Hall, Allan V. Prochazka, et al., *Informed Consent for Clinical Treatment*, 184 C.M.A.J., 533–540, (2012), (Oct. 19, 2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC 3307558/. *See* also, Omprakash V. Nandimath, *Consent and Medical Treatment: The Legal Paradigm in India*, 25 IJU, 343- 347 (2009).

surgery, etc.<sup>24</sup>, 3) Consent is mandatory in the context of organ and tissue procurement<sup>25</sup>. Consent is also important while dealing with a cadaver. Consent is specifically required for post-mortem removal of organs and tissues from a dead person or from a brain-dead person.<sup>26</sup> The legal framework for the requirement of consent and the importance of consent as a prerequisite for organ and tissue procurement in the context of commercialisation of the human body, organs and tissues is analysed here.

## 7.3. AUTONOMY VIS-À-VIS CONSENT

Traditionally 'autonomy' was used as a means of protecting the right to selfdetermination held by all people.<sup>27</sup> The concept of autonomy has assumed increasing importance in contemporary moral and political philosophy.<sup>28</sup> Today, the principle of respect for the patient's autonomy has become the focal point in medical law. It means that the individual patient or a research participant has the ultimate right to control their body and what is done with or to it.<sup>29</sup> On a closer

<sup>&</sup>lt;sup>24</sup> Mark Friedman, Wajih Arja, *Informed Consent for Blood Transfusion*, 138 American Journal of Clinical Pathology, 559–565 (2012), https://academic.oup.com/ajcp/article/138/4/559/1760948.

<sup>&</sup>lt;sup>25</sup> Statutes that regulate the procurement, retention and distribution of human organs and tissues mandates the application of the principle of consent. For a detailed analysis, *see* 7.6.

<sup>&</sup>lt;sup>26</sup> For a detailed analysis, *see* 7.5.3.

<sup>&</sup>lt;sup>27</sup> Kenyon Mason & Graeme Laurie, *Consent or Property? Dealing with the Body and Its Parts in the Shadow of Bristol and Alder Hey*, 64 The Modern L. Rev., 710-729, 718 (2001), (Dec. 13, 2017), http://www.jstor.org/stable/1097277?seq=1&cid=pdf-reference#references\_tab\_ contents.

<sup>&</sup>lt;sup>28</sup> Gerald Dworkin, *The Nature of Autonomy*, 2 Nordic J. of Studies in Educational Policy, (2015), (Aug. 11, 2018), https://doi.org/10.3402/nstep.v1.28479.

<sup>&</sup>lt;sup>29</sup> J. K. MASON & G. T. LAURIE, MASON AND MCCALL SMITH'S LAW AND MEDICAL ETHICS, (Oxford University Press, 8<sup>th</sup> edn.), 447 (2011).

analysis, it can be seen that the rules about the provision for consent are a means of providing for the autonomy of the individual.<sup>30</sup>

The word 'autonomy' is derived from ancient Greek<sup>31</sup> which literally means, 'the having or making of one's own laws'. <sup>32</sup> The word 'autonomy' is used synonymous with the terms, 'self-rule' or 'self-determination'.<sup>33</sup> It is the state of self-determination which imports the right to choose for oneself how to live one's life.<sup>34</sup> In contemporary medical law and ethics, consent has come to be treated as being synonymous with autonomy. Seen in these terms, autonomy and consent are individualistic and atomistic notions, focusing on the individual person and the protection or furtherance of their interests.<sup>35</sup>

The idea of autonomy has emerged as a central notion in the area of applied moral philosophy, particularly in the biomedical context.<sup>36</sup> According to Gerald Dworkin, autonomy is "an equivalent of liberty..., sometimes as equivalent of

<sup>&</sup>lt;sup>30</sup> Kenyon Mason & Graeme Laurie, *Consent or Property? Dealing with the Body and Its Parts in the Shadow of Bristol and Alder Hey*, 64 The Modern L. Rev., 710-729, 718 (2001), (Dec. 13, 2017), http://www.jstor.org/stable/1097277?seq=1&cid=pdf-reference#references\_tab\_ contents.

<sup>&</sup>lt;sup>31</sup> Autos means 'self' and namos means 'law'.

<sup>&</sup>lt;sup>32</sup> ROHAN HARDCASTLE, LAW AND THE HUMAN BODY: PROPERTY RIGHTS, OWNERSHIP AND CONTROL, (Hart Publishing, Oxford and Portland), (2007).

<sup>&</sup>lt;sup>33</sup> Dasari Harish, Ajay Kumar, et al., *Patient Autonomy and Informed Consent: The Core of Modern Day Ethical Medical Practice*, 37 J. Indian Acad. Forensic Med., 410-414 (2015), (Aug. 22, 2018), http://medind.nic.in/jal/t15/i4/jalt15i4p410.pdf.

<sup>&</sup>lt;sup>34</sup> Tuija Takala, *Concepts of 'Person' and 'Liberty,' and their Implications to our Fading Notions of Autonomy*, 33 J. Med. Ethics, 225-228 (2007), (Aug. 22, 2018), https://www.ncbi. nlm.nih.gov/pmc/articles/PMC2652781/.

<sup>&</sup>lt;sup>35</sup> Edward S. Dove, Susan E. Kelly, et al., *Beyond Individualism: Is There a Place for Relational Autonomy in Clinical Practice and Research?*, 12 Clinical Ethics, (Aug. 22, 2018), https://doi.org/10.1177/1477750917704156.

<sup>&</sup>lt;sup>36</sup> Gerald Dworkin, *The Nature of Autonomy*, 2 Nordic J. of Studies in Educational Policy, (2015), (Aug. 11, 2018), https://doi.org/10.3402/nstep.v1.28479.

self-rule or sovereignty, sometimes as identical with freedom of the will. It is equated with dignity, integrity, individuality, independence, responsibility, and self-knowledge. It is identified with qualities of self-assertion, with critical reflection, with freedom from obligation, with absence of external causation, with knowledge of one's own interests... Autonomy is a feature of persons and that it is a desirable quality to have."<sup>37</sup>

Autonomy is generally understood as self-determination: the freedom to pursue one's conception of the good life, just as long as it does not impinge upon another's identical freedom.<sup>38</sup> Autonomy requires the ability to decide for the self, free from control of the others, and with sufficient level of understanding so as to arrive at a meaningful choice.<sup>39</sup> Importance given to the freedom and values of individuals is captured in the concept of respect for autonomy. Bioethicists view consent as the practical embodiment of respect for persons and for individual autonomy. Autonomy also includes the notions of self-governance, liberty rights, and privacy.<sup>40</sup>

<sup>&</sup>lt;sup>37</sup> GERALD DWORKIN, THE THEORY AND PRACTICE OF AUTONOMY, Cambridge Studies in Philosophy, (Cambridge University Press), 6 (1988).

<sup>&</sup>lt;sup>38</sup> Kim Atkins, *Autonomy and the Subjective Character of Experience*, 17 J. of Applied Philosophy, 71-79, 74 (2000).

<sup>&</sup>lt;sup>39</sup> Dasari Harish, Ajay Kumar, et al., *Patient Autonomy and Informed Consent: The Core of Modern Day Ethical Medical Practice*, 37 J. Indian Acad. Forensic Med., 410-414 (2015), (Aug. 22, 2018), http://medind.nic.in/jal/t15/i4/jalt15i4p410.pdf.

<sup>&</sup>lt;sup>40</sup> Marcela G. del Carmena & Steven Joffe, *Informed Consent for Medical Treatment and Research: A Review*, 10 The Oncologist, 636-641 (2005), (Aug. 22, 2018), http://theoncologist. alphamedpress.org/content/10/8/636.full.pdf+html.

Autonomy is the capacity for self-determination. To respect a person's autonomy is to acknowledge his right to make choices and to take action based on his own values and belief system. The principle of respect for autonomy implies that one should be free from coercion in deciding to act, and that others are obligated to protect confidentiality, respect privacy, and to tell the truth. The current view of 'autonomy' is that it identifies the individual as an independent and unfettered 'chooser'.<sup>41</sup> The principle of autonomy emphasizes that a competent adult always has the right to decide what ought or ought not to be done to them.<sup>42</sup> The importance of autonomy and consent in the health care setting is that these principles legitimises the dealings between health care professionals or researchers and patients.<sup>43</sup> It implies that the doctor is obliged not only to respect the free choice of his patient, but more importantly, to facilitate in every reasonably possible way the making of such a free choice by the patient. Respect for patient autonomy involves not only ethical obligations to respect patient choices, but also obligation to promote both patient autonomy and autonomous choice.44

<sup>&</sup>lt;sup>41</sup> Kenyon Mason & Graeme Laurie, *Consent or Property? Dealing with the Body and its Parts in the Shadow of Bristol and Alder Hey*, 64 The Modern L. Rev., 710-729, 711 (2001), (Dec. 13, 2017), http://www.jstor.org/stable/1097277.

 <sup>&</sup>lt;sup>42</sup> Dasari Harish, Ajay Kumar, et al., *Patient Autonomy and Informed Consent: The Core of Modern Day Ethical Medical Practice*, 37 J Indian Acad. Forensic Med., 410-414 (2015), (Aug. 22, 2018), http://medind.nic.in/jal/t15/i4/jalt15i4p410.pdf.

<sup>&</sup>lt;sup>43</sup> Kenyon Mason & Graeme Laurie, *Consent or Property? Dealing with the Body and its Parts in the Shadow of Bristol and Alder Hey*, 64 The Modern L. Rev., 710-729, 711 (2001), (Dec. 13, 2017), http://www.jstor.org/stable/1097277.

<sup>&</sup>lt;sup>44</sup> Dasari Harish, Ajay Kumar, et al., *Patient Autonomy and Informed Consent: The Core of Modern Day Ethical Medical Practice*, 37 J. Indian Acad. Forensic Med., 410-414 (2015), (Aug. 22, 2018), http://medind.nic.in/jal/t15/i4/jalt15i4p410.pdf.

Autonomy has become the most fundamental ethical principle in modern times.<sup>45</sup> The emergence of autonomy as a guiding concept in biomedical ethics has occurred relatively recently and co-exists with the growth in the importance of the language of human rights.<sup>46</sup> Personal autonomy is closely interlinked with the broader concepts of human dignity and personal freedom.<sup>47</sup> Therefore, "the right to have autonomous decisions respected, supported by the developing sphere of privacy, is the mark of a mature society, and serves to maximise the potential for human liberty."<sup>48</sup>

## 7.4. LEGAL REQUIREMENTS OF A VALID CONSENT

For consent to be a legally valid one, the basic conditions such as voluntariness, legal capacity, knowledge, etc., has to be fulfilled.<sup>49</sup> Voluntariness implies that the patient should give consent voluntarily without any duress either from the physician or any relative or any third party. Consent obtained with compulsion either by the action or words of any other person is no consent at all.<sup>50</sup> It should

<sup>&</sup>lt;sup>45</sup> JONATHAN HERRING, MEDICAL LAW AND ETHICS, (Oxford University Press, 3<sup>rd</sup> edn.), 192 (2010).

<sup>&</sup>lt;sup>46</sup> SHEILA A. M. MCLEAN, AUTONOMY, CONSENT AND THE LAW, (Routledge-Cavendish), 7 (2010).

<sup>&</sup>lt;sup>47</sup> N. R. Koffeman, (The Right to) Personal Autonomy in the Case Law of the European Court of Human Rights, (2010), (Aug.29, 2018), https://openaccess.leidenuniv.nl/bitstream/handle/ 1887/15890/.

<sup>&</sup>lt;sup>48</sup> SHEILA A. M. MCLEAN, AUTONOMY, CONSENT AND THE LAW, (Routledge-Cavendish), introduction 2 (2010).

<sup>&</sup>lt;sup>49</sup> Sylvester C. Chima, *Evaluating the Quality of Informed Consent and Contemporary Clinical Practices by Medical Doctors in South Africa: An Empirical Study*, 14 BMC Med. Ethics, (2013), (Aug. 23, 2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3878312/.

<sup>&</sup>lt;sup>50</sup> Anil Chaturvedi, *Consent - Its Medico-Legal Aspects*, 17 Medicine Update, 883- 887, 884 (2007), (May. 22, 2015), http://www.apiindia.org/pdf/medicine\_update\_2007/153.pdf.

be a freely given consent and the doctor or the researcher should ensure that the patient has given such consent freely and voluntarily.

The second condition of legal capacity implies that the patient should fully understand the nature and implications of the proposed treatment. For that the age and the mental capacity of the patient should be taken into consideration.<sup>51</sup> If the patient is not of majority age or is mentally incapable of giving consent, the consent of the guardian is required.<sup>52</sup>

Knowledge forms the crux of the aspect of consent. It includes the understanding and knowledge about the nature of the diagnosis, nature of the treatment planned, foreseeable risk involved in the treatment and the knowledge about any alternative therapy and the aftereffects if the treatment is not carried out.<sup>53</sup> Patients must also be provided with sufficient information about the condition, investigation options, treatment options, benefits, possible adverse effects or complications, and the likely result if the proposed treatment is not undertaken, in order to be able to make their own decision about undergoing a procedure, treatment or operation.

<sup>&</sup>lt;sup>51</sup> Anil Chaturvedi, *Consent- Its Medico-Legal Aspects*, 17 Medicine Update, 883-887, 884 (May. 22, 2015), http://www.apiindia.org/pdf/medicine\_update\_2007/153.pdf.

<sup>&</sup>lt;sup>52</sup> Omprakash V. Nandimath, *Consent and Medical Treatment: The Legal Paradigm in India*, 25 IJU, 343-347 (2009), (Aug. 10, 2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2779959/.

<sup>&</sup>lt;sup>53</sup> Anil Chaturvedi, *Consent- Its Medico-Legal Aspects*, 17 Medicine Update, 883-887, 885 (May. 22, 2015), http://www.apiindia.org/pdf/medicine\_update\_2007/153.pdf.

Lord Goff of Chieveley in *Airedale NHS Trust v. Bland*<sup>54</sup> stated: "The first point to make is that it is unlawful so as to constitute both the tort and crime of battery, to administer medical treatment to an adult who is conscious and of sound mind, without his consent...Such a patient is completely at liberty to decline to undergo treatment, even if the result of his doing so will be that he will die."<sup>55</sup> Lord Goff went on further to state that "the principle of self-determination requires that respect must be given to the wishes of the patient, so that if an adult patient of sound mind refuses, however unreasonably, to consent to treatment or care by which his life would or might be prolonged, the doctors responsible for his care must give effect to his wishes, even though they do not consider it to be in his best interests to do so."<sup>56</sup>

## 7.5. TYPES OF CONSENT

Consent can be of various types. The most common types of consent seen in relation to the medical intervention on one's body is express consent<sup>57</sup> or implied consent<sup>58</sup>. Implied consent is the consent that may be inferred from the general submission by a patient to the orders given by a doctor during clinical

<sup>&</sup>lt;sup>54</sup> [1993] 1 All ER 821. Tony Bland had suffered brain damage as a result of severe chest injury and had remained in permanent vegetative state ever since. Question relating to allowing euthanasia was discussed by the House of Lords in this case.

<sup>&</sup>lt;sup>55</sup> [1993] 1 All ER 821, at 857.

<sup>&</sup>lt;sup>56</sup> [1993] 1 All ER 821, at 864.

<sup>&</sup>lt;sup>57</sup> "Consent that is clearly and unmistakably stated", BLACK'S LAW DICTIONARY, (Bryan A. Garner, ed. in chief, 8<sup>th</sup> edn.), 323 (2004).

<sup>&</sup>lt;sup>58</sup> "Consent inferred from one's conduct rather than from one's direct expression.", BLACK'S LAW DICTIONARY, (Bryan A. Garner, ed. in chief, 8<sup>th</sup> edn.), 323 (2004).

diagnosis.<sup>59</sup> Consent is implied or implicit when a physician is allowed to do routine physical examination and investigations. Whereas during the clinical examination, there might arise the need for an intimate examination of the patient. In such cases, the doctor must get the express consent of the patient.<sup>60</sup> This gets more restricted when a female patient has to be examined in a more intimate manner and when invasive investigations are required. The consent here will have to be more explicit in oral or written form.

In cases of "riskier interventions, surgical procedures, and instances of long-term follow-up are involved, written consent is required as a safeguard. Any violation by a physician can be liable under tort or criminal law, and the patient can sue for battery or negligence depending on the extent of alleged offence".<sup>61</sup>

As the law currently recognises, the form in which consent is granted should not matter. Consent does not need to be in any particular form.<sup>62</sup> It can be given verbally, by behaviour or in writing, provided, it is clear that permission has been granted. An explicit consent is less likely to be misunderstood. To reduce the risk of misunderstanding associated with implied consent, the healthcare

<sup>&</sup>lt;sup>59</sup> Omprakash V. Nandimath, *Consent and Medical Treatment: The Legal Paradigm in India*, 25 IJU, 343-347 (2009), (Aug. 10, 2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2779959/.

<sup>&</sup>lt;sup>60</sup> Ajay Kumar, Parul Mullick P., et.al., *Consent and the Indian Medical Practitioner*, 59 Indian J. Anaesthesia. 695-700 (2015), (Aug. 27, 2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4697240/.

 <sup>&</sup>lt;sup>61</sup> Nandini K. Kumar, *Informed Consent: Past and Present*, 4 Perspectives in Clinical Research, 21-25 (2013), (Aug. 22, 2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC 3601698/.
 <sup>62</sup> JONATHAN HERRING, MEDICAL LAW AND ETHICS, (Oxford University Press, 3<sup>rd</sup> edn.), 159 (2010).

professional should be shielded from liability only where the interference of consent was both honest and reasonable.<sup>63</sup> Moreover, consent should be morally and legally effective. The purpose behind requiring consent to be in writing is to ensure that there is a record of the process. However, the record serves only as evidence and not as proof of consent.<sup>64</sup>

The concept of express and implied consent is of generic use, however, many attributes of the same yields to yet another categorisation into informed consent and presumed consent.

## 7.5.1. INFORMED CONSENT

A person's agreement to allow something to happen to him, made with full knowledge of the risks involved and the alternatives is termed as informed consent.<sup>65</sup> It should be a person's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure.<sup>66</sup> The 'informed consent' doctrine is American in origin and relates to the amount of information that a patient should be provided with, in order to avoid any probable action in

<sup>&</sup>lt;sup>63</sup> ALASDAIR MACLEAN, AUTONOMY, INFORMED CONSENT AND MEDICAL LAW: A RELATIONAL CHALLENGE, (Cambridge: Law, Medicine & Ethics, Cambridge University Press), 255 (2009).

<sup>&</sup>lt;sup>64</sup> ALASDAIR MACLEAN, AUTONOMY, INFORMED CONSENT AND MEDICAL LAW: A RELATIONAL CHALLENGE, (Cambridge: Law, Medicine & Ethics, Cambridge University Press), 255 (2009).

<sup>&</sup>lt;sup>65</sup> BLACK'S LAW DICTIONARY, (Bryan A. Garner, ed. in chief, 8<sup>th</sup> edn.), 323 (2004).

<sup>&</sup>lt;sup>66</sup> Global Glossary of Terms and Definitions on Donation and Transplantation, 11 (2009), (Jun. 18, 2018), http://www.who.int/transplantation/activities/GlobalGlossaryonDonationTranspla ntation.pdf ?ua=1.

negligence.<sup>67</sup> The goal of informed consent is to respect patient autonomy and enable him to make decisions regarding his medical care, of his free will, without coercion, after understanding fully what he is consenting for.<sup>68</sup> "Informed consent is thus an 'autonomous authorisation' protecting both the autonomy of the individual and the fundamental right to decide. True informed consent is the specific consent given for well-defined uses".<sup>69</sup>

For a consent to be called as 'informed consent', certain important elements are to be fulfilled. There should be full disclosure of information,<sup>70</sup> competency,<sup>71</sup> understanding,<sup>72</sup> voluntariness,<sup>73</sup> and final decision<sup>74</sup>.<sup>75</sup> It requires intentional

<sup>&</sup>lt;sup>67</sup> Omprakash V. Nandimath, *Consent and Medical Treatment: The Legal Paradigm in India*, 25 *IJU*, 343-347 (2009), (Aug. 10, 2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2779959/.

<sup>&</sup>lt;sup>68</sup> Dasari Harish, Ajay Kumar, et al., *Patient Autonomy and Informed Consent: The Core of Modern Day Ethical Medical Practice*, 37 J. Indian Acad. Forensic Med., 410-414 (2015), (Aug. 22, 2018), http://medind.nic.in/jal/t15/i4/jalt15i4p410.pdf.

<sup>&</sup>lt;sup>69</sup> BIOTECHNOLOGY: FUNDAMENTALS IN BIOTECHNOLOGY, (Horst W. Doelle, Stefan Rokem, et al., eds.), Volume XII, (EOLSS Publishers/ UNESCO), 203 (2009).

<sup>&</sup>lt;sup>70</sup> "Information should be given to the patient regarding his disease, its complications, suggested treatments, risks involved, etc.", JONATHAN MONTGOMERY, HEALTH CARE LAW, (Oxford University Press), 233 (1997).

<sup>&</sup>lt;sup>71</sup> "Patients are presumed to be competent to comprehend the information unless proved otherwise.", JONATHAN HERRING, MEDICAL LAW AND ETHICS, (Oxford University Press, 3<sup>rd</sup> edn.), 152 (2010).

<sup>&</sup>lt;sup>72</sup> "It is presumed that the information shared to the patient is understood by him. And the physician is obliged to disclose only certain basic information required by the law, and not obliged to ascertain whether the patient is competent or has understood the shared information or not.", Sylvester C. Chima, *Evaluating the Quality of Informed Consent and Contemporary Clinical Practices by Medical Doctors in South Africa: An Empirical Study*, 14 BMC Med. Ethics, (2013), (Aug. 23, 2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3878312/.

<sup>&</sup>lt;sup>73</sup> "There must be a voluntary decision coming from the patient. He should not be under pressure or coercion. Even if a patient is competent and is aware of the crucial issues and the consent is not given freely, it will not be a valid consent.", JONATHAN HERRING, MEDICAL LAW AND ETHICS, (Oxford University Press, 3<sup>rd</sup> edn.), 157 (2010).

<sup>&</sup>lt;sup>74</sup> The patient must actually decide whether to undergo or opt out from the treatment after knowing all the risks involved, alternative treatments available, etc.

<sup>&</sup>lt;sup>75</sup> Marcela G. del Carmena & Steven Joffe, *Informed Consent for Medical Treatment and Research: A Review*, 10 The Oncologist, 636-641 (2005), (Aug. 22, 2018), http://the oncologist.alphamedpress.org/content/10/8/636.full.pdf+html.

non-coerced decision making based on sufficient information, substantial understanding, the possibility of dialogue, and time to think about the implications before a decision is taken.<sup>76</sup> "Consent should be given voluntarily and not be obtained under duress or coercion of any sort or by offering any undue inducements."<sup>77</sup>

The doctrine of informed consent was derived from malpractice cases involving non-consensual touching of the body.<sup>78</sup> If a patient had not authorised treatment, or a doctor had performed treatment substantially different from that consented to, the patient had a cause of action for the tort of battery.<sup>79</sup> The ethical imperative to obtain informed consent has become a powerful medico-legal norm in recent years. If the consent is not an informed one, it ceases to be a real and genuine one.

The practice of informed consent has historical roots in various disciplines, including medicine, moral philosophy, and the law.<sup>80</sup> "It is closely tied to

<sup>&</sup>lt;sup>76</sup> Lori Luther & Trudo Lemmens, *Human Genetic Data Banks: From Consent to Commercialisation - An Overview of Current Concerns and Conundrum*, BIOTECHNOLOGY: FUNDAMENTALS IN BIOTECHNOLOGY, (Horst W. Doelle, Stefan Rokem, et al., eds.) Volume XII, (EOLSS Publishers/ UNESCO), (2009).

<sup>&</sup>lt;sup>77</sup> Principle 5.1.2., ICMR National Ethical Guidelines for Biomedical and Health Research involving Human Participants, 2017, (Aug. 22, 2018), https://www.iitm.ac.in/downloads/ICMR\_Ethical\_Guidelines\_2017.pdf.

<sup>&</sup>lt;sup>78</sup> Erin Sheley, *Rethinking Injury: The Case of Informed Consent*, 2015 BYU L. Rev., 63 (2015), https://digitalcommons.law.byu.edu/lawreview/vol2015/iss1/4.

<sup>&</sup>lt;sup>79</sup> Cordelia Mary Thomas, *A Framework for the Collection, Retention and Use of Human Body Parts*, (2006), (Apr. 02, 2016), https://researcharchive.vuw.ac.nz/xmlui/bitstream/handle/ 10063/297/thesis.pdf?sequence=2.

<sup>&</sup>lt;sup>80</sup> Marcela G. del Carmena & Steven Joffe, *Informed Consent for Medical Treatment and Research: A Review*, 10 The Oncologist, 636-641 (2005), (Aug. 22, 2018), http://the oncologist.alphamedpress.org/content/10/8/636.full.pdf+html.

philosophical notions of respect for persons and respect for individual autonomy. Requirement for consent to treatment, autopsy, etc., is rooted in cases.<sup>81</sup> Consent to research, in contrast, has its basis in ethical codes, statutes, and administrative regulations, with the courts playing a lesser role."<sup>82</sup>

Informed consent in the context of research has evolved in parallel with but largely separate from informed consent to medical treatment.<sup>83</sup> "The participant must have the capacity to understand the proposed research, be able to make an informed decision on whether or not to be enrolled and convey her/his decision to the researcher in order to give consent."<sup>84</sup>

"Informed consent protects the individual's autonomy to freely choose whether or not to participate in the research. The process involves three components – providing relevant information to potential participants, ensuring the information is comprehended by them and assuring voluntariness of participation. Informed consent should explain medical terminology in simple terms and be in a language

<sup>&</sup>lt;sup>81</sup> In *AB v. Leeds*, 2004 EWHC 644 (QB), the plaintiffs complained that they were not given informed consent before post-mortem was carried out on their deceased children and that paediatric organs removed and retained in the post-mortem process (which were subsequently disposed of), were done without their authority. *Moore v. Regents of the University of California*, 51 Cal. 3d 120, involved the non-consensual use of the plaintiff's cancerous spleen cells to develop pharmaceutical products of enormous commercial value.

<sup>&</sup>lt;sup>82</sup> Marcela G. del Carmena & Steven Joffe, *Informed Consent for Medical Treatment and Research: A Review*, 10 The Oncologist, 636-641 (2005), (Aug. 22, 2018), http://the oncologist.alphamedpress.org/content/10/8/636.full.pdf+html.

<sup>&</sup>lt;sup>83</sup> Marcela G. del Carmena & Steven Joffe, *Informed Consent for Medical Treatment and Research: A Review*, 10 The Oncologist, 636-641 (2005), (Aug. 22, 2018), http://theoncologist. alphamedpress.org/content/10/8/636.full.pdf+html.

<sup>&</sup>lt;sup>84</sup> Principle 5.1.1., ICMR National Ethical Guidelines for Biomedical and Health Research involving Human Participants, 2017, (Aug. 22, 2018), https://www.iitm.ac.in/downloads/ICMR\_Ethical\_Guidelines\_2017.pdf.

that the participant understands."<sup>85</sup> The researcher must obtain voluntary written informed consent from the prospective participant for any biomedical and health research involving human participants.<sup>86</sup> This requirement is based on the principle that competent individuals are entitled to choose freely whether or not to participate or continue to participate in the research.

