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ETHICS IN BIOMEDICAL RESEARCH: WITH SPECIAL REFERENCE TO PSYCHIATRIC RESEARCH

Under the Guidance and Supervision of

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CERTIFICATE

This is to certify that **Ms. AIFOONA PUNNARAM, REG NO: LM0320002** has submitted her Dissertation titled **"ETHICS IN BIOMEDICAL RESEARCH: WITH SPECIAL REFERENCE TO PSYCHIATRIC RESEARCH"** in partial fulfilment of the requirement for the award of Degree of Masters of Laws in Public Health Law to the National University of Advanced Legal Studies, Kochi, under my guidance and supervision. It is also affirmed that the dissertation submitted by her is original, bona fide and genuine.

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NUALS, Kochi

Date: 11th October 2021

Place: Ernakulam

DECLARATION

I declare that this Dissertation titled **"ETHICS IN BIOMEDICAL RESEARCH: WITH SPECIAL REFERENCE TO PSYCHIATRIC RESEARCH"** is researched and submitted by me to the National University of Advanced Legal Studies, Kochi in partial fulfilment of the requirement for the award of Degree of Master of Laws in Public Health Law, under the guidance and supervision of Ms. P.B. Arya, Assistant Professor and is an original, bona fide and legitimate work and it has been pursued for an academic interest. This work or any type thereof has not been submitted by me or anyone else for the award of another degree of either this University or any other University.

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PREFACE

In the present time, when we are confronting a pandemic that requires awareness at the individual levels to protect the collective, the duties to develop scientific temper, humanism, and spirit of inquiry have become essential to be observed and practiced. It is the responsibility of every citizen to contribute to reform society for a better way of life.

Progress towards a world where all can relish optimal health and health care is vitally dependent on all kinds of research, including human research. Involving humans in medical research is crucial to improve the knowledge base on which medicine should be rooted. Meanwhile, persons participating in health-related research have inviolable human rights and have a right to be protected against the harms that research may cause them. The tension between these two considerations has induced the medical community to endorse ethical guidelines for health-related research.

Psychiatric research has increased remarkably over recent decades to help in understanding the current trends and better therapeutic options for illness. Compliance with ethical standards is required to maintain and increase the overall quality and acceptability of research. It is noteworthy that psychiatric research faces several unique ethical challenges. Hence, ethical guidelines are indispensable to safeguard the research participants.

ABBREVIATIONS

1.	A.I.R.	All India Reporter
2.	A.E.R.A.	American Educational Research Association
3.	A.M.A	American Medical Association
4.	A.P.A.	American Psychological Association
5.	A.S.A.	American Sociological Association
6.	BPS	British Psychological Society
7.	CDC	Centers for Disease Control and Prevention
8.	CDSCO	Central Drugs Standard Control Organisation
9.	CFR	Code of Federal Regulations
10.	CIOMS	Council for International Organizations of Medical Sciences
11.	CRISPR	Clustered Regularly Interspaced Short Palindromic Repeats
12.	DALY	Disability Adjusted Life Year
13.	DSM	Diagnostic and Statistical Manual of Mental Disorders
14.	ECT	Electroconvulsive therapy
15.	EMR	Electronic Medical Records

16.	Et. al.	Et alia (and others)
17.	EU	European Union
18.	fMRI	Functional Magnetic Resonance Imaging
19.	IACP	Indian Association of Clinical Psychologists
20.	IAPP	Indian Association of Private Psychiatry
21.	ICCPR	International Covenant on Civil and Political Rights
22.	ICESCR	International Covenant on Economic Social and Cultural Rights
23.	ICH-GCP	International Conference on Harmonisation - Good Clinical Practice
24.	ICMR	Indian Council of Medical Research
25.	IMHPJ	International Mental Health Professionals Japan
26.	IPS	Indian Psychiatric Society
27.	IRB	Institutional Review Boards
28.	IVRS	Interactive Voice Response System
29.	JPA	Japanese Psychological Association
30.	LAMIC	Low and Middle-Income Countries
31.	MADRS	Montgomery–Asberg Depression Rating Scale
32.	MHP	Mental Health Professional

33.	MHRB	Mental Health Review Board
34.	MRC	Medical Research Council
35.	NIH	National Institutes of Health
36.	NHS	National Health Service
37.	OPRR	Office for the Protection of Research Risks
38.	PMI	Persons with Mental Illness
39.	PPIE	Public and Patient Involvement and Engagement
40.	QALY	Quality Adjusted Life Year
41.	R&D	Research and Development
42.	s.	Section
43.	SOP	Standard Operating Procedures
44.	SUD	Substance Use Disorder
45.	UDHR	Universal Declaration of Human Rights
46.	UNESCO	United Nations Educational, Scientific And Cultural Organisation
47.	U.N.	United Nations
48.	UOI	Union of India
49.	U.S.A.	United States of America

50.	U.K.	United Kingdom
51.	v.	Versus
52.	Viz.	That is to say
53.	W.H.O.	World Health Organisation
54.	W.M.A.	World Medical Association
55.	W.P.A.	World Psychiatric Association

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INTRODUCTION

The World Psychiatric Association in its Code of Ethics for Psychiatry[1] defines psychiatry as "*the medical specialty that works with other medical specialties and with other mental health disciplines in the interest of preventing mental disorders, diagnosing and treating people with such disorders, rehabilitating them, managing psychological aspects of non-psychiatric illnesses, and promoting mental health."*[2]

Ethics in psychiatry is a complex topic. While involving in research, psychiatrists and researchers in different areas bring their values to their work. Additionally, they must also deal with the values of their colleagues and patients. There are chances that the intermixing of such values might result in issues relating to confidentiality, informed consent, and duties to third parties.

Importance of Ethics in Psychiatric Research

Advancements in medical care and disease prevention are based on understanding physiological and pathological processes or epidemiological findings and require research involving human subjects. The collection, interpretation, and analysis of data obtained from research involving human beings vastly improve human health.

The term 'ethics' is derived from the ancient Greek word, '*ethos*', which means understanding right and wrong.[3] It refers to moral standards and values that a person carries within him. The American sociologist Earl Robert Babbie defines research as "*a systematic inquiry to describe, explain, predict, and control the observed phenomenon.*" Ethics play a pertinent role in all kinds of research, including psychiatric research, as adherence to ethical norms is quintessential for protecting research participants and for an unmanipulated research outcome.

Historically, medical research has been conducted unethically, like the lack of informed consent and respect for autonomy. Some past instances include the 'warehousing' of psychiatric patients in asylums and experiments conducted by Nazis during World War II (e.g., forced sterilizations,

[1] https://www.wpanet.org/policies.
[2] World Psychiatric Association (WPA) is a global organisation of psychiatric societies, spread across 120 countries.
[3] MacKenzie C. R., *What would a good doctor do? Reflections on the ethics of medicine*, 5 HSS J. 196, 197 (2009).

hypothermia experiments)[4]. As a result of such events, countries codified a set of medical ethics for research and practice, such as the Nuremberg Code, the Declaration of Geneva, the Declaration of Helsinki, and the Belmont Report[5] [6] [7]. These documents formalized the four fundamental principles of medical ethics that physicians and scientists adhere: autonomy (including the necessity for informed consent), non-maleficence, beneficence, and justice.[8]

What is the need for ethical norms in psychiatric research?

1. Although psychiatry is a sub-field of medicine and mental health issues come within the scope of medical ones, there are many ethical issues in research and clinical care specific to mental health. For instance, familial pressures for treatment are less prominent in general medicine than in psychiatry. Also, rational decision-making is relatively less of a problem for general medical patients. Therefore, the need for addressing ethical issues in psychiatric research and practice is long overdue.

2. Research methods for evaluating the efficacy of behavioral health interventions are complicated. Also, these methods become ever more complex as more factors are identified that can undermine the validity of research studies. This is another reason why ethical norms are required in psychiatric research.

Importance of the Study

Psychiatry studies present unique challenges. Ethical issues relating to the risk of worsening of illness, the validity of informed consents, and the use of placebo are commonly faced. Site selection is also not easy due to the relative dearth of ICH-GCP (International Conference on Harmonisation - Good Clinical Practice) trained psychiatric investigators.

Moreover, evaluating the consent capacity of patients has its nuances. As the illness fluctuates, the consent capacity of the research subject/ patient may change, thus necessitating the continued

[4] LIFTON R. J., THE NAZI DOCTORS: MEDICAL KILLING AND THE PSYCHOLOGY OF GENOCIDE BASIC BOOKS (1986).
[5] Roberts L. W., Roberts B., *Psychiatric research ethics: an overview of evolving guidelines and current ethical dilemmas in the study of mental illness,* 46 BIOL PSYCHIATRY 1025, 1030 (1999).
[6] World Medical Association, World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects, 2013.
[7] National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects Of Research (1978).
[8] Bloch S., Green S. A., *An ethical framework for psychiatry*, 188 BR J PSYCHIATRY 7, 11 (2006).

assessment of consent capacity. The process of obtaining informed consent is frequently seen as a potential source of difficulty. For example, in the recruitment to trials of new agents for Alzheimer's disease, the question of how to ethically involve participants who may lack the capacity to give informed consent arises. Further, suppose a patient with schizophrenia is detained by law. In that case, the question is how we can ensure that he/she does not feel pressurised to participate in research conducted by the institution in which she is detained.

Psychiatry studies are connected with a high placebo response. Sometimes, despite the attendant difficulties, placebo-controlled studies are undertaken. Further, the high placebo response often results in failed trials.

Rating scales are required for assessing drug response. Some rating instruments and procedures may not be conducive to a cultural or national setting. There are also chances that technological developments may aggravate the procedural complexity but improve the quality of ratings.

Psychiatric-specific training and expertise are essential to ensure the successful conduct of research studies in a country. When conducting research, researchers and psychologists should respect the dignity of participants and act for the welfare of participants. Research must be undertaken following scientific standards and ethical principles governing research with human research participants.

This dissertation work reflects the role of ethics in psychiatric research. It presents how various countries have dealt with various ethical issues through legal instruments and how effective the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017, address the ethical concerns in psychiatric research.

Objectives of the Study

-To understand the ethical principles in biomedical research.

-To study the ethical concerns in biomedical research with particular reference to psychiatric research.

-To study the Indian and other legal/ regulatory positions on the conduct of psychiatric research.

Scope of the Study

The research focuses on examining the ethical principles and ethical concerns in psychiatric research. A particular focus is diverted to evaluating how psychiatric research is regulated by the Indian guidelines along with a comparative perspective of psychiatric guidelines in other countries, viz, U.S.A., U.K., China, Japan, and Germany.[9]

Research Questions

I.a. Whether psychiatric patients participating in psychiatric research can be subjected to placebo-controlled research studies?

I.b. Whether psychiatric patients participating in psychiatric research can be subjected to research relating to electro-convulsive therapy?

II. Evaluation of Certain Biomedical Principles in the context of Psychiatric Research

-How should informed consent be obtained in psychiatric research?

-How should confidentiality be maintained in psychiatric research?

III. Is the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017 sufficient to regulate psychiatric research's ethical concerns?

Hypothesis

-The National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017, is not sufficient to regulate the ethical concerns of psychiatric research.

-Subjecting psychiatric patients uncontrollably to invasive procedures like ECT is unethical. There must be separate guidelines that prescribe limits on subjecting psychiatric patients to processes like electro-convulsive therapy and placebo-controlled trials.

-There must be a psychiatric code in India to regulate psychiatric research and practice.

Outline of Study/ Chapterisation

[9] The comparative study of laws has been chosen in the countries mentioned above based on the top 5 countries spending the highest in research as per the United Nations Educational, Scientific and Cultural Organization (UNESCO).

Chapter 1: History of Law on Biomedical Research

Chapter 2: Ethical Principles

- Various philosophical approaches to medical ethics like utilitarianism, deontology are discussed. Ethical principles are explained along with how these principles apply to psychiatric research.

Chapter 3: Ethical Issues in Psychiatric Research

In this Chapter, the ethical issues in psychiatric research will be discussed. (For example, the specific ethical concerns that arise while giving consent, subjecting the psychiatric patient to placebo-controlled studies, electro-convulsive therapy etc.)

Chapter 4- Ethical Regulations in Psychiatric Research: Comparative Perspective

The ethical guidelines and other regulatory mechanisms governing psychiatric research in U.S., U.K., China, Japan, and Germany are specified.

Chapter 5- Ethics in Psychiatric Research: Indian Regulatory Position

Whether the Indian law and guidelines on Biomedical Research is sufficient to address the ethical concerns in psychiatric research?

Chapter 6- Conclusion and Suggestions

An analysis of the research study and suggestions on how to regulate psychiatric research in India are given.

Methodology of the Study

The doctrinal research method is adopted in this research work. The doctrinal research methodology is suitable to understand the ethical issues in psychiatric research. Also, the methodology would help determine the effectiveness of the ICMR Guidelines, 2017, in addressing the ethical issues in psychiatric research. A comparison of psychiatric guidelines in different countries is undertaken with the help of this research method.

Literature Review

1. ‘Ethics in Mental Health Research: Principles, Guidance and Cases’ by James M. DuBois, Oxford University Press, 2007.

It is a well-written volume that elaborates on the basic principles in medical ethics as applied to research. It also explains informed consent, capacity to consent, risk and benefit assessment, confidentiality, research design, justice issues in recruitment, and conflicts of interest. The author highlights many legitimate points of view within the wide boundaries of ethically justifiable behavior.

2. ‘Empathy in Mental Illness’ edited by Tom F. D. Farrow and Peter W. R. Woodruff, Cambridge University Press, 2007.

There have been several initiatives to understand mental illness from the point of view of neurobiology and genetics. However, this book focuses on ‘empathy’ to enhance the understanding of behaviour, mental illness and human relatedness, and behavioural treatment interventions. Tom Farrow and Peter Woodruff specify the various definitions of empathy and ways of learning about it by studying the behaviour of persons who seem to have deficits in empathy. Genetic, psychological, and anatomical approaches are mentioned in some of the studies in *Empathy in Mental Illness*. Such efforts are essential to developing knowledge about empathy, which may positively impact early intervention, treatment approaches, cure, prevention, further research, and social communication in general.

3. ‘Ethics in Psychological Research, A Practical Guide for the Student Scientist’ by Daniel P. Corts, Augustana College, Holly E. Tatum, Randolph College, SAGE Publications, 2019.

This book can be considered as a practical guide for instructional purposes. The role of ethics in psychiatric research is discussed. Each chapter begins by describing an ethical issue. Each chapter provides a background to the ethical issue, and further suggests ways how to avoid the problem. The entire book explains the ethical principles put forth by the American Psychological Association and the U.S. Federal Government.

Conclusion

The ethical issues affecting psychiatric research differ from other medical disciplines to a certain extent. These concerns relate to informed consent, confidentiality, conflict of interest, placebo related, operational challenges, etc.[10]

Ethics plays a crucial role in protecting the rights of persons with mental illness and safeguarding the interest of researchers. Ethical guidelines help to maintain transparency and accountability in research. As such, various ethical guidelines have been devised by national and international organizations.[11]

Medicine is a healing art and also a science. The dynamics of this combination are best observed in psychiatry, the branch of medicine that deals with the care and treatment of those who are ill or infirm, due to a mental disorder or impairment. Although social, cultural and national differences might be present in research, the requirement for ethical conduct in research and continual review of these standards is universal.[12] Research in psychiatry is not an exception in this regard and must conform to ethical principles.

[10] Venkoba Rao A., *Gita and Mental Sciences*, 22 INDIAN J PSYCHIATRY 19, 27 (1980).
[11] Shobhit Jain, Pooja Patnaik Kuppili et al., *Ethics in Psychiatric Research: Issues and Recommendations*, 39(5) INDIAN J PSYCHOL MED. 558, 565 (2017).
[12]World Psychiatry Association, Madrid Declaration on Ethical Standards for Psychiatry, 1996 (https://www.wpanet.org/current-madrid-declaration).

CHAPTER 1: HISTORY OF ETHICS IN BIOMEDICAL RESEARCH

1.1.Introduction

Biomedical research is multi-faceted. Through the vast arena of biomedical research, humanity has benefitted from new knowledge regarding the human body, ailments and in devising efficient prophylactics and treatments. On the flip side, it has inflicted loss and damage on research participants.[13] The question of substantial concern has always been regarding the conflict of commitments a researcher might face between his pursuit of knowledge (including how he must conform to scientific rigour and ethical principles) and the interests of the research participants.

There are numerous historical examples of abuse of animal and human subjects for research. After the Nazi atrocities and the Second World War, which displayed how biomedical research can go wrong, the scientific community has devised measures to protect human participants. Several legal instruments have been drafted to regulate biomedical research.[14]

The concern for medical and research ethics can be seen from the time of Hammurabi and Hippocrates. There were various instruments in the form of laws decrees, assumptions, and oaths prepared by physicians who enumerated the rights and safety of patients. Among the oldest of these instruments are the Code of Hammurabi[15] in Babylonia (1750 BCE), Egyptian papyri,[16] Indian and Chinese writings, and early Geek writers, most notably Hippocrates (460-377 BCE).

In ancient India, there was the 'Atreya Samhita,' which was a vow from prospective doctors by the Gurus, and it specified that "*Thy shouldst with thy whole heart strive to bring about the care of those that are ill-not even for thy sake extorting their substance*." In other words, utmost care should be given by doctors to their patients.

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[13] Wood A., Darbyshire J., *Injury to Research Volunteers- The Clinical Research Nightmare* 18 NEJM 354 (1869).
[14] MASON & LAURIE, LAW AND MEDICAL ETHICS 650 (Oxford University Press 2006).
[15] Hammurabi's Code of Laws is considered the first documented code ever used by human civilization in Mesopotamia. Hammurabi's Code of Law states that "If a surgeon performed a major operation on an 'awelum' (nobleman), with a lancet and caused the death of this man, they shall cut off his hands." Fees for lifesaving operations are also mentioned i.e., ten shekels of silver for 'awelum,' five shekels for 'mushkenu' (poor man) and two for a slave. Available at: Allen D. Spiegel, Christopher R. Springer, *Babylonian Medicine,, Managed Care and Codex Hammurabi*, Circa 1700 B.C., 22 J. COMMUNITY HEALTH 69,72 (1997).
[16] The papyri describe various diseases and enlist diagnosis and remedies for the specified diseases, including herbal remedies, surgery, and magical spells.

Cassiodorus, a Roman statesman in 530 A.D., wrote two documents that described the duties of physicians. The first document detailed the laity's monastic medical care, which guides monks who were physicians (Institutiones). The second document contained regulations regarding the activities of the civic physicians of Ostrogothic Rome[17] and the royal household (*Variae*).

Moreover, the Oath of Hippocrates is appraised as the first code written in an organised and logical way that describes physician and patient relationships. It is held sacred by physicians and mentions specific ethical standards to be followed, such as treating the patients to the best of one's ability and maintaining confidentiality. Several other codes were written in the medieval age regarding the practice of medicine and medical ethics. It was also the time when clergypersons practiced medicine.

Further, down the lane in the 18th century, Thomas Percival's writings represent one of the first ethical codes in the United States and the Western world.[18] In his work, 'Medical Ethics: a Code of Institutes and Precepts Adapted to the Professional Conduct of Physicians and Surgeons', physicians' moral authority and liberty in service to others, their responsibility towards the sick, and the principle of individual honor was emphasized.

(i) **Nuremberg Code**

During the second half of the nineteenth century, medical organisations published codes of medical ethics. The American Medical Association (A.M.A.) introduced its first ethics code in 1848.[19] This was the first ethical code of a professional organisation that laid down patients' and caregivers' rights. Over the years, several changes to this original code have been made. Further, the A.M.A. laid down the basis for the Council on Ethical and Judicial Affairs to advise legal and ethical issues and draft position papers. In the U.K., the British Medical Association published its first code regarding the medical conduct of physicians, i.e., the Medical Act, in 1858.[20]

[17] The *Ostrogoths* invaded Italy in 489 and developed an empire north of the Black Sea in the 3rd century.
[18] C.B. Chapman, *On the Definition and Teaching of the Medical Ethics*, 301 N ENGL J MED 630 (1979).
[19] BAKER R., CRISIS, ETHICS AND THE AMERICAN MEDICAL ASSOCIATION 163, 164(1997).
[20] The Medical Act 1858 created the General Medical Council to regulate doctors in the United Kingdom.

Further, the World Health Organisation (WHO)[21] issued the Declaration of Geneva in 1949. This is the first international medical ethical code and is built upon the Oath of Hippocrates. It is a declaration that came up during German-occupied Europe because of the commission of horrifying medical crimes.