Informed consent is also important when it comes to the matter of organ and tissue harvesting. Transplantable organs are sourced from both living and dead donors. Getting consent from the source person is a legal mandate before procurement of organs or tissues in many countries.<sup>87</sup> Apart from solid organs, tissues from human beings also have enormous potential value for research, transplantation, education, and training. Consent is required to legitimise such uses.<sup>88</sup> Tissues are also procured either from the living, or from cadavers or from the brain dead.<sup>89</sup> If the person did not express a desire about the use of their organs or tissues after death, the general practice is that, the next kin of the deceased shall make a determination of what the decedent would have wanted, and what is most consistent with their values.<sup>90</sup>

<sup>&</sup>lt;sup>85</sup> Principle 2.2., ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017, (Aug. 22, 2018), https://www.iitm.ac.in/downloads/ ICMR\_Ethical\_Guidelines\_2017.pdf.

<sup>&</sup>lt;sup>86</sup> ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017, (Aug. 22, 2018), https://www.iitm.ac.in/downloads/ICMR\_Ethical\_Guidelines\_2017.pdf.

<sup>&</sup>lt;sup>87</sup> For a detailed discussion, see paragraph 7.6. of chapter VII.

<sup>&</sup>lt;sup>88</sup> Peter Furness, *Consent to Using Human Tissue: Implied Consent Should Suffice*, 327 BMJ, 759–760, (2003), (May 30, 2016), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC214050/.

<sup>&</sup>lt;sup>89</sup> J. Savulescu, Death, Us and Our Bodies: Personal Reflections, (Jun. 1, 2012), http://jme. bmj.com/content/29/3/127.full.

<sup>&</sup>lt;sup>90</sup> J. Savulescu, Death, Us and Our Bodies: Personal Reflections, (Jun. 1, 2012), http://jme. bmj.com/content/29/3/127.full.

Thus the object of informed consent is to enable a person to arrive at a rational or informed decision and it is founded on the principle of respect for autonomy and the notion that individuals have a right to control their medical care and research participation.<sup>91</sup> Therefore, a physician/ researcher/ surgeon is under an obligation to obtain informed consent before subjecting any person for medical treatment, medical research or organ/ tissue procurement.

## 7.5.2. PRESUMED CONSENT

The concept of 'presumed consent' comes into application with the question of harvesting of organs and tissues for transplantation. As the demand for transplant organs continues to exceed the supply, various methods are being considered for increasing the availability of organs from cadaveric donors. One method in practice is 'presumed consent'.<sup>92</sup> Under presumed consent, the decedent would be 'presumed' to be willing to have their organs harvested upon death.<sup>93</sup> Presumed consent is alternatively known as an 'opt-out'<sup>94</sup> system.<sup>95</sup> Unless the

<sup>&</sup>lt;sup>91</sup> Marcela G. del Carmena & Steven Joffe, *Informed Consent for Medical Treatment and Research: A Review*, 10 The Oncologist, 636-641 (2005), (Aug. 22, 2018), http://the oncologist. alphamedpress.org/content/10/8/636.full.pdf+html.

<sup>&</sup>lt;sup>92</sup> JONATHAN HERRING, MEDICAL LAW AND ETHICS, (Oxford University Press, 3<sup>rd</sup> edn.), 435 (2010).

<sup>&</sup>lt;sup>93</sup> Maxwell J. Mehlman, *Presumed Consent to Organ Donation: A Re-evaluation*, 1 Health Matrix, 31 (1991).

<sup>&</sup>lt;sup>94</sup> It is also referred to as 'contracting out'. It is argued by many scholars that the presumed system is not a consent-based system, because consent is fictionalised in the absence of any positive indication that posthumous removal for transplantation has actually been agreed to. Imputed consent is no consent at all. SHAUN D. PATTINSON, MEDICAL LAW AND ETHICS, (Sweet & Maxwell), 429 (2006).

<sup>&</sup>lt;sup>95</sup> Simon Bramhall, "Presumed Consent for Organ Donation: A Case Against", 93 Ann. R. Coll. Surg. Engl., 270-272 (2011), (Oct. 26, 2016), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC 3363073/.

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deceased has expressed a wish in life not to be an organ donor, the consent will be assumed.

"A clinically and legally indicated candidate for cadaveric organ and tissue recovery is presumed to have consented to organ and tissue recovery if he or she had not registered a refusal."<sup>96</sup> It means, presuming that every person has consented to donate organs as well as tissues for transplantation in case they have not registered their will against such donation during life.<sup>97</sup> "A person who does not want his organs or tissues to be harvested from his body for transplantation after death is bound to document his will against donation during life as per the legal framework of a country; otherwise he is considered a willing organ/tissue donor.<sup>998</sup>

The application of this form of consent can be divided into 'hard opt-out' or a 'soft opt-out'.<sup>99</sup> Hard opt-out is a system where the wishes of the family of the deceased is not consulted before harvesting the organs. When the wishes of the

<sup>&</sup>lt;sup>96</sup> Organ Procurement and Transplantation Network, *A Report of the Presumed Consent Subcommittee of the Ethics Committee (June 1993)*, (Aug. 22, 2018), https://optn. transplant.hrsa.gov/resources/ethics/an-evaluation-of-the-ethics-of-presumed-consent/.

<sup>&</sup>lt;sup>97</sup> Reeta Dar, *Presumed Consent for Organ Donation: Illusion of A Choice*, 3 Int. J. Community Med. Public Health, 2691-2695 (2016), (Aug. 23, 2018), http://www.ijcmph.com/index.php/ ijcmph/article/ view/195/195.

<sup>&</sup>lt;sup>98</sup> Reeta Dar, *Presumed Consent for Organ Donation: Illusion of A Choice*, 3 Int. J. Community Med. Public Health, 2691-2695 (2016), (Aug. 23, 2018), http://www.ijcmph.com/index.php/ ijcmph/article/ view/195/195.

<sup>&</sup>lt;sup>99</sup> Simon Bramhall, *Presumed Consent for Organ Donation: A Case Against*, 93 Ann. R. Coll. Surg. Engl., 270-272 (2011), (Oct. 26, 2016), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC 3363073/.

family are considered, it comes under the category of soft opt-out.<sup>100</sup> A stricter version of presumed consent is termed as the 'conscription' system. In this system, tissues and organs can be removed posthumously for transplantation, irrespective of any consent or refusal. Under such a system, dead bodies and their parts would be treated as public property either indefinitely or for a limited period before what remains is released for burial.<sup>101</sup>

#### 7.5.2.1. ARGUMENTS IN SUPPORT OF PRESUMED CONSENT

In moral terms, presumed consent is based on the principle of utilitarianism. The morally right course is to be determined by estimating the total consequences of action and then choosing the one doing the greatest good.<sup>102</sup> Presumed consent is a system which increases the availability of transplantable organs and tissues. Every day, thousands of hearts, kidneys, lungs and other transplantable organs which are in good condition are destroyed by burial and cremation while thousands are suffering due to want of these organs for their survival.<sup>103</sup> Hence presuming consent for removal of organs is one alternative for increasing the supply of transplantable organs.

<sup>&</sup>lt;sup>100</sup> Simon Bramhall, *Presumed Consent for Organ Donation: A Case Against*, 93 Ann. R. Coll. Surg. Engl., 270-272 (2011), (Oct. 26, 2016), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC 3363073/.

<sup>&</sup>lt;sup>101</sup> SHAUN D. PATTINSON, MEDICAL LAW AND ETHICS, (Sweet & Maxwell), 429 (2006).

<sup>&</sup>lt;sup>102</sup> ROBERT M. VEATCH & LAINIE F. ROSS, TRANSPLANTATION ETHICS, (Georgetown University Press), 147 (2015).

<sup>&</sup>lt;sup>103</sup> M. S. Vinay Kumar & Sameer Valsangkar, *Ethical and Legal Issues of Presumed Consent*,
36 J. Indian Acad. Forensic Med., 404-406 (2014), http://medind.nic.in/jal/t14/ i4/jalt14
i4p404.pdf.

In countries like Spain and Belgium, presumed consent appears to procure organs more effectively than other systems, when compared to countries like United States, where informed consent forms the basic legal framework for organ harvesting.<sup>104</sup> "Explicit opt-out laws have long been among the major interventions used to increase the pool of potential donors in countries such as Austria, Belgium, the Czech Republic, Finland, France, Greece, Hungary, Israel, Italy, Luxembourg, Norway, Poland, Slovenia, Spain, Sweden and Turkey.<sup>105</sup> There is evidence that supports the association between presumed consent and increased donation rates and that countries with opt-out laws have rates 25 to 30% higher than those in countries requiring explicit consent."<sup>106</sup> Therefore, if we can presume the consent of the deceased for organ procurement, there will be a substantial increase in the transplantable organs.

# 7.5.2.2. ARGUMENTS AGAINST PRESUMED CONSENT

Presumed consent is based on the notion that, if structures are in place to allow for dissent and no steps have been taken, then consent can be presumed. The most pressing ethical problem with the presumed consent systems is its

<sup>&</sup>lt;sup>104</sup> David E. Jefferies, *The Body as Commodity: The Use of Markets to Cure the Organ Deficit*,
5 Indiana J. of Global Legal Studies, 621-658, 634 (1998), http://www.repository. law.
indiana.edu/ijgls/vol5/iss2/13.

<sup>&</sup>lt;sup>105</sup> For a detailed discussion, *see* paragraph 7.6.

<sup>&</sup>lt;sup>106</sup> Alejandra Zúñiga-Fajuri, Increasing Organ Donation by Presumed Consent and Allocation Priority: Chile, Bulletin of the World Health Organisation, (Aug. 23, 2018), http://www.who. int/bulletin/volumes/93/3/14-139535/en/. *See* also, Reeta Dar, *Presumed Consent for Organ Donation: Illusion of A Choice*, 3 Int. J. Community Med. Public Health, 2691-2695 (2016), (Aug. 23, 2018), http://www.ijcmph. com/index.php/ ijcmph/article/view/195/195.

impairment of individual autonomy and freedom.<sup>107</sup> Individual autonomy and presumed consent cannot go together. If autonomy is ethically essential, then presuming consent is wrong. Donation of organs should be the choice of the donor and must not be coerced.<sup>108</sup>

Another major criticism levelled against presumed consent is that, it is most likely to impact the lower socio-economic groups, who lack the knowledge or confidence to access the opt-out processes.<sup>109</sup> Presumed consent also poses a huge problem in persons who are incapable of making their personal decisions as in children and mentally incapacitated adults.<sup>110</sup> Children and mentally incompetent persons may have impaired ability to make or communicate their decisions. Although they are potential sources of organs and body parts, they may be unable to consent to such use.<sup>111</sup>

"The problem with 'presumed consent' is that, with a few exceptions, the existing laws never actually claim to presume consent, nor can they rightly be

<sup>&</sup>lt;sup>107</sup> David E. Jefferies, *The Body as Commodity: The Use of Markets to Cure the Organ Deficit*, 5 Indiana Journal of Global Legal Studies, 621-658, 640 (1998), (Jul. 25, 2016), http://www.repository.law.indiana.edu/ijgls/vol5/iss2/13.

 <sup>&</sup>lt;sup>108</sup> M. S. Vinay Kumar & Sameer Valsangkar, *Ethical and Legal Issues of Presumed Consent*,
 36 J. Indian Acad. Forensic Med., 404-406 (2014), (Nov. 18, 2017), http://medind.nic.in/jal/ t14/i4/jalt14 i4p404.pdf.

<sup>&</sup>lt;sup>109</sup> Cordelia Mary Thomas, *A Framework for the Collection, Retention and Use of Human Body Parts*, (2006), (Aug. 21, 2015), http://researcharchive.vuw.ac.nz/bitstream/handle/10063/297/ thesis.pdf.txt?sequence=4.

<sup>&</sup>lt;sup>110</sup> M. S. Vinay Kumar & Sameer Valsangkar, *Ethical and Legal Issues of Presumed Consent*, 36 J. Indian Acad. Forensic Med., 404-406 (2014), (Nov. 18, 2017), http://medind.nic.in/jal/t14/jalt14 i4p404.pdf.

<sup>&</sup>lt;sup>111</sup> Unknown Author, *The Sale of Human Body Parts*, 72 Michigan L. Rev., 1182-1264, 1194 (1974), (Apr. 14, 2016), https://www.jstor.org/stable/pdf/1287620.pdf?refreqid=excelsior% 3A08d8431f65d 76965823602c3f933d3af.

said to do so. They simply authorise the state's taking of the organs without explicit permission".<sup>112</sup> The State which routinely takes body parts without specific consent interferes with such basic human rights like the right to autonomy and bodily integrity and the right to self-determination of an individual.

Presumed consent takes the onus away from the individual to register in order to become an organ donor. Instead, the individual must sign a register in order to make his views known that he does not want to donate. Therefore, everyone is treated as a donor unless they implicitly opt out.<sup>113</sup> Moreover, presumed consent system is not designed for the benefit of the one from whom the organ or tissue is procured, but rather for the benefit of those who are at the receiving end.<sup>114</sup>

Even the supporters of the presumed consent system argue that there are no fundamental ethical or legal barriers to introducing soft presumed consent legislation. A hard system of presumed consent would almost certainly lead to an increase in rates of donation but its introduction would pose serious challenges on the basic human rights.<sup>115</sup> Thus an ideal consent system should

<sup>&</sup>lt;sup>112</sup> ROBERT M. VEATCH & LAINIE F. ROSS, TRANSPLANTATION ETHICS, (Georgetown University Press), 154 (2015).

 <sup>&</sup>lt;sup>113</sup> M. S. Vinay Kumar & Sameer Valsangkar, *Ethical and Legal Issues of Presumed Consent*,
 36 J. Indian Acad. Forensic Med., 404-406 (2014), (Nov. 18, 2017), http://medind.nic.in/jal/ t14/i4/jalt14 i4p404.pdf.

<sup>&</sup>lt;sup>114</sup> ROBERT M. VEATCH & LAINIE F. ROSS, TRANSPLANTATION ETHICS, (Georgetown University Press), 151 (2015).

<sup>&</sup>lt;sup>115</sup> Simon Bramhall, *Presumed Consent for Organ Donation: A Case Against*, 93 Ann R Coll. Surg. Engl. (2011) 270-272, (Oct. 26, 2018), https://www.ncbi.nlm.nih.gov/pmc/articles/ PMC3363073/.

serve the twin goals of increasing organ supply to eliminate the shortage of transplantable human organs and tissues, while preserving maximum autonomy for the individual.<sup>116</sup>

# 7.5.3. CONSENT WITH RESPECT TO THE CADAVERS

There is no doubt that consent should be obtained before dealing with a dead body. The next stage is to solve the remaining questions as to who should give that consent, on what basis, and for which all purposes. The consent of the deceased expressed when alive may be in conflict with the consent of the surviving relatives. Two propositions can be drawn in this regard.

Firstly, consent of the deceased person which has been expressed prior to death should be given predominance.<sup>117</sup> In the circumstances relating to the uses of a corpse, the wishes to be respected is that of the deceased, as the dead retain a number of residual interests after their passing.<sup>118</sup> Individuals should have the power to control their bodies after their death because this is an important part of being autonomous.<sup>119</sup>

<sup>&</sup>lt;sup>116</sup> David E. Jefferies, *The Body as Commodity: The Use of Markets to Cure the Organ Deficit*, 5 Ind. J. of Global Legal Studies, 621-658, 640 (1998), (Jul. 25, 2016), http://www.repository. law.indiana.edu/ijgls/vol5/iss2/13.

<sup>&</sup>lt;sup>117</sup> Kenyon Mason & Graeme Laurie, *Consent or Property? Dealing with the Body and Its Parts in the Shadow of Bristol and Alder Hey*, 64 The Modern L. Review, (2001), 710-729, 717, (Dec. 13, 2017), http://www.jstor.org/stable/1097277?seq=1&cid=pdf-reference#refer ences\_tab\_contents.

<sup>&</sup>lt;sup>118</sup> Kenyon Mason & Graeme Laurie, *Consent or Property? Dealing with the Body and Its Parts in the Shadow of Bristol and Alder Hey*, 64 The Modern L. Rev., (2001), 710-729, 716, (Dec. 12, 2015), http://www.jstor.org/stable/1097277?seq=1&cid=pdf-reference#references\_tab\_contents.

<sup>&</sup>lt;sup>119</sup> T. M. Wikinsin, *Individual and Family Consent to Organ and Tissue Donation: Is the Current Position Coherent?*, 31 J. Med. Ethics, 587-590 (2005), (May 19, 2015), http://www.jstor.org/stable/27719491.

Second proposition is that the consent of the next kin in this regard has to be considered. The right to give or withhold consent, has to be seen as a prerogative of the living.<sup>120</sup> Pre-death wishes do not matter much because, once deceased, the individual's welfare cannot be affected, or not greatly affected, by decisions about the use of their body. But this claim fails to recognise any posthumous interests of an individual.<sup>121</sup>

It should also be noted that "the earliest thinking about the basis for procuring organs reflected the common sense view that the body of the deceased - the 'mortal remains'- was no longer of any use to the dead person. It was not even of any use to the surviving family".<sup>122</sup> But in reality, we try to respect the autonomy of the deceased, yet relatives are just as likely, if not more so, to exercise a right to consent or refuse in a manner that reflects their own interests rather than those of the deceased. There would be very bad effects if there is a conflicting interest and this may cause great strain on family relations among the living or because it would harm significant posthumous interest.<sup>123</sup>

<sup>&</sup>lt;sup>120</sup> V. English & A. Sommervill, *Presumed Consent for Transplantation: A Dead Issue After Alder Hey*?, 29 J. of Med. Ethics, 147-152, 147 (2003).

<sup>&</sup>lt;sup>121</sup> T. M. Wikinsin, *Individual and Family Consent to Organ and Tissue Donation: Is the Current Position Coherent?*, 31 J. Med. Ethics, 587-590 (2005), (May 19, 2015), http://www.jstor.org/stable/27719491.

<sup>&</sup>lt;sup>122</sup> ROBERT M. VEATCH & LAINIE F. ROSS, TRANSPLANTATION ETHICS, (Georgetown University Press), 147 (2015).

<sup>&</sup>lt;sup>123</sup> T. M. Wikinsin, *Individual and Family Consent to Organ and Tissue Donation: Is the Current Position Coherent?*, 31 J. Med. Ethics, 587-590 (2005), (May 19, 2015), http://www.jstor.org/stable/27719491.

Article 9 of the Convention on Human Rights and Biomedicine,<sup>124</sup> also known as the Oviedo Convention, 1997<sup>125</sup> mandates that "the previously expressed wishes relating to a medical intervention by a patient who is not, at the time of the intervention, in a state to express his or her wishes shall be taken into account". Hence, it can be seen that unless there is an express wish which has been communicated by the decedent, the wishes of the relatives or legal heirs may act as the final word.

# 7.6. 'CONSENT' FOR ORGAN HARVESTING IN VARIOUS LEGAL FRAMEWORKS

Consent of the concerned person is considered to be utmost important in treatments, medical procedures as well as in organ procurement. Consent in relation to the treatments and medical intervention has been developed over years through a series of cases. Consent of the research participant in relation to research using human materials has also been brought under a proper regulatory machinery. Legal framework of consent in relation to organ harvesting in various countries have been discussed here.

<sup>&</sup>lt;sup>124</sup> Council of Europe, Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, European Treaty Series - No. 164, Oviedo, 4. IV.1997, (Jul. 12, 2016), https://rm. coe.int/ 168007cf98.

<sup>&</sup>lt;sup>125</sup> It is the first legally binding international text designed to preserve human dignity, fundamental rights and freedoms, through a series of principles against the misuse of biological and medical applications. The Convention is inspired by the principle of the primacy of human beings over the sole interest of science or society. It lays down a series of principles applying to medical practice as well as biomedical research, organ transplantation and genetics. *Guide to the Quality and Safety of Tissues and Cells for Human Application*, (Jul. 24, 2018), https://www.tripnet.nl/pages/nl/documents/Guidetothequalityandsafetyof tissuesandcellsforhumanapplication2ndedition.pdf.

Globally, organ procurement laws can be broadly classified as 'opt-in' system and 'opt out system'. Many European countries have adopted the 'opt-out' or the 'presumed consent' system for organ procurement. This system presumes that the decedent has consented to the harvest of his or her organs following death unless that decedent has recorded his or her objection to such a harvest.

In presumed consent laws, there are three legal possibilities: removal of organs without the knowledge of the family, removal of organs after informing the family, and removal of organs after informed consent of the family.<sup>126</sup> According to this, there are two main kinds of presumed consent laws: Strong or hard presumed consent laws rely solely on the individual citizen to declare himself or herself a non-donor. Weak or soft presumed consent laws allow the family members of a decedent to opt-out if they desire to do so.<sup>127</sup>

Presumed consent as a system is adopted in many European countries with an aim to increase the supply of transplantable human organs and tissues.<sup>128</sup> Countries such as Belgium<sup>129</sup>,

<sup>&</sup>lt;sup>126</sup> ORGAN SHORTAGE: THE SOLUTIONS, PROCEEDINGS OF THE 26TH CONFERENCE ON TRANSPLANTATION AND CLINICAL IMMUNOLOGY, (J. L. Touraine, J. Traeger, et al., eds.), 1995.

<sup>&</sup>lt;sup>127</sup> Sam Crowe & Eric Cohen, *Organ Transplantation Policies and Policy Reforms*, The President's Council on Bioethics, (Jun. 03, 2016), https://bioethicsarchive.georgetown.edu/pcbe/background/organ\_donation.html#part3.

<sup>&</sup>lt;sup>128</sup> Alejandra Zúñiga-Fajuri, Increasing Organ Donation by Presumed Consent and Allocation Priority: Chile, Bulletin of the World Health Organisation, (Aug. 23, 2018), http://www.who. int/bulletin/volumes/93/3/14-139535/en/.

<sup>&</sup>lt;sup>129</sup> In Belgium, "absolute priority is given to the will of the deceased. Every citizen has the right to decide to be a donor or to refuse donation and no one can over-rule this decision. In the town halls of all cities and villages, forms are available for the citizens to register their will and the data are entered in a national computerized registry accessible only to the transplant teams. At any time, individuals can modify their decision. If the deceased person did not register in

Spain<sup>130</sup>, Norway<sup>131</sup>, Finland<sup>132</sup>, Austria<sup>133</sup>, France<sup>134</sup>, etc., have adopted the

system of presumed consent in various degrees.

this way, the presumption is that he or she was willing to be an organ donor. The permission of the family is not required for organ retrieval but organs may not be removed if the family takes the initiative to oppose donation." Paul Michielsen, *Presumed Consent to Organ Donation: 10 years' Experience in Belgium*, 89 J. of the Royal Society of Medicine, 663-666, 663 (1996), (Aug. 27, 2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1296026/pdf/jrsocmed000 48-0009.pdf.

<sup>&</sup>lt;sup>130</sup> Spain is widely perceived in the transplant community as having one of the best organ donation programs in the world. Spain has by far the world's highest rate of organ donation from deceased donors. Spain has been following the system of presumed consent since 1979. *See*, Simon Bramhall, *Presumed Consent for Organ Donation: A Case Against*, 93 Ann. R. Coll. Surg. Engl., 270-272 (2011), (Oct. 26, 2016), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3363073/.

<sup>&</sup>lt;sup>131</sup> Persons who have reached the age of 16 have the right to consent that donation of organs, cells and tissues may be carried out after they have died. Once deceased has given consent, relatives cannot deny donation, Norwegian law on Donation and Transplantation of Organ, Cell and Tissue, Transplantation Act, 2015, (Jun. 23, 2018), https://www.global-regulation.com/translation/lop:norway/5961955/law-on-donation-and-transplantation-of-organ%252c-cell-an d-tissue-%2528 transplantation-act%2529.html.

<sup>&</sup>lt;sup>132</sup> "Organs, tissues and cells of a deceased person may be removed unless it is known or there is reason to assume that the person would have objected while still alive. If a person had, while still alive, forbidden the removal of his or her organs, tissues and cells, the measure may not be performed. Before removal of a deceased person's organs, tissues or cells for the purpose referred to in section 8 (1), the deceased person's opinion, while still alive, must be investigated as far as possible. If the deceased person is under-age, and due to his or her age and developmental level while still alive was not able to form an opinion of removal of his or her organs, tissues or cells, the measure can be performed unless the person's guardian objects to it. If an adult deceased person due to an illness, mental health disorder or for some other reason, while alive, was not able to form an opinion of removal of his or cells, the measure can be performed unless the person's guardian objects to it." § 9 of the Act on the Medical Use of Human Organs, Tissues and Cells, 2001, (Jul. 24, 2018), https://www.finlex.fi/en/laki/kaannokset/2001/en 20010101.pdf.

<sup>&</sup>lt;sup>133</sup> "Austria pursues a presumed-consent policy (opt-out system), i.e., organs, parts of organs or tissue may be removed from a potential donor if they did not object to organ donation during their lifetime. In order to ensure the effective documentation of objections against organ donation, Austria has established an opting-out registry of persons refusing organ donation. Besides objections documented in this registry, any other form of declaration of a deceased person's will regarding post-mortal organ donation, such as an informal document found among the identity papers of the deceased, or an oral declaration made in the presence of family members, is being respected", Legal regulations in Austria, (Aug. 15, 2018), http://www. drze.de/in-focus/organ-transplantation/modules/rechtliche-regelung-in-oesterreich?setlangua ge=en.

<sup>&</sup>lt;sup>134</sup> The French law of 1976 presumes the consent of persons who do not, during their lifetime, expressly refuse to have their organs taken upon their death. The law states that "an organ to be used for therapeutic or scientific purposes may be removed from the cadaver of a person who has not during his lifetime made known his refusal of such procedure", ARGUING ABOUT BIOETHICS, (Stephen Holland, ed.), (Roultedge) 265 (2012).

The situation in other European countries is varied, but none has regulations as restrictive as the United Kingdom.<sup>135</sup> The United Kingdom<sup>136</sup>, Sweden<sup>137</sup> and Denmark<sup>138</sup> have an 'opting-in' law.<sup>139</sup> United States is strictly following the volunteer organ donation system of informed consent.<sup>140</sup> The countries of Southern Europe, Scandinavia, Asia, and South America have adopted laws that permit procurement without consent.<sup>141</sup>

In India, under the Transplantation of Human Organs Act, 1994, (hereinafter referred to as THOA) the 'opting-in' form of consent for retrieval of organs from deceased is proposed. It is based on the principle of 'authorisation', an expression which is intended to convey that people have the right to express, during their lifetime, their wishes about what should happen to their bodies after

<sup>&</sup>lt;sup>135</sup> Peter Furness, Consent to Using Human Tissue: Implied Consent Should Suffice, 327 BMJ, 759–760, (2003), (May 30, 2016).

<sup>&</sup>lt;sup>136</sup> § 1 of the Human Tissue Act, 2004 provides for the requirement of appropriate consent for the activities specified under the Act. § 3 defines the term 'appropriate consent'. The statute gives much significance to the consent of the person concerned thereby emphasising on the opt-in system of consent for organ donation. (Apr. 19, 2016), https://www.legislation.gov.uk/ukpga/2004/30/pdfs/ukpga\_20040030\_en.pdf.

<sup>&</sup>lt;sup>137</sup> Sweden switched to a presumed consent system in 1996. In Sweden, health professionals do not override the deceased's registered wish to be a donor in the case of an objection from next-of-kin but will respect an objection if there is no such record. Amanda M. Rosenblum, Lucy D. Horvat, et al., *The Authority of Next-of-Kin in Explicit and Presumed Consent Systems for Deceased Organ Donation: An Analysis of 54 Nations*, 27 Nephrology Dialysis Transplantation, 2533-2546 (2012), (Aug. 27, 2018), https://doi.org/10.1093/ndt/gfr619.

<sup>&</sup>lt;sup>138</sup> Amanda M. Rosenblum, Lucy D. Horvat, et al., *The Authority of Next-of-Kin in Explicit and Presumed Consent Systems for Deceased Organ Donation: An Analysis of 54 Nations*, 27 Nephrology Dialysis Transplantation, 2533-2546 (2012), (Aug. 27, 2018) https://doi.org/10. 1093/ndt/gfr619.

<sup>&</sup>lt;sup>139</sup> P. Michielsen, *Effect of Transplantation Laws on Organ Procurement*, (1995), (Jul. 23, 2018), https://link.springer.com/chapter/10.1007%2F978-94-011-0201-8\_5.

<sup>&</sup>lt;sup>140</sup> BARBARA MAIER & WARREN A. SHIBLES, THE PHILOSOPHY AND PRACTICE OF MEDICINE AND BIOETHICS: A NATURALISTIC - HUMANISTIC APPROACH, (Springer), 323 (2011).

<sup>&</sup>lt;sup>141</sup> ROBERT M. VEATCH & LAINIE F. ROSS, TRANSPLANTATION ETHICS, Georgetown University Press, 148 (2015).

death, in the expectation that those wishes will be respected.<sup>142</sup> Authorisation to remove an organ of a deceased reflects the principle of 'consent' on which the THOA is based.

As biotechnology opens new doors to improve the quality of human life, the legal community must expand the existing legal framework to accommodate them. The increasing need for human tissues and body parts for transplantation, experimentation and education, coupled with a demonstrated public willingness to donate cadaver parts makes it necessary to lay down clearly the law to acquire consent for the same.

The laws relating to consent has to be viewed from the cultural background of various states or the form of society existing there. In practice, the societies of liberal Western culture like the United States emphasizes on the donation model where the doctrine of informed consent governs the practice of medicine as well as organ procurement. Confronted with a choice between the morality of organ donation and the autonomy of the individual, various European countries sacrificed the ideal of personal autonomy for a system of presumed consent.<sup>143</sup> Thus, the societies which give more central authority to the community or state,

<sup>&</sup>lt;sup>142</sup> Anju Vali Tikoo, *Transplantation of Human Organs: The Indian Scenario*, 1 ILI Rev., 147-174, 154 (2017).

<sup>&</sup>lt;sup>143</sup> David E. Jefferies, *The Body as Commodity: The Use of Markets to Cure the Organ Deficit*, 5 Ind. J. of Global Legal Studies, 621-658, 634 (1998), http://www.repository.law.indiana.edu/ ijgls/vol5/iss2/13.

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authorizes it to use the individual for important societal purposes even without individual consent.<sup>144</sup>

# 7.7. CONCEPT OF CONSENT IN MEDICAL RESEARCH

Fundamental ethical requirements in any intervention on the body of a person is that, it should be based on a voluntary and informed consent. Well-established guidelines and regulations governing the use of human subjects for research are already in place throughout the world. These principles have been articulated in various internationally recognized research ethics guidelines since the second world war. The earliest expression of the principle of consent in medical research is found in the Nuremberg Code, 1947<sup>145</sup>. The Code makes it mandatory to obtain voluntary and informed consent of human subjects.<sup>146</sup>

The Helsinki Declaration, 1964,<sup>147</sup> emphasised the importance of obtaining freely given informed consent for medical research by adequately informing the subjects about the aims, methods, anticipated benefits, potential hazards, and

<sup>&</sup>lt;sup>144</sup> ROBERT M. VEATCH & LAINIE F. ROSS, TRANSPLANTATION ETHICS, Georgetown University Press, 154 (2015).

<sup>&</sup>lt;sup>145</sup> "The Nuremberg Code was adopted immediately after World War II in response to medical and experimental atrocities committed by the German Nazi regime". Omprakash V. Nandimath, *Consent and Medical Treatment: The Legal Paradigm in India*, 25 IJU, 343-347 (2009), (Aug. 10, 2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2779959/.

<sup>&</sup>lt;sup>146</sup> Principle 1, Nuremberg Code, 1947, from Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10. Nuremberg, October 1946-April 1949. Washington, D.C.: U.S. G.P.O, 1949-1953. (Aug. 10, 2018), https://history.nih.gov/research/downloads/nuremberg.pdf.

<sup>&</sup>lt;sup>147</sup> The World Medical Association (hereinafter referred to as WMA) developed a set of guidelines to safeguard the rights and well-being of participants in clinical research. The set of guidelines was adopted by the 18<sup>th</sup> WMA General Assembly and was called the Declaration of Helsinki.

discomforts that the study may entail.<sup>148</sup> The Declaration also stressed the importance of having an ethics committee review a research proposal, which included an informed consent document comprising patient/participant information sheet and informed consent form.<sup>149</sup> Later, the Belmont Report, 1979, highlighted three main ethical principles while conducting research, namely, respect for persons, beneficence, and justice.<sup>150</sup>

Several international conventions and declarations have similarly ratified the importance of obtaining consent from patients before testing and treatment.<sup>151</sup> The Council for International Organizations of Medical Sciences<sup>152</sup> and the World Health Organization undertook and issued the proposed International Ethical Guidelines for Biomedical Research involving Human Subjects in 1982.<sup>153</sup> The purpose of the guidelines was to indicate the ethical

<sup>&</sup>lt;sup>148</sup> Principle 25 & 26 of WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects, Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964, (Aug. 10, 2018), https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/.

<sup>&</sup>lt;sup>149</sup> Nandini K. Kumar, *Informed Consent: Past and Present*, 4 Perspectives in Clinical Research, 21-25 (2013), (Aug. 22, 2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC 3601698/.

<sup>&</sup>lt;sup>150</sup> U.S. Department of Health and Human Services, Belmont Report, 1979, (Aug. 22, 2018), http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html.

<sup>&</sup>lt;sup>151</sup> Omprakash V. Nandimath, *Consent and Medical Treatment: The Legal Paradigm in India*, 25 IJU, 343-347 (2009), (Aug. 10, 2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2779959/.

<sup>&</sup>lt;sup>152</sup> "The Council for International Organizations of Medical Sciences (CIOMS) is an international nongovernmental organization in official relationship with WHO. It was founded under the auspices of WHO and the United Nations Educational, Scientific and Cultural and Organization (UNESCO) in 1949", *Preface to the International Ethical Guidelines for Health Related Research Involving Humans*, (Aug. 22, 2018), https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf.

<sup>&</sup>lt;sup>153</sup> "The aim of the guidelines was (and still is) to provide internationally vetted ethical principles and detailed commentary on how universal ethical principles should be applied, with particular attention to conducting research in low-resource settings", *International Ethical Guidelines for Health Related Research Involving Humans*, (Aug. 22, 2018), https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf.

principles that should guide the conduct of biomedical research involving human subjects.<sup>154</sup>

Chapter II of the European Convention on Human Rights and Biomedicine,<sup>155</sup> details about the requirement of free and informed consent. Article 5 of the Convention lays down the general rules with regard to the requirement of consent in the following words: "An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it. This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks." Moreover, it also stipulates that "the person concerned may freely withdraw consent at any time".<sup>156</sup> Further, Article 22 forbids the storage and use of the body material that was originally taken from the patient for another purpose without "appropriate information and consent procedures".<sup>157</sup>

Article 6 of the UNESCO<sup>158</sup> Universal Declaration on Bioethics and Human Rights, 2005 speaks about the requirement of consent.<sup>159</sup> Clause 1 of Article 6

<sup>&</sup>lt;sup>154</sup> The Guidelines was subsequently revised 3 times. In 1993, in 2002 and later in 2016. *International Ethical Guidelines for Health Related Research Involving Humans*, (Aug. 22, 2018), https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf.

<sup>&</sup>lt;sup>155</sup> Council of Europe, Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, European Treaty Series-No. 164, Oviedo, 4. IV.1997, (Jul. 12, 2016), https://rm.coe.int/168007cf98.

<sup>&</sup>lt;sup>156</sup> Chapter 2, Article 5 of the Convention on Human Rights and Biomedicine, 1997.

<sup>&</sup>lt;sup>157</sup> Article 5 of the Convention on Human Rights and Biomedicine, 1997.

<sup>&</sup>lt;sup>158</sup> The United Nations Educational, Scientific and Cultural Organization.

<sup>&</sup>lt;sup>159</sup> The UNESCO Universal Declaration on Bioethics and Human Rights, 2005 (Apr. 20, 2018), http://portal.unesco.org/en/ev.php-URL\_ID=31058&URL\_DO=DO\_TOPIC&URL\_SECTIO N=201.html.

mandates that "any preventive, diagnostic and therapeutic medical intervention is only to be carried out with the prior, free and informed consent of the person concerned, based on adequate information". The consent should, where appropriate, be express and may be withdrawn by the person concerned at any time and for any reason without disadvantage or prejudice. Clause 2 requires that "scientific research should only be carried out with the prior, free, express and informed consent of the person concerned."

Principle 4.1, of the International Society for Stem Cell Research, Guidelines for the Conduct of Human Embryonic Stem Cell Research, 2006, states that "Fundamental ethical requirements in research include review and approval of projects by a panel that is independent of the investigators, and voluntary and informed consent from any human participants."<sup>160</sup>

# 7.8. CONSENT: A LEGAL TOOL FOR TRANSACTIONS IN THE HUMAN BODY AND BODILY MATERIALS

If a doctor used the deceased's organs, and this conflicted with the deceased patient's values, then on one view, that patient's past autonomy is not respected. But likewise, if doctors do not use the deceased's organs, and the deceased patient would have wanted them used, then also there is a failure to respect the

<sup>&</sup>lt;sup>160</sup> International Society for Stem Cell Research, Guidelines for the Conduct of Human Embryonic Stem Cell Research, Version 1, 2006, (Aug. 20, 2018), https://www.forth.gr/\_gfx/pdf/ISSCRhESCguidelines2006.pdf.

deceased's past values and autonomy.<sup>161</sup> Therefore, the current practice across most part of the globe is to take consent of the donor for organ donation during life and consent of the relatives/legal heirs after death of the donor for organ procurement.<sup>162</sup>

Thus, a human person is not just the physical self which one see from outside. There is an inherent value or dignity attributed to every individual, what is referred to as 'personhood'. A sound and healthy person should be given the choice to take decisions pertaining to his life and his body. For this very reason, informed consent, bodily integrity and personal autonomy should be protected and well preserved. Thus, in the case of living people, the body parts can only be used with the consent of the individual. In case of the dead, organs can only be taken if they had consented for the removal prior to death.<sup>163</sup> In both the situations, consent of the source person should be predominant.

<sup>&</sup>lt;sup>161</sup> J. Savulescu, *Death, Us and Our Bodies: Personal Reflections*, (Jun. 1, 2012), http://jme. bmj.com/content/29/3/127.full.

 <sup>&</sup>lt;sup>162</sup> M. S. Vinay Kumar & Sameer Valsangkar, *Ethical and Legal Issues of Presumed Consent*,
 36 J. Indian Acad. Forensic Med., 404-406 (2014), http://medind.nic.in/jal/t14/i4/ jalt14
 i4p404.pdf.

<sup>&</sup>lt;sup>163</sup> J. Savulescu, Death, *Us and Our Bodies: Personal Reflections*, (Jun. 1, 2012), http://jme. bmj.com/content/29/3/127.full.

# VIII. LEGAL FRAMEWORK IN RELATION TO THE COMMERCIALISATION OF THE HUMAN BODYAND BODILY MATERIALS

# **8.1. INTRODUCTION**

The success and growth of organ and tissue transplantation worldwide has highlighted the fact that organ shortage would remain a universal problem, which prevents many patients from receiving the benefits of transplantation.<sup>1</sup> A serious consequence of this shortage is that many patients will not have access to the waiting lists for transplantation, and worse still, that a considerable number of patients on the waiting list will die every year without ever getting a transplant. Such deaths are, to a certain extent, avoidable if sufficient organs are available.<sup>2</sup>

It is not surprising that the desperation of patients waiting for transplants may lead to different forms of organ commercialisation, whereby organs and tissues from living and deceased persons, are bought and sold, which leads to the

<sup>&</sup>lt;sup>1</sup> Organ Shortage: Current Status and Strategies for Improvement of Organ Donation - A European Consensus Document, (Oct. 04, 2018), https://www.edqm.eu/medias/fichiers/Organ\_shortagecurrent\_status\_and\_strategies\_for\_improvement\_of\_organ\_donation\_A\_Euro pean\_consensus\_document.pdf.

<sup>&</sup>lt;sup>2</sup> Sebastian Giwa, Jedediah K. Lewis JK, et al., *The Promise of Organ and Tissue Preservation to Transform Medicine*, 35 Nature Biotechnology, 530-542 (2017), (Oct. 04, 2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5724041/. *See* also, *Trafficking in Human Organs*, European Parliament, DIRECTORATE-GENERAL FOR EXTERNAL POLICIES POLICY DEPARTMENT, 28 (Sept. 11, 2014), http://www.europarl.europa.eu/RegData/etudes/STUD/ 2015/549055/EXPO\_STU(2015)549055\_EN.pdf. *See* also, *Keeping Kidneys*, 90 Bulletin of the World Health Organization, 718-719 (2012), (Oct. 04, 2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3471055/.

trafficking of human beings for removing their organs.<sup>3</sup> In the past few decades, transplantation has become a successful worldwide practice. However, there are large differences between countries in access to suitable transplantation and in the level of safety, quality, efficacy of donation and transplantation of human cells, tissues and organs. The ethical aspects of transplantation are at the forefront. In particular, the shortage of availability of transplantable human organs has led to the temptation of trafficking in human body components for transplantation.<sup>4</sup>

The legal framework in relation to the commercialisation of human body and bodily materials is vague and sometimes confusing also. The policy of various legislatures on the question of property in human body, and commercialisation of the human body and body parts are meant with the term 'legal framework'.

# 8.2. COMMERCIALISATION OF THE HUMAN BODY: THE LEGAL FRAMEWORK

Whether or not statutory intervention is needed in matters that are directly related to medical practice was the question faced by various legislatures initially. "It was relatively uncommon for legislation to intervene directly in the practice of medicine, but early in the development of transplantation procedures it was felt

<sup>&</sup>lt;sup>3</sup> "Organ trafficking had over a period of last few decades changed from a hidden illicit activity into a widespread visible activity that involved thousands of illegal transplants per year, using organs from poor, vulnerable and poorly compensated 'donors', originating mainly from Pakistan, India, Egypt, the Philippines, China and Colombia", *Trafficking in Human Organs*, European Parliament, DIRECTORATE-GENERAL FOR EXTERNAL POLICIES POLICY DEPARTMENT, 30 (Sept. 11, 2014), http://www.europarl.europa.eu/RegData/etudes/STUD/ 2015/549055/EXPO\_STU (2015)549055\_EN.pdf.

<sup>&</sup>lt;sup>4</sup> World Health Organisation on Transplantation, (Jul. 18, 2018), http://www.who.int/ transplantation/en/.

appropriate to institute legal control over the purposes for which, and the circumstances in which, human tissue and/or organs could be used after death for transplantation and for the purpose of medical education and research."<sup>5</sup>

In the past decades a number of international and European standards have been developed to create a comprehensive ethical and legal framework, consisting of guidelines and binding legal instruments, that make it possible to prohibit commercialisation of human body parts and to combat and prevent trafficking in human beings for the removal of organs.<sup>6</sup>

# 8.2.1. INTERNATIONAL INITIATIVES TO COMBAT COMMERCIALISATION OF THE HUMAN BODY

Among the few international organisations<sup>7</sup> that have made statements on the status of human material, the tendency has been to present general policy positions rather than precise statements. The Committee on Morals and Ethics of

<sup>&</sup>lt;sup>5</sup> Sheila M. McLean, Alastair Campbell, et al., *Human Tissue Legislation and Medical Practice: A Benefit or a Burden?*, 8 Med. Law Int., 1-21 (2006), (Dec. 27, 2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2493386.

<sup>&</sup>lt;sup>6</sup> *Trafficking in Human Organs*, European Parliament, DIRECTORATE-GENERAL FOR EXTERNAL POLICIES POLICY DEPARTMENT, 28 (Sept. 11, 2014), http://www.europarl.europa.eu/RegData/etudes/STUD/2015/549055/EXPO\_STU(2015)549055\_EN.pdf.

<sup>&</sup>lt;sup>7</sup> The World Health Organization (WHO), the World Medical Association (WMA), The Transplantation Society (TTS), International Society of Nephrology (ISN), etc., have made important steps to help curb the growing problem of trafficking in human beings for the removal of organs.

the Transplantation Society<sup>8</sup> (hereinafter referred to as TTS) in 1970 made the first effort to prohibit commercialisation of human organs.<sup>9</sup>

In September 1985, Council of the TTS proposed a series of 'guidelines for the distribution and the use of organs from cadaver sources and from living unrelated donors'.<sup>10</sup> Paragraph 6 of the said guidelines prescribes that "transplant surgeons/physicians should not advertise regionally, nationally. or internationally".<sup>11</sup> Paragraph 2 of the guidelines for the donation of kidneys by unrelated living donors states: "It must be established by the patient and transplant team alike that the motives of the donor are altruistic and in the best interest of the recipient and not self-serving or for profit".<sup>12</sup> The Council of the same society in a special resolution stated: "No transplant surgeon/team shall be involved directly or indirectly in buying or selling of organs/tissues or in any transplant activity aimed at commercial gain to himself or an associated hospital

<sup>&</sup>lt;sup>8</sup> The Transplantation Society is the leading international society of physicians, surgeons and scientists involved in the transplantation of organs and tissues. It is a Non-Governmental Organization which serves as an international forum for the world-wide advancement of organ transplantation. It is comprised of more than 6700 members who are professionals with an active interest in basic science, clinical research and/or improving clinical practice in the field of transplantation. TTS is a diverse international Society with members across the globe where 105 countries are represented, (Jul. 18, 2018), https://www.tts.org/index.php?option=com\_ content&view=article&id=11&Itemid=223.

<sup>&</sup>lt;sup>9</sup> It affirmed that "The sale of organs by donors living or dead is indefensible under any circumstances", WHO, 44<sup>th</sup> World Health Assembly, A44/11, 15 Mar. 1991, (Jul. 18, 2018), http://apps.who.int/iris/bitstream/handle/10665/173746/WHA44\_11\_eng.pdf?sequence=1&is Allowed=y.

<sup>&</sup>lt;sup>10</sup> LEGISLATIVE RESPONSES TO ORGAN TRANSPLANTATION, World Health Organisation, (Martinus Nijhoff Publishers), 462 (1994).

 <sup>&</sup>lt;sup>11</sup> WHO, 44<sup>th</sup> World Health Assembly, A44/11, 15 Mar. 1991, (Jul. 18, 2018), http://apps. who.int/iris/bitstream/handle/10665/173746/WHA44\_11\_eng.pdf?sequence=1&isAllowed=y.
 <sup>12</sup> WHO, 44<sup>th</sup> World Health Assembly, A44/11, 15 Mar. 1991, (Jul. 18, 2018), http://apps. who.int/iris/bitstream/handle/10665/173746/WHA44\_11\_eng.pdf?sequence=1&isAllowed=y.

or institute. Violation of these guidelines by any member of the Transplantation Society may be cause for expulsion from the society."<sup>13</sup>

In addition, the 37<sup>th</sup> World Medical Association<sup>14</sup> (hereinafter referred to as WMA) at its meeting in Brussels, in October 1985, condemned the commercialisation of human organs. <sup>15</sup> Further, the 40<sup>th</sup> World Health Assembly<sup>16</sup> (hereinafter referred to as WHA) meeting in Geneva,<sup>17</sup> urged for the development of guiding principles on human organ transplants. The WHA affirmed that such trade is inconsistent with the most basic human values and contravenes the Universal Declaration of Human Rights, 1948<sup>18</sup> (hereinafter referred to as WHO) Constitution.<sup>19</sup>

<sup>&</sup>lt;sup>13</sup> The Transplantation Society, Policy and Ethics, (Jul. 18, 2018), https://www.tts.org/index.php?option=com\_content&view=article&id=11&Itemid=223.

<sup>&</sup>lt;sup>14</sup> Founded in 1947, the World Medical Association is an international and independent confederation of free professional medical associations, representing physicians worldwide., (Jul. 25, 2018), https://www.wma.net/.

<sup>&</sup>lt;sup>15</sup> WMA condemned purchase and sale of human organs for transplantation and called on the governments of all countries to take effective steps to prevent the commercial use of human organs. World Medical Association, *Statement on Live Organ Trade, 1985*, Adopted by the 37<sup>th</sup> World Medical Association, Brussels, Belgium, October 1985.

<sup>&</sup>lt;sup>16</sup> "The WHA is the decision-making body of the WHO. It is attended by delegations from all WHO Member States and focuses on a specific health agenda prepared by the Executive Board. The main functions of the World Health Assembly are to determine the policies of the Organization, appoint the Director-General, supervise financial policies, and review and approve the proposed programme budget.", (Oct. 04, 2018), http://www.who.int/mediacentre/ events/governance/wha/en./

<sup>&</sup>lt;sup>17</sup> Fortieth World Health Assembly, Geneva, 1987, WHA40.13 Development of guiding principles for human organ transplants, (Jul.25, 2018), http://www.who.int/transplantation/en/WHA40.13.pdf?ua=1.

<sup>&</sup>lt;sup>18</sup> Article 4 of the UDHR states: "No one shall be held in slavery or servitude; slavery and the slave trade shall be prohibited in all their forms".

<sup>&</sup>lt;sup>19</sup> WHA 40.13 Development of guiding principles for human organ transplants, (Jul.25, 2018), http://www.who.int/transplantation/en/WHA40.13.pdf?ua=1.

The WHA requested that the WHO<sup>20</sup> would develop guiding principles for human organ transplants. In pursuit of the WHA recommendation, the WHO developed the "Guiding Principles on Human Organ Transplantation" in 1991 to assist national authorities in developing robust national programmes for organ transplantation. In its 1991 Guiding Principles,<sup>21</sup> the WHO adopted the position that "the human body and its parts could not be subject to commercial transactions".<sup>22</sup>

In October 2000, the WMA adopted its Statement on Human Organ Donation and Transplantation.<sup>23</sup> It promoted a policy based on ethical principles to give guidance to medical associations, physicians and other healthcare providers on issues relating to organ donation and transplantation. The statement highlighted the universal principle of non-commercialisation of human organs. The statement of the 65<sup>th</sup> WMA General Assembly<sup>24</sup> urged for the prohibition of payment for organs. "A financial incentive compromises the voluntariness of the

<sup>&</sup>lt;sup>20</sup> Through Resolution WHA 40.13.

<sup>&</sup>lt;sup>21</sup> WHO Guiding Principles on Human Organ Transplantation, endorsed by the Assembly in 1991 in resolution WHA44.25.

<sup>&</sup>lt;sup>22</sup> WHO developed the Guiding Principles with the following key elements: 1) preference for deceased over living organ donors; 2) preference for genetically related over unrelated living donors; 3) preconditions in all cases: (a) informed consent by a competent person (b) free of undue influence or pressure 4) non-commercialization (no sale or purchase, no payment for organ, no profit from organ); and, 5) fair distribution of organs (equitable access to a common resource.), *WHO Guiding Principles on Human Organ Transplantation Report of the Regional Meeting*, WHO Regional Office for the Western Pacific Kuala Lumpur, Malaysia June 8 – 10, 5 (2009), (Jul. 18, 2018) http://www.wpro.who.int/health\_technology/documents/docs/Human OrganTransplantationMeetingReport.pdf.

<sup>&</sup>lt;sup>23</sup> WMA Statement on Human Organ Donation and Transplantation, (Jul. 25, 2016), https://www.wma.net/policies-post/wma-statement-on-human-organ-donation-and-transplantaion/.

<sup>&</sup>lt;sup>24</sup> Durban, South Africa, October 2014, (Jul. 25, 2018), https://www.wma.net/policiespost/wma-statement-on-human-organ-donation-and-transplantation/. The WMA Statement aims to provide guidance to all health professionals, both individual and as members of medical associations, but has no legally binding character.

choice and the altruistic basis for organ donation. Furthermore, access to needed medical treatment based on ability to pay is inconsistent with the principles of justice. Organs suspected to have been obtained through commercial transaction must not be accepted for transplantation."<sup>25</sup> In addition, the advertisement of organs in exchange for money should also be prohibited.<sup>26</sup>

In 2004, the issues and challenges in organ transplantation were discussed at the WHA and the member states were urged to implement effective national oversight of procurement, processing and transplantation of human cells, tissues and organs, including ensuring accountability for human material for transplantation and its traceability. The WHA also urged them to take measures to protect the poorest and vulnerable groups from 'transplant tourism' and the sale of tissues and organs, including attention to the wider problem of international trafficking in human tissues and organs. The WHO was asked to update its Guiding Principles of 1991 and ensure global harmonization of practices including safety, quality, efficacy and ethics.<sup>27</sup> Pursuant to that, in 2004, the WHO called on member states "to take measures to protect the poorest and vulnerable states and the sale of tissues and organs, including attention to the wider problem of practices including safety, quality, efficacy and ethics.<sup>27</sup> Pursuant to that, in 2004, the WHO called on member states "to take measures to protect the poorest and vulnerable groups from transplant tourism and the sale of tissues and organs,

 <sup>&</sup>lt;sup>25</sup> WMA Statement on Human Organ Donation and Transplantation, (Jul. 25, 2018), https://www.wma.net/policies-post/wma-statement-on-human-organ-donation-and-transplantation/.
 <sup>26</sup> WMA Statement on Human Organ Donation and Transplantation, (Jul. 25, 2018), https://

www.wma.net/policies-post/wma-statement-on-human-organ-donation-and-transplantation/. <sup>27</sup> WHO Guiding Principles On Human Organ Transplantation Report of the Regional Meeting, WHO Regional Office for the Western Pacific Kuala Lumpur, Malaysia June 8 – 10, 5 (2009), (Jul. 18, 2018) http://www.wpro.who.int/health\_technology/documents/docs/Human OrganTransplan tationMeetingReport.pdf.

including attention to the wider problem of international trafficking in human tissues and organs."<sup>28</sup>

As a result, WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation, 2010<sup>29</sup>, was framed. It endorses that "the cells, tissues and organs should only be donated freely, without any monetary payment or other reward of monetary value. Purchasing, or offering to purchase cells, tissues or organs for transplantation, or their sale by living persons or by the next of kin for deceased persons, should be banned".<sup>30</sup> The prohibition on sale or purchase of cells, tissues and organs does not preclude reimbursing reasonable and verifiable expenses incurred by the donor, including loss of income, or paying the costs of recovering, processing, preserving and supplying human cells, tissues or organs as well as any other commercial dealings in human tissues and cells should be prohibited by member states.<sup>32</sup>

 <sup>&</sup>lt;sup>28</sup> World Health Assembly Resolution 57.18, *Human Organ and Tissue Transplantation*, 22
 May 2004, (Jul. 18, 2018), http://www.who.int/gb/ebwha/pdf\_files/WHA57/A57\_R18-en.pdf.
 <sup>29</sup> As endorsed by the sixty-third World Health Assembly in May 2010, in Resolution WHA 63.22, (Aug 13, 2014), http://www.who.int/transplantation/Guiding\_PrinciplesTransplantation WHA63.22en.pdf.