The crimes committed by Nazi scientists and physicians during the Second World War under the guise of medical experimentation led to a global uproar. These events accelerated the need for a code of conduct for human research.[22] The biggest German Nazi concentration camp, Auschwitz, witnessed Josef Mengele's brutal experiments on Gypsy children, physically incapacitated adults, and twins. After the research came to a halt, they were killed and their organs autopsied and analyzed.[23] The research conducted by the Nazis involved prisoners of war and civilians. By the end of the research, the subjects either died or faced some disfigurement or permanent disability. These experiments, which the government promoted, included exposing the subjects to warm baths, freezing temperatures (hypothermia), and pharmacological agents. Apart from testing for infectious diseases and conducting genetic experiments, traumatic injury experimentation was also performed on subjects by amputating their limbs.[24]

After the war, 16 German physicians were tried and found guilty of nefarious crimes against humanity. As a result of this historic trial in 1947, the Nuremberg Code, a set of guidelines regarding research on human beings, was drafted. It is also one of the initial international documents on medical ethics and elaborated on ten principles such as patient consent and autonomy. The Nuremberg Code also vastly influenced the evolution of human rights law.[25]

[21] The World Health Organisation is a specialized agency of the United Nations, which was established in 1948 for monitoring and regulating international public health. W.HO's objective, as laid down in the W.H.O Constitution, is "the attainment by all peoples of the highest possible level of health."
[22] ARTHUR L. CAPLAN, WHEN MEDICINE WENT MAD: BIOETHICS AND THE HOLOCAUST (2012).
[23] L. M. LAGNADO AND S. COHN DEKEL, CHILDREN OF THE FLAMES: DR. JOSEF MENGELE AND THE UNTOLD STORY OF THE TWINS OF AUSCHWITZ (1992).
[24] J. KATZ, EXPERIMENTATION WITH HUMAN BEINGS: THE AUTHORITY OF THE INVESTIGATOR, SUBJECT, PROFESSIONS, AND STATE IN THE HUMAN EXPERIMENTATION PROCESS 292, 306 (New York, NY: Russell Sage Foundation, 1972).
[25] G. J. ANNAS AND M. A. GRODIN, THE NAZI DOCTORS AND THE NUREMBERG CODE: HUMAN RIGHTS IN HUMAN EXPERIMENTATION 2 (New York, NY: Oxford University Press, 1992).

However, it is noteworthy that the Nuremberg Code has not been officially recognised as law by any nation.[26] The Nuremberg Code's reference to Hippocratic duty and the importance of giving information was not initially supported by the American Medical Association. The Western practitioners considered it as a 'code for barbarians' and not for civilized medical practitioners. Also, the final judgment in the Nuremberg Trial[27] did not mention whether the Nuremberg Code should be applied to medical research involving political prisoners, convicted felons, and healthy volunteers. Some argued that the inflexible language of the Nuremberg Code portrayed that the Code was designed for singularly heinous transgressions.[28]

(ii) **Declaration of Helsinki**

Subsequently, in 1964, the World Medical Association issued the Declaration of Helsinki, which stipulated twelve essential principles for human biomedical research. However, these principles were substantially physician-oriented and were silent on the issue of research in developing countries. The Declaration emphasized the need for informed consent in all research. It highlighted that the "interest of science and society should never take precedence over considerations related to the wellbeing of the subject."[29] The Declaration of Helsinki was the basis for Title 45- Part 46 of the Code of Federal Regulations, which are the regulations concerning the ethical treatment of human subjects, published by the United States Department of Health and Human Services.

1.2. Instances of Violation of Ethics in Medical Research

Other instances of violation of ethics in medical research can be observed in the following incidents:

- **Tuskegee syphilis study (1932-1972)**

The Public Health Service in Macon County, Alabama, studied the bacterium *Treponema Palladium* (syphilis) in 1932. This study which spanned out 20 years, was carried on a group of selected African-American males. Out of the 600 patients that were selected, 399 of them were

[26] G. J. ANNAS AND M. A. GRODIN, THE NAZI DOCTORS AND THE NUREMBERG CODE: HUMAN RIGHTS IN HUMAN EXPERIMENTATION 2 (Oxford University Press, New York, 1992).
[27] *France and Ors.* v. *Göring (Hermann) and ors*, [1946] 22 IMT 203.
[28] Srinivasa Murthy R., *Informed Consent for During Trial: A Systematic Study* 2 NIMHANS 145, 146 (1988).
[29] Accessed on 25/02/2021- https://www.who.int/bulletin/volumes/86/8/08-050955/en/

infected with syphilis, and the rest were not. The group consisted of poor, uneducated men who were desperate to get free food provided by the public health services in exchange for the treatment.

The research objective was to study the untreated cases of latent syphilis in humans to investigate the "natural course" of the disease.[30] Informed consent was not obtained from the participants in this project. Those subjects infected with syphilis in the early 1930s were prescribed the standard available treatment at that time. This treatment involved administering 'heavy metals.' Later, antibiotics for syphilis were developed in the 1940s, and it was widely known that the use of these antibiotics would improve the infected person's health. Despite that, the antibiotic treatment was withheld from the infected subjects. The researchers were aware that if left untreated, the disease would become severe and result in death.

The national media exposed this experiment in 1972, which prompted government officials to end the experiment. Out of the total test subjects, 74 were still alive, but more than 100 had died directly from advanced syphilis.[31] An investigation began in mid-1972 about this study conducted by the Public Health Service. The review panel concluded the study to be 'ethically unjustified' and contended that the subjects should have been provided penicillin.

Apart from not obtaining consent, the subjects were not made aware of the particulars of the study. The subjects thought that they were getting free treatment from government doctors for a life-threatening disease and instead had no idea that they were volunteering for a project.

The fact that the survey was designed to detect syphilis was not revealed. Also, it was not revealed to the subjects that the treatment consisted of spinal taps. The subjects had a blind trust in the doctors.[32] One of the subjects opined that "We trusted them because of what we thought they could do for us, for our physical condition..."[33]

[30] BAKER R., CRISIS, ETHICS AND THE AMERICAN MEDICAL ASSOCIATION 163, 164(1997).
[31] SHARLENE NAGY HESSE-BIBER, PATRICIA L., THE PRACTICE OF QUALITATIVE RESEARCH 60 (Sage Publications, 2011).
[32] JAMES JONES, BAD BLOOD: THE TUSKEGEE SYPHILIS EXPERIMENT (1993).
[33] Supra note 31.

The investigation showed that the researchers took advantage of a vulnerable population who could not afford medical treatment. Moreover, the racist attitudes of researchers towards black males made them withhold treatment. As a result of this incident, the principle of informed consent acquired increased significance.

- **The massacre of Nanjing (1937)**

The Japanese doctors conducted several inhuman experiments in Unit 731 in wartime China. However, all the Japanese doctors were acquitted. Mass murder and rape took place after Japan seized Nanjing, the then capital of China. Matsui and Tani Hisao, the Lieutenant Generals who had committed murder and rape, were punished for war crimes by the International Military Tribunal for the Far East.

- **Mengele experiments (1946)**

Joseph Mengele, nicknamed the 'Angel of Death,' carried out heinous experiments on twins during Second World War. One of the twins was kept as the 'control' and the other as the 'guinea pig.' Hundreds of children were used in experimentation to study the inheritance of the propensity to having twins.

- **U.S. Syphilis experiment in Guatemala (1946-1953)**[34]

The researchers from the United States and Guatemala conducted non-consensual medical experiments on vulnerable populations in Guatemala. The experiments were conducted with the support of public institutions in the guise of supporting the advancement of science. People from marginalized sections in Guatemala were intentionally exposed to syphilis, gonorrhea, and chancroid. This resulted in permanent damage to their health.

Prisoners, soldiers, orphans, psychiatric patients, and sex workers were selected for the study. Except for sex workers, who were forced to have intercourse with prisoners and soldiers, the groups of individuals that were targeted lacked mobility. They were enclosed in an area for

[34] S. M. Reverby, *Ethical failures and history lessons: the U.S. Public Health Service Research Studies in Tuskegee and Guatemala*, 34 PUBLIC HEALTH REV. 1,5 (2013).

observation.[35] The study was funded by the U.S. National Institutes of Health (NIH) to the Pan American Sanitary Bureau, and there were a total of about 1,500 study subjects. The findings were not revealed.

Subjects were deliberately injected syphilis into their spinal fluid.[36] Susan Mokotoff Reverby, a professor at Wellesley College, found out about the stark reality of this study in 2005 while researching the Tuskegee syphilis study.[37] Later in October 2010, the U.S. government apologized formally and affirmed a violation of human rights in medical research.[38]

- **Vipeholm Dental Caries study (1954)**

The study was conducted in Vipeholm Hospital, Lund in Sweden, and was reported in 1954. The study was conducted in Vipeholm Hospital, Lund in Sweden, and was reported in 1954. The study involved placing more than 400 developmentally disabled patients on controlled diets, and they were observed for five years. The subjects were divided into groups. Some were given the complex and simple carbohydrates as meals, while others were given other food as snacks sweetened with sucrose and chocolate.[39]

- **Willow Brook Mental Hospital (1956)**

This was a study carried out in the 1950s to understand problems related to the transmission of the hepatitis virus in developmentally disabled children. The children were residents in the Willow Brook State School, New York. Healthy children were infected with hepatitis by feeding them a solution made from the feces of children with active hepatitis.

- **The Milgram experiment in 1963**

[35] D. G. McNeil Jr., *U.S. apologizes for syphilis tests in Guatemala*, NEW YORK TIMES (1 February 2021), http://www.nytimes.com/2010/10/02/health/ research/02infect.html?_r=1.
[36] Presidential Commission for the Study of Bioethical Issues, *Ethically impossible: STD research in Guatemala from 1946 to 1948*, (Washington, DC: US Government Printing Office, 2011).
[37] S. M. Reverby, *Normal exposure, and inoculation syphilis: a PHS 'Tuskegee' doctor in Guatemala, 1946-1948*, 23 J POLICY HIST 6,12 (2011).
[38] J. H. Tanne, *President Obama apologises to Guatemala over 1940s Syphilis Study*, 4 BMJ 341 (2010).
[39] Chris Beyrer, Nancy E. Kass, *Human rights, politics, and reviews of research ethics* 360 THE LANCET 246 (2002).

Another example of egregious violation of ethics in research can be seen from a 1963 project concerning 'obedience to authority.' Yale University psychologist- Stanley Milgram carried out this social psychology experiment. It was observed from the research that a high number of subjects would completely obey the instructions, albeit reluctantly.

The research protocol involved deceiving volunteer subjects into thinking that they were involved in an experiment on the effects of punishment on memory. In the process, the participant was paired with another person. After drawing lots, it would be decided amongst them who the teacher and learner are. The draw was manipulated so that the participant was always the teacher and the learner was one of Milgram's men (confederates) who pretended to be an actual participant. If the learner could not repeat the words back, the confederates would inflict an "electric shock" (but was not real), increasing the voltage for each wrong answer to determine whether shocking would enhance learning. Subjects had a fake voltage meter that displayed readings "from slight to severe shock."

In other words, Stanley Milgram's experiment manipulated and deceived his research participants. Informed consent was not obtained. The guidelines of this experiment prevented the subjects from quitting even when some cried it to be stopped. Some also experienced psychological trauma, knowing they really could administer a lethal shock to another person.

Jerry Burger replicated this obedience experiment after 40 years. Burger's results varied only a little from Milgram's result. Burger was allowed by the University to make specific changes to Milgram's original protocol. The maximum shock fixed was at 150 volts. Despite these changes, one might wonder whether these kinds of experiments were ethical and whether the end goal of this study would justify the means.

- **Jewish Chronic Disease Hospital (1965)**

Experiments were performed on chronically ill patients who were developmentally disabled also. The aim was to determine how a weakened immune system would affect the spread of cancer. Live cancer cells were injected into the subjects.

- **AIDS Clinical Trial Group Study 076 (1994)**

The United States and France conducted the first randomized controlled trial in 1994 in which an intervention reduced the presence of HIV infection.[40] Unethical studies were conducted on HIV-positive pregnant women in developing countries,[41] and this was funded by the National Institutes of Health (NIH), and the Centers for Disease Control and Prevention (CDC). These studies involved the use of placebo-controlled arms. It came to light that in one of the placebo-controlled NIH-funded studies designed for Ethiopia, the researchers had agreed to stop one arm of the study in which 300 women were to be given a placebo.[42] The efficacy of AZT in reducing maternal-infant HIV transmission (ACTG 076) was established. Even after knowing that a shorter course of AZT therapy might work and would be more efficacious than a placebo, right from early 1994 onwards, the AZT was not administered to the patients. The Government and the Public Citizen's Health Research Group sought action against the unethical research. The researchers were ordered to eliminate any arm of their studies in which women are prevented from access to antiretroviral drugs. They were ordered to give at least short-term AZT for all.

The use of placebos in these trials became public in September 1997. After that, there was a prolonged and contentious debate on the ethical aspects of such trials involving placebo. On the one hand, several ethicists argued that the trials infringed fundamental human rights. On the other hand, several other researchers emphasized the need for a pragmatic approach to public health interventions for preventing mother-to-child HIV transmission in developing countries.

- **Postobon Lab testing on Colombian children (2013-2018)**

'Liga contra el Silencio,' a group of journalists in Colombia on 13 February 2013 disclosed that Postobon, Colombia's largest beverage company, had doled out drinks containing uncertified chemical supplements. The drinks were distributed to more than 3,000 children from La Guajira to evaluate the effects of their products.[43] The aim was to analyse the biochemical changes

[40] Susan E. Herz, *HIV-Positive Pregnant Women and Newborns in South Africa: Medical Hope, Moral Risk* 60 AM J HEALTH SYST PHARM. 34 (2003).
[41] Nuffield Council on Bioethics. Ethical Issues in Research In Developing Countries. London: Nuffield Council on Bioethics discussion paper; 1999.
[42] Lurie P, Wolfe SM. *Unethical trials of interventions to reduce perinatal transmission of the human immunodeficiency virus in developing countries* 337 N ENG J MED 853 (1997).
[43] *Aclaración sobre información errónea acerca de KUFU*, POSTOBÓN (February 14, 2018), http:// www.postobon.com/sala-prensa/noticias/aclaracion-so-bre-informacion-erronea-acerca-kufu.

derived from the consumption of this drink containing vitamins and minerals. Postobon further emphasized that their objective was to evaluate the use and acceptance of the drink and impart training in nutrition to parents of these children from different educational institutions. The Colombian Ministry of Health enquired whether Postobon had authorization protocol for the research, but no reply was furnished. In other words, it was unsure whether parental/guardian consent for conducting this research was obtained. Many other aspects like whether the company had taken steps to reduce harm and increase the benefits to the participating children remained unanswered.[44]

1.3.Other Guidelines relating to Biomedical Research

These inhumane experiments in biomedical research resulted in the formulation of guidelines for human subject research for various kinds of research, apart from the Nuremberg Code and the Belmont Report. These instruments include:

(i) Universal Declaration of Human Rights

In 1948, the Universal Declaration of Human Rights was adopted by the UN General Assembly. For the Declaration to have legal and moral force, the General Assembly adopted the International Covenant on Civil and Political Rights (ICCPR) in 1966. Article 7 of the ICCPR emphasized that no person should be subjected to torture or cruel, inhuman, or degrading treatment or punishment. Also, no person should be subjected to medical or scientific experimentation without his free consent. Placing reliance on this provision, society demonstrates the fundamental human value held to regulate all research involving human subjects.

(ii) Belmont Report, 1979

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, established as a consequence of the National Research Act of 1974, had the main objective to carve out the basic ethical principles governing biomedical and behavioral research involving human subjects. The Commission resulted in the making of the Belmont Report. The

[44] R. DWORKIN, TAKING RIGHTS SERIOUSLY (Cambridge, MA: Harvard University Press, 1977).

Belmont Report mentions the principle of respect for persons, beneficence, and justice as the essential ones.

(iii) **CIOMS Guidelines, 1982**

The Council for International Organizations of Medical Sciences (CIOMS) is a global non-governmental organization working closely with the World Health Organization (WHO). It was formed with the assistance of the World Health Organisation and the United Nations Educational, Scientific and Cultural Organization (UNESCO) in 1949.

In the late 1970s, CIOMS, with the help of WHO, began its work on ethics relating to biomedical research. CIOMS keenly monitored research in developing countries, and later, it published its first guidelines. The CIOMS Guidelines did not favour the application of the Declaration of Helsinki in developing countries. They analysed the conditions and the needs of biomedical research in those countries and the impact of multinational or transnational research. These Guidelines were later revised in 1993.

The Guidelines reiterate that research involving human subjects should not infringe any universally applicable ethical standards but must conform with the principles of individual autonomy, informed consent and must agree with social and cultural values.[45]

Although these guidelines were extensively publicized by agencies involved in human research, their application and acceptance were largely voluntary. The discovery showcased that medical researchers intentionally prevented African- American patients with syphilis in Tuskegee.

(iv) **Guidelines for Good Clinical Practice for Trials on Pharmaceutical Products (WHO), 1995**

Good Clinical Practice (GCP) is an established ethical and scientific quality standard for conducting, monitoring, reporting, and auditing clinical trials. The objective of GCP is to safeguard the rights and confidentiality of clinical trial participants.[46]

[45] CLAYTON EW, GENETICS RESEARCH: TOWARDS INTERNATIONAL GUIDELINES 152 (2000).

Section 3 of the Guidelines for Good Clinical Practice for Trials on Pharmaceutical Products, 1995 protects trial subjects. It is stated that the personal integrity and welfare of the trial subjects (as laid down in the Declaration of Helsinki) must be the main concern of all parties involved in conducting a clinical trial. Nevertheless, it is another essential responsibility of the investigator to consider the scientific validity of the trial. Section 3.3 provides for informed consent also. Additionally, guidelines regarding the clinical protocol, record keeping, and training are mentioned. The purpose and obligations of institutional review boards, clinical trial sponsors, and clinical research investigators are also specified.[47]

(v) **International Ethical Guidelines for Biomedical Research Involving Human Subjects**

The 2002 Guidelines by CIOMS helped frame national policies on biomedical research ethics involving human subjects, implement ethical norms in local circumstances, and improvise the ethical review mechanisms. Another objective is to analyse the conditions and the needs of poor or low-resource countries and the effects for multinational research / transnational research in which they may be partners. The Guidelines, among other things, provide for the formation of ethical review committees[48], ethical review of externally sponsored research,[49] and how to obtain informed consent.[50].

In the 2016 version of the CIOMS Guidelines, several other vital issues in research ethics were focused. CIOMS in these guidelines emphasizes the need for research to embody scientific and social value,[51] lists out provisions regulating biomedical research involving vulnerable groups[52],

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[46] A. Vijayananthan, O. Nawawi, *The importance of Good Clinical Practice guidelines and its role in clinical trials* 4 BIOMED IMAGING INTERV J. 5 (2008).
[47] Principle 5 of GCP.
[48] Guideline 2 of CIOMS Guidelines 2002.
[49] Guideline 3 of CIOMS.
[50] Guideline 4 of CIOMS.
[51] Guideline 1 of CIOMS Guidelines 2016.
[52] Guideline 15 of CIOMS Guidelines 2016.

and stated the conditions under which biological samples and health-related data can be used for research.[53].

Other Documents

Contributions have also supplemented legal instruments regarding ethics in biomedical research in industrialized and developed countries, such as the consultations of the Nuffield Council for Bioethics in the United Kingdom. Nuffield Council on Bioethics has prepared a report on "Children and clinical research: ethical issues," which focuses on ethical issues of involving children in biomedical research and at the roles and responsibilities of children, guardians, and researchers.

Universal Declaration on Human Genome and Human Rights (1997) : Since 1985, UNESCO began focusing on ethical concerns arising in genetics. The International Bioethics Committee at UNESCO was established in 1992 to prepare the Universal Declaration on the Human Genome and Human Rights. The declaration was adopted in 1997. It relates to the human genome with human dignity and further focuses on the rights of the persons concerned by human genome research.

The International Declaration on Human Gene Data (2003) emphasizes the ethical principles that should regulate the collection and use of human genetic data. This resulted from the rise in the number of national genetic banking projects and the increased use of genetic data to resolve questions of paternity or its use in criminal cases. Later, the Universal Declaration on Bioethics and Human Rights was adopted by acclamation at the General Conference on 19 October 2005. This Declaration is non-binding. The Preamble to this Declaration reiterates the international community's commitment to adhere to the proper practices in developing science and technology and further states that it provides a basis for humanity's response to the burgeoning dilemmas that science and technology present for humankind and the environment.

In experimentation with human subjects, the human rights of participants sometimes get ignored. Take the instance of conducting oxygen experiments on premature babies without the knowledge

[53] Guideline 22 of CIOMS Guidelines 2016.

and consent of parents; and the experiments on whether cooling kidneys before a transplant would lead to fewer intricacies, carried out without properly evaluating the risks to transplant recipients.[54] With the emergence of new technologies, the close relationship between ethical principles and human rights in biomedical research becomes significant. For example, the use of new gene-editing technologies called CRISPR-Cas9 would result in challenges to protecting human rights and ethical principles such as informed consent, human dignity, and future generations' rights.[55] Firms are trying to obtain permission from regulators to begin CRISPR clinical trials for autoimmune and neurogenerative diseases in humans.

1.4.Conclusion

Bioethics may seem a challenging subject because it subjects the research work to moral scrutiny, and also, there are several facets of the discipline like historical, political, and conceptual aspects that pose hurdles to this line of scientific inquiry.[56]

Many efforts have been put to balance diverse approaches to scientific review in biomedical research, including psychiatric research, and formalize it within a governance framework on research integrity. Obtaining consensus in medical research with diverse stakeholders like funders, health service employers, researchers, professional associations, etc can be difficult. Certain principles of research integrity such as honesty, accountability, fairness, and professional courtesy have to be adhered to in all areas of biomedical research.

Undoubtedly, the history of the development of ethics in research has been built on egregious violations of humane, ethical values to a large extent. A journey through this history showcases valuable perspectives into the state of contemporary research ethics institutions, regulations, and other instruments that presently govern biomedical research.

[54] Michael Carome, *Outrage of the month: A steady stream of unethical human experiments*, PUBLIC CITIZEN (May 2016), https://www.citizen.org/news/outrage-of-the-month-a-steady-stream-of-unethical-human-experiments/.
[55] M. F. Riley, *CRISPR creations and human rights*, 11 LEHR 225,229 (2017).
[56] Lisa Rasmussen, *The Ethics of Bioethics*, 8 AM. J. BIOETHICS 53 (2008).