<sup>&</sup>lt;sup>30</sup> Principle 5 of the WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation, 2010, (Mar. 12, 2016), http://www.who.int/transplantation/Guiding\_Princip lesTransplantation\_WHA63.22en.pdf.

<sup>&</sup>lt;sup>31</sup> As endorsed by the sixty-third World Health Assembly in May 2010, in Resolution WHA 63.22, (Aug 13, 2014), http://www.who.int/transplantation/Guiding\_PrinciplesTransplantation\_WHA63.22en.pdf.

<sup>&</sup>lt;sup>32</sup> The WHO standards and principles provide guidance to countries' health authorities and health professionals, but they are not legally binding in character. *Trafficking in Human Organs*, European Parliament DIRECTORATE-GENERAL FOR EXTERNALPOLICIES POLICY DEPARTMENT, 28 (Sept. 11, 2014), http://www.europarl.europa.eu/RegData/ etudes/STUD/ 2015/549055/EXPO\_STU(2015)549055\_EN.pdf.

The commentary on Guiding Principle 5 states that the "payment for cells, tissues and organs is likely to take unfair advantage of the poorest and most vulnerable groups, undermines altruistic donation, and leads to profiteering and human trafficking".<sup>33</sup> Besides preventing trafficking in human materials, this Principle aims to affirm the special merit of donating human materials to save and enhance life.<sup>34</sup> It also mandates that "the national law should ensure that any gifts or rewards are not, in fact, disguised forms of payment for donated cells, tissues or organs".<sup>35</sup> It also adds that the incentives in the form of 'rewards' with monetary value that can be transferred to third parties are not different from monetary payments.<sup>36</sup>

Further, the WMA in 2010 required that the national legal frameworks should address each country's particular circumstances because the risks to donors and recipients vary.<sup>37</sup> Each jurisdiction should determine the details and method of the prohibitions it will use, including sanctions which may encompass joint action with other countries in the region. The ban on paying for cells, tissues and organs should apply to all individuals, including transplant recipients who

<sup>&</sup>lt;sup>33</sup> Such payment conveys the idea that some persons lack dignity, that they are mere objects to be used by others.

<sup>&</sup>lt;sup>34</sup> However, it allows for circumstances where it is customary to provide donors with tokens of gratitude that cannot be assigned a value in monetary terms.

<sup>&</sup>lt;sup>35</sup> The commentary on Principle 5 of the WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation, 2010, (Mar. 12, 2016), http://www.who.int/transplantation/Guiding\_Principles Transplantation\_WHA63.22en.pdf.

<sup>&</sup>lt;sup>36</sup> The commentary on Principle 5 of the WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation, 2010, (Mar. 12, 2016), http://www.who.int/transplantation/Guiding\_Principles Transplantation\_WHA63.22en.pdf.

<sup>&</sup>lt;sup>37</sup> As endorsed by the sixty-third World Health Assembly in May 2010, in Resolution WHA63.22, (Aug. 22, 2016), http://www.who.int/transplantation/Guiding\_PrinciplesTransp lantation\_WHA 63.22en.pdf.

attempt to circumvent domestic regulations by travelling to locales where prohibitions on commercialization are not enforced.<sup>38</sup>

The representatives of the world transplant community met in Istanbul<sup>39</sup> in 2008, to discuss the growing transplant commerce and transplant tourism. It defined 'transplant commercialism' as "a policy or practice in which an organ is treated as a commodity, including by being bought or sold or used for material gain".<sup>40</sup> Moreover, "organ trafficking and transplant tourism violate the principles of equity, justice and respect for human dignity and should be prohibited. Because transplant commercialism targets impoverished and otherwise vulnerable donors, it leads inexorably to inequity and injustice and should be prohibited".<sup>41</sup>

The Declaration of Istanbul is not a legally binding treaty or law enforcement instrument either, but essentially a statement aiming to guide the professional behaviour of physicians and health care institutions. It provides a set of moral principles to govern organ donation and transplantation in general, as well as practice proposals to combat, curb and prevent human organ trafficking. The Istanbul Declaration also proclaims that the poor who sell their organs are being

<sup>&</sup>lt;sup>38</sup> As endorsed by the sixty-third World Health Assembly in May 2010, in Resolution WHA63.22, (Aug. 22, 2016), http://www.who.int/transplantation/Guiding\_PrinciplesTransp lantation\_WHA 63.22en.pdf.

<sup>&</sup>lt;sup>39</sup> Declaration of Istanbul on Organ Trafficking and Transplant Tourism, 2008.

<sup>&</sup>lt;sup>40</sup> The Declaration of Istanbul on Organ Trafficking and Transplant Tourism, 2008, (Jul. 25, 2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2813140/.

<sup>&</sup>lt;sup>41</sup> Principle 6, The Declaration of Istanbul on Organ Trafficking and Transplant Tourism, Participants in the International Summit on Transplant Tourism and Organ Trafficking convened by The Transplantation Society and International Society of Nephrology in Istanbul, Turkey, April 30–May 2, 2008, (Jul. 18, 2018), http://multivu.prnewswire.com/mnr/transplant ationsociety/ 33914/docs/33914-Declaration\_of\_Istanbul-Lancet.pdf.

exploited, whether by richer people within their own countries or by transplant tourists from abroad.<sup>42</sup> Participants in the Istanbul Summit concluded that transplant commercialism, transplant tourism, and organ trafficking should be prohibited.<sup>43</sup> They also urged their fellow transplant professionals, individually and through their organizations, to put an end to these unethical activities and foster safe, accountable practices that meet the needs of transplant recipients while protecting donors.<sup>44</sup>

There are other important international documents which also which reaffirm that the human body and its parts should not give rise to financial gains. Some declarations by the United Nations Educational, Scientific and Cultural Organization (hereinafter referred to as UNESCO), particularly the Universal Declaration on the Human Genome and the Human Rights, 1997, <sup>45</sup> the International Declaration on Human Genetic Data, 2003,<sup>46</sup> and the Universal

<sup>&</sup>lt;sup>42</sup> The Declaration of Istanbul on Organ Trafficking and Transplant Tourism, 3 Clin. J. Am. Soc. Nephrol., 1227-1231 (2008), (Jul. 18, 2018), https://www.ncbi.nlm.nih.gov/pubmed/ 18701611/.

<sup>&</sup>lt;sup>43</sup> The Declaration of Istanbul on Organ Trafficking and Transplant Tourism, 3 Clin. J. Am. Soc. Nephrol., 1227-1231 (2008), (Jul. 18, 2018), https://www.ncbi.nlm.nih.gov/pubmed/ 18701611/.

<sup>&</sup>lt;sup>44</sup> The Declaration of Istanbul on Organ Trafficking and Transplant Tourism, 3 Clin. J. Am. Soc. Nephrol., 1227-1231 (2008), (Jul. 18, 2018), https://www.ncbi.nlm.nih.gov/pubmed/ 18701611/.

<sup>&</sup>lt;sup>45</sup> Article 4 states that "The Human Genome in its natural state shall not give rise to financial gains." (Aug. 04, 2018), http://unesdoc.unesco.org/images/0012/001229/122990eo.pdf.

<sup>&</sup>lt;sup>46</sup> Preamble of the International Declaration on Human Genetic Data, 2003 affirms the "increasing importance of human genetic data for economic and commercial purposes", International Declaration on Human Genetic Data. Paris, France: UNESCO, 2003. (Jul. 18, 2018), http://www.unesco.org/new/en/social-and-human-sciences/themes/bioethics/humangenetic-data/.

Declaration on Bioethics and Human Rights, 2005,<sup>47</sup> repeat the need for noncommercialization and prohibition of the use of the human body for profit.<sup>48</sup>

Thus, the principle that the human body and its parts cannot, as such, be an object of commercialisation or a source of profit is enshrined in numerous authoritative documents.<sup>49</sup>

### 8.2.2. EUROPEAN INITIATIVES

The human body and its parts are widely perceived as matters beyond commercial usage. This belief is codified in several national and European documents. This so called 'no-property rule' is held to be the default position across the countries of the European Union. <sup>50</sup> Article 21 of the European Convention on Human Rights and Biomedicine,<sup>51</sup> states that "the human body and its parts shall not, as such, give rise to financial gain". The Additional Protocol to the Convention on Human Rights and Tissues of Human Origin, 2002<sup>52</sup> for the first time

<sup>&</sup>lt;sup>47</sup> Universal Declaration on Bioethics and Human Rights, Paris, France, UNESCO; 2005, (Jul. 17, 2018), http://www.unesco.org/new/en/social-and-human-sciences/themes/bioethics/bio ethics-and human-rights/.

 <sup>&</sup>lt;sup>48</sup> Carlo Petrini, Ethical and Legal Considerations Regarding the Ownership and Commercial Use of Human Biological Materials and Their Derivatives, J. of Blood Med., 87-96, 90 (2012).
 <sup>49</sup> Carlo Petrini, Ethical and Legal Considerations Regarding the Ownership and Commercial

*Use of Human Biological Materials and their Derivatives*, 3 J. of Blood Med., 87-96, 90 (2012). <sup>50</sup> Christian Lenk, & Katharina Beier, *Is the Commercialisation of Human Tissue and Body Material Forbidden in the Countries of the European Union?*, 38 J.M.E., 342-346, (Jul. 12, 2016), http://www.jstor.org/stable/23215483.

<sup>&</sup>lt;sup>51</sup> Council of Europe, Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, European Treaty Series-No. 164, Oviedo, 4. IV.1997, (Jul. 12, 2016), https://rm. coe.int/168007cf98.

<sup>&</sup>lt;sup>52</sup> Council of Europe, European Treaty Series-No.186, 2002, (Jul. 25, 2018), https://rmcoe.int /1680081562.

directly prohibits organ and tissue trafficking.<sup>53</sup> It also formulates appropriate sanctions to any infringement of these provisions.<sup>54</sup> Similar provisions could be seen in the Council of Europe's Recommendation, 2006.<sup>55</sup> Article 7 of the same<sup>56</sup> states that "the biological materials should not, as such, give rise to financial gain".

Although the main purpose of the European Directive Concerning the Therapeutic use of Human Tissue and Cells,<sup>57</sup> is to ensure the safety of the therapeutic use of tissue and cells at a medical or technical level, it also contains an interesting paragraph about the principles that should guide the procurement of tissue and cells for therapeutic uses. Article 18 of the Directive<sup>58</sup> states that "as a matter of principle, tissue and cell application programmes should be founded on the philosophy of voluntary and unpaid donation, anonymity of both donor and recipient, altruism of the donor and solidarity between the donor and the recipient. Member States are urged to take steps to encourage a strong public and non-profit sector involvement in the provision of tissue and cell application

<sup>&</sup>lt;sup>53</sup> Article 22.

<sup>&</sup>lt;sup>54</sup> Article 24.

<sup>&</sup>lt;sup>55</sup> Council of Europe Committee of Ministers Recommendation [Rec (2006) 4] to the Member States on Research on Biological Materials of Human Origin, Adopted by the Committee of Ministers on 15 March 2006 at the 98<sup>th</sup> meeting of the Ministers' Deputies, (Jun. 09, 2018), https://www.coe.int/t/dg3/healthbioethic/Activities/10\_Biobanks/Rec%282006%294%20EM %20E.pdf.

<sup>&</sup>lt;sup>56</sup> Recommendations of the Council of Europe can give orientation in a specific field, but have no binding power.

<sup>&</sup>lt;sup>57</sup> The EU Tissue Directive (2004/23/EC) of the European Parliament and of the Council, 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells, (May 23, 2017), https://eur-lex.europa.eu/Lex-UriServ/LexUriServ.do?uri=OJ:L:2004:102:0048:0058:en:PDF. <sup>58</sup> The EU Tissue Directive (2004/23/EC), (May 23, 2017), https://eur-lex.europa.eu/Lex-UriServ/LexUriServ/LexUriServ/DF.

services and the related research and development."<sup>59</sup> This normative rule is surely compatible with the 'no-property rule' and also shows general support for non-profit activities.<sup>60</sup>

Moreover, many European Union countries have adopted the 'presumed consent'<sup>61</sup> system for organ procurement.<sup>62</sup> Presumed consent as a method of increasing organ supply was chosen over commercialisation because trade in human organs is inconsistent with the EU objective and the negative opinion of the European Parliament on commercialisation of organs is well known.<sup>63</sup> Thus the above mentioned high-profile European documents demonstrates a clear tendency towards the avoidance of commercialisation of human material.<sup>64</sup>

### 8.3 NATIONAL LEGISLATIONS IN RELATION TO COMMERCIALISATION OF

#### THE HUMAN BODY AND PARTS

Commercial transaction in human organs and human biological materials are controlled in various jurisdictions at various levels. Certain countries have completely prohibited any forms of commercial transactions involving human

<sup>&</sup>lt;sup>59</sup> The EU Tissue Directive (2004/23/EC), (May 23, 2017), https://eur-lex.europa.eu/Lex-Uri Serv/LexUriServ.do?uri=OJ:L:2004:102:0048:0058:en:PDF.

<sup>&</sup>lt;sup>60</sup> Christian Lenk, & Katharina Beier, *Is the Commercialisation of Human Tissue and Body Material Forbidden in the Countries of the European Union?*, 38 J.M.E., 342-346, (Jul. 12, 2016), http://www.jstor.org/stable/23215483.

<sup>&</sup>lt;sup>61</sup> This system presumes the decedent has consented to the harvest of organs following death unless that decedent has recorded his or her objection to such a harvest.

<sup>&</sup>lt;sup>62</sup> For a detailed discussion, *see* chapter VII.

<sup>&</sup>lt;sup>63</sup> David E. Jefferies, *The Body as Commodity: The Use of Markets to Cure the Organ Deficit*,
5 Indiana J. of Global Legal Studies, 621-658, 634 (Apr. 05, 2016), http://www. repository.
law.indiana.edu/ijgls/vol5/iss2/13.

<sup>&</sup>lt;sup>64</sup> Christian Lenk, & Katharina Beier, *Is the Commercialisation of Human Tissue and Body Material Forbidden in the Countries of the European Union?*, 38 J. M. E., 342-346, (Jul. 12, 2016), http://www.jstor.org/stable/23215483.

organs and materials, violation of which attracts penal provisions.<sup>65</sup> Certain other countries have controlled the commercial transactions in human materials by prescribing a well drafted regulatory framework.<sup>66</sup> Though trade in human materials are prohibited, non-profit altruistic donations are promoted where compensatory payments for such donations are allowed in some of the countries.<sup>67</sup> On the other extreme, we can see certain countries where commercial dealings are promoted in human organs and human tissues for monetary consideration.<sup>68</sup>

### 8.3.1. THE UNITED KINGDOM

United Kingdom<sup>69</sup> (hereinafter referred to as the UK) is one of the countries which has always tried to incorporate laws in tune with scientific advancements, especially in relation to medical science and biotechnology. UK law concerning the regulation of the use of human material has developed over time. This development in law is either motivated by the desire to regulate due to the concerns regarding new scientific developments or is driven by specific scandals.<sup>70</sup>

<sup>&</sup>lt;sup>65</sup> Countries like India, UK, Pakistan, USA, Canada, Australia, Norway, etc.

<sup>&</sup>lt;sup>66</sup> Countries like Spain, Belgium, Germany, etc.

<sup>&</sup>lt;sup>67</sup> Countries like USA, Canada, Pakistan, etc.

<sup>&</sup>lt;sup>68</sup> Islamic Republic of Iran, through Governmental policies, promotes commercial dealings in human organs for transplantation. For a detailed discussion, *see* 7.3.11.

<sup>&</sup>lt;sup>69</sup> The United Kingdom, made up of England, Scotland, Wales and Northern Ireland, is an island nation in north western Europe, with more than 6 crores population. (Oct. 05, 2018), https://en.wikipedia.org/wiki/United\_Kingdom.

<sup>&</sup>lt;sup>70</sup> PRINCIPLES OF MEDICAL LAW, (Andrew Grubb, Judith Laing, et al. eds.), (3<sup>rd</sup> edn., Oxford University Press), 1011 (2010).

The involvement of English Law in the use of human bodies for scientific purposes has a long history. Legislations of UK starting with the Murder Act, 1752 to the latest Human Tissue Act, 2004 (hereinafter referred to as HTA) has been covered in order to understand how the English statutory law has treated the human body and the materials procured from the human body.

The Murder Act, 1752 allowed the dissection of corpses of executed murderers in London. The Act provided that "in no case whatsoever shall the body of any murderer be suffered to be buried",<sup>71</sup> by mandating either 'public dissection' or the cadaver being 'hanged in chains'. The Act also stipulated that a person found guilty of murder should be executed two days after being sentenced.<sup>72</sup> The Act thus added dissection to the sentence of death with the requirement that the corpses of murderers in London were to be cut up at Surgeon's Hall.<sup>73</sup> Later, the Murder Act was repealed in 1828.

Some unsavoury practices of the late 18<sup>th</sup> and early 19<sup>th</sup> century anatomists<sup>74</sup> led to the passing of the Anatomy Act, 1832. This statute provided that anyone intending to practice anatomy should obtain a licence from the home secretary.<sup>75</sup>

<sup>&</sup>lt;sup>71</sup> §§ 85 of the Murder Act, 1752, *See*, JONATHAN SAWDAY, THE BODY EMBLAZONED: DISSECTION AND THE HUMAN BODY IN RENAISSANCE CULTURE, (Roultedge), 55 (2006).

<sup>&</sup>lt;sup>72</sup> (Dec. 27, 2017), https://en.wikipedia.org/wiki/Murder\_Act\_1751.

<sup>&</sup>lt;sup>73</sup> Susan C. Lawrance, *Beyond the Grave - The Use and Meaning of Human Body Parts: A Historical Introduction*, Faculty Publications, Department of History, University of Nebraska – Lincoln, Paper 37, 118 (1998), (Jun. 12, 2016), http://digitalcommons.unl.edu/historyfacpub. <sup>74</sup> "The shortage of corpses resulted in attempts to obtain bodies by whatever means, leading to body snatchers or 'resurrectionists' grave robbing and in some instances committing murder." *See*, PRINCIPLES OF MEDICAL LAW, (Andrew Grubb, Judith Laing et al. eds.), (3<sup>rd</sup> edn., Oxford University Press), 1011 (2010).

<sup>&</sup>lt;sup>75</sup> Anatomy Act, 1832, (Oct. 04, 2018), http://www.irishstatutebook.ie/eli/1832/act/75/enacted /en/print.html.

a person having lawful possession of a body may permit it to undergo anatomical examination, provided no relative object to it.<sup>76</sup> The Act also sanctioned the use of bodies of those persons who had died without relatives or with insufficient money to pay for the funeral.<sup>77</sup>

The next significant step in terms of formal regulation of the use of human material came in the form of the Human Tissue Act, 1961, (hereinafter referred to as HTA, 1961).<sup>78</sup> The HTA, 1961 gave statutory authority to the person lawfully in possession of a dead body to use that body towards certain designated ends. It governed the use of organs removed from cadavers<sup>79</sup> and enabled the people to choose to donate material before their death through a declaration in writing or orally in the presence of two witnesses.<sup>80</sup>

<sup>&</sup>lt;sup>76</sup> § 7 of the Anatomy Act, 1832.

<sup>&</sup>lt;sup>77</sup> This Act became the standard model for Anatomy Acts passed in Canada, Australia and other British Territories as well as in various States in America from the mid 1930's to 1920's. *See* Susan C. Lawrance, *Beyond the Grave - The Use and Meaning of Human Body Parts: A Historical Introduction*, Faculty Publications, Department of History, University of Nebraska – Lincoln, Paper 37, 118, (1998), (Jun. 12, 2016), http://digitalcommons.unl.edu/historyfacpub. <sup>78</sup> Enacted soon after the first organ transplantation.

<sup>&</sup>lt;sup>79</sup> PRINCIPLES OF MEDICAL LAW, (Andrew Grubb, Judith Laing, et al. eds.), (3<sup>rd</sup> edn., Oxford University Press), 1012 (2010).

<sup>&</sup>lt;sup>80</sup> § 1 of the Human Tissue Act, 1961 states: (1) "If any person in writing at any time or orally in the presence of two or more witnesses during his last illness has expressed a request that his body or any specified part of his body be used after his death for therapeutic purposes or for purposes of medical education or research, the person lawfully in possession of the body after his death may, unless he has reason to believe that the request was subsequently withdrawn, authorise the removal from the body of any part or, as the case may be, the specified part, for use in accordance with the request.

<sup>(2)</sup> Without prejudice to the foregoing subsection, the person lawfully in possession of the body of a deceased person may authorise the removal of any part from the body for use for the said purpose if, having made such reasonable enquiry as may be practicable, he has no reason to believe - a. that the deceased had expressed an objection to his body being so dealt with after his death, and had not withdrawn it; or b. that the surviving spouse or any surviving relative of the deceased objects to the body being so dealt with."

The HTA, 1961 also enabled the person lawfully in possession of the body to authorise removal of organs after death.<sup>81</sup> This legislation, which applied throughout UK, was passed at a time when transplantation was in its early stages. Its terms related to the removal of organs/tissue from cadavers for medical purposes, such as for transplantation, research and education. It was concerned with the uses to which removed organs could lawfully be put to and under whose authority it could be done. The HTA, 1961 is, however, simply an enabling statute, in that it does not give any substantive rights over a human body. It merely legitimises certain dealings in very specific circumstances.<sup>82</sup> The HTA, 1961 insisted that the removal of organs shall be done by a registered medical practitioner, who must have satisfied himself by personal examination of the body that the life is extinct.<sup>83</sup> The statute also provides for the procedure to be followed when the body is lying in a hospital or a nursing home.<sup>84</sup>

The statute enabled organs and tissue to be used for therapeutic purposes, including transplantation, and/or for all or part of a body to be donated for the purposes of medical education or research. It is this legislation that provided the authority for hospital post mortems.<sup>85</sup> Even then, HTA, 1961 did not contain a regulatory framework. Nor does it explicitly require consent to be given for the taking, storage or use of organs or tissue, though it does require 'reasonable

<sup>&</sup>lt;sup>81</sup> § 1 of the Human Tissue Act, 1961, (May. 20, 2016), http://www.legislation.gov.uk/ukpga/ 1961/54/pdfs/ ukpga\_19610054\_en.pdf.

<sup>&</sup>lt;sup>82</sup> § 1 of the Human Tissue Act, 1961.

<sup>&</sup>lt;sup>83</sup> § 1 (4) of the Human Tissue Act, 1961.

<sup>&</sup>lt;sup>84</sup> §§ 1(5), (6), (7) & (8) of Human Tissue Act, 1961.

<sup>&</sup>lt;sup>85</sup> § 1 of the Human Tissue Act, 1961.

enquiry' to be made of relatives to establish 'lack of objection' where the deceased person had not made his or her wishes known.<sup>86</sup>

Later, the Anatomy Act of 1984 was enacted to make provisions for the use of bodies of the deceased persons and body parts for anatomical examination and regarding the possession and disposal of bodies of deceased persons and parts of such bodies, etc. The statute stressed on the requirement of licence from the Secretary of the State to carry out anatomical examination or to have possession of anatomical specimens. Under the statute, consent of the person during his last illness is required in order to use his body after his death for anatomical examinations.<sup>87</sup> This statute is of relevance only to the dissection of the human body for the purposes of teaching or studying, or researching into morphology.<sup>88</sup> Regulation of anatomy included a requirement for whole bodies to be specifically bequeathed for use in medical education.<sup>89</sup> Bodies bequeathed under the Anatomy Act, 1984 cannot be used for surgical skills training or for research.<sup>90</sup> The Act was repealed in whole by the Human Tissue Act, 2004, (hereinafter referred to as HTA).

<sup>&</sup>lt;sup>86</sup> Human Bodies: Human Choices, The Law on Human Organs and Tissue in England and Wales, A Consultation Report, by the Department of Health, (Jan. 03, 2018), http://webarchive. Nationalarchives.gov.uk/0120106110916/, http://www.dh.gov.uk/prod\_consum\_dh/groups/d h\_di gitalassets/@dh/@en/documents/digitalasset/dh\_4060264.pdf.

<sup>&</sup>lt;sup>87</sup> § 4 of the Anatomy Act, 1984 provides that the person concerned, either in writing at any time or orally, in the presence of two or more witnesses during his last illness, has expressed a request that his body be used after his death for anatomical examination.

<sup>&</sup>lt;sup>88</sup> § 1(1) of the Anatomy Act, 1984.

<sup>&</sup>lt;sup>89</sup> § 1(5) of the Anatomy Act, 1984.

<sup>&</sup>lt;sup>90</sup> Sheila M. McLean, Alastair Campbell et al., *Human Tissue Legislation and Medical Practice: A Benefit or a Burden?*, 8 Med. Law Int., 1-21 (2006), (Dec. 27, 2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2493386/.

The Corneal Tissue Act, 1986 and the Human Organ Transplants Act, 1989 deal directly with the aspects of transplantation. The Corneal Tissue Act, 1986 permitted removal of eyes or parts of eyes for therapeutic purposes and purposes of medical education and research by persons who are medically qualified. This statute was also repealed by the Human Tissue Act, 2004.<sup>91</sup>

The Human Organ Transplants Act, 1989 was enacted to prohibit the sale for transplantation, not only of living organs but, also, of dead organs.<sup>92</sup> It established a blanket ban on commercial dealings in human organs.<sup>93</sup> The statute also criminalised commercial dealings and advertisement for commercial dealing.<sup>94</sup> The said statute restricted the transplantation of organs between persons who are not genetically related,<sup>95</sup> although permission for unrelated donation could be obtained from the Unrelated Live Transplants Regulatory Authority<sup>96</sup>. The whole statute has been repealed by the HTA.

<sup>&</sup>lt;sup>91</sup> It was passed following the scandals at the Bristol Royal Infirmary and the Royal Liverpool Children's Hospital (Alder Hey) in 1999-2000. The details of these scandals were revealed in the Kennedy and Redfern inquiries. "It was discovered that body parts and organs from dead children were retained without consent or knowledge of the parents. It was discovered that there were 54,000 organs and body parts of children and fetuses retained, mostly without proper consent having being obtained". *See* JONATHAN HERRING, MEDICAL LAW AND ETHICS, (3<sup>rd</sup> edn., Oxford University Press), 400-401 (2010).

<sup>&</sup>lt;sup>92</sup> This Statute was also enacted in the backdrop of a scandal, popularly known as the Crocket Case. Poor Turkish organ donors were brought over to the UK and were paid to donate organs for transplantation. PRINCIPLES OF MEDICAL LAW, (Andrew Grubb, Judith Laing, et al. eds.), (3<sup>rd</sup> edn., Oxford University Press), 1012 (2010).

<sup>&</sup>lt;sup>93</sup> § 1 of the Human Organ Transplants Act, 1989.

<sup>&</sup>lt;sup>94</sup> § 1 (2) of the Human Organ Transplants Act, 1989.

<sup>&</sup>lt;sup>95</sup> § 2 of the Human Organ Transplants Act, 1989. § 2(2) explains that the persons genetically related are "natural parents, children, brothers and sisters of whole or half blood, the brothers and sisters of whole or half-blood of either of his natural parents and the natural children of his brothers and sisters of the whole or half blood or of the brothers and sisters of the whole or half blood or of the brothers and sisters of the whole or half-blood of either of his natural parents.

<sup>&</sup>lt;sup>96</sup> Unrelated Live Transplants Regulatory Authority (ULTRA) was established in 1990, to consider applications made by registered medical practitioners seeking approval to transplant

The HTA makes provisions to regulate activities involving human tissues. It prohibits commercial dealings in human material for transplantation.<sup>97</sup> The HTA deals with only certain kind of human material<sup>98</sup> and does not deal with some kind of human materials such as sperm, eggs, embryos, etc.<sup>99</sup> The HTA on the whole does not give any property rights in the human body or bodily materials. On a plain reading, one may conclude that the HTA eschews any appeal to a property model in respect of human material, preferring instead a system of consent or dissent to legitimise certain key uses in the contexts of therapy, education or research. But, on a detailed analysis, it can be seen that the statute recognises the Common Law principle of 'application of human skill' as a condition for attributing property interest to human materials.<sup>100</sup>

an organ between 2 living unrelated persons in the United Kingdom. In September 2006, the ULTRA disbanded. Its functions were transferred to the Human Tissue Authority, a Non-departmental public body of the Department of Health in 2006.

<sup>&</sup>lt;sup>97</sup> § 32 states thus: "Prohibition of commercial dealings in human material for transplantation (1) A person commits an offence if he— (a) gives or receives a reward for the supply of, or for an offer to supply, any controlled material; (b) seeks to find a person willing to supply any controlled material for reward; (c) offers to supply any controlled material for reward; (d) initiates or negotiates any arrangement involving the giving of a reward for the supply of, or for an offer to supply, any controlled material; (e) takes part in the management or control of a body of persons corporate or un incorporate whose activities consist of or include the initiation or negotiation of such arrangements. (2) Without prejudice to subsection (1)(b) and (c), a person commits an offence if he causes to be published or distributed, or knowingly publishes or distributes, an advertisement - (a) inviting persons to supply, or offering to supply, any controlled material for reward, or (b) indicating that the advertiser is willing to initiate or negotiate any such arrangement as is mentioned in subsection (1)(d)."

<sup>&</sup>lt;sup>98</sup> § 32 (8). For the purposes of this section, controlled material is any material which - (a) consists of or includes human cells, (b) is, or is intended to be removed, from a human body, (c) is intended to be used for the purpose of transplantation, and (d) is not of a kind excepted under subsection (9).

 $<sup>^{99}</sup>$  § 32 (9). The following kinds of material are excepted - (a) gametes, (b) embryos, and (c) material which is the subject of property because of an application of human skill.  $^{100}$  § 32 (9)(c) of the Human Tissue Act, 2004.

Thus the outright buying and selling of human organs remains severely restricted by the HTA. Pursuant to Section 32, any commercial dealings in human organs or other bodily material for the purposes of transplantation constitutes a criminal offence, punishable by imprisonment for up to 3 years, and/or a fine. The blanket ban does not equally apply where the purpose of the commercial dealing is something other than transplantation, although such transfers are none the less subject to certain licensing conditions and the need to obtain 'appropriate consent' as defined by the Act.<sup>101</sup> Thus the HTA is recognising that the use of human tissue is enormously important for research into medical illness and for training.<sup>102</sup>

Further, the Human Fertilization and Embryology Act, 1990 (hereinafter referred to as HFEA) specifically deals with the human materials that are exempted<sup>103</sup> from the scope of the HTA. Clause (e) of Section 12 specifically mandates that "no money or other benefit shall be given or received in respect of any supply of gametes or embryos unless authorised by Directions".<sup>104</sup> Clause 8 of Section 41

<sup>&</sup>lt;sup>101</sup> Kate Greasley, *A Legal Market in Organs: The Problem of Exploitation*, 40 J. of Med. Ethics, 51-56, 51 (2014), (Jul. 14, 2018), http://www.jstor.org/stable/43282912.

<sup>&</sup>lt;sup>102</sup> JONATHAN HERRING, MEDICAL LAW AND ETHICS, (Oxford University Press, 3<sup>rd</sup> edn.), 413 (2010).

<sup>&</sup>lt;sup>103</sup> Under clause 9 of § 32, human gametes and embryos are exempted from the purview of the Human Tissue Act, 2004.

<sup>&</sup>lt;sup>104</sup> Under the Human Fertilisation and Embryology Act 1990, the HFE Authority has the power to issue Directions - or rules, (May 22, 2016), http://www.hfea.gov.uk/188.html.

provides for stringent offences and penalties.<sup>105</sup> Clause 9 of Section 41 prescribes the punishment for any contravention.<sup>106</sup>

## 8.3.2. **BELGIUM**

Belgium<sup>107</sup> is a member of Eurotransplant<sup>108</sup> which is a consortium of eight European countries<sup>109</sup> that follows specific rules regarding organ distribution.<sup>110</sup> Belgium enacted an 'opt-out' system for human tissue in the case of deceased donors, applying the rules of its organ donation law<sup>111</sup> of 1986. For cadaveric donation, an 'opting-out' system is proposed, with the possibility for the Belgian

<sup>&</sup>lt;sup>105</sup> "Where a person to whom a licence applies or the holder of the licence gives or receives any money or other benefit, not authorised by directions, in respect of any supply of gametes, embryos or human admixed embryos, he is guilty of an offence."

<sup>&</sup>lt;sup>106</sup> A person guilty of an offence under subsection (8) above is liable on summary conviction to imprisonment for a term not exceeding six months or a fine not exceeding level five on the standard scale or both.

<sup>&</sup>lt;sup>107</sup> Belgium is a country in Western Europe bordered by France, the Netherlands, Germany and Luxembourg. It covers an area of 30,528 square kilometres and has a population of more than 11 million. This European country has been very active in the field of transplantation. Clinical transplantation activities were initiated in the early 1960s with the first, living and deceased, kidney transplantations. During these pioneering years, Belgium was recognized for carrying out the first deceased organ donation after the diagnosis of brain death in 1963, and the first long-term survival (10 months) after lung transplantation in 1968. Olivier Detry, Dominique Van Deynse et al., *Organ Procurement and Transplantation in Belgium*, 101 www.transplantjournal.com, 1953-1955, 1953 (2017), (Jul. 18, 2018), https://pdfs.Semantic scholar.org/3198/ 653fa9e8bc90f82f8e3a30938a66 c6bc16b2.pdf.

<sup>&</sup>lt;sup>108</sup> Established in 1967.

<sup>&</sup>lt;sup>109</sup> Austria, Belgium, Croatia, Germany, Hungary, Luxemburg, The Netherlands, and Slovenia, (Jul. 15, 2018), http://www.eurotransplant.org/cms/index.php?page=home.

<sup>&</sup>lt;sup>110</sup> *Commercialisation of Body Part- Health\_Belgium*, Advisory Committee for Bioethics, Opinion No. 43 of 10 Dec. 2007 on the Problem of Commercialisation of Human Body Parts, (Jun. 30, 2018), https://www.health.belgium.be/sites/default/files/uploads/fields/fpshealth\_theme\_file/15532535/Opinion%20no.%2043%20of%2010%20December%202007%20on% 2 0the%20problem%20of%20commercialisation%20of%20human%20body%20parts%20.pdf.

<sup>&</sup>lt;sup>111</sup> Law on Procurement and Transplantation of Organs, Belgian Official Journal, 14 Feb. 1987, *Ministère de la Justice et Ministère de la Santé Publique et de l'Environnement, Loi sur le prélèvement et la transplantation d'organes. Belgian Monitor (Moniteur Belge), Belgisch Staatsblad,* February 14, 1987: 2129-2140, (Aug. 05, 2018), http://www.aciirt.be/downloads/loi19860613donorganes.pdf.

citizens to register 'for' or 'against' organ donation.<sup>112</sup> This legislation makes a distinction between removal from a living donor and removal after death. It prohibits people from parting with organs or tissues for the purpose of profit.<sup>113</sup> This requirement does not prevent the donor from being reimbursed for the costs he has incurred or for any loss of earnings he may have suffered as a direct result of the donation. The Belgian transplantation law <sup>114</sup> also allows organ procurement from informed live adult donors. It also forbids any financial remuneration for deceased or living organ donation.<sup>115</sup> The law regulates the procurement of organs for therapeutic purposes only. It also applies to the harvesting and transplantation of tissues.<sup>116</sup>

According to the Belgian law, "human tissue becomes a 'good' after separation from the human body, which can then be owned by the research institution".<sup>117</sup> "Access to the Belgian transplant waiting lists is limited to the citizens of Eurotransplant countries, or to candidates not from Belgium who have been

<sup>&</sup>lt;sup>112</sup> Olivier Detry, Dominique Van Deynse et al., *Organ Procurement and Transplantation in Belgium*, 101 www.transplantjournal.com, 1953-1955, 1953 (2017), (Jul. 18, 2018), https://pdfs.semantic scholar.org/3198/653fa9e8bc90f82f8e3a30938a66 c6bc16b2.pdf.

<sup>&</sup>lt;sup>113</sup> Chapter 1, Article 4 of Law on Procurement and Transplantation of Organs, Belgian Official Journal, 14 Feb. 1987.

<sup>&</sup>lt;sup>114</sup> Law on procurement and transplantation of organs, Belgian Official Journal, 14 Feb. 1987, *Ministère de la Justice et Ministère de la Santé Publique et de l'Environnement. Loi sur le prélèvement et la transplantation d'organes. Belgian Monitor (Moniteur Belge), Belgisch Staatsblad,* February 14, 1987: 2129-2140, (Aug. 05, 2018), http://www.aciirt.be/downloads/ loi19860613donorganes.pdf.

<sup>&</sup>lt;sup>115</sup> Olivier Detry, Dominique Van Deynse et al., *Organ Procurement and Transplantation in Belgium*, 101 www.transplantjournal.com, 1953-1955, 1953 (2017), (Jul. 18, 2018), https://pdfs.semanticscholar.org/3198/653fa9e8bc90f82f8e3a30938a66 c6bc16b2.pdf.

<sup>&</sup>lt;sup>116</sup> B. Roels & Y. Vanrenterghem, *Legal Aspects of Organ and Tissue Donation in Belgium*, 1 Annals of Transplantation, 39-43, 39 (1996).

<sup>&</sup>lt;sup>117</sup> Christian Lenk, & Katharina Beier, *Is the Commercialisation of Human Tissue and Body Material Forbidden in the Countries of the European Union?*, 38 J. M. E., 342-346, (Jul. 12, 2016), http://www.jstor.org/stable/23215483.

officially registered as residents in a Eurotransplant country for a period of more than six months".<sup>118</sup>

The law of 1994 on blood and blood derivatives of human origin<sup>119</sup> makes provision for a total ban on profit when blood and blood derivatives are removed. Blood is taken from volunteering unpaid donors, with their consent<sup>120</sup> and the price at which blood and blood derivatives are handed over and supplied is established in such a way that any possibility of profit being made is ruled out.<sup>121</sup> Moreover, no provision is made for the donor's costs to be reimbursed.<sup>122</sup>

Further, Article 5 of the law of 2003 on *in-vitro* embryo research<sup>123</sup> makes provision for a ban on embryos, gametes and embryonic stem cells being used for commercial purposes.<sup>124</sup> The law of 2007 on medically assisted reproduction and the use of surplus embryos and gametes<sup>125</sup> requires that donation of surplus embryos or gametes, and their use in a research programme, occurs on a non-

<sup>&</sup>lt;sup>118</sup> Olivier Detry, Dominique Van Deynse et al., *Organ Procurement and Transplantation in Belgium*, 101 www.transplantjournal.com, 1953- 55, 1953 (2017), (Jul. 18, 2018), https://pdfs. semanticscholar.org/3198/653fa9e8bc90f82f8e3a30938a66 c6bc16b2.pdf.

<sup>&</sup>lt;sup>119</sup> Belgian Official Journal, 8 October 1994.

<sup>&</sup>lt;sup>120</sup> Article 5.

<sup>&</sup>lt;sup>121</sup> Article 6.

<sup>&</sup>lt;sup>122</sup> Commercialisation of Body Part - Health\_Belgium, Advisory Committee for Bioethics, Opinion No. 43 of 10 Dec. 2007 on the Problem of Commercialisation of Human Body Parts, (Jun. 12, 2018), https://www.health.belgium.be/sites/default/files/uploads/fields/fpshealth\_ theme\_file/15532535/Opinion%20no.%2043%20of%2010%20December%202007%20on% 20the%20problem%20of%20commercialisation%20of%20human%20body%20parts%20.pdf <sup>123</sup> Belgian Official Journal, 28 May 2003.

<sup>&</sup>lt;sup>124</sup> Commercialisation of Body Part - Health\_Belgium, Advisory Committee for Bioethics, Opinion No. 43 of 10 Dec. 2007 on the Problem of Commercialisation of Human Body Parts, (Jun. 12, 2018), https://www.health.belgium.be/sites/default/files/uploads/fields/fpshealth\_ theme\_file/15532535/Opinion%20no.%2043%20of%2010%20December%202007%20on%2 Othe20problem%20of % 20commercialisation%20of%20human%20body%20parts%20.pdf.
<sup>125</sup> Belgian Official Journal, 17 July 2007.

fee-paying basis. The law expressly forbids the trade in surplus embryos<sup>126</sup> and more generally in human embryos and gametes<sup>127</sup>. With regard to the removal of gametes, the law states that the King may determine an allowance to cover travel expenses or loss of salary incurred by the person from whom the removal is effected, and the costs of hospital associated with the removal of ova in donors.<sup>128</sup> Here one can find the distinction between remuneration<sup>129</sup> and reimbursement<sup>130</sup> of costs.<sup>131</sup>

The statute on the procurement and use of the human body material destined for human medical applications or for scientific research purposes, 2008, defines the 'human body material'.<sup>132</sup> According to the statute, the human body material can only be procured by medical doctors in recognised hospitals and collected by a bank for the human body material, which must be operated by a certified hospital. From then on, the 'human body material manager'<sup>133</sup> is responsible for the use of the material, including the allocation to a patient or tissue establishment<sup>134</sup>. Banks for the human body materials should be set up as not-

<sup>&</sup>lt;sup>126</sup> Article 19.

<sup>&</sup>lt;sup>127</sup> Article 22 & Article 48.

<sup>&</sup>lt;sup>128</sup> Article 48.

<sup>&</sup>lt;sup>129</sup> Remuneration is forbidden where parts or products of the human body are concerned.

<sup>&</sup>lt;sup>130</sup> Reimbursement is allowed because it does not imply profit.

<sup>&</sup>lt;sup>131</sup> Commercialisation of Body Part - Health\_Belgium, Advisory Committee for Bioethics, Opinion No. 43 of 10 Dec. 2007 on the Problem of Commercialisation of Human Body Parts, (Jun. 12, 2018), https://www. health.belgium.be/sites/default/files/uploads/fields/fpshealth\_ theme\_file/15532535/Opinion%20no.%2043%20of%2010%20December%202007%20on%2 Othe%20problem%20of %20commercialisation%20of%20human%20body%20parts%20.pdf.
<sup>132</sup> Human biological material is defined as "any biological body material, including human tissues and cells, gametes, embryos and foetuses, as well as substances extracted there from, whatever the degree to which they have been processed".

<sup>&</sup>lt;sup>133</sup> A medical doctor affiliated to the bank.

<sup>&</sup>lt;sup>134</sup> "A tissue establishment means a tissue bank or a unit of a hospital or another body where activities of donation, procurement, testing, processing, preservation, storage or distribution of

for profit establishments.<sup>135</sup> Further, the prices for human tissue and cell 'products' and for some processes are fixed by Ministerial Decree. These prices basically cover the costs of processing and leave no room for unreasonable profits, thereby inherently preserving the not-for-profit character of these activities.<sup>136</sup>

Thus, in Belgium, the human body is considered property of the state. The medical profession is free to perform autopsies without being required to obtain an informed consent from the families of deceased persons. If the person himself has not objected in advance to autopsy, his or her consent is presumed.<sup>137</sup> Moreover, in Belgium, the legislation on the removal of organs after death is based on implicit consent, i.e., as long as no express objection has been made, every person who has been registered in the register of births, deaths and marriages, or in the aliens register, for at least six months, is considered a donor. Law provides for the possibility of this consent being explicitly confirmed. Finally, Belgium is the only European country which has fixed prices for body

human tissues and cells for human application are undertaken", (Oct. 04, 2018), https://www.hpra.ie/docs/default-source/publications-forms/guidance-documents/ia-g0024-guide-to-completion-of-tissue-establishment-annual-report-v5.pdf?sfvrsn=15.

<sup>&</sup>lt;sup>135</sup> Jean-Paul Pirnay et al., Access to Human Tissues for Research and Product Development: From EU Regulation to Alarming Legal Developments in Belgium, 16 EMBO Reports 557-562 (2015), (17 Apr. 2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4428037/pdf/embr 0016-0557.pdf.

<sup>&</sup>lt;sup>136</sup> Jean-Paul Pirnay et al., *Access to Human Tissues for Research and Product Development: From EU Regulation to Alarming Legal Developments in Belgium*, 16 EMBO Reports 557-562 (2015), (17 Apr. 2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC 4428037/pdf/embr 0016-0557.pdf.

<sup>&</sup>lt;sup>137</sup> OWNERSHIP OF THE HUMAN BODY - PHILOSOPHICAL CONSIDERATIONS ON THE USE OF HUMAN BODY AND ITS PARTS IN HEALTH CARE, (Henk A.M.J. Ten Have & Jose V.M. Velie, Eds.), (Kluwer Academic Publishers), 9 (1998).

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material.<sup>138</sup> It is the only European country where the EU Tissue Directive for the Therapeutic Use of Human Tissue and Cells was implemented into national law by also extending it to research on human tissue and cells.<sup>139</sup>

## 8.3.3. GERMANY

Germany<sup>140</sup> gives considerable space for the commercialisation of the human body material. In Germany, the body material becomes a possessable object after its separation from the human body. This object is then automatically owned by the person from whom it stems.<sup>141</sup> For conducting research with this body material, it is necessary that the initial owner transfers the property in the body material to the research institution - an act that is normally performed as part of the informed consent procedure.<sup>142</sup>

<sup>&</sup>lt;sup>138</sup> Christian Lenk, & Katharina Beier, *Is the Commercialisation of Human Tissue and Body Material Forbidden in the Countries of the European Union?*, 38 J.M.E., 342-346, (Jul. 12, 2016), http://www.jstor.org/stable/23215483.

<sup>&</sup>lt;sup>139</sup> Jean-Paul Pirnay et al., Access to Human Tissues for Research and Product Development: From EU Regulation to Alarming Legal Developments in Belgium, 16 EMBO Reports 557-562 (2015), (17 Apr. 2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4428037/pdf/ embr0016-0557.pdf.

<sup>&</sup>lt;sup>140</sup> Federal Republic of Germany is a sovereign state in central-western Europe. With nearly 83 million inhabitants, Germany is the most populous member state of the European Union. (Jul. 23, 2018), https://en.wikipedia.org/wiki/Germany. Germany is also a member of Eurotransplant along with Austria, Belgium, Croatia, Hungary, Luxemburg, The Netherlands, and Slovenia, (Jul. 15, 2018), http://www.eurotransplant.org/cms/index.php?page=home.

<sup>&</sup>lt;sup>141</sup> Christian Lenk, & Katharina Beier, *Is the Commercialisation of Human Tissue and Body Material Forbidden in the Countries of the European Union?*, 38 J. M. E., 342-346, (Jul. 12, 2016), http://www.jstor.org/stable/23215483.

<sup>&</sup>lt;sup>142</sup> Christian Lenk, & Katharina Beier, *Is the Commercialisation of Human Tissue and Body Material Forbidden in the Countries of the European Union?*, 38 J.M.E., 342-346, (Jul. 12, 2016), http://www.jstor.org/stable/23215483.

The German Transplantation Act, 1997<sup>143</sup> (*Transplantationsgesetz*), (hereinafter referred to as TPG) was enacted with an intention to create safety in core medical ethics issues and improve trust in transplant medicine. <sup>144</sup> The Act was thoroughly revised in 2012. <sup>145</sup> TPG deals with the donation, removal and transplantation of organs. It applies to the donation and removal of human organs, parts of organs or tissues for the purpose of transplanting of such organs. TPG prohibits trade in human organs. <sup>146</sup> But the provisions of this Act does not apply to blood and marrow or embryological and foetal organs and tissues. <sup>147</sup> The removal and transplantation of tissues is regulated by the Tissue Law, 2007. <sup>148</sup>

Section 17 of TPG imposes restrictions to carry on commerce with organs for therapeutic purposes, but includes no general prohibition of the commercialisation of the human body parts. Similarly, the German Transfusion Act, 1998,<sup>149</sup> under section 10 formulates that "taking of the donation shall take place gratuitously". However, taken literally, such wording does not forbid

<sup>&</sup>lt;sup>143</sup> Gesetz über die Spende, Entnahme und Übertragung von Organen und Geweben (*Transplantationsgesetz* - TPG), 1997, (Aug. 05, 2018), https://www.gesetze-im-internet.de/tpg/TPG.pdf.

<sup>&</sup>lt;sup>144</sup> Siegmund-Schultze Nicola, Organ Donation in Germany: Getting Out of a Tense Situation, (2013), (Jul. 19, 2018), https://ec.europa.eu/health/sites/health/files/blood\_tissues\_organs/ docs/ev\_20 131007\_art21\_en.pdf.

<sup>&</sup>lt;sup>145</sup> Organ Donation and Transplantation in Germany, 2012, (Oct. 05, 2018), https://www.dso. de/uploads/tx\_dsodl/DSO\_JB\_D\_2012\_e.pdf.

<sup>&</sup>lt;sup>146</sup> § 17 German Transplantation Act.

<sup>&</sup>lt;sup>147</sup> PETER DE CRUZ, COMPARATIVE HEALTHCARE LAW, Cavendish Publishing, 561 (2013).

<sup>&</sup>lt;sup>148</sup> German Tissue Act, 2007 defines the quality and safety standards for the donation, procurement, testing, processing, preservation, storage, and distribution of human tissues and cells.

<sup>&</sup>lt;sup>149</sup> *Gesetz zur Regelung des Transfusionswesens (Transfusionsgesetz* - TFG), (Oct. 05, 2018), https://www.gesetze-im-internet.de/tfg/TFG.pdf.

financial reward for the blood donor and can rather be seen as a normative ideal for the process of blood donation.<sup>150</sup>

# 8.3.4. NORWAY<sup>151</sup>

Norwegian law on donation and transplantation of organ, cell and tissue<sup>152</sup>, prohibits commercial exploitation under Section 20.<sup>153</sup> Section 18 makes provisions for compensation for expenses and lost revenue in connection with the donation.<sup>154</sup> The Health Research Act, (*Helseforskningsloven*) 2008<sup>155</sup>, also prohibits the commercial exploitation of research participants and human biological materials.<sup>156</sup>

<sup>&</sup>lt;sup>150</sup> Christian Lenk, & Katharina Beier, *Is the Commercialisation of Human Tissue and Body Material Forbidden in the Countries of the European Union?*, 38 J.M.E., 342-346, (Jul. 12, 2016), http://www.jstor.org/stable/23215483.

<sup>&</sup>lt;sup>151</sup> Norway, officially the Kingdom of Norway, is a Nordic country in North Western Europe with a population of 52.3 lakhs, (Oct. 10, 2018), https://en.wikipedia.org/wiki/Norway. <sup>152</sup> Lov om donasjon og transplantasjon av organ, celler og vev (transplantasjonslova), 2015, (Oct. 05, 2018), https://lovdata.no/dokument/NL/lov/2015-05-07-25.

<sup>&</sup>lt;sup>153</sup> § 20 states: "All actions that are intended to achieve financial gain as a result of the donation of organ, cells or tissues for transplantation, is prohibited. The same applies to all actions that contribute to that someone been received such financial gain", Lov *om donasjon og transplantasjon av organ, celler og vev (transplantasjonslova)*, (Jul. 20, 2018), https://www.global-regulation.com/translation/norway/5961955/law-on-donation-and-transplantation-of-or gan%252c-cell-and-tissue-%2528transplantation-act%2529.html.

<sup>&</sup>lt;sup>154</sup> § 18, Lov *om donasjon og transplantasjon av organ, celler og vev (transplantasjonslova)*, (Jul. 20, 2018), https://www.global-regulation.com/translation/norway/5961955/law-on-dona tion-and-transplantation-of-organ%252c-cell-and-tissue-%2528transplantation-act%2529.ht ml.

<sup>&</sup>lt;sup>155</sup> (Oct. 05, 2018), http://www.lovdata.no/all/hl-20080620-044.

<sup>&</sup>lt;sup>156</sup> § 8 of the Health Research Act, 2008, states: "Commercial exploitation of research participants, human biological material and personal health data in general is prohibited".

#### 8.3.5. SPAIN<sup>157</sup>

Human organ transplantation in Spain dates back to 1965 when the first renal grafts were performed in Barcelona and Madrid.<sup>158</sup> Spain enacted its first transplant legislation in 1979 and later in 1989 the National Transplantation Organisation (*Organización Nacional De Trasplantes*, hereinafter referred to as ONT) was established with the aim to promote transplantation.

Transplantation rates in Spain plateaued between the mid to late 1980's and it was not until the 1990s that significant improvements in rates were seen. These changes seemed to coincide with Spain abandoning its separate provincial organ donation programmes and nationalising control of its organ donation programme.<sup>159</sup> The Spanish system of organ donation has long been considered to be the 'gold standard' of deceased organ donation.<sup>160</sup> The Spanish model of organ procurement consists of eight main elements. They are: 1) three levels of transplant coordination system: national, regional and hospital, 2) a requirement that transplant coordinators be medical doctors, especially intensivists, 3) a

<sup>&</sup>lt;sup>157</sup> Officially the Kingdom of Spain, is a country mostly located on the Iberian Peninsula in Europe. Spain is a EU Community country with 39.66 million inhabitants divided into 17 autonomous regions, B. Miranda, M. Fernandez, et al., *Organ Donation in Spain*, 14 Nephrol. Dial. Transplant, 15-21 (1999), (Jul. 18, 2018), https://watermark.silverchair. com/140015.pdf?.

<sup>&</sup>lt;sup>158</sup> B. Miranda, M. Fernandez, et al., *Organ Donation in Spain*, 14 Nephrol. Dial. Transplant, 15-21 (1999), (Jul. 18, 2018), https://watermark.silverchair.com/140015.pdf?.