CHAPTER 2: ETHICAL PRINCIPLES

"Only one rule in medical ethics need to concern you – that action on your part which best conserves the interests of your patient." -Martin H. Fischer[57]

2.1. Introduction

Ethics plays a pivotal role in medical practice. It can be observed that there is conformity of medical concepts to legal forms of thought and reason. This appears to be an interesting constatation as it is predominantly present in not merely medical thinking but also in clinical practice and bioethics with its standard procedures, steering committees, counseling, and clinical context[58].

Medical ethics is defined as "*the analytical activity in which the concepts, assumptions, beliefs, attitudes, emotions, reasons and arguments underlying medico-moral decision making are examined critically*.[59]" In other words, ethics has a close nexus to choices, decisions based on the choice and the duties of a doctor to the best interest of the patient. Medical professionals may face a variety of perplexing ethical problems in their day-to-day medical practice.

Generally, ethical issues revolve around the moral dilemmas arising due to conflicts in obligations and their after-effects. The four fundamental ethical principles in psychiatric research and other areas of medicine and research are autonomy, beneficence, non-maleficence, and justice. Much of the ethical issues in the medical field relate to patient's autonomy and the fundamental principles of informed consent and confidentiality.

Robertson and Walter[60] have formulated a taxonomy of normative theories in psychiatric ethics, divided into the following categories– instrumental, reflective, and integrative. The instrumental approach utilizes a method of reasoning to create a workable output or solution to an ethical conundrum. Here, the solutions may be reliable but can interfere with the sensibilities of the moral agent and not mesh well with a person's value system. That said, reflective approaches to psychiatric ethics encourage the moral agent to pertain to a process of reflection to solve the

[57] STRAUSS M. B., FAMILIAR MEDICAL QUOTATIONS 157 (1968).
[58] Jan M. Broekman, *Bioethics and Law*, 28 RECHTSTHEORIE 1, 2 (1997).
[59] GILLON R, PHILOSOPHICAL MEDICAL ETHICS 4 (1997).
[60] ROBERTSON M, WALTER G., ETHICS AND MENTAL HEALTH - THE PATIENT, PROFESSION AND COMMUNITY 16 (2013).

ethical dilemma that accords with a value system or consistent approach to moral action. On the other hand, integrative approaches employ various theoretical ideas to specific aspects of clinical practice or social action.

2.2. Philosophical Approaches

Several normative ethical theories or philosophical approaches have emerged with the times, which are discussed below:

(v) Teleology and Utilitarianism

The term 'teleology' originates from the Greek words 'telos' and theory 'logos' which means goals and theory. Teleology focuses on the consequences of actions as the primary step in analyzing whether an activity is good or not. Consequentialism is another term given to this class of theories.[61] This philosophical approach evaluates the acts solely on consequences. In other words, consequentialism determines the rightness or the wrongness of an action based on the consequences brought by that action. One of the common forms of consequentialism is utilitarianism or social consequentialism, which states that one should act for the greatest good for the greatest number.[62]

The prominent supporters of the utilitarian approach were Jermy Bentham (1748-1832) and John Stuart Mill (1806-1873). As per Bentham's delineation, utilitarianism means that right actions ought to produce the greatest happiness for the greatest number of people[63]. This perception of utility by Bentham and Mill in terms of happiness or pleasure led them to be classified as hedonistic utilitarians.

Utilitarianism focuses on the value of well-being, which may be examined in terms of pleasure, happiness, welfare, or the like. It is noteworthy that they emphasize stringently one basic principle of ethics: the principle of utility. Utility is a measure of a group's relative happiness or satisfaction regarding access to resources. The availability of such resources, such as goods or

[61] Marshall P, Thomasma DC et. al., *Intercultural reasoning: The Challenge for International Bioethics*, 3 CAMB Q HEALTH ETHICS. 321, 328 (1994).
[62] PELLEGRINO ED, THOMASMA DC., A PHILOSOPHICAL BASIS OF MEDICAL PRACTICE: TOWARD A PHILOSOPHY AND ETHIC OF THE HEALING PROFESSIONS 45 (Oxford University Press 1981).
[63] Donovan L. J., *Ethics: Our heritage*, 27 GEORGETOWN MAGAZINE 37, 39 (1995).

liberties, is instrumental to pleasure and the absence of pain. As the foundation of moral philosophy, 'ethical hedonism' aims to maximise pleasure.[64] Utilitarianism has been so widespread in moral philosophy that it is argued that it is the genesis for all ethical considerations.[65] It may be that there is a survival benefit for species that follow the utilitarian approach, as elevating group needs over individual needs may help primitive communities to thrive.[66]

Criticism of Utilitarianism

One of the drawbacks of the concept of hedonistic utilitarianism is the difficulty in quantifying the level of pleasure obtained by an action.[67] This theory has also been condemned because one cannot foresee the outcome of actions in advance. As such, it is unfeasible to set the standers of one's moral action based on the act itself[68].Another issue is for utilitarians concerned about the maximisation of individual preferences when some of these individuals have contemplated what judgments showcase as morally unacceptable preferences. For instance, the only way to obtain the maximal utilitarian result is to perform an immoral act such as killing a person and later distributing his organs to others who will die without them. As per utilitarianism, such killing is not only permissible but, more importantly, morally obligatory.[69]

Utilitarianism and Psychiatry

It is noteworthy that the suitability of utilitarianism as a basis of psychiatric ethics has been discussed in the book- 'Utilitarianism as the theoretical basis of Psychiatric Ethics - A Critique' by Robertson M.[70] The writer also takes note of R. M. Hare's[71] explanation of how utilitarianism applies in psychiatry. Hare advocated a version of utilitarianism as a basis for psychiatric ethics,[72] based upon his previous work in moral theory.[73] He argued that the utilitarian influences

[64] CYRIL BAILEY, THE EXTENT REMAINS 22 (Oxford: The Clarendon Press 1926).
[65] KYMLICKA W., CONTEMPORARY POLITICAL PHILOSOPHY 12 (Oxford University Press 2002).
[66] SINGER P. THE EXPANDING CIRCLE: ETHICS AND SOCIOBIOLOGY 56 (1981).
[67] WILLIAMS B., A CRITIQUE OF UTILITARIANISM 131 (Cambridge University Press 1973).
[68] Marshall P, Thomasma DC et. al., *Intercultural reasoning: The Challenge for International Bioethics*, 3 CAMB Q HEALTH ETHICS. 321, 330 (1994).
[69] GRABER G. C., THOMASMA D. C., THEORY AND PRACTICE IN MEDICAL ETHICS 21 (1989).
[70] ROBERTSON M., WALTER G., UTILITARIANISM AS THE THEORETICAL BASIS OF PSYCHIATRIC ETHICS - A CRITIQUE 51 (2007).
[71] An English Moral Philosopher; developed many meta-ethical theories like 'universal prescriptivism.'
[72] HARE R., THE PHILOSOPHICAL BASIS OF PSYCHIATRIC ETHICS 47 (Oxford University Press 1993).
[73] HARE R., MORAL THINKING 79 (Oxford University Press 1981).

in psychiatric ethics are often ignored unnecessarily because of the discord between agent-relevant duties of psychiatrists towards their patients.

Peter Singer's[74] writings of utilitarianism introduce a debatable principle of equality present in all beings (including other species) with interests and, therefore, preferences.[75] There is no doubt that all species prefer to avoid pain, but Singer emphasizes that only sentient humans maintain an interest in developing their unique individual abilities. He bases this distinction as the justification of differential consideration of different preferences. Moreover, Singer proposed the concept of 'diminishing marginal utility' in which the utilitarian consideration of preferences reviews both the need and the desire for the preference. He also introduces a 'journey model of life', which analyses the merits of how preferences fit within a life journey's goals. It is worth mentioning here that a personal aim in continuing to live and not suffer to fulfill an individual life journey is the highest order of preference in Singer's utilitarian approach.[76]

However, adopting Singer's views entirely to psychiatry may be worrisome. No doubt, mental illness obstructs one from fulfilling his/her life goals compared to other forms of physical illness. Patients with severe schizophrenia will be unable to accomplish their aims, mainly where negative symptoms or disorganisation will dominate the clinical picture. Therefore, comparing the different prognostic effects of psychiatric diagnoses leads to distinctions on the value-laden concept of quality of life. An example of Singer's variation of utilitarianism to psychiatry would be where the preference of a person with severe schizophrenia is placed second to the desire of the patient with an anxiety disorder to return to college studies and continue a fulfilling life journey.

Also, in the utilitarian-based decisions about allocating limited health resources, the 'diminishing marginal utility doctrine' becomes more relevant. This is because the preferences of many in society are satisfied by the 'mildly disabled' returning to employment and contributing to social welfare through individual fulfillment, rather than the preferences of those patients with an acute

[74] An Australian moral philosopher; Professor of Bioethics at Princeton University. He specialised in applied ethics and approaches ethical issues from a secular, utilitarian perspective.
[75] SINGER P., PRACTICAL ETHICS 15 (1993).
[76] SINGER P, KUHSE H., SHOULD THE BABY LIVE? THE PROBLEM OF HANDICAPPED INFANTS 29 (1985).

psychiatric disability to remove or reduce suffering.[77] The standard measure of utility in this aspect is the 'Disability Adjusted Life Year' (DALY) and the 'Quality Adjusted Life Year' (QALY).[78] Singer asserts that the use of QALY justifies the favouring of the preferences of those not severely affected by mental illness[79] [80].

Further, it is observed that two factors extraneous to psychiatry may have encouraged the adoption of utilitarianism in psychiatric ethics. First of all, the legal responsibilities of psychiatrists concerning public safety (concerning patients with severe psychiatric illness when let free) have effectively trumped any ethical code of conduct intrinsic to the psychiatric profession.[81] Such legal mandates are fundamentally utilitarian and have usually originated on the backdrop of social and political responses to problems such as public safety.[82]

The other factor infiltrating utilitarian thinking in psychiatric ethics has been the changes to health-care systems caused by globalisation and financial pressures, especially in the developed countries. Indeed, as Dyer has opined, medicine has become a three-way relationship between doctor, patient, and the third-party provider.[83] The problem here is that when the utilitarian approach is followed in mental health-care decision-making, there would be an indifference to the uniqueness of the person as more importance is given to maximizing the common good.[84] Green and Bloch, in their article[85] also comment that such an approach would eventually make the psychiatrist fall prey to a market-driven approach in the management of mental illness. Additionally, in their writing[86], Robertson and Walter have contended that the actions spawned

[77] Singh B, Hawthorne G. et. al., *The Role of Economic Evaluation in Mental Health Care*, 35 AUST NZ J PSYCHIAT 104, 109 (2001).
[78] BELL J., MENDUS S., PHILOSOPHY AND MEDICAL WELFARE 116 (1988).
[79] Singer P., McKie J., Kuhse H, Richardson J. Double jeopardy and the use of QALYs in health care allocation *Journal of Medical Ethics.* 1995; 21. :144-150.
[80] Chisholm D, Healy A et. al., QALYs and Mental Health Care, 32 SOC PSYCHIATRY PSYCHIATR EPIDEMIOL.70 (1997).
[81] Bloch S, Pargiter R., *A History of Psychiatric Ethics*, 25 PSYCHIATR. CLIN. N. AM. 512 (2002).
[82] Bloch S, Pargiter R., *A History of Psychiatric Ethics*, 25 PSYCHIATR. CLIN. N. AM. 509 (2002).
[83] DYER A., ETHICS AND PSYCHIATRY: TOWARD A PROFESSIONAL DEFINITION 57 (1988).
[84] Green S, Bloch S., *Working in a Flawed Mental Health-care System: An Ethical Challenge*, 158 AM. J. PSYCHIATRY 1380 (2001).
[85] Supra.
[86] ROBERTSON M, WALTER G., UTILITARIANISM AS THE THEORETICAL BASIS OF PSYCHIATRIC ETHICS – A CRITIQUE, 2007.

by utilitarian calculations violate the non-malfeasance principle of medical ethics and do not serve as a sound basis of psychiatric ethics. [87]

ii. **Duty Ethics (Deontology)**

Deontology is an ethical theory where the morality of an action depends on the nature of the action. Here, harm is impermissible irrespective of its consequences. The philosopher Immanuel Kant devised this philosophical approach and hence popularly called as the 'Kantian deontology.'

The three main philosophical works of Kant are (i) '*Groundwork for the Metaphysics of Morals'* (1785),[88] (ii) *'Critique of Practical Reason'* (1787)[89] and (iii) *'Metaphysics of Morals'* (1797).[90] The central ethical question for Kant was prescriptive – 'what ought I do?' Kant's valorisation of human reason highlighted that the answer to this question had no connection to the concept of goodness or virtue. Kant based his views on 'action' alone, without focusing on desires, circumstances, or social relations. As per Kant's prescription, there were two types of duties- 'perfect duties,' which are required of all moral agents always; and 'imperfect duties'. The latter type proscribes neglecting our duties to others in need.

Deontological or non-consequentialist theory means the study of duty, or more precisely of what one ought to do.[91] It calls forth for the application of the same rule for everyone in all circumstances.[92] The decisions as per the deontological approach may be beneficial for an individual but does not necessarily generate a good outcome for the society. To a certain extent, the nature of doctor-patient interaction is considered to be deontological. It is when this deontological practice is breached, the issue of medical negligence arises. The deontological tradition encourages clinicians to do good to patients, thereby strengthening the doctor-patient bond.

[87] Adshead G., *Care or Custody? Ethical Dilemmas in Forensic Psychiatry*, 26 J. MED. ETHICS. 302 (2000).
[88] KANT I., GROUNDWORK FOR THE METAPHYSICS OF MORALS 65 (1997).
[89] KANT I., CRITIQUE OF PRACTICAL REASON 88 (1997).
[90] KANT I., THE METAPHYSICS OF MORALS 82 (1996).
[91] GRABER G. C., THOMASMA D. C., THEORY AND PRACTICE IN MEDICAL ETHICS 24 (1989).
[92] MARTY M. E., VAUX K. L., HEALTH/MEDICINE AND THE FAITH TRADITIONS 166 (1982).

The concept of individual autonomy plays a vital role in the Kantian approach. According to Kant, autonomy is the capacity for free, rational moral choice. Men should not be influenced by 'divine command of superstition', but instead follow the notion of secular, rational morality. Also, Kant turns a blind eye towards other forms of moral sensibility like emotions or filial bonds. He further advocates that the indication of a good moral agent is the possession of goodwill. The moral value of an act is its nexus to goodwill. The moral worth of an act is not dependent on intentions or consequences. In other words, deontic ethics means doing the right thing for the right reasons. Moreover, the purpose of good actions is respect for persons as beings who are intrinsically valuable.

Criticism to Deontology

Deontology is criticized because it cannot resolve conflicts among two or more moral persons who profoundly disagree. Some common limitations of Kant's ethics are mentioned by O'Neil, which are:[93]

i. Rigorism – Deontic ethics are rigid with no nuance or subtlety.
ii. Abstraction –They are too abstract to guide action
iii. Conflicting Grounds of Observation – There is no clarity on what to do when there is a conflict between duties.
iv. Place of the Inclinations– Deontic ethics do not consider moral impulses.
v. No Account of wrongdoing – Deontic ethics does not explain what constitutes wrong actions.

Also, some consider acting solely out of duty to be morally repugnant. Acting from duty does not suggest that the person has compassion for others but merely fulfills an obligation. This would be odious to a psychiatrist dedicated to relieving of human suffering. Above all, acting merely from duty and denying human feelings such as care, empathy, or compassion may spawn attitudes of objectification towards others. If doctors act as if they have mere obligations towards psychiatric patients, rather than compassion for people who have a mental illness, it would objectify them.

Kantian Ethics and Psychiatry

[93] SINGER P., A COMPANION TO ETHICS 179 (1991).

It is noteworthy that the Kantian concept of autonomy is qualitatively different from what is applied in biomedical ethics. However, the notion of reason as the mark of human function is a helpful construct in psychiatry. Also, the Aristotelian notion that human *telos* is one of excellence in reason has contended as a pivotal issue in understanding mental health and illness.[94] [95]

The ethical code for psychiatrists in all countries requires psychiatrists to respect the essential humanity of their patients. The Kantian view is that human beings are rational beings and can construct maxims of rational moral action. Applying this to psychiatric ethical codes, one should understand that the essence of the humanity of patients is not in their suffering or their circumstances, or their rights as citizens; but in their capacity to legislate moral action. Kant's formula of humanity requires the psychiatrists to take action based on the patient's understanding and reason. Seeing from the patient's perspective and his/her reason is quintessential for providing the proper treatment. If a person's rational capacity to take moral action is impaired, the patient must be subjected to coercive or involuntary treatment. The restoration of that reason is the objective of psychiatric intervention. This Kantian concept called '*Menscheit'* does not focus on actions or choices but on the capacity to make such choices. Further, codes of ethics are undoubtedly prescriptive duties and, therefore, are Kantian in spirit.

iii. Virtue Theory

Virtue theories can be traced to Socrates, who merged his ideas with Plato's and discussed the merits of virtue and its need to live a good human life. On the other hand, Aristotle devised virtue theory as a branch of politics or the study of the larger virtues of public life. Undoubtedly, the virtues were grounded in both human psychology (the potentialities, emotions, behaviour, and proclivities of persons) and human affairs (the actual relations of persons to one another in friendship and community).

Virtue in Antiquity

[94] Wakefield J., *Aristotle as Socio-biologist: The "Function of a Human Being" Argument, Black Box Essentialism, and the Concept of Mental Disorder*, 7 PPP 35 (2000).
[95] Robertson M., *Mad or Bad, Have We Been Had? A response to Patfield (Letter)*, 15 AUSTRALAS. PSYCHIATRY 78 **(**2007).

Virtue is considered to be a quality of moral excellence. In Nicomachean Ethics, Aristotle elaborated the concept of virtue as "*a settled disposition of the mind determining the choice of actions and emotions, consisting essentially in the observance of the mean relative to us…as the prudent man would determine it*."[96] Aristotle made scrutiny of great men and described what makes them great. The capacity for reason is the foremost characteristic that helps men to achieve greatness. He noted that happiness, or eudemonia, was found in the life of rational excellence. The four fundamental virtues in antiquity were: courage, prudence, temperance, and justice. The concept of virtue is a habit of establishing a balance or choosing between extremes. Let us take the aspect of justice. Here, the mean lies between being excessively generous[97]and being excessively rude. So, here, the habit of striking a balance is a dialectic reasoning in that constructing an action or thought emerges from the differences between two alternate views.

In order to find the 'mean,' one should possess prudence or phronesis (i.e., practical wisdom) before the other virtues. To put it differently, a virtuous individual possesses the judgment to find the mean and the practical ability to implement it. Phronesis may have several components like:[98]

i. "*The acknowledgment of specific ethical principles where appropriate; the integration of experience on the present situation;*
ii. *the capacity to contrast and explain from paradigm cases to particular ones;*
iii. *the capacity to 'parallel process' other issues to guide moral inquiry by egg psychodynamic implications; and*
iv. *the capacity to include all four aspects to devise a mode of praxis*.[99]"

Virtue theory and Psychiatry

In psychiatry, virtue entails the integration of its 'telos' (goal) and 'techne' (the use of skills) to achieve it. The virtuous psychiatrist will possess the practical wisdom to do what is right to alleviate the patient's suffering.

The application of virtue theory has provided good points of reflection. Arendt,[100] while observing the trial of Adolf Eichmann, the architect of the Holocaust, commented in her book

[96] 2 ARISTOTLE, NICOMACHEAN ETHICS 134 (1566).
[97] Munson R., *Why Medicine Cannot be a Science*, 6 J. MED. PHILOS.189 (1981).
[98] Tallmon J., *Casuistry*, in Sloane T, ENCYCLOPAEDIA OF RHETORIC 85 (2001).
[99] Supra.

that Eichmann realised the banal consequences of his evil very late and, this late realisation was a failure to reflect upon the nature of his actions and his mindlessly servile attitudes to duty.[101]

Arendt also distinguished between the virtues of individual life and that of the world of action *('viva activa')*.[102] In the former, self-interest played an important role. A revision of virtue ethics happened aftermath of the deadly events of the Twentieth Century. Applying to the craft of psychiatry, one must ask whether the psychiatrist can be genuinely virtuous without being involved in the public or political sphere.