<sup>&</sup>lt;sup>159</sup> Brian H Willis & Muireann Quigley, *Opt-out Organ Donation: On Evidence and Public Policy*, 107 J. of the Royal Society of Medicine, 56-60, (2014), (Aug. 5, 2018), https://www.ncbi.nlm.nih.gov/pmc/ articles/PMC3914429/.

<sup>&</sup>lt;sup>160</sup> Brian H. Willis & Muireann Quigley, *Opt-out Organ Donation: On Evidence and Public Policy*, 107 J. of the Royal Society of Medicine, 56-60, (2014), (Aug. 5, 2018), https://www.ncbi.nlm.nih.gov/pmc/ articles/PMC3914429/.

central office of transplantation supporting all processes associated with transplantation, 4) quality assurance in the process of organ donation, 5) continuing effort to conduct a well-programmed training course for transplant coordinators, 6) financial support for both organ procurement and transplantation hospitals, 7) dedication to mass media publicity campaign, 8) adequate legislation including a definition of the brain death and the conditions for organ extraction.<sup>161</sup>

Spain has been known as the world-leading country for organ transplantation. The so-called Spanish Model is seen as the key to the improvement of facilitating transplantation in Spain. The Spanish Model has brought success to other countries such as Croatia, Portugal, etc.<sup>162</sup>

#### 8.3.6. FINLAND

Finland<sup>163</sup> belongs to Scandiatransplant.<sup>164</sup> Finnish Law on the medical use of human organs and tissues lays down provisions on 1) removal, storage and use of human organs, tissues and cells for the treatment of human disease or injury,

<sup>&</sup>lt;sup>161</sup> Mayumi Kobayashi, Joichi Usui, et al., *Situation Surrounding Organ Transplantation: A Comparison Between Spain and Japan*, Journal of Clinical Case Reports, (2015), (Jul. 03, 2018), https://www.omicsonline.org/open-accesssituation-surrounding-organ-transplantation-a-comp arison-bet ween-spain-and-japan-2165-7920-1000589.php?aid=60915.

<sup>&</sup>lt;sup>162</sup> Mayumi Kobayashi, Joichi Usui, et al., *Situation Surrounding Organ Transplantation: A Comparison Between Spain and Japan*, J. of Clinical Case Reports, (2015), (Oct. 05, 2018), https://www.omicsonline.org/open-accesssituation-surrounding-organ-transplantation-a-comp arison-between-spain-and-japan-2165-7920-1000589.php?aid=60915.

<sup>&</sup>lt;sup>163</sup> Republic of Finland is a country in Northern Europe. It is a Nordic country with a population of 5.5 million populations.

<sup>&</sup>lt;sup>164</sup> Scandiatransplan, founded in 1969, is the organ exchange organization for the countries Denmark, Finland, Iceland, Norway, Sweden and Estonia. It covers a population of about 28.4 million inhabitants., (Jul 23, 2018), http://www.scandiatransplant.org/.

and cells removed during diagnosis and treatment of human disease; 2) retention, storage and use for medical purposes of organs, tissues and cells removed during diagnosis and treatment of human disease; 3) donation, procurement, testing, processing, preservation, storage and distribution at a tissue establishment or commissioned by a tissue establishment of human tissues and cells intended for human applications and of products made of human tissues and cells and intended for human applications; 4) use of human embryos for a purpose other than fertility treatment or medical research; 5) use of human organs, tissues, cells and tissue samples for a purpose other than that for which they were removed or retained; 6) use of a cadaver for medical teaching and research.<sup>165</sup>

In comparison with other countries, the Finnish law is generally regarded as progressive insofar as it is consistent with the desire of Western medical institutions whose aim is to increase the number of transplantations and who therefore present the scarcity of transplantable organs as a major problem.<sup>166</sup> After the amendment in August 2010, health authorities can rely on the principle of 'presumed consent', that is, they have the right to remove a person's organs unless he or she has explicitly forbidden it and this is known by health authorities in time.

<sup>&</sup>lt;sup>165</sup> § 1 of the Act on the Medical Use of Human Organs, Tissues and Cells, 2001, (Jul. 24, 2018), https://www.finlex.fi/en/laki/kaannokset/2001/en20010101.pdf.

<sup>&</sup>lt;sup>166</sup> Susanna Lindberg, *The Obligatory Gift of Organ Transplants: The Case of the Finnish Law* on the Medical Use of Human Organs, Tissues, and Cells, 38 Alternatives: Global, Local, Political, 245-255 (2013), (Jul. 23, 2018), http://www.jstor.org/stable/24569453.

Section 18 of the Act<sup>167</sup> prohibits commercialization. The section prohibits the donor or assignee of a donor to collect a fee for the removal and use of an organ, tissue or cells or for the donation of a cadaver. Advertisement for the need or availability of organs for the purpose of offering or seeking financial gain or comparable benefit is explicitly prohibited.

The donor of an organ, tissue or cells who suffers loss of income because of removal of an organ, tissue or cells as referred to in the statute to meet a vital transplantation need or for essential related tests and examinations, is entitled to a daily allowance.<sup>168</sup> Moreover, a health care unit or other unit involved in removing, retaining, storing or using organs, tissues and cells may not pursue financial gain from the activities provided for in the Act.<sup>169</sup>

#### 8.3.7. UNITED STATES OF AMERICA

In the United States, the legal regulation of the human body and the bodily materials are covered under two main statutes. Firstly, the National Organ Transplant Act, 1984 (hereinafter referred to as NOTA), and secondly, the Uniform Anatomical Gift Act, (hereinafter referred to as UAGA), which was

<sup>&</sup>lt;sup>167</sup> Act on the Medical Use of Human Organs, Tissues and Cells, 2001, (Jul. 24, 2018), https://www.finlex.fi/en/laki/kaannokset/2001/en20010101.pdf.

<sup>&</sup>lt;sup>168</sup> Under the Health Insurance Act, 2004.

<sup>&</sup>lt;sup>169</sup> § 18 of the Act on the Medical Use of Human Organs, Tissues and Cells, 2001, (Jul. 24, 2018), https://www.finlex.fi/en/laki/kaannokset/2001/en20010101.pdf.

originally enacted in 1968, amended in 1987 and then again in 2006. Presently the Act in operation is Uniform Anatomical Gift Act, 2008.<sup>170</sup>

The NOTA prohibits acquiring or receiving organs for valuable consideration. It provides for the establishment of the Task Force on Organ Transplantation and Organ Procurement. A transplantation network is also established to authorise financial assistance for organ procurement organisations. Section 301 prohibits organ purchases by stating that "it shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ <sup>171</sup> for valuable consideration<sup>172</sup> for use in human transplantation if the transfer affects interstate commerce".<sup>173</sup>

Prior to 1968, there were no federal laws dealing with organ and tissue donation and the same was handled at the state level only. But the state laws differed considerably. UAGA, 1968 was intended to address these problems by providing a framework of uniform laws in the United States relating to organ and tissue transplantation. It also attempted to increase the number of available organs by making it easier for individuals to make anatomical gifts.

<sup>&</sup>lt;sup>170</sup> David Price, *Human Tissue in Transplantation and Research: A Model Legal and Ethical Donation Framework*, (Cambridge University Press), 13 (2010).

<sup>&</sup>lt;sup>171</sup> § 301 (c) (1) of NOTA explains the term human organ. "The term human organ means, human kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone and skin, and any other human organ specified by the Secretary of Health and Human Services by Regulation".

 $<sup>^{172}</sup>$  § 301 (c) (2) of NOTA states that "valuable consideration does not include the reasonable payments associated with the removal, transportation, implantation, processing, preservation, quality control and storage of human organ or the expenses of travel, housing, and lost wages incurred by the donor of a human organ in connection with the donation of the organ".  $^{173}$  § 274 (e) of NOTA.

Section 3 of the UAGA, 2006 applies to an anatomical gift<sup>174</sup> or amendment to, revocation of, or refusal to make an anatomical gift, whenever made. An anatomical gift of a donor's body or part may be made during the life of the donor for the purpose of transplantation, therapy, research, or education.<sup>175</sup> The same also provides for the manner of making anatomical gifts before the death of the donor.<sup>176</sup>

The UAGA, 2006 does not prohibit sales, but it explicitly addresses gifts made during life or upon death. During life, people may donate certain parts of their bodies. Upon death they may, by will or other appropriate document, donate either parts or the entire corpse. Strong property rights are illustrated by the power to sell bodily fluids, such as blood and semen, and in certain

 <sup>&</sup>lt;sup>174</sup> § 2 (3). "Anatomical gift" means a donation of all or part of a human body to take effect after the donor's death for the purpose of transplantation, therapy, research, or education.
 <sup>175</sup> § 4, UAGA, 2006.

<sup>&</sup>lt;sup>176</sup> "(a) A donor may make an anatomical gift:

<sup>(1)</sup> by authorizing a statement or symbol indicating that the donor has made an anatomical gift to be imprinted on the donor's driver's license or identification card;

<sup>(2)</sup> in a will;

<sup>(3)</sup> during a terminal illness or injury of the donor, by any form of communication addressed to at least two adults, at least one of whom is a disinterested witness; or

<sup>(4)</sup> as provided in subsection (b).

<sup>(</sup>b) A donor or other person authorized to make an anatomical gift under Section 4 may make a gift by a donor card or other record signed by the donor or other person making the gift or by authorizing that a statement or symbol indicating that the donor has made an anatomical gift be included on a donor registry. If the donor or other person is physically unable to sign a record, the record may be signed by another individual at the direction of the donor or other person and must: (i) be witnessed by at least two adults, at least one of whom is a disinterested witness, who have signed at the request of the donor or the other person; and (ii) State that it has been signed and witnessed as provided in paragraph (1).

<sup>(</sup>c) Revocation, suspension, expiration, or cancellation of a driver's license or identification card upon which an anatomical gift is indicated does not invalidate the gift.

<sup>(</sup>d) An anatomical gift made by will takes effect upon the donor's death whether or not the will is probated. Invalidation of the will after the donor's death does not invalidate the gift."

circumstances, to contract for the future delivery of one's body after death in return for the present medical care or present or future monetary payment.<sup>177</sup>

## **8.3.8.** CANADA<sup>178</sup>

Even though the first kidney transplantation in Canada took place in 1958, Canada's organ donation rate remains one of the lowest in the industrialised world.<sup>179</sup> Organ donation and transplantation in Canada is regulated at the provincial level.<sup>180</sup>

The first laws in Canada with provisions on organ transplantation and commercialisation were the Anatomy Acts which existed in the various provinces. Though the provisions of each of these Acts were different, a few of them attempted to regulate organ commercialisation.<sup>181</sup> In Manitoba, the Anatomy Act, 1954 prohibited the sale and traffic in the bodies of dead persons.<sup>182</sup> In 1965, the Uniform Law Conference of Canada (hereinafter

<sup>&</sup>lt;sup>177</sup> STEPHEN MUNZER, A THEORY OF PROPERTY, (Cambridge Studies in Philosophy and Law, Cambridge University Press), 52 (1990).

<sup>&</sup>lt;sup>178</sup> Canada is located in the northern part of North America. Its ten provinces and three territories covers 9.98 million square kilometers, making it the world's second-largest country by total area. It has a population of 3.63 crores, (Jul. 24, 2018), https://en.wikipedia. org/wiki/Canada. The Canadian legal system is unique in the world. Two official languages (English and French) and two legal traditions (the common law and civil law) co-exist within Canadian system of justice. *Canada's System of Justice*, (Jul. 24, 2018), http://www.justice. gc.ca/eng/csj-sjc/.

<sup>&</sup>lt;sup>179</sup> TERRY O. ADIDO, TRANSPLANT TOURISM: AN INTERNATIONAL AND NATIONAL LAW MODEL TO PROHIBIT TRAVELLING ABROAD FOR ILLEGAL ORGAN TRANSPLANTS, (Brill Sense and Hotei Publishing), 78 (2018).

<sup>&</sup>lt;sup>180</sup> This is because Canada runs a federal system of government with powers divided between the federal and provincial/ territorial governments by the Canadian Constitution Act.

<sup>&</sup>lt;sup>181</sup> TERRY O. ADIDO, TRANSPLANT TOURISM: AN INTERNATIONAL AND NATIONAL LAW MODEL TO PROHIBIT TRAVELLING ABROAD FOR ILLEGAL ORGAN TRANSPLANTS, (Brill Sense and Hotei Publishing), 78 (2018).

<sup>&</sup>lt;sup>182</sup> (Jul. 26, 2018), http://web2.gov.mb.ca/laws/statutes/ccsm/a080e.php.

referred to as ULCC) created the Uniform Human Tissue Gift Act (UHTGA) which led to the adoption of statutes by the various provinces modelled after the UHTGA. These provincial statutes had specific provisions on organ transplantation. Currently, every province in Canada has statutes regulating organ donation and transplantation.<sup>183</sup> Though these legislations were passed at different times, they are all similar with only slight variations.<sup>184</sup>

Section 15 (1) of the Human Tissue Gift Act, 1987 of the province of Manitoba states: "No person shall buy, sell, or otherwise deal in, directly or indirectly, for valuable consideration, any tissue for a transplant, or any body or parts of it other than blood or a blood constituent, for therapeutic purposes or for purposes of medical education or scientific research, and any such dealing is invalid as being contrary to public policy."<sup>185</sup> In Nova Scotia, Human Tissue Gift Act, 1989, which follows on the same lines, prohibits dealings in tissue or body parts under Section 11.<sup>186</sup> The Civil Code of Québec provides that "The alienation by a person of a part or product of his body shall be gratuitous..." <sup>187</sup>

<sup>&</sup>lt;sup>183</sup> These provincial enactments are specifically discussed in the following paragraphs.

<sup>&</sup>lt;sup>184</sup> TERRY O. ADIDO, TRANSPLANT TOURISM: AN INTERNATIONAL AND NATIONAL LAW MODEL TO PROHIBIT TRAVELLING ABROAD FOR ILLEGAL ORGAN TRANSPLANTS, (Brill Sense and Hotei Publishing), 78 (2018).

<sup>&</sup>lt;sup>185</sup> Manitoba Human Tissue Gift Act, 1987, C.C.S.M. c. H180, (Aug. 01, 2018), http://web2.gov.mb.ca/laws/statutes/ccsm/h180e.php.

<sup>&</sup>lt;sup>186</sup> § (11) states: "No person shall buy, sell or otherwise deal in, directly or indirectly, for a valuable consideration, any tissue for a transplant or any body or part or parts thereof, other than blood or a blood constituent, for therapeutic purposes, medical education or scientific research, and any such dealing is invalid as being contrary to public policy", (Jul. 19, 2018), https://nslegislature.ca/sites/default/files/legc /statutes/ humants.htm.

<sup>&</sup>lt;sup>187</sup> Art. 25 of Civil Code of Québec, 1991, (Jul. 29, 2018), http://www.legisquebec.gouv .qcca/en/showdoc/cs/CCQ-1991.

In Ontario, Section 10 of Trillium Gift of Life Act, 1990 bars individuals from buying, selling or otherwise dealing with the human body parts for valuable consideration. Any such sale of human organs is deemed to be contrary to public policy.<sup>188</sup> This prohibition does not affect the sale of blood or its constituents which remains legal.<sup>189</sup> Contravention of this provision attracts penalty of fine or imprisonment or both.<sup>190</sup>

In British Columbia, the Human Tissue Gift Act, 1996 is similar to that of Ontario. Section 10 prohibits commercial dealings in the human body parts.<sup>191</sup> Human Tissue Gift Act, 2004 of Brunswick under Section 10(1) prohibits dealings in tissue or body parts.<sup>192</sup> Clause 2 of section 10 provides for the penal provisions for the violation of section 10.<sup>193</sup> In Alberta, the Human Tissue and Organ Donation Act, 2006, under section 3(2) bars individuals from receiving

<sup>&</sup>lt;sup>188</sup> § 10 (1) "No person shall buy, sell or otherwise deal in, directly or indirectly, for a valuable consideration, any tissue for a transplant, or any body or part or parts thereof, for therapeutic purposes, medical education or scientific research, and any such dealing is invalid as being contrary to public policy"., (Jul. 22, 2018), R.S.O. 1990, c. H.20, s. 10; 2014, c. 14, Sched. 1, s. 15 (1), https://www.ontario. ca/laws/statute/90h20#BK37.

<sup>&</sup>lt;sup>189</sup> § 10 (2) "Despite anything else in this Act or the regulations, blood and blood constituents shall not be considered to be tissue or part of a body for the purposes of subsection (1). 2014, c. 14, Sched. 1, s. 15 (2), (Jul. 15, 2018), /(https://www.ontario.ca/laws/statute/90h20#BK37.
<sup>190</sup> § 12 Trillium Gift of Life Act, 1990.

<sup>&</sup>lt;sup>191</sup> § 10 of the BC Human Tissue Gift Act, 1996 states: "A person must not buy, sell or otherwise deal in, directly or indirectly, for a valuable consideration, any tissue for a transplant, or any body or parts other than blood or a blood constituent, for therapeutic purposes, medical education or scientific research", (22/Jul. 2018), http://www.bclaws.ca/civix /document /id/complete/statreg/96211\_01.

<sup>&</sup>lt;sup>192</sup> § 10 (1) states: "No person shall buy, sell or otherwise deal in, directly or indirectly, for a valuable consideration, any human tissue for a transplant or any human body or part of any human body, other than blood or a blood constituent, for therapeutic purposes or for the purposes of medical education or scientific research."

<sup>&</sup>lt;sup>193</sup> § 10 (2) of New Brunswick Human Tissue Gift Act, 2004, http://www.gnb.ca/legis/bill/pdf/55/1/Bill-37.pdf.

rewards or benefits for tissue, organ or body donations used for transplantation and other legal purposes.<sup>194</sup>

Other provinces such as Saskatchewan<sup>195</sup>, Prince Edward Island, etc.,<sup>196</sup> also prohibits commercial dealings in the human body and body parts. Thus, in Canada, law preventing commercialisation of human organs and body parts is governed by provincial legislations which, in general, bans the exchange of any 'benefit' or any form of 'valuable consideration' in return for an organ.<sup>197</sup>

Canada's organ donation system is premised on altruism and Canadian lawmakers have gone to great lengths to ensure that the system is structured to prevent commercial exchange of organs.<sup>198</sup> The provincial laws that form the primary framework of the organ donation system, also regulates the commercial transactions in human organs and tissues, and is one of the earliest of its kind. The legislations in each province sets norms regarding organ donation, and each such statute includes what amounts to a ban on the buying and selling of

<sup>&</sup>lt;sup>194</sup> § 3 (2) of the Human Tissue and Organ Donation Act, 2006 states: "No person shall offer, give or receive any reward or benefit for any tissue, organ or body for use in transplantation, medical education or scientific research". http://www.qp.alberta.ca/documents/Acts/h14p5. pdf.

<sup>&</sup>lt;sup>195</sup> § 11 of the Human Tissue Gift Act, 2015, prohibits sale, etc. of tissues., http://www. publications. gov.sk.ca/freelaw/documents/English/Statutes/Repealed/H15.pdf.

<sup>&</sup>lt;sup>196</sup> Clause 1 of § 15 of the Human Tissue Donation Act, 2011 of Prince Edward Island reads as: "No person shall buy, sell or otherwise for remuneration or other financial benefit deal in, directly or indirectly, any tissue, body or body part.", (Aug. 06, 2018), https://www.princeed wardisland.ca/sites/default/files/legislation/H-12-1-Human%20Tissue%20Donation%20Act. pdf.

<sup>&</sup>lt;sup>197</sup> Timothy Caulfield, Erin Nelson et al., *Incentives and Organ Donation: What's (really) Legal in Canada?*, 1 Canadian Journal of Kidney Health and Disease, (2014), (Jul. 23, 2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4349723/#Abs1title.

<sup>&</sup>lt;sup>198</sup> Timothy Caulfield, Erin Nelson et al., *Incentives and Organ Donation: What's (really) Legal in Canada?*, 1 Canadian Journal of Kidney Health and Disease, (2014), (Jul. 23, 2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4349723/#Abs1title.

organs. Although there is some variation in the exact wording of the relevant provisions, every province has a prohibition that, taken literally, is tremendously broad in scope.<sup>199</sup>

Furthermore, the Canadian Society of Transplantation and the Canadian Society of Nephrology shares one policy document on organ trafficking and transplant tourism. A statement issued by both societies in the policy document states that they "condemn the practices of transplant tourism, organ trafficking and commercialisation of organs".<sup>200</sup>

### 8.3.9. SRI LANKA

In Sri Lanka<sup>201</sup>, the Transplantation of Human Tissues Act, 1987, provides for the donation of human bodies and tissues for therapeutic, scientific, educational and research purposes; for the removal of such tissues and its use on living persons; for the preservation of such tissues, etc. Section 17 prohibits any sale, dealing in or disposal of a body, or any part or tissue.<sup>202</sup> Moreover, the statute

<sup>&</sup>lt;sup>199</sup> Timothy Caulfield, Erin Nelson et al., *Incentives and Organ Donation: What's (really) Legal in Canada?*, 1 Canadian Journal of Kidney Health and Disease, (2014), (Jul. 23, 2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4349723/#Abs1title.

<sup>&</sup>lt;sup>200</sup> John S. Gill, Aviva Goldberg, et al., *Policy Statement of Canadian Society of Transplantation and Canadian Society of Nephrology on Organ Trafficking and Transplant Tourism, 90 Transplantation,* 817-820 (2010), (Jul. 27, 2017), https://journals.lww.com/transplantjournal/Fulltext/2010/10270/Policy\_Statement\_of\_Canadian\_Society\_of.3.aspx.

<sup>&</sup>lt;sup>201</sup> Democratic Socialist Republic of Sri Lanka is an island country in South Asia, located in the Indian Ocean, with a population of 2.12 crores, (Jul. 27, 2018), https://en.wikipedia. org/wiki/Sri\_Lanka.

 $<sup>^{202}</sup>$  § 17(1) states: "No person shall buy, sell, dispose of, or otherwise deal in, directly or indirectly, for a valuable consideration, any body, or any tissue or part thereof...".

makes it punishable if the human body, or part or tissue is used for a purpose other than for which it is donated.<sup>203</sup>

### 8.3.10. PAKISTAN

Pakistan<sup>204</sup> has long been a safe haven for 'organ tourists' from all over the world.<sup>205</sup> Over a prolonged period, Pakistan has emerged as one of the largest known centers for renal trafficking owing to a lack of regulation and the presence of a large vulnerable rural population.<sup>206</sup> It was one of the largest centers for commercial renal transplantation.<sup>207</sup> According to WHO estimates, Pakistan hosts up to 1500 transplant tourists every year, second only to China.<sup>208</sup>

Pakistan did not have any law to curb human organ trade until a decade ago. In July, 2007 the Supreme Court of Pakistan issued a ruling<sup>209</sup> which ordered the Government of Pakistan to enact a law regulating the illegal organ trade in the country, especially in kidneys. Following the intervention by the Supreme Court of Pakistan, an ordinance to regulate organ transplantation and to curb the

<sup>&</sup>lt;sup>203</sup> § 13 of the Transplantation of Human Tissues Act, 1987.

<sup>&</sup>lt;sup>204</sup> Islamic Republic of Pakistan is a country in South Asia. It is the fifth-most populous country with a population exceeding 21 Crores and in area, it is the 33<sup>rd</sup> largest country in the world, (Jul. 23, 2018), https://en.wikipedia.org/wiki/Pakistan.

<sup>&</sup>lt;sup>205</sup> Mohammad A. Rai & Omer Afzal, *Organs in the Bazaar: The End of the Beginning?*, 26 Politics and the Life Sciences, 10-11 (2007), (Jul. 10, 2018), http://www.jstor.org/stable/ 40072922.

<sup>&</sup>lt;sup>206</sup> K.M. Bile, et al., *Human Organ and Tissue Transplantation in Pakistan: When a Regulation Makes a Difference*, 16 EMHJ, Supplement, S160 (2010).

<sup>&</sup>lt;sup>207</sup> K.M. Bile, et al., *Human Organ and Tissue Transplantation in Pakistan: When a Regulation Makes a Difference*, 16 EMHJ, Supplement, S160 (2010).

<sup>&</sup>lt;sup>208</sup> *FACTBOX - Five Organ Trafficking Hotspots*, Reuters, (Jul. 12, 2018), https://www.reuters. com/article/idUSL01426288.

<sup>&</sup>lt;sup>209</sup> This ruling came out as a response of complaints that poor people were forced to sell their kidneys by middlemen for very meagre monetary compensations.

burgeoning kidney trade was drafted by the Ministries of Health and Law. The Transplantation of Human Organs and Tissues Ordinance, 2007, was then promulgated by the President of Pakistan, regulating the removal, storage and transplantation of human organs and tissues for therapeutic purposes and related procedural matters. Thus the Transplantation of Human Organs and Tissues Act, 2009 (hereinafter referred to as THOTA) came into existence.<sup>210</sup>

THOTA defines the term 'payment' as payment in money or money's worth but does not include any payment for defraying or reimbursing.<sup>211</sup> Section 9 of the THOTA prohibits the removal or transplantation of human organs for any purpose other than for therapeutic purpose.<sup>212</sup> In order to prevent commercialisation, THOTA proposes a number of measures, including the restriction of organ donation only to close blood relatives who are over the age of 18 years as well as a ban on donations by those who are not related to the

<sup>&</sup>lt;sup>210</sup> Came into force on 17<sup>th</sup> March, 2010, (Oct. 06, 2018), http://www.transplant-observatory. org/download/transplantation-of-human-organs-and-tissues-act-pakistan-march-2010/.

<sup>&</sup>lt;sup>211</sup> § 2 (g) of Transplantation of Organs and Tissues Act, 2009, includes (i) the cost of removing, transporting or preserving the human organ to be supplied; or (ii) any expenses or loss of earnings incurred by a person so far as reasonably and directly attributable to his supplying any organ from his body.

<sup>&</sup>lt;sup>212</sup> § 9 of Transplantation of Organs and Tissues Act, 2009, states: "No donor and no person empowered to give authority for removal of any human organ shall authorize the removal of any human organ for any purpose other than the therapeutic purposes."

recipients.<sup>213</sup> As per this law, every donation has to be evaluated by a committee of medical experts that would determine that the donation is fully voluntary.<sup>214</sup>

Commercial dealings in human organs are considered as an offence, being punishable with imprisonment for up to 10 years along with monetary penalty and possible removal of the practitioner's name from the register of the Pakistan Medical and Dental Council, initially for a 3-year period and permanently for subsequent offences.<sup>215</sup> Furthermore, transplantations are to be carried out by transplantation surgeons and physicians after ensuring that written certification had been obtained from the evaluation committee. The Monitoring Authority is mandated to publish a list of medical institutions and hospitals that are recognized for the practice of operative surgery in transplantation of human organs and tissues.<sup>216</sup>

<sup>&</sup>lt;sup>213</sup> § 3 of THOTA provides for the conditions for the donation of organ or tissue by a living person. (1) Notwithstanding anything contained in any other law for the time being in force, a living donor who is not less than eighteen years of age, may during his life-time voluntarily donate any organ or tissue of his body to any other living person genetically and legally related, who is a close blood relative and the donation of organ or part or tissue by such person for therapeutic purpose shall be regulated in the manner as may be prescribed. In the case of regenerative tissue, i.e. stem cells, there is no restriction of age between siblings.