Several authors and professional bodies have provided a list of desirable virtues in physicians, often extrapolated from the four cardinal virtues. Beauchamp and Childress consider compassion, integrity, trustworthiness, discernment, and conscientiousness as the most important virtues. On the other hand, Engelhardt[103] lists tolerance, liberality, and prudence as virtues required of a physician. Of course, compassion, humility, fidelity, trustworthiness, veracity, prudence, warmth, sensitivity, respect for confidentiality, humility, and perseverance. Virtue ethics are seen as a foundation of psychiatric ethics,[104] with some opining that the sole virtue of phronesis can provide a comprehensive account of ethics in psychiatry.[105]

Criticism

One significant criticism of virtue ethics as a moral philosophy in psychiatry is that it seems to have impractical expectations of individuals and views the individual amid a potentially disabling "psychodynamic process of identification with the idealised ethical superman."[106] The model of good conduct and the search for and development of a "good life" require considerable public agreement and reinforcement of behaviour that is respectful of others, honest, and dedicated. Virtue ethics cannot by itself act as clear action guides. Also, it is prone to individual definitions of virtue. Social consensus about good and evil (like in the Nazi examples of loyalty

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[100] Hannah Arendt (German-born American political theorist) wrote several books on political theory and philosophy.
[101] ARENDT H., EICHMANN IN JERUSALEM: A REPORT ON THE BANALITY OF EVIL 114 (1963).
[102] ARENDT H. THE HUMAN CONDITION 254 (1958).
[103] ENGELHARDT H., THE FOUNDATIONS OF BIOETHICS 81 (1996).
[104] FRASER A., ETHICS FOR PSYCHIATRISTS DERIVED FROM VIRTUE THEORY. PAPER PRESENTED AT: 4TH INTERNATIONAL CONFERENCE ON PHILOSOPHY AND PSYCHIATRY 46 (2000).
[105] Tobin B., *Code of Ethics: Why we also need practical wisdom*, 2 AUSTRALAS. PSYCHIATRY 55 (1994).
[106] DYER A., ETHICS AND PSYCHIATRY: TOWARD A PROFESSIONAL DEFINITION 76 (1988).

to one's nation and race) can also influence an individual. The virtue theory must be conditioned in some prior theory of what is right and good so that humans can better understand and apply them.. It also requires a community of values to sustain its practice.[107]

iv. Principlism

Principle-based ethics play a significant role in Western medical ethics.[108] [109] [110] It is an approach of ethical reasoning first formulated for biomedical ethics by the U.S. philosophers- Tom Beauchamp and James Childress. The method also reflects many aspects of WD Ross's work, who asserted that ethical duties were related to '*prima facie responsibilities to essential ethical principles*.'[111] It is also affected by a form of common morality regulating public behaviour.[68]

Danner Clouser and Bernnard Gert coined the term- 'principlism'. This theory is also called the 'four principles approach'. The principlism approach affirms that the four principles express the general values underlying rules in common morality.[112] The common morality is ''*the set of norms that all morally serious persons share*[113]'' and applied to solve the contemporary ethical dilemmas.[114] Beauchamp and Childress commented that this theory is not intended to be a general moral theory but rather aid those in the medical field to identify ethical problems and decide what to do. According to Raanan Gillon[115], this approach can justify all the substantive moral claims in medical ethics.[116] Although this approach is sometimes condemned for its lack of foundational theory and its western-centric methodology, principlism is commonly used as a starting point for practical ethical decision-making in the clinical, technological, and epidemiological professions.[117]

When approaching moral dilemmas, the physicians should consider four core principles: 1. Respect for autonomy, 2. Beneficence (including utility), 3. Non-Maleficence and 4. Justice.

[107] Thomasma D. C., *Bioethics and International Human Rights*, 25 J LAW MED ETHICS. 299 (1997).
[108] BEAUCHAMP T, CHILDRESS J., PRINCIPLES OF BIOMEDICAL ETHICS 51 (2001).
[109] Beauchamp T., *Methods and principles in biomedical ethics*, 29 J. MED. ETHICS 269, 271 (2003).
[110] Gillon R., *Medical ethics: Four principles plus attention to scope*, 30 BMJ 186 (1994).
[111] Supra note 53.
[112] GRABER G. C., THOMASMA D. C., THEORY AND PRACTICE IN MEDICAL ETHICS 23 (1989).
[113] Ibid.
[114] ENGELHARDT H. T. JR., BIOETHICS AND SECULAR HUMANISM: THE SEARCH FOR A COMMON MORALITY 42 (Trinity Press International Philadelphia, 1991).
[115] RAANAN GILLON, PHILOSOPHICAL MEDICAL ETHICS 41(1986).
[116] MARTY M. E., VAUX K. L., HEALTH/MEDICINE AND THE FAITH TRADITIONS 163 (1982).
[117] Thomasma D. C., *Bioethics and international human rights*, 25 *J Law Med Ethics* 295, 299 (1997).

There are several derivative rules such as veracity, privacy, fidelity and confidentiality, and various other rules like informed consent.

Respect for autonomy requires one to act intentionally after providing sufficient information and time to decide for the patient. To ensure the autonomy of patients/ research participants, they must realise the potential risks and benefits of treatment/ participation. Also, the patients/participant should not be subjected to undue influence and coercion, which might affect their decision to participate. The principle of non-maleficence means that harm should not be caused; at the very least, there must be minimization of harm which can be achieved by careful decision-making and adequate training. On the other hand, beneficence requires the doctor to act for the benefit of the patient. In biomedical research, beneficence involves the maximization of benefits to promote the well-being of research participants and society. The principle of justice ensures equitable distribution of social benefits so that burdens and benefits of research are shared fairly and equitably by society.[118]

- Autonomy

As expounded by philosophers Immanuel Kant (1724–1804) and John Stuart Mill (1806–1873), the philosophical underpinning for autonomy is that all persons have intrinsic worth. As such, they should have the power to make rational decisions and moral choices. Each person should be allowed to exercise his or her capacity for self-determination.[119] This ethical principle was highlighted in a case decided by Justice Cardozo in 1914 wherein it was stated that, "*Every human being has a right to choose what shall be done with his own body*."[120] In *Schloendorff* v. *Society of New York Hospital,* 105 N.E. 92 (N.Y. 1914), Justice Cardozo stated that the concept of consent is covered by the principle of autonomy.

Autonomy has to be weighed against competing moral principles, and in some instances, may be overridden. For example, if the patient's individual choice harms another person(s). This principle does not apply to persons who cannot act autonomously. Some ethicists have proposed a broader concept of relational autonomy. Relational autonomy is influenced by social

[118] TRIVEDI J. K., TRIPATHI A., MENTAL HEALTH IN SOUTH ASIA: ETHICS, RESOURCES, PROGRAMS AND LEGISLATION 16 (2014).
[119] Guyer P., *Kant on the theory and practice of autonomy*, 20 SOC PHILOS POLICY 70, 76 (2003).
[120] Schlendorff v. the Society of the New York Hospital, 105 N.E. 92 (*N.Y.* 1914).

relationships and determinants such as gender, culture, and ethnicity.[121] They argue that the right to autonomy must be understood concerning substantive equality of opportunity and sufficient social support.

The principle of autonomy is essential in psychiatric ethics. Reason and self-interest are faculties that can be harmed due to mental illness.[122] The concept of autonomy is focused more on 'autonomous choice' rather than issues of self-governance. Psychologists and researchers should show their respect to every person and respect their right to privacy, confidentiality, and self-determination.

- Non-maleficence

The principle of non-maleficence states that the doctor should not harm the patient. The practical application of non-maleficence requires the doctor to consider the benefits of all treatments, avoid those unseemly burdensome treatments, and choose the best one for the patient. This is crucial in end-of-life care decisions wherein withholding life-sustaining treatment, and medically administered nutrition/ hydration would occur. In *Betancourt* v. *Trinitas Hospital*, 2010 N.J. Super. LEXIS 168 (App. Div. Aug. 13, 2010), the issue was whether the hospital might unilaterally refuse to treat the patient on the ground that there is little chance of improvement. However, the court did not decide due to the patient's death regarding the question moot.

- Beneficence

The principle of beneficence implies that the doctor should act for the patient's benefit and should prevent/remove conditions that will cause harm. It is worth noting that, in this principle, the duty here is one of positive requirements. The principle aims for not just avoiding harm, but also to benefit patients and to promote their welfare. While physicians' beneficence confirms to moral rules, and is altruistic, it is also true that in many cases it can be considered a payback for the debt to society for education (often supported by governments), privileges, and to the patients themselves (for improving their knowledge and research).

[121] MACKENZIE C. M., STOLJAR N., RELATIONAL AUTONOMY: FEMINIST PERSPECTIVES ON AUTONOMY, AGENCY, AND THE SOCIAL SELF 51 (2000).
[122] RADDEN J., THE PHILOSOPHY OF PSYCHIATRY 138 (2004).

The doctors while rendering service must act beneficially for improving the patient's health and should:

i. Facilitate the quick recovery of health of the patient;
ii. Avoid or reduce the suffering of the patient;
iii. Provide emotional support, if needed;
iv. His goal should be compassionate care and not just providing medical treatment.

- Justice

The principle of justice requires the fair, equitable, and appropriate treatment of persons. *Distributive justice plays a significant role in medical ethics*. Distributive justice is defined as the "fair, proper, and equitable distribution of health-care resources determined by justified norms that structure the terms of social cooperation."[123] Distributive justice is ensured when the distribution occurs in a way that every person either (i) gets an equal share or,(ii) according to his/her need or, (iii) according to his/her effort or, (iv) according to his/her contribution or, (v) according to his/her merit. Here, each condition is not exclusive and can be combined in an application sometimes.

In hospital and clinical settings, this can mean the allotment of scarce resources and the proper time for inpatient and outpatient services.[124] Exercising fairness by doctors is fundamental. An example of infringement of this principle would be when a particular treatment is chosen over others, or an expensive drug is selected over an equally effective but less costly one because it benefits the physician, financially or otherwise.

Principlism and Psychiatry

One of the common ethical issues that psychiatrists face is regarding involuntary treatment. There might be a prima facie conflict between the patient's autonomy to refrain from treatment and the need for beneficence to relieve suffering. In most cases, the conflict is vitiated by the effects of mental illness (like psychosis) on the patient's capacity for autonomy. As such, the

[123] FLEISHACKER S., A SHORT HISTORY OF DISTRIBUTIVE JUSTICE 33 (2005).
[124] American College of Physicians, *Medical professionalism in the new millennium: A physician charter,* 136 ANN INTERN MED. 243, 244 (2002).

scales are tipped towards the beneficent obligation to alleviate the patient's suffering. When the patient's autonomy is not significantly diminished, like in cases involving the involuntary treatment of patients who have personality disorders, or those who suffer from alcohol or substance abuse, the required deliberations become more complicated. Here, careful consideration of the effects of the patient's psychopathology upon autonomy, and the expected benefits of treatment, is needed.

Criticism

Clarity and simplicity are the strengths of the principlism approach. The four-principle approach has been viewed as a credible method of medical ethics in various cultural settings.[125] However, there is controversy regarding its productive application outside the English-speaking world.

Patient autonomy, the very centre of the 4P's approach, has been depicted by Pellegrino as a cultural artifact.[126] This position is clearly supported by several studies that have analysed a cross-cultural study of autonomy in medical ethics in U.S. and Japan. In Japan, prioritising individual autonomy may isolate patients from their families, which might subsequently affect patient care prejudicially.[127] Diagnostic and prognostic information is often withheld from Japanese patients at the request of their kith and kin.[128] In the contentious issue of suicide in Japanese culture, problems regarding autonomy are pretty incidental to the ethical considerations around the area.[129] In African cultures, it is observed that autonomy is suppressed by communal bonds and responsibilities and is of peripheral relevance in ethical deliberation.[130] In post-communist Russia, physicians are still mainly duty-bound to the state, despite efforts to legislate on behalf of patient autonomy.[131] In China, bioethical issues are starting to be deliberated away from traditional morality as a reaction to "a naïve acceptance of western moral philosophical approaches and the bioethical perspectives they produced."[132]

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[125] GILLON R., PRINCIPLES OF HEALTH CARE ETHICS 67 (1994).
[126] Pellegrino E., *Is truth telling to the patient a cultural artifact?* 268 JAMA 1734, 1735 (1992).
[127] Miyaji N., *The power of compassion: truth telling among doctors in the care of dying patients*, 36 SOC. SCI. MED. 249, 252 (1993).
[128] Ishiwata R., Sakai A., *The physician-patient relationship and medical ethics in Japan*, 2 CAMB. Q. HEALTHC. ETHICS 45, 46 (1994).
[129] Young J., *Morals, suicide, and psychiatry: a view from Japan*, 16 BIOETHICS. 412,419 (2002).
[130]ROBERT VEATCH, CROSS CULTURAL PERSPECTIVES IN MEDICAL ETHICS 44 (1989).
[131] *Id*. at 242.
[132] Chen X., *Clinical Bioethics in China: The Challenge of Entering a Market Economy*, 31 J. MED. PHILOS. 7, 11 (2006).

Also, Gert and Clouser have[133] [134] [135] criticised principlism as doing little more than giving a checklist of duties with no specific guidance solving a conflict. They also consider Beauchamp and Childress's assertion that beneficence or non-maleficence are substantive principles of obligation as being superficial.[136] In response, Beauchamp and Childress have stated that Clouser and Gert's view as being based on a mistake of relevance – "correct but irrelevant."[137]

Engelhardt believes principlism is a form of procedural morality, merely providing a 'non-foundational approach' to bioethics.[138] Engelhardt prefers the principle of 'permission', instead of autonomy, as permission is constitutive and philosophically before beneficence. Further, he opines that beneficence is a negotiated or 'contractarian' arrangement. It is not a universal foundation principle. Moral authority is derived from mutual consent. Besides, Engelhardt does not consider justice or non-maleficence as substantive, seeing the former as redundant and defining the latter as applied beneficence.

The lack of contextualisation in the principlism approach has been a source of reproval. Some have argued that virtue ethics can inform the 4P's approach to achieve a more inclusive framework in psychiatric ethics and bioethics generally.[139]

- ***Consent***

The main objective of consent is to ensure an individual's autonomy and the right to choose by rational decision-making. It is an essential component of biomedical research and health-care today.[140] There is implicit and explicit consent. In implied or implicit consent, the consent is not expressed but is implied through the act of the particular person. In explicit consent, the consent

[133] Ishiwata R., Sakai A., *The physician-patient relationship and medical ethics in Japan*, 2 CAMB. Q. HEALTHC. ETHICS 45, 46 (1994).
[134] Miyaji N., *The power of compassion: truth telling among doctors in the care of dying patients*, 36 SOC. SCI. MED. 249, 253 (1993).
[135] Clouser C., Gert B., *A critique of principlism*, 15 J. MED. PHILOS. 219, 228 (1990).
[136] Supra.
[137] BEAUCHAMP T, CHILDRESS J., PRINCIPLES OF BIOMEDICAL ETHICS 57 (2001).
[138] ENGELHARDT H., THE FOUNDATIONS OF BIOETHICS 79 (1996).
[139] Campbell A., *The virtues (and vices) of the four principles*, 29 J. MED. ETHICS. 292, 294 (2003).
[140] Gupta U. C., *Informed consent in clinical research: Revisiting few concepts and areas*, 4 PERSPECT CLIN RES. 26, 30 (2013).

is expressed in clear terms, either verbally or in writing. Furthermore, valid consent contains the following three elements such as (a) voluntariness, (b) information, and (c) competency.

If the patient cannot give consent, it must be obtained from his/her legal representatives. Psychologists and psychiatric researchers must inform their patients/participants about the course of treatment/ activity. The psychologists must inform about the risks involved and the alternative treatments that are available to the patient. This duty to inform also encompasses information regarding compensation in psychiatric research that results in injuries to the research participant.[141]

Informed consent and Real consent: There are two significant schools of thought regarding consent in law. According to the informed consent doctrine, it is the responsibility of the doctor to disclose all the necessary information to the patient. The 'reasonably prudent patient' test[142], was formulated in the Canterbury case. According to this rule, a patient must know and understand the diagnosis and the nature and purpose of the treatment, the know risks and consequences involved, except those consequences that are too remote and improbable or too well known to affect the treatment decision. The success and failure rates of the proposed treatment should be informed.[143]

There is also the doctrine of 'real consent,' which evolved from Bolam's test. According to the doctrine of real consent, the doctor must inform his patient of the risks inherent in the recommended treatment. The terms of giving such warning or information must agree with the practice accepted at that time and considered proper by a responsible body of medical practitioners skilled in that particular field.[144] As per Bolam's test, before deciding whether a doctor's act is negligent or not, the act of another doctor in similar circumstances should be considered. Also, the knowledge and skill of the treating doctor should be contrasted with that of

[141] Geiderman J. M., *Ethics seminars: physician complicity in the Holocaust: historical review and reflections on emergency medicine in the 21st century*, 9 ACAD EMERG MED. 223, 228 (2002).
[142] Aggarwal K. K., *Real consent and not informed consent applicable in India*, 25 INDIAN J CLIN PRACT. 591, 592 (2014).
[143] BEAUCHAMP T., CHILDRESS J., PRINCIPLES OF BIOMEDICAL ETHICS 62 (1994).
[144] Rangaramanujam A., *Liberalizing consent – Supreme court's preference for real consent over informed consent*, 18 INDIAN J RADIOL IMAGING. 195, 197(2008).

another doctor having the same educational background.[145]In other words, doctors will be held to a standard of care that an average doctor generally practices at that particular time.

2.3. Conclusion

Psychiatric researchers should be required to justify their scientific approaches and methods adopted in the research. They must safeguard the well-being of people with mental illness who participate in research and experiments. The investigators should be educated about research ethics and aware of the ethical implications of decisions and actions. Also, they must possess skills in ethical problem solving, including ascertainment and resolution of conflicts of interest. An ethical research design must ensure that the study has scientific merit and that the methods used yield knowledge of value and minimize risks to participants. Therefore, psychiatric researchers must be prepared for the ethical responsibilities of their research to help ensure that it is carried out with integrity, embodies the highest ethical and scientific standards, and provides appropriate protections for research participants.

[145] Yadav M., Thakur P. S., Rastogi P., Role of Informed Consent in India; Past, Present and Future Trends, 36 J INDIAN ACAD FORENSIC MED. 411, 417 (2014).

CHAPTER 3: ETHICAL ISSUES IN PSYCHIATRIC RESEARCH

3.1.Introduction

"We might say that science is a calling and not an occupation only, or at any rate, that it cannot flourish if it is always an occupation only. The difference between these two sorts of pursuits lies in this that we choose an occupation while a calling chooses us; we are impelled to the calling from within, which is to say that we are committees to its values."

-Abraham Kaplan[146]

As medicine developed into an experimental discipline since the middle of the nineteenth century, the ethical problem in conducting medical experiments on human beings and animals was raised. Claude Bernard, a famous French physiologist and pharmacologist, had expressed in 1856 that medical researchers, through their experiments, should never risk harming a human being, even if their experiment would subsequently help in healing others. However, in their pursuit of money and recognition, biomedical institutions and researchers sometimes turn a blind eye towards following the established ethical norms and principles while conducting research.

Psychiatric research conducted to study the causes and effects of various mental illnesses to improve the healthcare of persons with mental disorders is of great pertinence. The ethical issues in psychiatric research include informed consent, capacity to consent, risk and benefit assessment, use of placebo, confidentiality, research design, justice issues in recruitment, and conflicts of interest.[147] For instance, a person with cognitive deficits would find it difficult to understand a research study and grant informed consent, but he would want to participate. Furthermore, some studies collect private information about medical records or illegal behaviours that could cause emotional, social, or legal harm if shared. Still, state laws and institutional review boards may oblige researchers to breach confidentiality in specific situations. As mental health consumers and research participants would be familiar with past cases of abuse of human subjects, there is also mistrust and unnecessary apprehensions.

[146] Abraham Kaplan is an American philosopher who wrote a book on behavioral sciences 'The Conduct of Inquiry.'
[147] JAMES M. DUBOIS., ETHICS IN MENTAL HEALTH RESEARCH: PRINCIPLES, GUIDANCE AND CASES 11 (Oxford University Press 2007).

Milgram's series of experiments must undoubtedly be specified, particularly among the experiments that have contributed to our awareness of ethical issues in psychology. Milgram described his initial experiments on obedience to authority in 1961 in an unpublished research report, which gathered no scrutiny. His experiments became a grave ethical issue until the project was published in a series of articles from 1963 onwards. This publication may be considered the starting point of enforcing stricter professional and governmental regulations of research.

This Chapter discusses the various ethical issues in psychiatric research.

3.2.Ethical Issues

(i) Issue of Informed Consent in Psychiatric Research

It is noteworthy that informed consent to treatment honors patient autonomy. However, informed consent is controversial in psychiatric clinical settings because informing a patient/his family about a mental health diagnosis is seen to affect his lifestyle, future choices, and resilience.[148] Also, there is no standardized informed consent process in many countries.

Few studies have addressed the issue of informed consent in psychiatric practice. According to one study, information on their illness had not been revealed to 60.84% of inpatients with major depression.[149] As per another study, 49.2% of psychiatrists expressed that they wanted to inform the patient or guardian of only the treatment plan.[150] It is observed that western studies have a low prevalence rate in disclosing diagnosis plans for schizophrenia and general mental health disorders (30%–88%).[151] The reasons for such kinds of practices can be attributable to factors such as stigma,[152] patients' mental capacity,[153] service-user and clinician characteristics,[154] and cultural factors.

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[148] Michelle *Cleary*, Glenn E *Hunt et al., Receiving difficult news: Views of patients in an inpatient setting*, 48 J PSYCHOSOC NURS MENT HEALTH SERV 40, 42 (2010).
[149] Li W. et al., *A preliminary analysis on the attitude of psychiatrist, schizophrenic patients, and their caregivers to the process of informed consent*, 15 CHINESE J BEHAV MED SCI 715, 715 (2006).
[150] Hwang W., *Diagnostic non-disclosure of schizophrenia to Chinese American patients*, 15 ASIAN J COUNS 1, 12 (2008).
[151] Milton A. C., Mullan B. A., *Communication of a mental health diagnosis: a systematic synthesis and narrative review*, 23 J MENT HEALTH 261, 262 (2014).
[152] O. Reilly, Bell J. S., et al., *Exploring the relationship between mental health stigma, knowledge and provision of pharmacy services for consumers with schizophrenia* 11 RES SOC ADM PHARM 101, 105 (2015).

It must be realised that people with mental illness face more problems in consent process compared to other ailments.[155] Informed consent is based on three facets:

a. Providing information: The objective behind informed consent procedures in medical settings is to inform the participant about the research protocol. Research subjects may find it difficult to distinguish between the imperatives of clinical research and ordinary treatment.[156] Also, they may not have a clear picture of how their treatment will be individualized to meet their needs and the likelihood of benefit from participation.[157] Dr. Appelbaum[158], in 2004, reviewed 44 clinical trials and found out therapeutic misconception in 62% of studies.[159] He reported high therapeutic misconception in genetic studies (74%)[160] and psychiatric research (69%).[161]

b. Competence: The participants must have the ability to understand the information and make rational decisions. Although the information provided to the participants may be sufficient, consent in psychiatry research is intricated by the inability of persons with a mental illness to understand the provided information adequately. This may be because of a lack of awareness of illness or cognitive changes during illness.

c. Autonomy: The principle of autonomy is adhered to in research when the patient can take autonomous decisions without being swayed by the disease process, cultural factors, or other extraneous factors. Autonomy comprises of (i) choice of participants and (ii) non-coercion.

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[153] Moye J., Gurrera R. J., et al., *Empirical advances in the assessment of the capacity to consent to medical treatment: clinical implications and research needs* 26 CLIN PSYCHOL REV 1054, 1057 (2006).
[154] Supra note 3.
[155] Stanley B., et al., *Psychiatric patients' comprehension of consent information*, 23 PSYCHOPHARMACOL BULL 375, 376 (1987).
[156] Henderson G. E., Churchill L. R., et al., *Clinical trials and medical care: Defining the therapeutic misconception*, 4 PLOS MED 324,327 (2007).
[157] Appelbaum P. S., Lidz C. W., *Twenty-five years of therapeutic misconception*, 38 Hastings Cent Rep. 5,6 (2008).
[158] Emeritus Professor and the founding editor of Psychological Methods.
[159] Paul S. Appelbaum, *Must We Forgo Informed Consent to Control Health Care Costs? A Response to Mark A. Hall*, 71 MILBANK Q. 669, 671 (1993).
[160] Jeste D. V., Appelbaum, Golshan S, Glorioso D, Dunn LB, et al., *A new brief instrument for assessing decisional capacity for clinical research*, 64 Arch Gen Psychiatry 966 (2007).
[161] Supra note 14.

Sometimes, patients may lack decision-making capacity in psychiatric research, which is not a static phenomenon but a dynamic one. This is because their ability to understand and decide may fluctuate from time to time.[162] This decisional impairment depends on the severity of the ailment, diagnosis, and response to treatment.

(ii) **Multitude of diagnostic classifications**

The diagnosis of mental illness is depended on diagnostic criteria. Diagnostic criteria may comprise subjective symptoms and behaviour observation, which is frequently revised from time to time to improvise diagnostic classification. Due to too many classifications, distinguishing normal and abnormal behaviour often becomes vague.[163] Symptoms used in diagnosis may occur in individuals usually. However, the difference in frequency or severity of these symptoms determines whether an individual has a mental illness or not.

With the rise of research in psychiatry, the number of diagnoses has multiplied in newer classificatory systems. E.g., There were 106 classifications in Diagnostic and Statistical Manual of Mental Disorders (DSM I) (1st edition, 1952); 182 in DSM II (1968), 265 in DSM III (1980), 297 in DSM IV (1994), and approximately 340 in DSM V (2013).[164] Moreover, newer classificatory systems have either re-categorized or added new diagnosis. For instance, in the Diagnostic and Statistical Manual of Mental Disorders, several categories of mental illness like OCD, disruptive mood dysregulation disorder, somatic symptom disorder, illness anxiety disorder, binge eating disorder can be found. Such re-categorization is seldom seen in other branches of the medical fraternity.

The diagnosis of mental illness even now is rooted mainly in symptomatology and observations. There is a lack of laboratory markers to aid in diagnosing mental illness correctly. As a result, mental conditions are sometimes incorrectly diagnosed or differently diagnosed by different clinicians. Labeling a person with mental illness will have inevitable psychological and social consequences like shame, exclusion, secrecy, danger, discrimination, blame, and stigma, leading

[162] Candia P. C., Barba A. C., *Mental capacity and consent to treatment in psychiatric patients: The state of the research*, 24 CURR OPIN PSYCHIATRY 442, 444 (2011).
[163] Quitkin F. M., *Placebos, drug effects, and study design: A clinician's guide*, 156 AM. J. PSYCHIATRY. 829, 832 (1999).
[164] Ibid.

to isolation and rejection.[165] A wrong diagnosis might have prejudicial implications for researchers, as everything depends upon the diagnosis.

(iii) **Researcher-participant relationship**

Unquestionably, mental illness affects persons' behaviour, cognitive functions, and emotions, spawning issues relating to decision-making capacity, transference, and counter-transference. Researchers are held in high esteem and are given authority by affected persons and caregivers. However, they might misuse the authority conferred upon them and violating persons with mental illness rights. They may take advantage of issues of informed consent, therapeutic misconception, provide wrong information, unnecessarily prolong investigations, exposure to harm related to investigations, pharmacological and non-pharmacological treatment, and may indulge in malicious intimate relationships. As such, in such an uneven power relationship, it is easy for ethical issues to emerge.

(iv) **Behavioural Freedom**

Another problem researchers and experimental psychologists face is the unique nature of the object of research, i.e., the human subject. Observing the behaviour of humans in complex everyday situations and inferring regularities from their behaviour is arduous. Also, human beings tend to alter their behaviour when they realize that they are being observed. Therefore, researchers must conduct experiments with strictly controlled conditions and considerably reduced complexity.

Human beings can control and influence to a certain extent the connection between experience and behavior. In other words, research participants get to control stimulus and response inherently. This 'behavioural freedom' in responding makes it harder to find out genetic and other causes and establish nomothetic regularities like those in the natural sciences. Compared to the behaviour of objects observed in the natural sciences, the presumed greater variability of human behavior is partially a function of this capacity for self-control and self-direction. So, employing unique methods of investigation by psychiatric researchers becomes necessary in some instances, whereby it is also easy for professional, legal, and ethical problems to be caused.

[165] HELMCHEN H, SARTORIUS N, ETHICS IN PSYCHIATRY 199,201 (2010).

(v) **The Advent to Participatory Research**

To democratize knowledge production in the health sciences, funders prefer research protocols to involve patients or the public in developing and circulating the research findings. This has led to the evolution of what is called as 'participatory research' (or user involvement, or 'public and patient involvement and engagement (PPIE)', or patient and service user engagement, co-production, or user-led research and citizen science).[166]

Diana Rose emphasizes two aspects for involving the public in research which is (i) ethical reasons and (ii) epistemic reasons. She further opines that "First, there is a strong current of opinion that says that the type of knowledge generated is not especially relevant because what matters is the ethical dimension in that those who research is for should have a stake in how it proceeds. In the second, which has not been developed at all, it is argued that the value of PPI [public and patient involvement] must be related to how changing the knowledge producers changes the knowledge." [167]

The inclusion of participatory health research in psychiatry has drawn different responses from stakeholders (e.g., researchers, patients, funders). Some consider the advent of participatory research a sudden step, with little justification, which might subsequently result in role confusion and tokenism.[168] Some others have embraced this change with skepticism, as it makes research more strenuous and expensive.[169] Another sector of people views this as a long-awaited development after many years of activism.[170] Some of the problems of including participatory research in psychiatry are:

Skepticism: If a positive impact accrues the research by involving the public, then those results are used to convince doubtful researchers that participatory research will improve their work.

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[166] Phoebe Friesen et al., *Measuring the impact of participatory research in psychiatry: How the search for epistemic justifications obscures ethical considerations*, 6 HEALTH EXPECT. 1 (2019).
[167] Rose D., *Patient and Public involvement in Health research- ethical imperative or radical challenge?* 19(1) J HEALTH PSYCHOL. 149, 151 (2014).
[168] Brett J.O., Staniszewska S. et al., *Mapping the impact of patient and public involvement on health and social care research*, 17 HEALTH EXPECT. 637,645 (2012).
[169] Rutter D., Manley C., et al., *Patients or partners- Case studies of user involvement in the planning and delivery of adult mental health service in London*, 58 SOC SCI MED. 1973 (2004).
[170] Beresford P., *User involvement in research and evaluation- liberation or regulation?* 1 SOC POL SOC. 95, 98 (2002).

However, the downfall is that the researchers might view this involvement as a process to aid them in achieving their research goals. On the other hand, if their research does not benefit or is not improvised by involving the public, the investigators will become skeptical about the importance of participatory research. [171] [172]

Tokenism: Sometimes, investigators involve patients or the public in a tokenistic or non-committal way. Sometimes, investigators involve patients or the public in a tokenistic or non-committal way. As participatory research undertaken without a precise aim does not result in any benefits, such instances serve to remind about the inability of the public to interact with researchers and policymakers, or to contribute to the scientific literature, directly."[173] This is deemed by many as the self-fulfilling prophecy of tokenism in participatory research. "Public involvement when undervalued leads to tokenism in involvement practice; tokenistic practice fails to demonstrate the value of PI; and hence, PI is therefore perceived as not adding value to health and social care research."[174]

Negative experiences: Negative experiences: More importantly, when participatory research does harm than benefit to research, it will badly affect the service users through disempowering or stigmatizing experiences. Lydia Lewis refers to an interview with a service user who felt undermined by others in meetings to avoid her opinions based on her diagnosis or symptoms. Statements in the line of, "Oh well, she is not feeling very well at the moment" were prevalent whenever she had voiced her opinions.[175] Thus, participatory efforts can be impaired by stereotypes between service users and between service users and others.[176]

(vi) **Confidentiality**

[171] Supra note 168.
[172] Domecq J. P., Prutsky G., Elraiyah T., et al., *Patient engagement in research: a systematic review*, 14 BMC HEALTH SERV RES. 89 (2014).
[173] Jones N, Harrison J., et al., *Transforming research for transformative change in mental health: towards the future, in*: Nelson G, Kloos B, Ornelas J, eds. COMMUNITY PSYCHOLOGY AND COMMUNITY MENTAL HEALTH 351, 363 (Oxford University Press 2014).
[174] Snape D, Kirkham J, Britten N, et al., *Exploring perceived barriers, drivers, impacts and the need for evaluation of public involvement in health and social care research- a modified Delhi study*, 4 BMJ Open. 76 (2014).
[175] Lewis L., *Politics of recognition: what can a human rights perspective contribute to understanding users' experiences of involvement in mental health services?* 8 SOC POLICY SOC. 257, 265 (2009).
[176] FRICKER M., EPISTEMIC INJUSTICE: POWER AND THE ETHICS OF KNOWING 54 (Oxford University Press 2007).

Confidentiality breaches in the healthcare sector are not new. In December 2018, it was reported that the electronic medical records (EMR) of over 35,000 patients held by a Maharashtra-based pathology lab were leaked.[177] As per the US Department of Health and Human Services, there were no less than 2,181 healthcare data violations between 2009 and 2017 exposing 176,709,305 medical records.[178]

Information learned during research must not be disclosed to anyone in psychiatric research without the patient's permission. Some new neurobiological[179] and genetic markers of mental illness are often used without clarity regarding whether it will be a valuable tool for diagnosis. On the one hand, non-disclosure of the findings of a person's investigations prejudices the person's right. On the other hand, disclosure of results obtained from unproven markers leads to ethical issues. There are also instances under the State law where the psychiatrist must disclose information regarding his/her patient, which might raise confidentiality concerns. For example, under POCSO Act, 2012, if a researcher knows about child sexual abuse in his participant, he must inform the authorities.

Obtaining consent beforehand is mandatory in every scenario of privilege communications. While collecting information from the participants, the researchers have to respect the participants' right to confidentiality. The participants should not be interviewed in front of others, including relatives. Also, their records should not be left carelessly to be accessed by persons other than the researchers. Wherever disclosure of the information is required to fulfill legal obligations, participants must be informed. The information disclosed in such a case should contain only the issue's facts and only to the concerned authority.

(vii) **Electroconvulsive therapy**

Electroconvulsive therapy (ECT) is a treatment mechanism primarily provided to individuals suffering from severe episodes of major depression, usually when other treatment alternatives

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[177] Akhil Deo, *Without Data Security and Privacy Laws, Medical Records in India Are Highly Vulnerable*, THE WIRE (April 25, 2021), https://thewire.in/law/without-data-security-and-privacy-laws-medical-records-in-india-are-highly-vulnerable.

[178] Supra.

[179] Neuro-biological imaging techniques are used to detect mental illness. Also, functional MRI (fMRI) has been used for brain imaging and has also helped to gain insights into psychopathology, behaviour, and cognition.

fail.[180] In rare cases, where it is urgent, or ECT has proven necessary in earlier episodes, ECT is extended before these treatment alternatives fail.

One of the major issues in research related to electroconvulsive therapy (ECT) is informed consent, as the patients planned for ECT usually lack decision-making ability. There is no doubt that unmodified ECT causes pain and discomfort to the patients. Moreover, the use of ECT is depended on the severity of illness or treatment resistance. As such, issues of beneficence and non-maleficence happen in conducting sham procedures on severely ill or resistant cases.[181]

Informed consent is indispensable for the administration of ECT. Informed consent involves the delivery of comprehensive and correct information to the consenter and the ability of the consenter to understand, process, and act upon this information. In most situations, the patient serves as the consenter. In this regard, the presence of psychosis or other irrational thought patterns does not in itself hinder the capacity to consent.

That being the case, there might be circumstances where the capacity to consent is lacking. In these situations, how consent should be obtained is laid down by state law. Depending upon the state, the applicable rules range from surrogate consent by the significant other to a judicial determination of a guardian who has to provide consent for ECT.

Several ethical questions relating to informed consent may arise while deciding the application of ECT. Firstly, when does a recommendation for ECT by a researcher amounts to coercion? There should always be definite reasons for choosing ECT in place of other treatments. The researcher should not compel the patient to take the treatment, nor should any threats to the patient be extended if the recommendation is not followed.[182]

The second question is regarding how and by whom capacity for consent is determined. This determination is sometimes elucidated by state law. In other cases, it is for the research team to

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[180] Avery D. H., Lubrano A., et al., *Depression treated with imipramine and ECT: the DeCarolis study reconsidered*, 136 *AM J PSYCHIATRY*. 559,561 (1979).
[181] Srinivasan T. N., Suresh T. R., et al., *Issues in the use of maintenance electroconvulsive therapy*, 37 INDIAN J PSYCHIATRY. 139, 141 (1995).
[182] ARLINGTON, THE PRACTICE OF ELECTROCONVULSIVE THERAPY: RECOMMENDATIONS FOR TREATMENT, TRAINING AND PRIVILEGING 15 (American Psychiatric Publishing Inc 2001).

decide. In such situations, the determination of capacity should be based upon the patient's ability:

1. To understand that he/she has a health condition for which the treatment is being recommended.
2. To comprehend other consent-related materials which are provided.
3. To process this information so that he/she can make a proper decision.

Importantly, this determination should not be controlled by the whims of the physician or significant others. The third ethical question concerns the extent to which the patient's wishes (who lacks capacity) should be incorporated into the decision-making process. A surrogate consenter has to consider such wishes and act in the patient's best interest. Whether to administer ECT or not is similar to determining the right to have a treatment or not. Respect for autonomy should not be abridged in any medical interventions. There might be circumstances where ECT has to be administered to a non-consenting patient. When the repercussions of withholding treatment may be life-threatening, the principle of beneficence should be given more significance than the principle of respect for autonomy.[183] Furthermore, sham procedures on severely ill or resistant cases should never be conducted.[184]

(viii) **Placebo trials**

The psychiatric investigator may also face issues while obtaining a patient's informed consent to use a placebo.[185] Whether it is more problematic to withhold from the subjects the information that they are participating in a conditioning experiment or the information that they are receiving a placebo instead of the expected medication must be considered.

Placebo response in depression studies ranged from 10% to 50%, with an average of 30%. This implies that even inactive treatment may show a significant reaction. Therefore, it raises doubt

[183] Hermann R. C., Ettner S., et al., (1998), *Characteristics of psychiatrists who perform ECT*, 155 AM J PSYCHIATRY 889, 890 (1998).
[184] Prudic J., Sackeim H. A., *Electroconvulsive therapy and suicide risk*, 60 J. CLIN. PSYCHIATRY 104, 107 (1999).

[185] Henry A. Davidson, Legal and Ethical Aspects of Psychiatric Research, 126 AM. J. PSYCHIATRY 237, 238 (1969).

over the results of non-placebo studies. There are concerns in selecting inactive placebo in non-pharmacological modes of treatment also.

Moreover, placebo-controlled studies need to be considered over uncontrolled studies. However, concern about placebo-induced worsening of symptoms had led to suggestions that any new psychoactive medication should be studied against an active comparator only.[186] [187]

In an investigation conducted by Shapiro and Struening in 1973, they asked 240 physicians about using placebos in therapy and research.[188] The study found that a clear connection exists between the extent of research activities and the lack of concern about the use of pseudo medicines with patients in need of treatment.

Difficulty in distinguishing therapy from research

Paradoxically, the difficulty of separating research and therapy in psychiatry has helped the researchers to obtain subjects quickly. Mainly, this difficulty occurs because an experiment may be similar to an attempt at therapy in a given case. There are also cases where the experiment is made to seem similar to therapy. The non-transparency of the methods chosen for research and its concealment from patients and guardians is deliberately utilised to benefit research goals. The seeming identity of experiment and therapy may drive the patients to consent to a method that would be discarded if it seemed merely part of a research project. If the patients are informed that:

i. the methods used are not therapies;
ii. that the procedure used might be of questionable value;
iii. that a particular procedure will benefit only future patients; or
iv. that it may cause harm, then it would be detrimental for future research activities and the public image of the physician.

[186] Walsh B. T., Seidman S. N., Sysko R., et al., *Placebo response in studies of major depression: Variable, substantial, and growing*, 287 JAMA. 1840, 1842 (2002).
[187] Khan A, Detke M. et al., *Placebo response and antidepressant clinical trial outcome*, 191 J NERV MENT DIS. 211, 212 (2003).

[188] HEINZ SCHULER, ETHICAL PROBLEMS IN PSYCHOLOGICAL RESEARCH 72 (2013).

(ix) **Coercion**

There is no doubt that psychiatric coercive measures constitute a serious break with common health law principles about patient autonomy. Although autonomous decision-making may be maliciously affected because of the power relationship between the skilled practitioner and the unskilled patient, this power divide is more prevalent in psychiatry because of the nature of the mental illness.[189] Coercion in psychiatric care can be observed in the form of involuntary admission, involuntary treatment, outpatient commitment, seclusion/restraint, and also surreptitious treatment. Coercion can be seen in day-to-day interaction between the researcher and the participant. Patient interaction should involve the use of appropriate speech and behaviour with patients.

However, coercion is necessary for some special clinical situations. A person who has a mental problem of a severe nature may be subjected to a medical intervention without consent, provided that without such treatment, serious harm would accrue. That said, efforts must always be exercised to obtain the consent of the patient.

(x) **Conflict of interest**

When a set of conditions unduly affects a primary interest (like the patient's welfare or the validity of research) because of secondary interest (like financial gain or professional gain), then a conflict of interest tends to occur.

Pharmaceutical companies nowadays widely influenced journals, publishers, and conferences[190], and they tend to publish the research for their financial gains. Due to a lack of resources for high-quality research in developing and underdeveloped countries, they often become prey to these predatory journals. Retraction due to fraud and error was highly prevalent among journals with higher impact factors, whereas plagiarism and duplicate publications were more common among journals with lower impact factors.[191]

(xi) **Deception or Misinformation**

[189] Roberts L. W., *Informed consent and the capacity for voluntarism*, 159 AM J PSYCHIATRY 705, 709 (2002).
[190] Healy D. T., *Transparency and trust: Figure for ghostwritten articles was misquoted*, 329 BMJ 1345 (2004).
[191] Fang F. C., Casadevall A., *Retracted science and the retraction index*, 79 INFECT IMMUN. 3855, 3858 (2011).

The deception of subjects, notably observed in social psychology[192] research, has received substantial attention. Whether to reveal information to the subjects or conceal it begins as a methodological question. When the subjects become aware that they are being observed and that the observer is analysing their behaviour, they tend to alter their behaviour.

There are three ways in which the subjects can be observed without their knowledge:

1. Arranging for observation so that the subjects are not aware of any facets of the investigation.
2. Conceal those aspects of the investigation that might stir them to alter their behavior.
3. Arranging for observation in such a manner that the subjects misinterpret the characteristics of the investigation.

In specific scenarios, withholding information from the subjects may be required. As per S. W. Cook, details like the subjects were selected for research due to certain criteria (because they were particularly low achievers or had certain prejudices) need not be disclosed.[193] Sometimes, the consequences of a deception can be harmless. It is noteworthy that craftiness and self-interest can be the source of deception, but so can compassion.

Two measures can be applied for clarifying the extent to which it is imperative to misinform subjects: (i) to try out a variation of role-playing, and (ii) to question subjects, researchers, and others on the acceptability of various research procedures.[194] Only when the psychologists came to see the experiment as a social situation, interest in the subjects' views was adopted.

Various studies have taken note of the frequency of deceptive procedures. Menges (1973) examined various American Psychological Association journals published in 1971, which included approximately 1000 reports of investigations. He found that complete information had been provided only in about 3% of the cases, false information in 17%, and incomplete information in 80%.[195] Whereas, in Stricker's statistics (1967), it was discovered that 19.3% of a

[192] A study of how people's feelings, thoughts, and behaviours are affected by the actual, imagined, or implied presence of others. In experiments in social psychology, certain kinds of dishonesty are part of the usual procedure and are also covered by conventions.
[193] S.W. Cook, *The systematic analysis of socially significant events: A strategy for social research*, 18 J SOC ISSUES 66, 72 (1962).
[194] HEINZ SCHULER, ETHICAL PROBLEMS IN PSYCHOLOGICAL RESEARCH 68 (2013).
[195] Supra, Pg. 77.

total of 457 studies had active deceptive procedures. Moreover, the percentage of the studies using deception varied depending on the area of research. Conformity studies were the forerunner, with 81.2% use of deception.[196] Deception is less observed in experimental and clinical psychology when compared to personality and social psychology.