<sup>&</sup>lt;sup>214</sup> Explanation to § 3 of THOTA mandates that the transplantation shall be voluntary, genuinely motivated and without any duress or coercion and the Evaluation Committee shall ascertain the matter.

<sup>&</sup>lt;sup>215</sup> As per the Act, activities constituting an offence included making or receiving any payment for supply of, or for an offer to supply, any human organ, seeking to find a person willing to supply for payment any human organ, offering to supply any human organ for payment, and publishing or distributing any advertisement inviting persons to supply for payment any human organ, or offering to supply any human organ for payment, or indicating that the advertiser is willing to undertake any commercial arrangement.

 $<sup>^{216}</sup>$  § 2 (i) of THOTA defines the recognized institution as "a medical institution or hospital for practice of operative surgery in transplantation of human organs/tissues to be recognized by the Monitoring Authority" and mandates under § 6(3) that the Government shall publish in the official Gazette the list of medical institutions and hospitals as recognized medical institutions and hospitals for practice of operative surgery in transplantation of human organs and tissues.

### 8.3.11. IRAN

Iran<sup>217</sup> is the only country in the world which offers people a legal way to sell their kidneys. The Iranian government has taken the unusual step of legalising payment for kidney donations. In 1988, the Iranian government introduced a compensation scheme for living donors who were unrelated to the organ recipient.<sup>218</sup> A government foundation registers donors and recipients, matches them up and sets a fixed price per organ. Organ transplantation services, particularly kidney transplants, have been provided in a fairly large number and good quality in Iran since 1990, and there are currently more than 25 kidney transplant centers that provide transplant operations.<sup>219</sup> Since then, doctors in Iran have performed more than 30,000 kidney transplants.<sup>220</sup>

Iran has provided a flexible and relatively regulated environment for organ transplantation, especially regarding the possibility of unrelated living organ donation.<sup>221</sup> This renal transplantation programme is funded and regulated by the government, with the objectives to establish a regularised system of kidney

<sup>&</sup>lt;sup>217</sup> Islamic Republic of Iran, located in South West Asia (part of the Middle East), covers an area of 1.65 million square kilometres and has nearly 75 million inhabitants.

<sup>&</sup>lt;sup>218</sup> Organ Donations in Iran, Centre for Public Impact, Mar. 8, 2016, (Jul. 24, 2018), https://www.centreforpublicimpact.org/case-study/organ-donations-in-iran/.

<sup>&</sup>lt;sup>219</sup> Nader Ghotbi, *The Ethics of Organ Transplantation in the Islamic Republic of Iran*, 23 Eubios Journal of Asian and International Bioethics, 190 (2013), (Jul. 24, 2018), https://www.personaedanno.it/dA/39f7bb0413/allegato/EJAIB112013\_(p2-5)[1].pdf.

<sup>&</sup>lt;sup>220</sup> Shashank Bengali & Ramin Mostaghim, *'Kidney for Sale': Iran has a Legal Market for the Organs, but the System Doesn't Always Work*, Oct. 15, 2017, LA Times, (Jul. 20, 2018), http://www.latimes.com/world/middleeast/la-fg-iran-kidney-20171015 -story.html.

<sup>&</sup>lt;sup>221</sup> Nader Ghotbi, *The Ethics of Organ Transplantation in the Islamic Republic of Iran*, 23 Eubios Journal of Asian and International Bioethics, 190 (2013), (Jul. 24, 2018), https://www.persona edanno.it/dA/39f7bb0413/allegato/EJAIB112013\_(p2-5)[1].pdf.

donation and to eliminate the long waiting list of patients requiring kidney transplants.

"As a result of the payments in money and in kind for kidneys the number of renal transplants performed substantially increased such that in 1999, the renal transplant waiting list was completely eliminated.<sup>222</sup> By the end of 2006, 21,359 kidney transplants were performed in Iran from living related donors (15.2%), living unrelated donors (79.6%), and deceased donors (5.2%)." Furthermore, the annual number of kidney transplants was steadily increasing from fewer than 100 in 1986 to 1858 in 2000, taking it to 26.5 kidney transplants per million population per year.<sup>223</sup> The possibility of monetary compensation for unrelated kidney donors in Iran has helped expand the supply of donated organs, especially of kidneys, to a number almost equal to the demand.<sup>224</sup>

Further, in 2000, the Organ Transplantation Brain Death Act was enacted by the Iranian Parliament followed by the establishment of the Iranian Network for

<sup>&</sup>lt;sup>222</sup> Organ Donations in Iran, Centre for Public Impact, Mar. 8, 2016, (Jul. 24, 2018), https://www.centreforpublicimpact.org/case-study/organ-donations-in-iran/.

<sup>&</sup>lt;sup>223</sup> Organ Donations in Iran, Centre for Public Impact, Mar. 8, 2016, (Jul. 24, 2018), https://www.centreforpublicimpact.org/case-study/organ-donations-in-iran/.

<sup>&</sup>lt;sup>224</sup> "By the end of 2012, there were 34166 kidney (including 4436 deceased-donor) and 2021 liver (including 1788 deceased-donor), 482 heart, 147 pancreas, 63 lung, and several intestine and multiorgan transplants performed in Iran. In 2011, there were 2771 solid-organ transplants performed in Iran (37 transplants per million population), and Iran ranked as number 33 among the 50 most active countries worldwide. In 2011 and 2012, Iran was ahead of all country members of the Middle East Society for Organ Transplantation in performing deceased-donor kidney and liver transplants". Ghods A. J., *The History of Organ Donation and Transplantation in Iran*, 12 Exp. Clin. Transplant., 38-41 (2014), (Jun. 09, 2018), https://www.ncbi.nlm.nih. gov/pubmed/24635790.

Transplant Organ Procurement in 2002. This Act legalised the procurement of organs from clinically brain-dead patients for transplantation.

# 8.3.12. CHINA<sup>225</sup>

China's organ transplantation program began during the 1960's, but the programme was not publicly announced until 1974.<sup>226</sup> In the late 1970's, there reportedly "arose a high tide of kidney, liver, heart and lung transplants across the country".<sup>227</sup> But the success rate remained low, and by the early 1980's the country's organ transplant program appeared to be faltering. Since 1983, the commencement of a series of 'crackdown on crime' campaigns greatly increased the number of criminals sentenced to death and hence the potential supply of transplantable organs. The introduction to China of immunosuppressant drugs also increased the success rates of transplantations in China.<sup>228</sup>

China is accused to provide an example of state-sponsored execution for organs.<sup>229</sup> China has officially allowed the harvest of organs from executed

<sup>&</sup>lt;sup>225</sup> The People's Republic of China (PRC), is a unitary one-party sovereign state in East Asia and the world's most populous country, with a population of around 1.404 billion. Covering approximately 9,600,000 square kilometers, (Jul. 20, 2018), https://en.wikipedia.org/ wiki/China.

<sup>&</sup>lt;sup>226</sup> Organ Procurement and Judicial Execution in China, 9 Human Rights Watch/ Asia Report, 1994, (Jul. 28, 2018), https://www.hrw.org/reports/1994/china1/china\_948.htm.

<sup>&</sup>lt;sup>227</sup> Organ Procurement and Judicial Execution in China, 9 Human Rights Watch/ Asia Report, 1994, (Jul. 28, 2018), https://www.hrw.org/reports/1994/china1/china\_948.htm.

<sup>&</sup>lt;sup>228</sup> Organ Procurement and Judicial Execution in China, 9 Human Rights Watch/Asia Report, 1994, (Jul. 28, 2018), https://www.hrw.org/reports/1994/china1/china\_948.htm.

<sup>&</sup>lt;sup>229</sup> Organ Procurement and Judicial Execution in China, 9 Human Rights Watch/ Asia Report, 1994, (Jul. 28, 2018), https://www.hrw.org/reports/1994/china1/china\_948.htm.

prisoners since 1984.<sup>230</sup> By Chinese law, harvest is allowed in one of three circumstances: (1) if the prisoner's body is not claimed; (2) if the prisoner has consented; or (3) if the prisoner's family has consented.<sup>231</sup> The consent of prisoners to use their organs after death, although required by law, appears rarely to be sought.<sup>232</sup> The execution procedure prescribed by Chinese law (shooting in the back of the head), is sometimes violated in order to expedite harvesting of prisoners' organs.<sup>233</sup> According to Chinese legal authorities, some executions are even deliberately mishandled to ensure that the prisoners are not yet dead when their organs are removed.<sup>234</sup> Chinese system, is thus accused of horrific human rights abuses in allegedly executing prisoners in order to harvest their organs.<sup>235</sup>

The Regulations on Human Organ Transplantation, which was the first law of organ transplantation in China was promulgated in 2007.<sup>236</sup> This law has led the

<sup>&</sup>lt;sup>230</sup> A. Sharif, M. Fiatarone Singh et al., *Organ Procurement from Executed Prisoners in China*, 14 Am. J. of Transplantation, 2246-2252 (2014), (Jul. 18, 2018), https://onlinelibrary.wiley. com/doi/pdf/10.1111/ajt.12871.

<sup>&</sup>lt;sup>231</sup> David E. Jefferies, *The Body as Commodity: The Use of Markets to Cure the Organ Deficit*,
5 Ind. J. of Global Legal Studies, 621-658, 643 (Apr. 05, 2016), http://www.repository.law.
indiana.edu/ijgls/vol5/iss2/13.

Organ Procurement and Judicial Execution in China, 9 Human Rights Watch/ Asia Report, 1994, (Jul. 28, 2018), https://www.hrw.org/reports/1994/china1/china\_948.htm.

Organ Procurement and Judicial Execution in China, 9 Human Rights Watch/ Asia Report, 1994, (Jul. 28, 2018), https://www.hrw.org/reports/1994/china1/china\_948.htm.

Organ Procurement and Judicial Execution in China, 9 Human Rights Watch/ Asia Report, 1994, (Jul. 28, 2018), https://www.hrw.org/reports/1994/china1/china\_948.htm.

<sup>&</sup>lt;sup>235</sup> Jefferies, David E. (1998), *The Body as Commodity: The Use of Markets to Cure the Organ Deficit*, 5 Ind. J. of Global Legal Studies, (Jul. 11, 2016), http://www.repository.law.indiana. edu/ijgls/vol5/iss2/13.

<sup>&</sup>lt;sup>236</sup> "These Regulations are formulated for the purpose of standardizing transplantation of human organs, ensuring the quality of medical treatment, safeguarding human health and protecting the lawful rights and interests of citizens. These Regulations apply to transplantation of human organs conducted within the territory of the People's Republic of China, but do not apply to transplantation of human cells and such human tissues as corneas and bone marrow.", Articles 1 & 2 of the Regulations on Human Organ Transplantation, (Jul. 28, 2018), http://www.chinadaily.com.cn/m/ chinahealth/2014-06/05/content \_17566177.htm.

Chinese organ transplantations onto a trajectory of law-based regulation, signifying the beginning of China's organ transplantation reform. Article 3 of the Regulation expressly prohibits trade in human organs.<sup>237</sup> China's organ transplantation law has accomplished remarkable reform since then.<sup>238</sup>

Further, Amendment (VIII) to the Criminal Law of the People's Republic of China, 2011, criminalised trafficking of human organs.<sup>239</sup> These efforts have tried to regulate the organ transplantation framework in China.

Chinese government announced that from January 1, 2015, China would stop obtaining organs from executed prisoners and ensure that voluntary donation from its citizens shall be the sole legal source of human organs.<sup>240</sup> Since then, China has eliminated the use of prisoner organs, and now only uses organs from

<sup>&</sup>lt;sup>237</sup> Article 3 states: "No organization or individual may, in any form, trade in human organs or engage in any activities related to such trade.", Regulations on Human Organ Transplantation, (Jul. 28, 2018), http://www.chinadaily.com.cn/m/chinahealth/2014-06/05/ content\_17566177.htm.

<sup>&</sup>lt;sup>238</sup> Jiefu Huang, *The "Chinese Mode" of Organ Donation and Transplantation*, 6 Hepatobiliary Surg. Nutr., 212-214 (2017), (Jun. 07, 2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5554773/.

<sup>&</sup>lt;sup>239</sup> Article 234A states: "Whoever organizes others to sell human organs shall be sentenced to imprisonment of not more than 5 years and a fine; or if the circumstances are serious, be sentenced to imprisonment of not less than 5 years and a fine or forfeiture of property. Whoever removes any other person's organ without such other person's consent, removes any organ of a person under the age of 18 or forces or deceives any other person into donating any organ shall be convicted and punished according to the provisions of Articles 234 and 232 of this Law. Whoever removes a dead person's organ against the person's near relatives in violation of the provisions of the state provided that there is no consent from the person before his death shall be convicted and punished according to the provision of Article 302 of this Law.", Eighth Amendment to the Criminal Law of the People's Republic of China, which came into effective on May, 2011. (Jul. 17, 2018), https://www.cecc.gov/resources/legal-provisions/eighth-amend ment-to-the-criminal-law-of-the-peoples-republic-of-china.

<sup>&</sup>lt;sup>240</sup> Jiefu Huang, *The "Chinese Mode" of Organ Donation and Transplantation*, 6 Hepatobiliary Surg. Nutr., 212-214 (2017), (Jun. 07, 2018), https://www.ncbi.nlm.nih.gov/ pmc/articles/ PMC5554773/.

donors who die in the intensive-care units of hospitals.<sup>241</sup> Today, donation from condemned prisoners is no longer the main source of organs for transplantation in China.<sup>242</sup>

# 8.3.13. AUSTRALIA

Like Canada, Australia<sup>243</sup> also has a federal system of Government with powers divided between the central government and the states/territories<sup>244</sup> by the Commowealth of Australia Constitution Act, 1900.<sup>245</sup> Organ donation and transplantation is a residual matter which is not regulated by the federal government.<sup>246</sup> Each state and territory in Australia has its own organ transplant law.

These laws were enacted following the 1977 Report of the Australian Law Reform Commission on Human Tissue Transplants. In addition to the various state and territorial laws on organ transplant, Australia also has a federal organ transplant Act called the Organ and Tissue Donation and Transplantation

<sup>&</sup>lt;sup>241</sup> Matthew Robertson & Jacob Lavee, *China's Organ Transplant Problem*, The Diplomat, Mar. 29, 2017, (Jul. 18, 2018), https://thediplomat.com/2017/03/chinas-organ-transplant-problem/.

<sup>&</sup>lt;sup>242</sup> Lei Zhang, et al., *Transformation of Organ Donation in China*, Transplant International, https://onlinelibrary.wiley.com/doi/pdf/10.1111/tri.12467.

<sup>&</sup>lt;sup>243</sup> Commonwealth of Australia is a sovereign country comprising the mainland of the Australian continent, the island of Tasmania and numerous smaller islands. It is the largest country in Oceania and the world's sixth-largest country by total area and 2.41 crores population, (Jul. 31, 2018), https://en.wikipedia.org/wiki/Australia.

<sup>&</sup>lt;sup>244</sup> Australia comprises of six states: New South Wales (NSW), Queensland (Qld), South Australia (SA), Tasmania (Tas), Victoria (Vic) and Western Australia (WA) and two Territories: Australian Capital Territory (ACT) and the Northern Territory (NT).

<sup>&</sup>lt;sup>245</sup> (Jul. 31, 2018), https://www.australia.gov.au/.

<sup>&</sup>lt;sup>246</sup> TERRY O. ADIDO, TRANSPLANT TOURISM: AN INTERNATIONAL AND NATIONAL LAW MODEL TO PROHIBIT TRAVELLING ABROAD FOR ILLEGAL ORGAN TRANSPLANTS, (Brill Sense and Hotei Publishing), 82 (2018).

Authority Act, 2008. The statute aims to create an efficient organ and tissue donation and transplantation system in Australia by establishing an Authority and a Board for the said purpose.<sup>247</sup>

The Transplantation and Anatomy Act, 1978 of the Australian Capital Territory bars individuals from entering into contracts or arrangements for the sale or supply of body tissues and makes all such contracts or agreements void.<sup>248</sup> The bar on receiving compensation for organ donations does not, however, affect arrangements for the reimbursement of expenses necessarily incurred by donors.

Section 39 of Queensland Transplantation and Anatomy Act, 1979, defines trading, of tissue.<sup>249</sup> Further, Section 40 prohibits unauthorized buying of tissue. Section 41 restricts advertisements relating to buying of tissue.<sup>250</sup> Under section 42, unauthorised selling of tissues are also prohibited.

Part VIII of the Human Tissue Act, 1982, Victoria, prohibits unauthorised selling of tissues under Section 38. The Act prevents a person from selling or agreeing

<sup>&</sup>lt;sup>247</sup> Australian Government Federal Register of Legislations, (Jul. 31, 2018), https://www.legis lation.gov.au/Details/C2017C00206.

<sup>&</sup>lt;sup>248</sup> § 44 of the TAA.

<sup>&</sup>lt;sup>249</sup> The term 'trading of tissue' shall include- "(a) buying, agreeing to buy, offering to buy, holding out as being willing to buy, or inquiring whether a person is willing to sell the tissue; (b) selling, agreeing to sell, offering to sell, holding out as being willing to sell, or inquiring whether a person is willing to buy the tissue; (c) any act mentioned in section 41(a), (b) or (c) for an advertisement relating to the buying of the tissue".

 $<sup>^{250}</sup>$  A person shall not— (a) publish or disseminate by newspaper, other periodical, book, broadcasting, television, cinematograph or other means whatever; or (b) exhibit to public view in a house, shop or place; or (c) deposit in the area, yard, garden or enclosure of a house, shop or place;

to sell tissue, including his own tissue, or the right to take tissue from his body. The statute does not prevent receipt of reasonable expenses.

Section 32 of the New South Wales Human Tissue Act, 1983 prohibits trading in human tissues.<sup>251</sup> The offence attracts a maximum penalty of 40 penalty units or 6 months imprisonment or both.<sup>252</sup> But clause 3 of section 32 excludes a contract or arrangement providing for the reimbursement of any expenses necessarily incurred by a person in relation to the removal of tissue in accordance with this statute.

The Transplantation and Anatomy Act, 1983 of South Australia, prohibits certain contracts to be void including the contract or agreement for the sale or supply of tissue from one's body or from the body of another person, whether before or after one's death or the death of the other person, as the case may be.<sup>253</sup> Clause 7 of Section 35 prohibits advertisements relating to the selling or buying in Australia of tissue or of the right to remove tissue from the bodies of persons.

Similar provisions can be seen in the Western Australia's Human Tissue and Transplant Act, 1982<sup>254</sup>, and the Northern Territory Human Tissue Transplant

<sup>&</sup>lt;sup>251</sup> § 32 states: "Trading in tissue prohibited (1) A person must not enter into, or offer to enter into, a contract or arrangement under which any person agrees, for valuable consideration, whether given or to be given to any such person or to any other person: (a) to the sale or supply of tissue from any such person's body or from the body of any other person, whether before or after that person's death or the death of that other person, as the case may be, or (b) to the postmortem examination of any such person's body after that person's death or of the body of any other person after the death of that other person.

<sup>&</sup>lt;sup>252</sup> § 32.

<sup>&</sup>lt;sup>253</sup> § 35(1)(a).

<sup>&</sup>lt;sup>254</sup> § 29.

Act, 1995.<sup>255</sup> Except the Tasmanian Human Tissue Act, 1985, every state and territory of Australia have laws specifically preventing sale or trade in human tissues.

# 8.3.14. CUBA

Cuban Constitution, which was adopted in 1976<sup>256</sup>, obligates the State to assure that there shall be "no sick person who does not receive medical attention".<sup>257</sup> It also articulates specific obligations of the State to provide a full range of universally accessible health services, free of charge, as well as to guarantee the promotion and protection of the health of the individuals<sup>258</sup>. Thus, as early as 1976, the Cuban law established a constitutional framework for the development of a comprehensive and universal program of health services.

Nephrology as a medical specialty in Cuba began in 1962 and was formalized in 1966.<sup>259</sup> Cuba is one of the first countries with a comprehensive program for renal patient care.<sup>260</sup> Kidney transplantation in Cuba is totally free of costs for its citizens like the rest of other health services in the country.<sup>261</sup> The 11.2 million inhabitants of Cuba have full access to universal public healthcare coverage,

<sup>&</sup>lt;sup>255</sup> Part V prohibits trading in tissues.

<sup>&</sup>lt;sup>256</sup> Constitution of the Republic of Cuba, 1976 as amended in 2002.

<sup>&</sup>lt;sup>257</sup> Article 9, Constitution of the Republic of Cuba, 1976 as amended in 2002, (July 22, 2018), https://www.constituteproject.org/constitution/Cuba\_2002.pdf?lang=en.

<sup>&</sup>lt;sup>258</sup> Article 50, Constitution of the Republic of Cuba, 1976 as amended in 2002, (July 22, 2018), https://www.constituteproject.org/constitution/Cuba\_2002.pdf?lang=en.

<sup>&</sup>lt;sup>259</sup> Jorge P. Alfonzo, *Four Decades of Kidney Transplantation in Cuba*. 15 MEDICC Review (2013), (Jul. 31, 2018), http://www.redalyc.org/articulo.oa?id=437542091006.

<sup>&</sup>lt;sup>260</sup> Jorge P. Alfonzo, *Four Decades of Kidney Transplantation in Cuba*. 15 MEDICC Review (2013), (Jul. 31, 2018), http://www.redalyc.org/articulo.oa?id=437542091006.

<sup>&</sup>lt;sup>261</sup> Jorge P. Alfonzo, *Four Decades of Kidney Transplantation in Cuba*. 15 MEDICC Review (2013), (Jul. 31, 2018), http://www.redalyc.org/articulo.oa?id=437542091006.

including organ transplantation and immunosuppressive drugs. Since 1982, Cuban citizens have had the opportunity on their identity cards to affirm or deny their wishes for organ donation after death.<sup>262</sup>

8.3.15. INDIA<sup>263</sup>

The first kidney transplantation in India took place in May 1965.<sup>264</sup> Since then, India has been a leading country in the field of transplantation in the Asian subcontinent.<sup>265</sup>

The subject 'health' falls under Entry 6<sup>266</sup>, of List II (State List) in the Seventh Schedule to the Constitution of India, 1950. Generally, the Parliament has no power to make laws for the States with respect to any of the matters listed in Part II of the Seventh Schedule. But, pursuant to Articles 249<sup>267</sup> and 252<sup>268</sup>, of the Constitution of India, 1950, the Parliament enacted the Transplantation of Human Organs Act, 1994 (hereinafter referred to as THOA).

 <sup>&</sup>lt;sup>262</sup> Anselmo Abdo, *Liver Transplantation in Latin America*, 99 Transplantation, (2015), (Aug. 1, 2018), https://journals.lww.com/transplantjournal/Fulltext/2015/02150/Liver\_Transplantat ion\_in \_Latin\_America.42.aspx.

<sup>&</sup>lt;sup>263</sup> Republic of India, also known as Bharat, is a country in South Asia. It is the 7<sup>th</sup> largest country by area and the 2<sup>nd</sup> most populous country with a population over 1.4 billion people, (Oct. 05, 2018), https://en.wikipedia.org/wiki/India.

<sup>&</sup>lt;sup>264</sup> Acharya V. N., Status of Renal Transplant in India, 40 J. Postgrad. Med., 158 (1994).

<sup>&</sup>lt;sup>265</sup> H. R. Keshavamurthy, *Organ Donation and Transplantation Provides Second Life*, Press Information Bureau, Government of India, (Oct. 09, 2018), http://www.pib.nic.in/newsite/mb Erel.aspx?relid=118012.

<sup>&</sup>lt;sup>266</sup> Entry 6 of List II reads as: "Public health and sanitation; hospitals and dispensaries", Seventh Schedule of the Constitution of India, 1950.

<sup>&</sup>lt;sup>267</sup> "Power of Parliament to legislate with respect to a matter in the State List in the national interest".

<sup>&</sup>lt;sup>268</sup> "Power of Parliament to legislate for two or more States by consent and adoption of such legislation by any other State".

THOA provides for the regulation of removal, storage, and transplantation of human organs for therapeutic purposes and for the prevention of commercial dealings in human organs. It was enacted on the model of the United Kingdom, Human Organ Transplants Act, 1989<sup>269</sup>. THOA establishes an institutional structure to authorise and regulate human organ transplantations and to register and regulate the hospitals that are permitted to perform such transplantations. Later, the THOA was amended vide the Transplantation of Human Organs (Amendment) Act, 2011, which was notified in 2014. The 2011 amendment was intended to regulate the removal, storage and transplantation of human organs and tissues for therapeutic purposes and for prevention of commercial dealings in human organs and tissues.

The THOA recognises two types of donations namely, organ donation by a living person and that by a deceased donor. It also recognises the concept of brain-stem death<sup>270</sup>, facilitating a cadaver-based organ transplantation programme. Under the THOA, donation of organs and tissues for transplantation can be done by two categories of donors only. Firstly, by a 'donor' who may be a 'near relative'<sup>271</sup> of the patient, namely "spouse, son, daughter, father, mother, brother, sister,

<sup>&</sup>lt;sup>269</sup> "An Act to prohibit commercial dealings in human organs intended for transplanting; to restrict the transplanting of such organs between persons who are not genetically related; and for supplementary purposes connected with those matters", (May. 17, 2016), https://www.legislation.gov.uk/ukpga/1989/31/pdfs/ukpga\_19890031\_en.pdf.

 $<sup>^{270}</sup>$  § 2(d) defines brain-stem death. It means the stage at which all functions of the brain-stem have permanently and irretrievably ceased and is so certified under § 3 (6).

 $<sup>^{271}</sup>$  § 2(i) defines 'near relative'.

grandfather, grandmother, grandson or granddaughter".<sup>272</sup> Secondly, it permits donations from persons, who do not fall within the above-mentioned definition of relatives but out of "reason of affection or attachment towards the recipient or for any other special reasons", to donate provided they have prior permission from the Authorisation Committee established under the statute.<sup>273</sup>

The THOA also details actions that amounts to direct participation in or abetment of the organ trade and makes these offences punishable. Section 19 deals with the punishment for commercial dealings in human organs.<sup>274</sup> Section 19A further deals with the punishment for illegal transactions in human tissues.<sup>275</sup>

 $<sup>^{272}</sup>$  § 9 imposes restrictions on removal and transplantation of human organs or tissues or both. It states thus: "No human organ or tissue or both removed from the body of a donor before his death shall be transplanted into a recipient unless the donor is a near relative of the recipient".  $^{273}$  § 9 (3) states that, "If any donor authorises the removal of any of his human organs or tissues or both before his death... for transplantation into the body of such recipient, not being a near relative, as is specified by the donor by reason of affection or attachment towards the recipient or for any other special reasons, such human organ or tissue or both shall not be removed and transplanted without the prior approval of the Authorisation Committee".  $^{274}$  § 19 states: "Whoever—

<sup>(</sup>a) makes or receives any payment for the supply of, or for an offer to supply, any human organ;(b) seeks to find a person willing to supply for payment any human organ;

<sup>(</sup>c) offers to supply any human organ for payment; or

<sup>(</sup>d) initiates or negotiates any arrangement involving the making of any payment for the supply of, or for an offer to supply, any human organ;

<sup>(</sup>e) takes part in the management or control of a body of persons, whether a society, firm or company, whose activities consist of or include the initiation or negotiation of any arrangement referred to in clause (d); or

<sup>(</sup>f) publishes or distributes or causes to be published or distributed any advertisement, —

<sup>(</sup>a) inviting persons to supply for payment of any human organ;

<sup>(</sup>b) offering to supply any human organ for payment; or

<sup>(</sup>c) indicating that the advertiser is willing to initiate or negotiate any arrangement referred to in clause (d);

<sup>(</sup>g) abets in the preparation or submission of false documents including giving false affidavits to establish that the donor is making the donation of the human organs, as a near relative or by reason of affection or attachment towards the recipient, shall be punishable with imprisonment for a term which shall not be less than five years but which may extend to ten years and shall be liable to fine which shall not be less than twenty lakh rupees but may extend to one crore rupees".