Efforts were made to systematize the types of deception found in psychological research methods. F. J. Arellano-Galdames, in his doctrinal dissertation in 1972 ('*Some Ethical Problems in Research on Human Subjects' at the* University of New Mexico, Albuquerque) distinguished between active and passive deception. The different types of active deception (deception by commission) include:

- "*Misrepresentation of the purpose of the investigation*
- *Untrue statements about the identity of the researcher*
- *False promises*
- *Violation of the promise of anonymity*
- *Incorrect explanations of equipment and procedures*
- *Use of pseudo subjects*
- *False diagnoses and other reports*
- *Pseudo-interaction*
- *Use of placebos and secret application of medications and drugs*
- *Misleading settings for the investigations and corresponding behavior by the experimenter."*[197]

On the other hand, the following comes under passive deception (deception by omission):

- *"Unrecognized conditioning*
- *Provocation and secret recording of negatively evaluated behavior*
- *Concealed observation*
- *Unrecognized participant observation*
- *Use of projective techniques and other personality tests"* [198]

[196] Supra.
[197] S. W. Cook, L. H. Hicks, G. A. Kimble, et al., *Ethical Standards for Research with Human Subjects*, 3 APA Monitor 1,6 (1972).

To put it concisely, the use of deception in psychiatric research, like in any other scientific research, is unacceptable. Lack of transparency in research is, first of all, detrimental to the internal validity of the research. Equally, it is prejudicial to the overall political and ethical principle of trust because it contradicts efforts to improve individual and institutional accountability and responsibility.[199]

Conclusion

Inarguably, research ethics involve requirements on daily work, the safeguarding of subjects' dignity, and the accurate publication of the information in the research. While doing research, the researchers must execute the principles of beneficence and non-maleficence while balancing with patients' autonomy. Therefore, psychiatric research must be conducted in consonance with the ethical principles; otherwise, ethical issues are bound to happen.

[198] Supra.
[199] OLE DÖRING, BIOMEDICAL RESEARCH AND ETHICAL REGULATIONS IN CHINA: SOME OBSERVATIONS ABOUT GENE THERAPY, HUMAN RESEARCH, AND STRUGGLES OF INTEREST 143 (2006).

CHAPTER 4: ETHICAL REGULATIONS IN PSYCHIATRIC RESEARCH: COMPARATIVE PERSPECTIVE

4.1.Introduction

Like all other professions, the medical profession is regulated not only by law but also by the application of ethical codes. Some of these rules are extracted from moral philosophy and others from an inductive assessment of the values and practices of the profession. The 'codes' achieve a different status because authoritative bodies within the professions issue them and because they are 'express ante' conduct rules.

There are several ethical issues in psychiatric research like the issue of confidentiality, informed consent, use of placebo, etc. Countries have already framed their ethical codes to regulate psychiatric research considering the increased possibility of exploitation. The Global Target 1.2 of the Mental Health Action Plan states that 50% of countries will have framed or updated their law for mental health confirming to international and regional human rights instruments by the year, 2020.[200]

As per the World Health Organisation's Mental Health Atlas 2017[201], 72% of Member States have a stand-alone policy for mental health, and 57% have a stand-alone mental health law. As per the official data published on the website of the United Nations Educational, Scientific and Cultural Organization (UNESCO), the top five countries spending the most in research and development (in billion U.S. dollars) in 2020 were: United States, China, Japan, Germany and India.[202]

This chapter focuses on the ethical codes and regulations in psychiatric research in the United States, China, Japan, and Germany to understand where India is behind in regulating psychiatric research's ethical aspects. As the United Kingdom has one of the earliest mechanisms for regulating health research, the author has also included the regulatory system in the United Kingdom.

[200] Mental Health Atlas 2017, World Health Organisation (April 11, 2021).
[201] Supra.
[202] HOW MUCH DOES YOUR COUNTRY INVEST IN R&D? , http://uis.unesco.org/apps/visualisations/research-and-development-spending/ (last visited Feb 5, 2020). Also, available at: https://www.rdworldonline.com/global-rd-investments-unabated-in-spending-growth/.

4.2.United States

During 1960-1970, reports of research on persons without free and voluntary consent came to light.[203] In cases like the 'Tuskegee Syphilis Study' which was sponsored by the United States Public Health Service, the participants did not know that they were being used in research.[204] In some other cases like the 'Willowbrook State School hepatitis studies', it was found that the subjects' parents had been strongly influenced to enroll their children in a study where they would be intentionally infected with hepatitis.[205]

Public revelation of these cases, especially in 1972 after the Tuskegee Syphilis Study, led to congressional action and the enactment of the National Research Act in 1974.[206] This act led to the establishment of the Office for the Protection of Research Risks (OPRR) and the framing of a set of guidelines called the Common Rule[207].

The Common Rule specified that any institution receiving federal funds for research must have an institutional review committee. These committees came to be called the 'Institutional Review Boards' (IRBs). IRBs are responsible for monitoring research proposals that involve working with human subjects and animals. Universities and colleges. They are responsible for implementing the U.S. government regulations proposed for human research and overseeing aspects relating to the study's benefits risks, consent procedures, etc.

Moreover, the National Commission for the Protection of Subjects of Biomedical and Behavioral Research urged special protection for vulnerable subjects in biomedical research. As a result, subparts B, C, and D of the Common Rule restrict the research conducted on vulnerable groups. It is mentioned that when the subjects are likely to be vulnerable to coercion or undue influence (like children, prisoners, pregnant women, mentally disabled persons, or economically or

[203] H. K. Beecher, *Ethics and Clinical Research*, 24 NEJM 1354 (1966).
[204] J. H. JONES, BAD BLOOD: THE TUSKEGEE SYPHILIS EXPERIMENT 12 (1993).
[205] D. J. ROTHMAN AND S. M. ROTHMAN, THE WILLOWBROOK WARS 41 (2005).
[206] National Research Act of1974 The National Research Act led to the establishment of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research to formulate guidelines for human subject research and to oversee and monitor the use of human experimentation in medicine.
[207] The Common Rule is a portion of the Code of Federal Regulations that governs much of the human research conducted in the US.

educationally disadvantaged persons), then there should be additional safeguards for the protection of the rights and welfare of these subjects."[208]

At present, professional associations for each discipline, such as the American Educational Research Association (A.E.R.A.), the American Sociological Association (A.S.A.), and the American Psychological Association (A.P.A.), have established their general ethical guidelines, which elaborate and sometimes extend federal guidelines.

The President's Council on Bioethics, the successor to the National Bioethics Advisory Commission, was established in 2001 to enhance the protection of the rights and welfare of human research subjects and to address the issues in the management and use of genetics information, including but not limited to, human gene patenting.[209]

Laws regulating Psychiatric Research: When it comes to the field of psychiatric research alone, one cannot ignore the contributions of the American Psychological Association (A.P.A.). The American Psychological Association is the largest psychiatric body regarding the number of psychologists in the United States.

American Psychological Association (A.P.A.) has published its ethical code. The A.P.A. ethics code acts as a guide to psychologists so that they possess the knowledge of what to do when facing any moral or ethical dilemma. Some of the provisions in the ethical code are principles or values that psychologists should aspire to uphold. Then, other provisions stipulate standards that are enforceable expectations. The first ethics code of the American Psychological Association was published in 1953, and it has been continuously updating code ever since. The present version of the ethics code was evolved in 2002 and later amended in 2010 and 2016.

The Five Ethics**:** The APA Ethical Code contains five essential ethical principles to help psychologists to make sound ethical choices within their profession. These ethical principles are:

[208] 45 CFR 46.111(b).
[209] James F Childress, *Reflections on the National Bioethics Advisory Commission and Models of Public Bioethics* 47 HASTINGS CENT REP. 20, 22 (2017).

(i) Beneficence and Non-maleficence

Psychologists must act in the best interest of their patients/ participants. No harm should be caused to the patients/ participants in the course of treatment and research. They further have the duty to protect the rights and welfare of those with whom they work professionally. This includes the clients they treat, animals involved in research and experiments, and anyone else with whom they have professional interaction.

(ii) Fidelity and Responsibility

Furthermore, psychologists have a moral obligation to ensure that others working in their profession also confirm high ethical standards. This principle calls for psychologists to participate in activities that raise their colleagues' ethical compliance and conduct. For example: serving as a mentor, participating in peer-review.

(iii) Integrity

Psychologists, in the course of practice and research, should not deceive or misrepresent. Manipulating results in some way to achieve the desired outcomes amounts to deception. Psychologists should adhere to the principles of transparency and honesty at all times.

(iv) Justice

The principle of justice relates to a duty to be fair and impartial. Moreover, people have the right to access benefits from research. It is also essential for psychologists to treat people without any discrimination.

(v) Respect for People's Rights and Dignity

The dignity, privacy, and confidentiality of the patients/ subjects should be protected. Psychologists should also strive to reduce their own biases. They must be aware of issues relating to diversity and the concerns of particular populations. For instance, people may have specific issues concerning their age, gender, religion, race, socioeconomic status, ethnicity, or disability.

Ethical violations: The APA also covers the various ethical issues in psychiatry like informed consent[210], privacy and confidentiality[211], etc. In case of an ethical violation, an investigation regarding the same would be conducted. After the investigation, if a report of unethical conduct is received, the A.P.A. may censure or reprimand the psychologist or revoke the person's A.P.A. membership. Complaints may be made to the state professional licensing boards as well. Even the State psychological associations, professional groups, and licensing boards may impose sanctions against the psychologist.

The victims of ethical violations may seek monetary damages in civil courts. If it is an illegal activity, it may be prosecuted in the criminal courts. If this results in a felony conviction, the infringer may be suspended or expelled from state psychological associations.

It is also noteworthy that the American Psychological Association has developed 'practice guidelines' and a specific code of ethics relating to social workers and for marriage and family therapy.[212] The objective in formulating separate guidelines was to assist psychiatrists in their clinical decision making, with the ultimate goal of enhancing the care of patients.

4.3.U.K.

In the United Kingdom, since the mid-2000s, there has been a substantial increase in health-related research. Most of the health-related research pertains to basic biomedical science.[213] The share of total spending accounted by the Medical Research Council (MRC)[214] has escalated from 16 percent to 24 percent between the years, 2004 and 2015, which is a 75% increase in real terms.[215]

[210] Section 3.10 of the APA Ethical Principles of Psychologists and Code of Conduct, 2017.
[211] Section 4 of the APA Ethical Principles of Psychologists and Code of Conduct, 2017.
[212] Example: American Association for Marriage and Family Therapy: Code of Ethics, National Association of Social Workers: Code of Ethics (1999).
[213] Basic research, also called 'fundamental' or 'blue skies' research focuses on health and disease-related matters without any primary goal for practical application.
[214] The Medical Research Council (MRC) is a fundamental body under the United Kingdom Research and Innovation (UKRI). Medical Research Council aims to co-coordinate and fund medical research in the United Kingdom.
[215] Richard Jones, James Wilsdon, *It's time to burst the biomedical bubble in UK research*, THE GUARDIAN (last visited June 16, 2021, 10.30 am), https://www.theguardian.com/science/political-science/2018/jul/12/its-time-to-burst-the-biomedical-bubble-in-uk-research.

The Department of Health's Research Governance Framework[216] regulates all health and biomedical research bodies. The framework applies to all research that pertains to the responsibilities of the Secretary of State for Health. In other words, it covers clinical and non-clinical research carried out by the Department of Health, the National Health Service[217], non-departmental public bodies, research charities, research councils, research conducted by industries, and by the universities working within the health and social care system.

Also, it is noteworthy that the significant funders of health research and development (R&D) in the UK are industry, government, and research charities. Although the UK has an applaudable mechanism for financing biomedical research, a government-commissioned review has urged for a change from basic research towards translational and applied research[218] to ensure better use of the National Health Service and to increase health benefits for every citizen.[219]

Another notable aspect is that medical and legal professionals contributed to the development of bioethics in the U.K. Compared to the United States, where theologians and philosophers first influenced bioethics, lawyers played a significant role in shaping bioethics in the United Kingdom. This is reflected from Ian Kennedy's work in BBC Reith Lectures titled 'Unmasking Medicine' in the 1980s.[220]

Laws governing psychiatric practice and research: Law governing compulsory treatment for mental disorder comprises specific mental health legislation in the U.K., i.e., the Mental Health Act in England and Wales, 1983, and the Mental Health Care and Treatment Act, 2003 in Scotland. In Northern Ireland, a different approach has been adopted through the Mental Capacity Act *(*Northern Ireland) 2016, wherein mental health is managed through more general capacity legislation rather than statute specifically for mental disorders.

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[216] The Department of Health's Research Governance Framework is a set of national standards for health care with the objective of improving safeguards for research participants.
[217] National Health Service is a comprehensive public-health service under the U.K. government. It was established by the National Health Service Act of 1946. It is mainly financed by general taxes, with smaller contributions from local taxes, payroll contributions, and patient fees.
[218] Translational research means the process of applying the findings from basic / clinical research and using them to bring in innovation in healthcare settings. Other than translational research, there is basic research.
[219] Supra note 15.
[220] REUBI D., SOCIAL THEORY & HEALTH 215 (2013).

Both the Mental Health Act (England and Wales), 1983, and the Mental Health (Care and Treatment) (Scotland) Act 2003 provides regulations regarding the assessment, treatment, and rights of people with mental health problems. However, these statutes do not regulate participation in research as this is generally considered an issue for capacity legislation.

The law relating to capacity is laid down by the Mental Capacity Act, 2005 in England and Wales (except for Northern Ireland) and by the Adults with Incapacity Act, 2000 in Scotland. The objective of this legislation is to set up a legal mechanism for acting and deciding on behalf of adults who cannot decide for themselves. That said, the Mental Capacity Act (Northern Ireland) 2016 provides a legal framework for the non-consensual medical treatment of all citizens irrespective of what the illness is and empowers the health authorities to decide for the benefit of the patient.

Generally, capacity is deemed to exist unless proven otherwise and is viewed as being task-specific. It is to be noted that capacity depends on the person's decision and his/ her cognitive functioning at the time of decision-making. However, the decision about the capacity of a person admitted to a mental health institution to participate in research is determined by the clinical staff (not by the study researchers).[221]

When an individual lacks capacity, the decision to include them in the research must be taken after informing them of the potential pros and cons of participation. A clear picture regarding whether the potential benefit will outweigh the risks involved must be provided. If no direct benefits would be accrued to the participants, then the risks should also be negligible.[222]

When it comes to health research, the Health Research Authority (HRA) is responsible for regulating it. It is a component of the U.K. Research Ethics Service is a framework consisting of local research ethics committees that authorise ethical approval for research and clinical trials in

[221] Section 3.1, Chapter 3 of the Mental Capacity Act, 2005.
[222]Guidelines for researchers and for research ethics committees on psychiatric research involving human participants, Royal College of Psychiatrists, Council report CR82, 2001, (accessed on June 18, 2021), https://www.rcpsych.ac.uk › academic-psychiatry.

the U.K. Any research that involves patients must be reviewed by Research Ethics Committees.[223]

Research ethics committees were created in response to the 'Recommendations Guiding Physicians in Biomedical Research Involving Human Subjects' adopted at the 18th World Medical Assembly held in Helsinki in 1964 (also called the Declaration of Helsinki). Committees of this kind in the U.K. were formed for the first time in 1967, after the recommendation by the Royal College of Physicians of London that clinical research investigations should be subjected to ethical review.[224] Currently, there are two types of research ethics committee primarily:

- Recognised Research Ethics Committees: They are recognised by the U.K. Ethics Committee Authority under the Medicines for Human Use (Clinical Trials) Regulations 2004 to review 'Clinical Trial of Investigational Medical Products'[225].

- Authorised Research Ethics Committees are those bodies permitted by U.K. health departments or local appointing authorities to conduct ethical review of health-related research within the National Health Service, either for a particular area or for the entire country.

Apart from the parliamentary legislations, several medical Royal Colleges have published guidance documents for their members. The Royal College of Psychiatrists prepared its first guidance document in 1989. This document focused on specific problems likely to be faced in mental health research (like the problem of detained patients and incompetent adults). A Council Report superseded it called the '*Guidelines for researchers and for research ethics committees*

[223] Section 8, Principle 9 of the UK Policy Framework for Health and Social Care Research, Health Research Authority (June 18, 2021) https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/uk-policy-framework-health-and-social-care-research/.
[224] Osborn D. P. J., *Research and ethics- Leaving exclusion behind*, 12 CURR OPIN PSYCHIATRY 601 (1999).
[225] 'Clinical Trial of Investigational Medical Products' is a study evaluating the efficacy of a drug.

on psychiatric research involving human participants' in 2001, which engulfed all aspects of psychiatric research.[226]

There is also the code of conduct issued by the British Psychological Society (initially issued in 1978 and last amended in 2018) which lays down the standards of ethical conduct and behaviour that the members of the British Psychological Society are expected to follow.[227] Further, the British Medical Association's Handbook of Medical Ethics is an authoritative guidance document covering medico-legal issues faced by medical professionals relating to the Mental Capacity Act, Human Tissue Act, and Human Fertilisation and Embryology Act.

4.4.China

China broadly recognises the fact that bioscience has a significant role in global competitiveness. This is evident from China listing the various areas of medical science and regenerative medical techniques as strategic fields and industries in China's 13th Five-Year Plan.

In the 1980s, clinical pharmacologists- Li Jiatai, Sang Guowei, and their team[228] introduced the concept of ethical review. However, the institutionalization of research ethics review started only in the 1990s. As a result, research ethics committees were established at leading university-affiliated hospitals such as the Xiangya Hospital (1994), and the Peking Union Medical College Hospital (1996). Later, in March 1997, the Chinese Government directed research ethics committees to be established at medical research institutions also.

Laws governing mental health and psychiatric research in China: By the late 1990s, it was realised that the principles and approaches for mental health care should be revisited.[229] In 2002, the first National Mental Health Plan (2002-2010) was signed by the Ministries of Health, Public Security and Civil Affairs, and China Disabled Persons' Federation (CDPF). The National

[226] Guidelines for researchers and for research ethics committees on psychiatric research involving human participants, Royal College of Psychiatrists, Council report CR82, 2001 (June 18, 2021) https://www.rcpsych.ac.uk › academic-psychiatry.
[227] B.P.S. Code of Ethics and Conduct, British Psychological Society, 2018 (June 18, 2021) https://www.bps.org.uk/news-and-policy/bps-code-ethics-and-conduct.
[228] They are founders of clinical trials in China.
[229] Jin Liu, Hong Ma, Yang-Ling He et al., *Mental health system in China: history, recent service reform and future challenges* 10 WORLD PSYCHIATRY 210 (2011).

Mental Health Plan provided a framework to achieve the objectives of 1) creating an effective mental health care system led by the government with the participation of other sectors; 2) enhancing the implementation of mental health legislation; 3) creating awareness of mental health among people; 4) improvising mental health services to reduce burden and disability, and 5) creating human resources and improvising the capacity of current psychiatric hospitals.[230]

Since 2000, various regulations and measures relating to research ethics have been undertaken. By 2010, research ethics committees were established in most of the tertiary hospitals in Beijing, which played a pivotal role in safeguarding the rights and interests of human research participants.[231]

Subsequently, the Mental Health Act, containing 7 chapters and 85 articles, was adopted in 2013 after 27 years of planning. The Act's objective is to safeguard the human and individual rights of patients and to increase trust in psychiatric institutions.[232]Further, Article 37 of the Act protects persons with mental disorders by mandating that they be informed about their health.[233] Article 39 specifies the informed consent process and Article 40 provides for a written informed consent procedure if physical restraint is employed.

The role played by the National Expert Committee on Medical Ethics in Chinese medical research is unequaled. The committee is responsible for monitoring ethical issues in biomedical research involving human participants, advising policymakers, and inspecting and evaluating the work of the expert committees on medical ethics from the provincial level onwards. [234]

Besides, the Chinese Psychological Society has formulated 'Code of Ethics for Counseling and Clinical Practice' which acts as an ethical guide to guarantee and enhance the standards of the

[230] National Mental Health Plan (2002-2010), Ministries of Health, Public Security, Civil Affairs, and CDPF.
[231] Zhou Ping, Zhang Shike, Wu Rong et. al, *Analysis of the Composition of Hospital-affiliated Ethics Review Committees in Shanghai*, 11 CHINESE HEALTH RESOURCES 265,266 (2008).
[232] https://www.bustle.com/p/what-does-mental-health-care-look-like-abroad-this-is-how-9-countries-treat-mental-illness-2885010
[233] Article 37 of the Mental Health Act 2013 reads, "Medical facilities and the health care providers in these facilities shall inform patients or their guardians of the rights that patients with mental disorders have during the process of diagnosis and treatment".
[234] Chen H. H., Phillips et al., *Mental health law of the People's Republic of China (English translation with annotations)* 24 SHANGHAI ARCH PSYCHIATRY 305, 312 (2012).

service provided in the field of psychotherapy and counseling practice.[235] The Code safeguards the rights and interests of those who seek professional service and that of the clinical and counseling psychologists. Regarding research and publication, Ethical Standard 6.1 in this Code states that fundamental human rights should be respected while conducting research. Further, research should be conducted in a way that is consistent with ethical principles, laws, host institutional regulations, and scientific research standards. Ethical Standard 6.2 makes it mandatory to obtain informed consent from participants or guardians of participants. The nature, purpose, and process of research and the methods and techniques used in the research, must be explained to the participants.