<sup>&</sup>lt;sup>275</sup> § 19 A states "Whoever—

Further, the Transplantation of Human Organs and Tissues Rules was notified in the year 2014. The Rules provide for the procedure under which a living person may authorise the removal of any organ or tissue of his or her body<sup>276</sup>, procedure for the certification of brain-stem death<sup>277</sup>, the duties of a registered medical practitioner<sup>278</sup>, procedure for donation of organ or tissue in medico legal cases<sup>279</sup>, composition, powers and functions of the Authorisation Committee, etc. Authorisation Committees shall be constituted at the State level, and additional Authorisation Committees may be set up at the district level, institutional or hospital levels.<sup>280</sup> The primary duty of the Authorisation Committee is to establish that the unrelated donors are not under any coercion or undue influence from any type of monetary consideration to donate their organs. The Committee

<sup>(</sup>a) makes or receives any payment for the supply of, or for an offer to supply, any human tissue; or

<sup>(</sup>b) seeks to find a person willing to supply for payment and human tissue; or

<sup>(</sup>c) offers to supply any human tissue for payment; or

<sup>(</sup>d) initiates or negotiates any arrangement involving the making of any payment for the supply of, or for an offer to supply, any human tissue; or

<sup>(</sup>e) takes part in the management or control of a body of persons, whether a society, firm or company, whose activities consist of or include the initiation or negotiation of any arrangement referred to in clause (d); or

<sup>(</sup>f) publishes or distributes or causes to be published or distributed any advertisement—

<sup>(</sup>i) inviting persons to supply for payment of any human tissue; or

<sup>(</sup>ii) offering to supply any human tissue for payment; or

<sup>(</sup>iii) indicating that the advertiser is willing to initiate or negotiate any arrangement referred to in clause (d); or

<sup>(</sup>g) abets in the preparation or submission of false documents including giving false affidavits to establish that the donor is making the donation of the human tissues as a near relative or by reason of affection or attachment towards the recipient, shall be punishable with imprisonment for a term which shall not be less than one year but which may extend to three years and shall be liable to fine which shall not be less than five lakh rupees but which may extend to twenty-five lakh rupees".

<sup>&</sup>lt;sup>276</sup> § 3 of the Transplantation of Human Organs and Tissues Rules, 2014.

<sup>&</sup>lt;sup>277</sup> § 4 of the Transplantation of Human Organs and Tissues Rules, 2014.

<sup>&</sup>lt;sup>278</sup> § 5 of the Transplantation of Human Organs and Tissues Rules, 2014.

<sup>&</sup>lt;sup>279</sup> § 6 of the Transplantation of Human Organs and Tissues Rules, 2014.

<sup>&</sup>lt;sup>280</sup> §§ 11-13 of the Transplantation of Human Organs and Tissues Rules, 2014.

is to give definite reasons for rejecting or approving an application in writing.<sup>281</sup> The Rules also lays down the procedure to be followed in cases of donation by near relatives<sup>282</sup>, in cases of donors other than near relatives<sup>283</sup>, in cases when the proposed donor or the recipient are foreigners<sup>284</sup>, etc.

The Rules also provides for the licencing and registration of the hospitals, organ or tissue transplantation centres, tissue banks, and organ retrieval centres.<sup>285</sup> The Rules also lays down the manner in which the Human Organs and Tissue Removal and Storage Networks are established under the national, regional or state levels, as well as their functions.<sup>286</sup> The networking organisations are mandated to coordinate retrieval, storage, transportation, matching, allocation and transplantation of organs and tissues and shall develop norms and standard operating procedures for such activities and for tissues to the extent possible.<sup>287</sup>

The living transplantation program in India has evolved in the past four decades and is currently the second largest transplantation program in numbers after the one in the USA.<sup>288</sup> Even though the cadaveric organ donation is accepted under the THOA, the actual number of cadaveric donation in India remains very low.<sup>289</sup>

<sup>&</sup>lt;sup>281</sup> § 6 of the Transplantation of Human Organs and Tissues Rules, 2014.

<sup>&</sup>lt;sup>282</sup> § 18 of the Transplantation of Human Organs and Tissues Rules, 2014.

<sup>&</sup>lt;sup>283</sup> § 19 of the Transplantation of Human Organs and Tissues Rules, 2014.

<sup>&</sup>lt;sup>284</sup> § 20 of the Transplantation of Human Organs and Tissues Rules, 2014.

<sup>&</sup>lt;sup>285</sup> §§ 24-28 of the Transplantation of Human Organs and Tissues Rules, 2014.

<sup>&</sup>lt;sup>286</sup> § 31 of the Transplantation of Human Organs and Tissues Rules, 2014.

<sup>&</sup>lt;sup>287</sup> § 31 (5) of the Transplantation of Human Organs and Tissues Rules, 2014.

<sup>&</sup>lt;sup>288</sup> Sunil Shroff, *Current Trends in Kidney Transplantation in India*, 32 IJU ,173–174, (2016), (Oct. 09, 2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4970385/.

<sup>&</sup>lt;sup>289</sup> According to the data published by the National Organ and Tissue Transplantation Organisation, the number of living donation took place between 1995 and 2014 in India is

Any law enacted for dealing with the transplantation of human organs and tissues should primarily fulfil two main objectives. Firstly, it should prevent commercial dealings in the human organs and materials and secondly, it should increase the availability of transplantable human organs. In India, despite the THOA being in force for 24 years, neither could it prevent the commerce in human organs and tissues, nor have the number of deceased donors increased to take care of the organ shortage.<sup>290</sup> Despite the THOA, organ commerce generally and especially kidney scandals are regularly reported in India.<sup>291</sup>

Organ and tissue commercialism, which targets vulnerable populations<sup>292</sup> in resource-poor countries, has been condemned by the international community.<sup>293</sup> Most organ transplant laws across jurisdictions prohibit or regulate the sale or commercialisation of human organs and tissues. Apart from that, these statutes covers the procedure for donation, types of consent required, establishment of the transplant waiting lists, allocation of organs, certification of brain death,

<sup>14038.</sup> Whereas, in comparison, the total number of cadaver transplantation during the said period is 315, (Oct. 09, 2018), http://www.notto.gov.in/organreport.htm.

<sup>&</sup>lt;sup>290</sup> Sunil Shroff, *Legal and Ethical Aspects of Organ Donation and Transplantation*, 25 IJU, 348–355 (2009), (Oct. 09, 2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2779960/.

<sup>&</sup>lt;sup>291</sup> Anju Vali Tikoo, *Transplantation of Human Organs: The Indian Scenario*, 1 ILI Law Review, 152, (Summer Issue, 2017).

<sup>&</sup>lt;sup>292</sup> "Such as illiterate and impoverished persons, undocumented immigrants, prisoners, and political or economic refugees", *The Declaration of Istanbul on Organ Trafficking and Transplant Tourism*, 3 Clin. J. Am. Soc. Nephrol., 1227-1231 (2008), (Jul. 20, 2018), (Aug. 23, 2016), https://www.ncbi.nlm.nih.gov/pubmed/ 18701611/.

<sup>&</sup>lt;sup>293</sup> See, United Nations Convention against Transnational Organized Crime, 2000, Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Transplantation of Organs and Tissues of Human Origin, 2002.

performance of the transplant procedure, and management of post-transplant

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issues.294

In recent years, as a consequence of the increasing ease of internet communication and the willingness of affluent patients to travel and purchase organs, organ trafficking and transplant tourism have grown into global problems.<sup>295</sup> A near-universal ban on the sale of human organs around the world, coupled with a widespread reluctance in many cultures to donate organs even after death, has created this ever growing market.<sup>296</sup> Organ shortage leads to deaths and poor quality of life for those on the waiting list. Organ shortage also implies increased costs to the healthcare systems. The benefits of transplantation have also been marred by the growing phenomenon of organ trafficking and transplant tourism, practices that violate fundamental human rights and threaten individual and public health.<sup>297</sup>

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<sup>&</sup>lt;sup>294</sup> Arthur Chern, *Regulation of Organ Transplants: A Comparison Between the Systems in the United States and Singapore* (April 2008), (Jul. 26, 2018), https://dash.harvard.edu/bitstream/handle/1/8963882/Arthur%20Chern%20-%20Food%20%20Drug%20Law%20Final%20Pap er%20-%20Regulation%200f%20Organ%20Transplants.pdf?sequence=.

<sup>&</sup>lt;sup>295</sup> The Declaration of Istanbul on Organ Trafficking and Transplant Tourism, 3 Clin. J. Am. Soc. Nephrol., 1227-1231 (2008), (Jul. 20, 2018), https://www.ncbi.nlm.nih.gov/pubmed/1870 1611/.

<sup>&</sup>lt;sup>296</sup> Uditha Jayasinghe, *Sri Lanka Suspends Kidney Transplants for Foreigners After India Arrests*, India Real Time, Jan. 28, 2016, (Jul. 15, 2018), https://blogs.wsj.com/indiarealtime/2016/01/28/sri-lanka-suspends-kidney-transplants-for-foreigners-after-india-arrests/.

<sup>&</sup>lt;sup>297</sup> R. Matesanz, B. Dominguez-Gil et al., *How Spain Reached 40 Deceased Organ Donors Per Million Population*, 17 American Journal of Transplantation, 1447-1454, (Aug. 5, 2018), https://onlinelibrary.wiley.com/doi/epdf/10.1111/ajt.14104.

# IX. CONCLUSIONS AND SUGGESTIONS

#### 9.1. SUMMARY OF RESEARCH

The problems pertaining to the commercialisation of the human body and bodily materials were identified in the prologue to this thesis. The hypothesis and the research questions were also presented therein.

The 'human body' and 'human bodily materials', were defined in chapter I from a legal context. The human body is broadly classified as a living body or a dead human body, and the chapter examined how the law treats the human body when alive and after death. Legal questions that arises in dealing with a human body and bodily materials were introduced and further developed in the subsequent chapters.

An insight into the concept of property, its definitions and classifications over the ages were addressed in chapter II. Modern readings on property in the light of the human body and bodily materials are also discussed in this chapter. Developments in science and technology have created novel transactions. This raises new legal questions on the contours of existing legal concepts, including the concept of property. Hence there is a need for developing alternatives to address such issues.

Chapter III analyses the property interests specific to the human body and bodily materials. Complexities in the utilisation of the human body, both living and

dead, as a source of bodily materials for transplantation and research are addressed here. An analysis of cases involving transactions in the human body and bodily materials points towards the frequent usage of the legal concept of property as a tool by the courts to resolve these complexities.

The legal treatment of the human gametes and the basis for a differential treatment of the same from other human bodily materials are discussed in chapter IV. In numerous cases on claims related to gametes, the courts, without exception to jurisdiction have used the legal concept of property for settlement of the same. The chapter, also focuses on the legal regulation of commercial transactions involving human gametes.

Chapter V discusses the special status attributed to the human embryos in the light of the questions concerning their storage, use, destruction, etc. The creation of and commercial transactions involving embryos poses serious legal and ethical questions and has resulted in a series of cases. An analysis of these cases reveals that the embryos are treated both as 'persons' and as 'property'. It also reveals a much accepted middle view which claims that embryos can neither be treated as 'persons' nor as 'property' in its strict sense. They are considered as 'special entities' that have the potential to become persons, and therefore, warrant special status and respect.

Chapter VI looks into the reality of the market economy which is inclined to commodify the human body and bodily materials. There is a huge demand for human corpses, transplantable organs, tissues and other bodily materials, including gametes and foetal tissues. In the absence of a legal impediment, the tendency is to use the market principles in transactions involving the human body and bodily materials. Arguments in support of and against commercialisation are analysed in this chapter. Supporters of commercialisation of the human materials stress on the utilitarian principles. Those who oppose such a move bases their arguments on the principles of autonomy, dignity and bodily integrity of a person.

Chapter VII elaborates on the legal requirement of valid consent as a *sine qua non* for therapeutic and research uses of the human body and bodily materials. The chapter analyses how various legal systems recognises the aspect of 'consent' in their legislations with respect to the procurement of the human body and bodily materials. This analysis reveals that 'consent' in its strict jurisprudential sense is used when the same is focusing on the dignity of the person, while a very diluted concept of 'consent' is applied for ensuring maximum availability of the human bodily materials.

Chapter VIII is a study on the regulatory framework of the transactions involving human organs and tissues in different jurisdictions. Initiatives of the international agencies in relation to the transactions involving human bodily materials are dealt with under this chapter in detail.

# **9.2.** VERIFICATION OF THE HYPOTHESIS

As stated in the prologue, the research is based on the hypothesis that,

"The existing legal framework is inadequate to deal with the commercialisation of the human body and bodily materials."

The following research questions are raised, the answer to which, it was expected, will help in the testing of the hypothesis:

- 1. Whether the existing legal concept of 'property' is appropriate while discussing the status of the human body and bodily materials?
- 2. Whether the human body and bodily materials can be treated as entities amenable to commercial transactions?
- 3. What is the role of 'consent' in transactions involving the human body and bodily materials?

In the light of the research undertaken in the previous chapters, each of the above questions are analysed in the following paragraphs.

# 9.2.1. RESEARCH QUESTION 1

Whether the existing legal concept of 'property' is appropriate while discussing about the status of the human body and bodily materials?

Technology is the biggest challenge before the law. The impact of the same in the society is enormous and has left the law lagging much behind the technology. Law is often forced to stretch the existing legal concepts to find solutions to disputes resulting from technological advancements. Most often this stretching of legal concepts go to the extreme and diminishes or even negates their settled attributes.

The human body and bodily materials have become a desired 'thing' owing to the growth of medical and biotechnological advancements. The human body was within the concept of 'person' since the same was always a sort of corpus with respect to the legal concept of person. Chapter II discusses the scope of the legal concept of property within the traditional jurisprudential framework. The limited issue of claims over dead human body was not a big concern for the legal system. The practice was to apply the 'no-property rule'. However, certain specific cases, discussed in detail in chapter III, had prompted the courts to bring in the 'exception of work and skill' to provide an equitable remedy to the claimants. The said principle of the early twentieth century was accepted and in turn confirmed by the subsequent cases towards the end of twentieth century and thereafter. Thus, in a rudimentary form, it can be seen that, there is an acceptance of the concept of 'property' with respect to the human body and bodily materials.

Medical and biotechnological advancements have brought in new dilemmas for the legal systems prompting the courts as well as the legislatures to find solutions to the new questions raised as a result of these developments. In chapter III, the question whether the human body and bodily materials are property or not is discussed. This chapter analyses the relevant cases in this area. This analysis reveals that, without doubt, the courts use the legal concept of 'property' for resolving challenges brought by technological advancements. In chapter VIII, initiatives of international agencies as well as statutory prescriptions of various countries with respect to the transactions involving the human body and bodily materials are analysed. There is an absence of universally accepted legal concepts in regulating the transactions involving the human body and bodily materials. In the absence of such legal concepts with universal acceptance in this area, courts and legislatures of various jurisdictions have relied upon the legal concept of 'property' to regulate transactions in respect of the human body and bodily materials. In the light of this handicap in general jurisprudence, the way forward is to utilize the concept of 'property' for solving issues in respect of transactions involving the human body and bodily materials.

### 9.2.2. RESEARCH QUESTION 2

# What is the role of 'consent' in transactions involving the human body and bodily materials?

'Consent' is of great significance in a legal system since the same is the tool identified and utilised by the law for determining the validity of acts and omissions. Though it does not permit uncontrolled exercise of autonomy by the subjects, the 'concept of liberty' provides a sphere within which the will of the subjects can be exercised. The concept of 'consent' is in reality the exercise of the free will of a person. The adjective 'free' only implies that the consent is devoid of mitigating factors.

As mentioned above, there is a sphere within which this exercise of consent is permitted by legal systems. What is to be done by a person is actually determined by that persons' exercise of free will, recognized and accepted as the concept of 'consent' in law. The legal recognition of the testament of a deceased person indicates the legal system's acceptance of (valuing of) even the earlier expressed will of a person who is now dead. The testament of a deceased person regarding how to dispose of his body was also appreciated. Thus, the desire of a person whereby he expressly conveys his interest for donating his body for being used in medical studies or for research purposes is also recognized and accepted by the legal systems. In the absence of expression of such an interest by the deceased person, the desire as expressed by the near ones of the deceased person is also taken into consideration by the law.

When medical science developed to utilise human organs, for purposes like transplantation and research, legal issues arising out of the same were solved by applying the concept of 'consent'. Express consent of the person or in the absence of the same, the desire conveyed by the near ones of the said person was taken into consideration. Chapter VII discusses the importance of consent vis-à-vis autonomy and identifies numerous legal instruments to indicate that consent is the predominant element in sanctifying transactions in one's body and bodily materials. Chapter III, while discussing about the transactions with respect to the excised bodily materials, refers to various cases that demonstrates the use of 'consent' as a crucial factor for approving transactions in human bodily materials.

Even though the human body and bodily materials form the corpus of the legal concept of 'person', once the aura of personality is no more, or when a bodily material is severed from the human body, it becomes a 'thing' over which decisions can be taken by the person concerned on the basis of the concept of consent. 'Consent' thus gives legal sanctity for such decisions.

Hence, it is found that among the available legal options, only the concept of 'consent' of the concerned person is capable of ensuring that there is the element of equity and justice with respect to the transactions involving the human body and bodily materials.

#### 9.2.3. RESEARCH QUESTION 3

# Whether the human body and bodily materials can be treated as entities amenable to commercial transactions?

A legal system is concerned only about the legal relationship which exist between person and person and between person and property. In a market driven economy, once something is categorised as 'property', it is usual to permit absolute discretion to the person who is having control over the said property. Even then, the legal system was never hesitant in creating riders on this absolute discretion given to the owner of a property. For example, the utilisation of a person's landed property is controlled by the municipal licensing terms. Even the owner can use such property only for permitted purposes. Similarly, conditions are prescribed with respect to the scope of utilisation of commodities when the same is identified as essential ones. Further, the doctrine of '*eminent*  *domain*' is applied so that the State can take over any private property by giving 'just compensation', provided, the same is for public purposes. Thus, umpteen examples can be cited to show that the owner does not have an absolute right over of his property.

Hence the concepts of 'property' and 'consent' are identified to be best suited to deal with transactions involving the human body and bodily materials. There is sufficient scope for interference by the legal system so that no absolute discretion is exercised by the person concerned over the human body and bodily materials. In a society or system wherein once the human body and bodily materials are accepted as property and consent is used as a means for exercise of discretion with respect to the same, in the absence of a control by the legal system, there is high chances of its commercialisation just like any other 'thing'. However, since the legal system reserves the power to interrupt the exercise of such an absolute discretion, the legal concepts of 'property' and 'consent' can be used for ensuring that there are no commercial angles to the transactions with respect to the human body and bodily materials also. Chapter VI demonstrates that there is a need for the human body and bodily materials and there is also a dearth of the same. This shortage definitely is capable of creating a commercial interest in the human body and bodily materials and has in fact done so.

Chapter VIII discusses the laws of various countries with respect to the control of commercial transactions in the human body and bodily materials. Many countries have utilised the available powers of the state to ensure that there is no chance for commercialisation of the human body and bodily materials. At the same time, there are countries without any legal regulation in the said area. Further, statutes of certain countries indicate that the existing legal framework is not sufficient enough to avoid the commercialisation of the human body and bodily materials. There are also certain exceptional situations wherein almost a free market is permitted.

Chapter VIII also covers the initiatives of the international agencies wherein there is a constant attempt to avoid commercialisation by laying down the standards to be followed. However, as evident from statutes in various countries, this non-commercial approach is not there throughout the world. Therefore, it can be seen that the efforts of international agencies are not having a uniform impact on all countries. Further, there is a definite inflow of persons in requirement of bodily materials moving to such countries for commercially exploiting the absence of a legal control. Therefore, it can be seen that when a particular country is strict in avoiding commercialisation, there is a flow of affluent people from such countries to countries where there is a scope for commercial exploitation. The invariable conclusion is that a uniform legal system against commercialisation needs to be present throughout the world to ensure that there is absence of commercialisation in the human body and bodily materials. Hence it can safely be concluded that even after using the concepts of 'property' and 'consent', the legal systems throughout the world needs to take sufficient precautions against commercialisation of the human body and bodily materials.

# 9.3. RESEARCH FINDINGS

Before venturing to give suggestions to ensure a better regulatory framework for preventing commercial transactions in the human body and bodily materials, it would be worthwhile to recapitulate the important findings of this research:

- 1. The human body and bodily materials are very significant in researches that leads to the growth of medical science and biotechnology. In fact, the growth of these branches of science depends upon the availability of human cadavers and other bodily materials. Retention, use and destruction of the human body and bodily materials are matters of concern for the law.
- 2. Increase in the demand for the human body and bodily materials have augmented its commercial value, which prompted the law to interfere in the control which a person has over his own body and the body of others.
- 3. Normally, a person cannot own his own body. Whereas, a dead human body can be owned and possessed by another entity. Therefore, property interests in a cadaver arises at the point of death, then pass it on to the representative of the deceased. The rights of living persons over their excised biological materials and their prospective rights to control the disposition of their bodies after death raise complex legal issues.

- 4. Organs and tissues for transplantation can be sourced either from the living, the dead or from the brain dead. Either with regards to the living or the dead, there are a lot of limitations attached to the procurement of organs. The best and viable option is to source the required human organs and tissues from the brain-dead persons.
- 5. It is pertinent to note that any commercial transaction is accompanied by commodification, objectification and exploitation. With the increase in commercial use of the human body and bodily materials, exploitation associated with the market framework has also increased. This has resulted in the exploitation of the people involved, especially vulnerable sections of the population.
- International institutions have taken initiatives to curtail the growth of 'transplant commercialism', 'transplant and reproductive tourism', etc., across the national borders.
- 7. Various legal systems across the globe, with a few exceptions, have developed a legal framework to prevent commercial dealings in the human body and bodily materials and which tries to promote 'altruistic donation' through stringent anti-commercialisation laws.
- 8. When legal systems regulated transactions involving the human body and bodily materials, it became a scarce resource. This has increased the demand for human organs and other bodily materials.

- 9. Difficulty in the procurement of human cadavers for medical studies and materials for transplantation and research, has led to the rise of black markets in the same.
- 10. It is imperative that there should be stringent laws to prevent commercial exploitation of the human beings on the one hand, and to ensure the supply of human cadavers, transplantable human organs and other bodily materials, which is essential for medical studies, transplantation surgeries and other therapies as well as research leading to the development of medical science and biotechnology.
- 11. Entry of the human body and bodily materials into the market scenario has brought in the concept of 'property' to the forefront. Acknowledging property interests in the human body and bodily materials is a frequently applied formula to solve the immediate problem. Courts have drawn distinction as to which all human bodily materials could be treated as property and which all materials could not be brought into the framework of 'property'.
- 12. A human person is not just the physical self which one see from outside. There is an inherent value or dignity attributed to every individual, that can be referred to as 'personhood'. A sound and healthy person should be given the choice to take decisions pertaining to his life and his human body. For this very reason, informed consent, bodily integrity and personal autonomy of persons should be protected and well preserved through the law.

# 9.4. SUGGESTIONS

On the basis of the above research findings, the following suggestions are proposed to prevent the commercialisation of the human body and bodily materials, which has led to the exploitation and objectification of human beings.

- Legal framework of a specific country, even if it is effective, is incapable of preventing the movement of its subjects to countries with less stringent laws for bypassing the restrictive laws in their own country. Thus, the anticommercialisation laws of individual countries alone will not be sufficient to avoid commercialisation of the human body and bodily materials.
- 2. Since commercialisation of the human body and bodily materials have turned to be a problem beyond the national frameworks, the international community should address the issue on a larger framework. International conventions regulating commercialisation should be adopted and made use of to combat transnational commercial transactions in the human body and bodily materials.
- 3. An accessible, authentic, transparent, dynamic and secure database at the national level may be created by legislation to contain the details of persons who are consenting for donating their body and bodily materials as well as the persons or institutions in need of the same for therapeutic, educational or research purposes.
- 4. A competent statutory authority to control such a database is required. All the transactions in relation to the human body and bodily materials have to be

permitted only through this centralised database. It can be seen that similar idea (example, Eurotransplant, Scandiatransplant, etc.) has been implemented successfully at a regional level. The said authority should also have sufficient infrastructure to act in a time bound manner.

- 5. Similarly, the proposed authority should also have the power to equitably distribute donated human body materials in the most appropriate manner. The qualifications for the donors as well as the recipients are to be specified in the statute itself. It is suggested that in the larger interest, the said category should be limited to subjects of the said jurisdiction.
- 6. With respect to the living donors, undoubtedly, there is a cost incurred by them in the donation process like medical expenses, loss of income due to unproductive time spent in the process as well as in aftercare. Moreover, the said donor continues to live with the risk consequent to the donation process and there needs to be a uniform compensating mechanism to cover the cost incurred by such donors. Here donors may be categorised according to the nature of the human material they are donating.
- 7. The statute should provide for a definite and specific regulatory mechanism for the declaration of brain-stem death to avoid exploitation of the same for ulterior purposes. The aim should be to increase the availability of and facilitate the procurement of organs and tissues from the brain-stem dead donors and reduce the over reliance on living donors.
- 8. With respect to educational, medical and research institutions, which deals with the human cadavers and other human bodily materials, there should be

- a proper accreditation mechanism and framework for identifying their requirements. It should also ensure that the said institutions are not using the donated human materials for purposes other than the permitted ones. The scope of permitted purposes should be well defined so as to satisfy the contemporary moral and ethical standards of each jurisdiction. At the global level also, there should be a minimum understanding with respect to the extent to which the works of such institutions may be permitted and individual jurisdictions should not permit utilisation of the human bodily materials beyond such limit.
- 9. Among the statutes of the countries that were analysed, it can be seen that there exist wide variations in the legal framework as well as the practical implementation of the same. In many countries, there exists either no law or no effective law for avoiding commercialisation of the human body and bodily materials. It can be seen that there is a movement of affluent people to the countries where transplantation and infertility treatments can be availed at low cost and with less legal constraints. It is suggested that a proper international agency needs to be identified and entrusted with the task of creating a model law that could be followed by the individual countries to combat commercialisation.
- 10. The vulnerable persons may need particular legislative protections. Even if the body parts are treated as property, to cater to their special character, the law must also incorporate concepts such as autonomy and informed consent along with the property interests. It is the law of consent that determines the

circumstances in which tissues can be removed from the body of a person. However, to avoid legal gaps after excision, both the law of consent and the law of property need to operate in tandem.

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## ANNEXURE I

# Containing Human Trafficking for Removal of Organs: Need for New Approach

# **ANNEXURE II**

# Working Women's Extended Reproductive Freedoms