Another vital document providing sound psychiatric healthcare is the Proposal on Further Strengthening Mental Health Work (2015-2020), approved in August 2014 by the government. This proposal encapsulated guidelines on interventions for psychological and behavioral problems for specific subgroups (i.e., children and adolescents, women, the elderly, and victims of disasters)[236], treatment of mental disorders[237], research on mental health[238], the protection of the rights of the mentally ill and surveillance of mental disorders[239]. The Proposal is considered as the de facto Chinese national mental health policy.

4.5.Germany

Germany is one of the countries credited for its significant investment in research and development. Several efforts to support clinical research by pharmaceutical and biotech companies, academic research groups, mainly through the Federal Ministry of Education and Research, the German Research Foundation, and the German Cancer Aid, can be observed. The government also provides labour-related incentives like recruitment support, wage subsidies, and training support to help reduce the costs of medical research.

Currently, Germany has fifty-three research ethics committees (thirty-three of them attached to Faculties of Medicine/Universities, seventeen committees attached to Medical Associations or

[235] Chen Z., Wang H. G. et al., *Life sciences and biotechnology in China*, 362 PHILOS TRANS R SOC LOND B BIOL SCI.947, 950 (2007).
[236] Part B of the Proposal on Further Strengthening Mental Health Work (2015-2020).
[237] Part C, section 1 of the Proposal on Further Strengthening Mental Health Work (2015-2020).
[238] Part D, section 4 of the Proposal on Further Strengthening Mental Health Work (2015-2020).
[239] Part C, section 1 of the Proposal on Further Strengthening Mental Health Work (2015-2020).

Ärztekammern in the States, and three are attached to States governments). These committees are entrusted with the obligation to examine all kinds of biomedical research, including drug research.

In case of an accident during research, compulsory accident insurance has to be provided as far as pharmaceutical trials and the testing of medical devices are concerned. The amount paid by the insurance company is set off against damages for negligence. It is observed that strict liability is not present for medical experimentation. However, the German courts are expected to form high standards for medical care in experimentation.[240]

Regulating mental health and psychiatric research in Germany: When it comes to mental health, Germany's mental healthcare system is known for its efficient mental health treatment and integration. Furthermore, the country has propagated for community-based mental healthcare since the 1970s, easy access to healthcare services, and financial support to patients.[241]

To monitor that the research undertaken in the country complies ethical norms and standards, two institutions have been established: 1) the National Council for Ethics ('Deutscher Ethikrat'), and 2) the Central Ethics Committee of the German Medical Association ('Zentrale Ethikkommission zur Wahrung ethischer Grundsätze in der Medizin und ihren Grenzgebieten bei der Bundesärztekammer'). These bodies deal with general ethical issues and have the authority to advise other Ethics Committees of the Medical Association at their request. However, the advice is not binding.

Ethical principles of the German Psychological Society (DGP) and the Association of German Professional Psychologists (BDP) were released in 1999. Principle B.II.3. of this ethical code laid down that information regarding patients must be kept confidential in exercising their professional activities except in those exceptional cases defined by law. Matters, findings, or the outcomes of consultations or treatment should not be revealed as well.[242] Further, Principle

[240] MÜLLER-HILL B., MURDEROUS SCIENCE: ELIMINATION BY SCIENTIFIC SELECTION OF JEWS, GYPSIES, AND OTHERS, GERMANY 11 (1988).
[241] LIFTON R. J., THE NAZI DOCTORS: MEDICAL KILLING AND THE PSYCHOLOGY OF GENOCIDE 51 (1986).
[242] FRIEDLANDER H., THE ORIGINS OF NAZI GENOCIDE. FROM EUTHANASIA TO THE FINAL SOLUTION 24 (1995).

B.III.2. (on records, data collection, and storage) require the psychologists to obtain permission from their clients before recording their voices or images during a consultation/treatment or before permitting third parties to listen to/view such material. On the other hand, Principle B.V.6. allows psychologists to publish scientific reports which refer to their name in journals.

4.6.Japan

After the Second World War, Japan formulated laws governing modern psychiatric treatments. The Japanese Psychological Association (JPA) has its code. The Preamble to this code emphasizes that the JPA members shall recognise and respect the fundamental rights of all people. The members are bound to maintain the welfare of and protection of non-human creatures and assume responsibility for their actions as professional psychologists. Whenever a question as to a specific action on the part of a psychologist/ researcher is ethical or not arises, then the principles and guidelines laid down by the JPA Code has to be employed.[243] [244]

There is also the International Mental Health Professionals Japan (IMHPJ), an interdisciplinary conference that aims to bring together various clinicians from different disciplines engaged in providing mental health services to the international community in Japan.

4.7.Conclusion

Innovation in science and technology and the production of good-quality research accelerates the economic growth of a nation. In psychiatric research, it is especially vital to have proper ethical codes in place to ensure that the researchers do not exploit the research participants. Countries have formulated their regulatory mechanisms to ensure excellent and ethical psychiatric research.

Variations in psychological ethical codes and regulatory machineries can be observed. These variations show us the consistency of values essential to psychologists in various countries. However, culture, geography, religion, etc., can influence the shaping of these ethical codes.

[243] https://psych.or.jp/english/ethical/

[244] Konishi R., Usami S., Ohi M., et al., *Current Ethical Issues and Future Challenges in Psychiatric Nursing: Based on the Pilot Test Outcome*, Bulletin of Kumamoto University, School of Health Sciences (Medicine), 10 JPS 37 (2014).

Nevertheless, the increase in the number of psychologists and psychologists' associations across the world necessitates the assurance that the highest ethical standards must be abided by to protect the welfare of the client/ research participants in the course of research.

CHAPTER 5: ETHICS IN PSYCHIATRIC RESEARCH: INDIAN REGULATORY POSITION

5.1. Introduction

Mental health concerns are a pervasive problem in India**.** According to World Health Organisation, 7.5% of the total country's population is hit by mental illness.[245] Moreover, India accounts for approximately 15% of the global mental, neurological, and substance abuse disorder burden.[246]

Acknowledging the importance of mental disorders in decreasing the total disease burden, India introduced its first National Mental Health Policy in 2014. Later, in 2017, India brought out a revised Mental Healthcare Act to provide affordable, equitable, and universal access to mental health care. What adds more note-worthiness is that the vastness of the country and the various mental institutions has facilitated psychiatric research to flourish in several directions simultaneously.

In *Swasthya Adhikar Manch* v. *Union of India*,[247] the Supreme Court observed that the 'uncontrolled' clinical trials of drugs by large companies were wreaking 'havoc' in the country. The Supreme Court directed the CDSCO to issues directions, including a notification making the audio-video recording (AVR) of informed consent proceedings during trials mandatory for all clinical trials.

After the emergence of the COVID pandemic, the Government also came out with the National Guidelines for Ethics Committees reviewing Biomedical and Health Research during COVID-19 Pandemic, 2020, which required the researchers to be more careful in matters of privacy and confidentiality of the participants as there is enormous scope for stigmatization and discrimination.

5.2. Statutory Position

[245] Neerja Birla, *Mental health in India: 7.5% of country affected; less than 4,000 experts available*, THE ECONOMIC TIMES (June 7, 2021, 10:47 AM), https://economictimes.indiatimes.com/magazines/panache/mental-health-in-india-7-5-of-country-affected-less-than-4000-experts-available/articleshow/71500130.cms.
[246] Ibid.
[247] WRIT PETITION (CIVIL) NO(s). 33 of 2012.

Statutes and guidelines in India governing mental health and psychiatric research can be traced down to the Mental Healthcare Act, 2017 and the ICMR National Ethical Guidelines for Bio-Medical and Health Research involving Human Participant, 2017. That said, there are other statutes specifically covering clinical trials like the New Drugs and Clinical Trial Rules, 2019, Drugs and Cosmetics Act, and the Guidelines on Good Clinical Practice in India.

I. i. Mental Healthcare Act, 2017

At present, there is the Mental Healthcare Act, 2017, which has been a significant revolution for the right of people suffering from mental illnesses.

Mental illness has been lucidly defined in the Act.[248] One of the other essential features of the Act is that substance use disorder is included in the definition of mental illness itself. This is made evident by the words used in Section 2(s), i.e., "*mental conditions associated with the abuse of alcohol and drugs*." Another notable feature of the Act is that a person with mental illness can be admitted and treated without his consent in certain situations.[249] According to Section 89, involuntary treatment may be allowed after a request for the same is made to a nominated representative.

The Act also specifies various rights of a person with mental illness. These include, among others, access to affordable health care (s. 18), informed consent and power to take decisions (section 86[250]**,** section 89[251]**),** right to confidentiality (s. 23)[252], right to information (s. 22)[253],

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[248] Mental illness means *"a substantial disorder of thinking, mood and perception, orientation, or memory that grossly impairs judgment, behavior, capacity to recognize reality or ability to meet the ordinary demands of life, mental conditions associated with the abuse of alcohol and drugs. Nevertheless, it does not regard mental retardation, a condition of arrested or incomplete development of mind of a person, especially characterized by subnormality of intelligence, as mental illness."*

[249] Section 89 of the Act lays down that involuntary treatment can be allowed if he/she has "*……tried or threatening to harm himself or has behaved violently or is causing another person to fear bodily harm from the person with mental illness, or has shown/is showing inability to care for himself to a degree that places the individual at risk of harm to himself.*"

[250] Section 86 (5) reads "*An independent patient shall not be given treatment without his informed consent*."

[251] Section 87(7) reads "*A minor shall be given treatment with the informed consent of his nominated representative.*"

[252] Section 23 (1) reads "*A person with mental illness shall have the right to confidentiality in respect of his mental health, mental healthcare, treatment and physical healthcare.*"

[253] Section 22(1) reads "*A person with mental illness and his nominated representative shall have the rights to the following information, namely:—*

(a) the provision of this Act or any other law for the time being in force under which he has been admitted, if he is being admitted, and the criteria for admission under that provision;

right to live in a community (s.19)[254], and right to protection from cruel, or degrading treatment (s. 20)[255]. The right to protection from cruel, inhuman, or degrading treatment is very crucial from the perspective of the treatment of substance use disorder (SUD) in India as considerable evidence suggests that cruel and inhuman treatment is commonly meted out to patients with SUD in many rehabilitation centers.[256]

Some other characteristics of the new Act 0f 2017 include the provisions for 'Advance Directive', prohibited procedures, decriminalization of suicide attempt, the role of Central Mental Health Authority, and emergency treatment which are encapsulated below:

a. Advance Directive

A person who is 18 years older, possessing mental capacity can write a directive as specified by mental health authority regarding his intention for the manner he/she wishes to be cared for and can appoint a 'nominated representative' (NR).[257] This can be done despite whether he/she had a history of illness or had treatment for mental illness. The signatures of the nominated representative and two witnesses have to be obtained. Without an Advance Directive, the patient

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(b) of his right to make an application to the concerned Board for a review of the admission;
(c) the nature of the person's mental illness and the proposed treatment plan which includes information about treatment proposed and the known side effects of the proposed treatment;
(d) receive the information in a language and form that such person receiving the information can understand."

[254] Section 19 reads "*Persons with mental illnesses have the right to live in a community and cannot be segregated from society. For those whom this is not possible, the government must provide legal and other necessary forms of support to help them live a regular life*."

[255] Section 20(2) reads "*Every person with mental illness shall be protected from cruel, inhuman or degrading treatment in any mental health establishment and shall have the following rights, namely:*
(a) to live in safe and hygienic environment;
(b) to have adequate sanitary conditions;
(c) to have reasonable facilities for leisure, recreation, education and religious practices;
(d) to privacy;
(e) for proper clothing so as to protect such person from exposure of his body to maintain his dignity;
(f) to not be forced to undertake work in a mental health establishment and to receive appropriate remuneration for work when undertaken;
(g) to have adequate provision for preparing for living in the community;
(h) to have adequate provision for wholesome food, sanitation, space and access to articles of personal hygiene, in particular, women's personal hygiene be adequately addressed by providing access to items that may be required during menstruation."

[256] Report Uncovers Torture, Abuse and Deaths in de-Addiction Centres in Delhi, INDIAN EXPRESS (June 7, 2021, 10:56 AM), https://www.indianexpress.com/article/india/report-uncovers-torture-abuse-and-deaths-in-delhi-de-addiction-centres-5232022/.

[257] Section 5 of the Mental Healthcare Act.

with mental illness may be provided treatment after obtaining consent and admitted as an inpatient admission.

b. Prohibited Procedures

According to section 95, specific procedures are prohibited as they are gruesome and violative of human rights. These are:

- Electroconvulsive therapy without applying muscle relaxants and anesthesia,
- Electroconvulsive therapy for minors,
- Sterilization of men or women, when such sterilization is intended as a treatment for mental illness,
- Chained in any manner or form whatsoever.

c. Role of Central Mental Health Authority[258]

The Central Mental Health Authority must enlist and register all the mental healthcare institutions under the control of the Central Government.[259] It has to fund and direct quality services that need to be maintained for different types of mental institutions. Further, the authority has to prepare a list of all the medical professionals to be contacted in case of an emergency.

d. Decriminalisation of attempt to suicide

Section 115(1) decriminalises attempt to suicide. A man who attempts to commit suicide shall be presumed to suffer from severe stress and shall not be tried and punished under the said code. The Appropriate Government is obliged to provide care, treatment, and rehabilitation to a person, suffering from severe stress and who attempted to commit suicide.

e. Emergency treatment (Section 94)

[258] Chapter VII of the Mental Healthcare Act.
[259] Section 41 of the Mental Healthcare Act.

Medical treatment has to be provided to a person with mental illness by a registered medical practitioner, either at a health establishment or at the community, for a maximum period of 72 hours. The treatment should be given after obtaining informed consent of the Nominated Representative to i. prevent death or harm to the person or (ii) person inflicting serious harm to himself or (iii) person causing severe property damage. Electroconvulsive therapy (ECT) should not be utilised as a treatment mechanism for an emergency.

I. ii. S. 99 of Mental Healthcare Act, 2017 and Psychiatric Research

The Mental Healthcare Act 2017[260] introduces the concept of 'Informed Consent.' As per section 2 of the Act, 'informed consent' is provided for a particular intervention without undue influence, force, fraud, threat, mistake, or misrepresentation. Informed consent is obtained after revealing adequate information to the person, including risks and benefits of intervention and alternatives to the specific intervention in a language and manner that can be comprehended by the person.[261]

Through the concept of mental capacity and informed consent, the Act of 2017 gives utmost importance to the patient's autonomy and his/her meaningful participation in all treatment-related decisions. The presumption under the Act is that all persons with mental illness (PMI) possess the capacity to make decisions concerning their mental health care. The *onus* is on the mental health professional (MHP) to prove otherwise. The Act clearly states the procedure for informed consent for indoor admission, electroconvulsive therapy, and discharge planning. Also, an independent expert board's opinion and permission from the Mental Health Review Board (MHRB) should be obtained in psychosurgery and ablative procedures.[262]

Section 99 of the Act is very significant as it pertains to psychiatric research.[263] The said provision mandates that informed consent should be obtained from all persons with mental

[260] Mental Healthcare Act, 2017. [Accessed on June 10, 2021]. Available from: https://www.prsindia.org/uploads/media/Mental%20Health/Mental%20Healthcare%20Act,%202017.pdf.
[261] Aggarwal K. K., *Real consent and not informed consent applicable in India (Part III)*, 25 INDIAN J CLIN PRACT. 591, 593 (2014).
[262] Section 96 of the Act.
[263] Section 99 of Mental Healthcare Act: (1) The professionals conducting research shall obtain free and informed consent from all persons with mental illness for participation in any research involving interviewing the person or psychological, physical, chemical or medicinal interventions.

illness for participating in any research. Suppose the research pertains to any psychological, physical, chemical, or medicinal interventions to be conducted on a person who is incapable of consenting. In that case, permission should be obtained from the particular State Authority. The State Authority shall allow the research to be carried out after getting informed consent from the nominated representative if it is satisfied that:

(a) "The proposed research cannot be conducted on persons who can give informed consent freely;

(b) the proposed research is essential to enhance the mental health of the population represented by the proposed subject;

(c) the objective is to derive knowledge relevant to the particular mental health needs of persons with mental illness;

(d) the interests of parties conducting the proposed research are fully disclosed, and no conflict of interest is found;

(e) the proposed research complies all the national and international guidelines, and ethical approval has been obtained from the institutional ethics committee."[264]

For research, section 99(4) permits using the case records of patients, provided the patient's anonymity is maintained. The participant has been conferred the right to withdraw his/her consent also. Thus, section 99 of the Mental Healthcare Act, 2017 specifies the requirements of the informed consent procedure related to clinical research.

II. i. National Ethical Guidelines for Biomedical and Health Research involving Human Participant, 2017

(2) In case of research involving any psychological, physical, chemical or medicinal interventions to be conducted on person who is unable to give free and informed consent but does not resist participation in such research, permission to conduct such research shall be obtained from concerned State Authority.

[264] Section 99(3) of the Mental Healthcare Act, 2017.

The National Ethical Guidelines for Biomedical and Health Research involving Human Participants, 2017[265], was published on 12th October, 2017, by the Hon'ble Union Minister of Health and Family Welfare. One of the striking facets of the National Ethical Guideline of 2017 has been including the principle of social responsibility and environmental protection. This inclusion has been done to protect social and cultural harmony and preserve our limited resources in the conduct of biomedical and health research.

Section 1 covers general principles applicable to biomedical research like voluntariness, non-exploitation, privacy, and risk minimization. Section 2 of the Guideline deals with 'General Ethical Issues' that might be spawned while conducting research, including issues relating to privacy, informed consent, risk assessment, distributive justice, etc. In section 3, the facets of 'responsible conduct of research' have been explained. The values that the researchers have to follow, research planning, data acquisition, data sharing, and research misconduct, are covered under section 3.

As per section 4, there must be an Ethics Committee. The affiliation, qualifications, role, and responsibilities of the Ethics committee have also been specified. In order to harmonise and explain the differences between regulatory clinical trials, non-regulatory clinical trials, and academic clinical trials, efforts have been made. Information regarding the establishment of independent ethics committees with particular reference to when and how the services of other ECs can be utilised is also provided.

A whole section is dedicated to the informed consent process, i.e., section 5. If it is high-risk research, then a test of understanding must be conducted to conclude whether the participants understood the particulars of research provided to them.[266] There is a description on the use of electronic methods for obtaining consent[267], waiver of consent[268], consent under special situations involving gatekeepers, community[269] and vulnerable groups obtaining assent for children and processes involved after obtaining consent.

[265] ICMR National Ethical Guideline, 2017. [Accessed on June 10, 2021]. Available from: https://ethics.ncdirindia.org/ICMR_Ethical_Guidelines.aspx
[266] Section 5.3.7 of the Guidelines.
[267] Section 5.5 of the Guidelines.
[268] Section 5.7 of the Guidelines.
[269] Section 5.10 of the Guidelines.

Section 6 of the Guidelines specifies the additional protections to be present for conducting research involving vulnerable people. Vulnerable people would include women, children, sexual minorities, cognitively affected/impaired persons, those with reduced autonomy, sex workers, tribal populations, terminally ill patients, or those who are economically and socially disadvantaged. The underlying assumption is that they cannot protect themselves sufficiently from exploitation; and, therefore, need protection.

The Guidelines also stress that no group should be deprived of the potential benefits of research. Proper justification for researching vulnerable populations must be provided.[270] In research involving vulnerable groups, a greater responsibility is cast on all stakeholders, i.e., researchers, ethics committees, and sponsors. Extra care for safeguarding the confidentiality and the data of such a population[271] has to be taken as any unauthorized disclosures might increase vulnerability.

In the Guidelines, the clinical trials section has been enlarged considerably, and guidance regarding investigator-initiated trials, device trials, academic research, student research, multicentre trials, community trials, trials involving traditional systems of medicine has been mentioned.[272] The significance of a priori arrangements for post-trial access and benefit sharing after completion of research has been emphasized. Such arrangements need to be made to ensure that the outcomes are translated into benefits for participants or communities and that they do not remain limited to publication alone.[273]

Further, the Guidelines make it clear that the donor or research participant owns the biological sample.[274] For data that is collected, institutions/bio-banks are the custodians or trustees through their Ethics Committees and that the researchers have no claim for either ownership or custodianship.[275] Section 12 on 'Research during humanitarian emergencies and disasters,' has been included on account of recent events like the Chennai floods, the Ebola and Zika virus

[270] Section 6.2.1 of the Guidelines.
[271] Section 6.1.5 of the Guidelines.
[272] Section 7 of the Guidelines.
[273] Section 2.4.4 of the Guidelines.
[274] Section 11.4.1 of the Guidelines.
[275] Supra.

infection which called for emergency research. The requirements for emergency review by the EC[276], informed consent[277], prior preparedness, sensitivity involved in dealing with the affected group, protection of privacy[278] are specified while balancing these with the need for conducting research.

II. ii. ICMR Guidelines 2017[279] and Psychiatric Research

Provisions dealing with psychiatric research can be found in section 9 of the ICMR Guidelines. Section 9 focuses on 'Social and Behavioural Sciences Research for Health.' Social and behavioural sciences comprise of anthropology, sociology, psychology, philosophy, political science, economics, history, communications, and education.[280] Section 9.1.3 clarifies that the principles of social science research ethics are similar to those for biomedical and public health research.

Ethical issues in social and behaviour sciences studies are:

- Risks are non-measurable and dynamic. As a result, they might be misconstrued as no/minimum risk research.
- Duties concerning data sharing, incidental findings, and post-research benefits to the study population should have to be reviewed by the Ethics Committee on a case-by-case basis. For this purpose, prior approval from the EC should be obtained for any exemptions. After the initial request for approval from Ethics Committee, the researchers often neglect to obtain approval for incidental findings.
- Ancillary care during different stages of research is needed and has to be considered on a case-by-case basis by the Ethics Committee. However, there is ambiguity regarding what constitutes 'ancillary care.'
- It is noteworthy that as part of the research protocols, socially, legally, medically, and technically inappropriate practices, techniques, and behaviour may be discovered, documented, or observed. While researchers are not recommended to interrupt such

[276] Section 12.5 of the Guidelines.
[277] Section 12.2 of the Guidelines.
[278] Section 12.4 of the Guidelines.
[279] National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017.
[280] Section 9

behaviours to establish the truth, they must record these aspects in the research findings. They should reveal the findings for the larger social good.

- The researchers are required to maintain the privacy and confidentiality of the participant's identity. However, the researchers are required to report the extent or the patterns of their behaviour. Here, whether to report a pattern of behaviour would depend upon the researcher's judgment which can change from time to time and from person to person.

It is worth highlighting that ethical review in social and behavioural studies differs from other subjects. Firstly, the research approaches employed in Social and Behavioural Sciences are not always positivist. As such, the formulation of a hypothesis may not be possible at the starting point of research. Also, documents prepared during the research study are reflective and may change as the research advances. The changes made must be informed to the Ethics Committee must be kept informed, and proper consent should be retaken from the participants. Permission must be obtained from the Ethics Committee for undertaking audio/ video recording of participants' interviews.[281]

The Guideline has elaborately discussed informed consent in social and behavioural sciences research on health (applicable to psychology). Also, the Guidelines have discussed the use of deception in research and the circumstances under which it can be allowed.[282] The duty to maintain confidentiality[283], to disclose sensitive information[284], and to ensure the safety of participants etc are reiterated.

5.3. Is the National Ethical Guidelines for Biomedical and Health Research involving Human Participants, 2017 sufficient to regulate ethical concerns in psychiatric research in India?

There is no doubt that psychiatry has advanced to an established field of medical sciences in India. Though the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017, have addressed some aspects of psychiatric research in 'Socio and

[281] Section 9.2.2 of the Guidelines.
[282] Section 9.2.9 of the Guidelines.
[283] Section 9.2.7 of the Guidelines.
[284] Section 9.2.8 of the Guidelines.

behavioural science' in section 9, the question is whether the Guidelines alone are sufficient to govern psychiatric research in India.

It is evident from the discussion of ethical issues in the National Ethical Guidelines of 2017 that the focus was on social sciences like political science, sociology, economics, and anthropology. In psychiatric research, relevant ethical issues like the use of placebo and rating scales find a meager place in the National Guidelines. These are discussed below.

i. **The National Ethical Guidelines for Biomedical and Health Research involving Human Participants, 2017, are only guidelines.**

The 2017 guidelines emphasize the need for capacity building in the field of ethics to improvise the ethical conduct of medical research. The preface to the National Ethical Guidelines for Biomedical and Health Research involving Human Participants, 2017, clearly specifies that it will serve as only a 'guide' to address the challenges caused by the emerging ethical issues in medical research.

Thus, there is only a 'National Guideline' regulating biomedical and health research (including psychiatric research) in India. It is noteworthy that there was always a question regarding the nature of guidelines, directions, and policies issued by the Government and whether they are merely advisory or not.

In other words, the question is whether the National Ethical Guidelines 2017 are binding. For any administrative direction to have binding authority, it needs to be backed by a statutory provision. If the National Ethical Guidelines, 2017, have to stand the test of time and be enforceable by law, there needs to be a statute/ statutory provision that makes it binding.

In *Sri Ram Vilas Service* v. *Road Traffic Board*, (1948) 1 MLJ 85, the Madras Government issued guidelines that the traffic board authority had to comply for granting licenses to different transport carriers. When its binding nature was challenged, the Madras High Court held that the Motor Vehicles Act 1988 contains no provision that permits such directions to be issued by the government to the subordinate authority, except a notification made under Section 43 of the Act. The Court made it clear that the boards are independent, and their independence is essential for their efficient functioning. Subsequently, an amendment was made to the Motor Vehicles Act,

1988, whereby Section 43A was inserted, which empowered the government to issue directions to the transport authorities.

In *GJ Fernandez v. State of Mysore & Ors.*,[285] the Supreme Court considered whether the instructions specified in the Mysore Public Work Department Code have statutory force or not. It was held that for executive instructions to be binding, it must be proved that they have been framed: (i) either under the authority conferred on the State Government by some statute or, (ii) under some provision of the Constitution enabling so. In this case, the code was not issued meeting these two conditions. So, the Court concluded it to be like administrative instructions and not statutory rules. Further, it was held that such administrative instructions, which are not binding, cannot confer any right on any person to ask for a writ against the Government (by a petition under Article 226 of the Constitution).

Considering the increasing number of ethical and other violations in psychiatric research, a binding statute that addresses all the concerns is the need of the hour. The addressing mechanism of these ethical issues in psychiatric research should not be confined to just guidelines.

ii. **<u>The use of placebo</u>**

Another problematic aspect of psychiatric research is controlling the placebo response. Placebo is defined as "*an inactive substance visually identical in appearance to a drug being tested in a clinical trial*."[286] Testing of placebo comes under 'investigational product' under section 2(s) of the New Drugs and Clinical Trials Rules 2019.[287]

It is noteworthy that placebo and 'placebo response' are two different things. Placebo response means the response or improvement that can be observed in participants who are on the placebo arm of the trial. Placebo response happens due to many reasons. One reason is the indirect psychotherapeutic support offered by the consumption of a placebo. In other words, a placebo works well in certain situations because of the complex neurobiological reaction that takes place. This can be in the form of an increase in feel-good neurotransmitters, like endorphins and

[285] *AIR 1967 SC 1753.*
[286] Section 2(bb) of the New Drugs and Clinical Trials Rules 2019.
[287] Section 2(s) defines 'investigational product' as the pharmaceutical formulation of an active ingredient or placebo being tested or utilised in a clinical trial.

dopamine, or in the form of greater activity in specific brain regions related to emotional reactions, moods, and self-awareness.

Another reason is the patient's and the researcher's expectation of improvement during treatment. Expectations, or what one believes that he/she will experience, have been found to play an essential role in the placebo effect.[288] People who are highly motivated and believe that the treatment will turn out to be fruitful have a greater chance of experiencing the placebo effect.

Conditioning can be another reason. A person might have a placebo response when he/she forms a connection between two stimuli. For example, if an individual is provided the same arthritis drug to relieve sore joints, then he might think that the drug relieves pain.

Apart from conditioning, genetics can also induce a placebo response. Ina particular study, it was found that people with a gene variant that produces higher levels of dopamine are more likely to have the placebo effect than those with low-dopamine levels.[289] People with high dopamine levels of this gene are likely to experience higher levels of pain perception and reward-seeking.[290]

In psychiatry studies, the placebo effect is of great importance and is increasing over time. A meta-analysis study established that the placebo response in depression studies ranged from 10% to 50%, with an average of 30%.[291] This implies that an experimental intervention may depict a response rate as high as 50% even if it was inefficacious. Therefore, it is essential to conduct 'placebo-controlled' studies.

Merely causing a response is not adequate; it can be deemed effective if a drug is proportionately better than a placebo. Concern about the placebo-induced aggravation of symptoms has spawned opinions that any new psychoactive medication should be studied against an active comparator

[288] Brown W. A., *Expectation, the placebo effect and the response to treatment*, 98 R I Med J 19, 21 (2013).
[289] Hall K. T., Lembo A. J., Kirsch I., et al., *Catechol-O-methyltransferase val158met polymorphism predicts placebo effect in irritable bowel syndrome*, 7 PLoS One 1 (2012).
[290] Supra.
[291] Khan A., Khan S., Kolts R., Brown W. A., *Suicide rates in clinical trials of SSRIs, other anti-depressants, and placebo: analysis of FDA reports*, 260 AM J PSYCHIATRY 790 (2003).

only.[292] However, studies conducted without the placebo group or using an active comparator may expose more participants to potential risks. As such, for ethical and methodological reasons, placebo-controlled studies are required. However, the key is to control the potential risks appropriately. In this regard, it is vital to note that the National Ethical Guidelines of 2017 remain silent on the use of placebo and the management of placebo-response in psychiatric research.

Furthermore, a high placebo response is one of the leading reasons for failed late-phase trials.[293] If the placebo response is lesser, the chances of accurately knowing if the experimental drug is effective or not is higher. The task then is to limit the placebo response. Thus, it is also essential to have regulatory provisions that provide for limiting the placebo response.

iii. **The issue of rating scales**

In Psychiatry, diagnosis is made based on diagnostic criteria like the Diagnostic and Statistical Manual (DSM) criteria. Further, the assessment of improvement mainly depends on rating scales (like the Montgomery–Asberg Depression Rating Scale (MADRS) for depression). These rating scales aid in converting the subjective improvement into objective data, which is then analyzed and assessed. However, due to the lack of consistent diagnostic criteria in psychiatry, there are unique challenges.

One of the challenges is to ensure that the rating scales note only the actual change in the illness due to the active drugs and not the non-specific placebo effects. Because of this peculiarity, raters in psychiatry studies are subjected to thorough training, including didactic training, supervised interviews, and recorded interviews. However, the patients/ participants in such training (whether actual patients or actors) are usually western patients. Consequently, the lessons that Indian raters imbibe from such training are not culturally applicable to the clinical settings in India.

[292] Supra.
[293] Khan A., Detke M., Khan S. R., Mallinckrodt C., *Placebo response and antidepressant clinical trial outcome*, 191 J NERV MENT DIS 211 (2003).

Likewise, rating instruments and structured interview guides in psychiatry are generally made keeping in line with the western culture, and some of them may not be culturally suitable for non-western patients even after translations into local languages.[294] This aspect not only makes the conduct of the studies more challenging but also detrimentally affects the validity of the instruments; which in turn impacts the quality of data obtained from Indian subjects.

The latest innovations in this area are the use of independent raters, cross-over raters, audio taping of interviews for quality checks, use of Interactive Voice Response System (IVRS), video conferencing with centralized raters etc.[295] Development of newer techniques to improve data quality are not farther in the field of psychiatric research; mainly after considering the increasing number of studies that fail due to high placebo responses.[296] [297]Simultaneously, one has to keep in mind that innovations are also likely to create new technological challenges for the conduct of psychiatry studies.

iv. **The issue of ECT**

The contribution of researchers from India in the field of electroconvulsive therapy has been vast. Initially, some reports recorded the positive experience of ECT use in groups of patients who have either schizophrenia or manic depressive psychosis. [298] Although ECT was introduced after its success in schizophrenia, the use of ECT in treating other psychiatric conditions have become less frequent.

Electroconvulsive therapy (ECT) is utilised only as a last resort after subjecting patients to numerous medication trials. However, the use of ECT today has become entangled in legal regulations. The treating psychiatrist must obtain valid informed consent before administering ECT, and the failure to do so would attract professional liability. The shift to increased judicial

[294] Alem A., Kebede D., *Conducting psychiatric research in the developing world: challenges and rewards*, 1 BR. J. PSYCHIATRY 185 (2003).
[295] Glaudin V., Smith W. T., et al., *Discriminating placebo and drug in generalized anxiety disorder (GAD) trials: single vs. multiple clinical raters*, 30 PSYCHOPHARMACOL BULL 175 (1994).
[296] Hyler S. E., Gangure D. P. et al., *Can telepsychiatry replace in person psychiatric assessments? A review & meta-analysis of comparison studies*, 10 CNS SPECTR 403, 408 (2005).
[297] Kobak K. A., Kane J. M., Thase M. E., et al., *Why do clinical trials fail? The problem of measurement error in clinical trials: time to test new paradigms?* 27 J CLIN PSYCHOPHARMACOL 1, 4 (2007).
[298] Agarwal A. K., Andrade C., *Indian psychiatrists' attitudes towards Electroconvulsive Therapy*, 39 INDIAN J PSYCHIATRY 54, 57 (1997).

scrutiny of ECT has caused both clinical and ethical dilemmas in psychiatric research, particularly in the context of the emerging concept of the right to effective treatment.[299]

If the patients are incapable of consenting for ECT, then judicial consent can be obtained. Judicial consent for the application of ECT will be given only when the illness is life-threatening and the treatment is life-saving.[300] The question of whether the principle of beneficence should be prioritized over the principle of autonomy in such circumstances remains. However, another severe issue is that there are no provisions in the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017, which clarify when and when not to use invasive and controversial treatment methods for research purposes like electroconvulsive therapy procedure (ECT). Indeed, this needs urgent address.

v. **The need for robust ethical committees in India**

The existence of ethical committees does not eliminate the issues of ethical violations in medical research. Ethical Committees are mired in several challenges, including inadequate formal training, and inadequate contribution from non-technical members, deficient administrative support, heavy workload, and the absence of Standard Operating Procedures (SOPs). Moreover, each ethics committee, irrespective of whether it is an independent or institutional one, works in isolation with its own sets of problems.

It has been observed that journals from 'low and middle-income countries' (LAMIC) often publish research papers of poor quality when compared to international journals.[301] In a study, Balhara and Mishra (2015) reviewed retraction rates of articles published on psychiatric illness and found that the retraction rate was slowly rising from 3.56 per 10,000 published articles on mental disorders in the year, 2005, to 49.25 per 10,000 published articles on mental disorders in

[299]Gregory B. Leong et al., *Legal and Ethical Issues in Electroconvulsive Therapy,* 14 PSYCHIATR. CLIN. NORTH AM. 1007, 1016 (1991).
[300] Supra.
[301] Zhang D., Freemantle N., et al., *Are randomized trials conducted in China or India biased? A comparative empirical analysis,* 64 J CLIN EPIDEMIOL. 90, 92 (2011).

the year, 2012.[302] Further, the retraction rates were higher in articles from LAMIC (especially from Asian countries compared to non-Asian countries).[303]

In a review carried out by Chaturvedi and Somashekar, the ethical aspects of articles published in the Indian Journal of Psychiatry were checked. Informed consent was present only in 51% of studies in 2000 and 82% in 2007, whereas ethical approval was observed only in 2% of studies in 2000 and 25% in 2007. This spawns concerns on ethical standards of research in the Indian context.[304]

India is rapidly transforming into a research hub for human research. After globalization and industrialization, multinationals have an increasing interest in medical research, inclusive of psychiatric research.[305] It is a grave concern that research in developing countries like India, with the lack of robust ethical committees and proper ethical regulations, will further result in exploitation and injustice.[306] As such, it is quintessential to have efficient, ethical committees that strictly monitor research in psychiatry and other medical fields.

5.4. Conclusion

The National Ethical Guidelines for Biomedical and Health Research involving Human Participants, 2017, will not alone be sufficient to govern various aspects of psychiatric research in India. Moreover, the ICMR Guidelines of 2017 lacks statutory binding. Considering the present times where ethical violations in research are increasing, it is essential to have a good law in place that curbs these violations and provides for fines and correctional mechanisms to address them. Also, psychiatric research may involve the use and application of questionable therapies like electro-convulsive therapy. As such, there should be a statute that elucidates when and when not to employ such techniques. Thus, it is high time to formulate a separate law to regulate psychiatric research in India.

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[302] Balhara Y. P., Mishra A., *A study exploring attributes and nature of the retracted literature on mental disorders*, 12 INDIAN J MED ETHICS 30, 33 (2015).
[303] Supra.
[304] Chaturvedi S. K., Somashekar B. S., *Reporting ethical aspects in published research articles in the Indian Journal of Psychiatry*, 51 INDIAN J PSYCHIATRY 34 (2009).
[305] A. K. AGARWAL, S. C. GUPTA, TEXTBOOK OF POSTGRADUATE PSYCHIATRY 1019 (1999).
[306] Chaturvedi S. K., *A review of Indian publications on ethical issues regarding capacity, informed consent, and placebo controlled trials*, 5 INT. J. MENT. HEALTH 12 (2008).

CHAPTER 6: CONCLUSION AND SUGGESTIONS

6.1. Introduction

Psychiatric research has gained momentum in the country.[307] Psychiatric research conducted in India relates to various areas from biological psychiatry, psychopharmacology, cross-cultural psychiatry, social psychiatry, consultation psychiatry, ethics, service research, phenomenology, and other related areas.

Proper law to regulate an activity is indispensable. Just as much legal regulations are necessary to oversee things, ethical regulations are also essential to ensure that no harm is caused to anything or anyone. According to Pellegrino and Thomasma[308], "*Law is in many ways the coarse adjustment of society to ensure that certain obligations are fulfilled. . . . law, for example, can guarantee the validity of consent.., and that penalties are imposed… What is transferred to law is by definition taken out of the realm of the voluntary recognition of moral responsibility. By doing so, something subtle and exquisite is lost. Law cannot guarantee the quality of human transactions even though it may protect the rights of the parties to the transactions ....Ethics, in contrast to law, is the fine adjustment of men for the voluntary assumption of obligations because they are demanded by the very nature of certain relationships between humans. Ethics sets a higher ideal than law, simply because it is not guaranteeable*."[309]

Some of the insights derived from the past Chapters are mentioned below:

6.2. Analysis (Findings)

First of all, when diagnosing a person with mental illness while recruitment in research, one must consider various psychological and social consequences of diagnosis affecting the patient/ research subject. The patient's interest must be favoured over research interest if any doubts/inconsistencies in diagnosis arise.

Informed Consent: Informed consent procedures should be strictly followed. This includes ensuring that the research participants are enrolled voluntarily, without any undue influence.

[307] Sagar R., Sarkar S., *Psychiatry research in India: Current status and future directions*, 22 J MENTAL HEALTH HUM BEHAV 77 (2017).
[308] Edmund Pellegrino (an American bioethicist, academician) and David Thomasma (American theologian) have written extensively on the philosophy of medicine, professionalism, bioethics, healthcare ethics, and patients' rights.
[309] Joe Jacob, *Biomedical Law: Lost Horizons Regained*, 46 MOD. L. REV. 21 (1983).

When the research subject's capacity to give consent is impaired, a proper method to obtain substituted decision-making should be present. Sufficient time must be given to the research participants to give consent.

For getting proper informed consent, an information leaflet explaining the research project clearly should be provided to each participant. The leaflet should contain information about the research like title, aims, research design and methodology, duration of research, investigational procedures, any incentives provided for participation, probable harms, and compensation.

In circumstances where competency is initially compromised, advance directives, if available, need to be respected. In case of non-availability of advance directives, consent needs to be obtained from the legally authorized representative.

Moreover, there are chances that the person's decision-making capacity may improve by providing repeated information using different methods (conversation, pamphlets, group discussion, videos, etc). As such, the consent process should be continuous and not one time.[310]

Approval and Research Ethics Committees: Obtaining ethical approval for a project should not be considered an obstacle. Research ethics committees were established mainly to protect patients from faulty research. However, they have a secondary duty to foster good research. Research is improved by independent consideration of its ethical dimension, particularly by focusing on the participant's experience.[311]

The research ethics committees are constituted: (i) to protect the lawful rights and interests of human research participants and to safeguard their dignity, (ii) to ensure the ethical compliance of biomedical research by performing an ethical review of their institutions' biomedical research activities. This can be through initial review, tracking review and re-examination, and organization of relevant ethical review training.

Differences in psychiatric research ethics in different countries: Variations in psychiatric research ethics show valuable information regarding the practice of psychology globally. Values

[310] Palmer B. W., Savla G. N., *Changes in capacity to consent over time in patients involved in psychiatric research* 202 Br J PSYCHIATRY 454, 456 (2013).
[311] Research Governance Framework for Health & Social Care, UK Department of Health, 2005.

are desirable conceptions that make people analyse events and act in a specific manner. As values are considered goals, their attainment must serve either an individual (e.g., psychologist, research subject) or a collective (e.g., psychological organization). Therefore, values on which ethical guidelines are based should serve the psychologists/ research subjects in a particular country.[312] One of three perspectives guides ethical acts: (1) relativism, (2) absolutism, and (3) universalism.[313]

(i) As per relativism, each culture will be based on its context, so outside criteria cannot morally judge it. Generally, ethics are based on internal group criteria. Also, the over-lapping of ethics across cultures is not that predominant.

(ii) Absolutism puts forth a position purportedly devoid of ethnocentrism. Ethical guidelines within this philosophical position are applied to everyone regardless of culture or beliefs. Everyone is subjected to the same standards by the dominant group and, comparisons across groups are encouraged. Much of the Ethical Principles of Psychologists and Code of Conduct (1992) from the American Psychological Association (APA), the largest membership of any psychological organization internationally, has resorted to an absolutist position.

(iii) Universalism, on the other hand, accepts that people are both different and the same. Although the fundamental psychological constructs may be similar, there are differing manifestations. Comparisons are possible across cultural groups by distinguishing the process from the manifestation.

Comparison of ethical guidelines: Through the shrinking of the globe with various advancements in science and technology, there has been increased emphasis on ethics across countries and scientific fields. However, international ethical debates have focused on bioethics, medical research, nursing and technology, civic education, and child welfare legislation. Some countries have updated their psychiatric ethical guidelines, but very little has been written regarding the similarities and differences between psychological ethics internationally.

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[312] Kluckhohn, C., *Values and Value-Orientations in the Theory of Action: An Exploration in Definition and Classification* (1951) In PARSONS T. AND SHILS E., TOWARD A GENERAL THEORY OF ACTION 388-433 (Harvard University Press, 1951).

[313] BERRY, J. W., POORTINGA, Y. H., SEGALL ET AL., CROSS-CULTURAL PSYCHOLOGY: RESEARCH AND APPLICATIONS (Cambridge University Press, 1992).

Heinz Schuler surveyed professional psychological organizations globally and compared ethical research guidelines from nine countries ((Austria, France, Canada, Germany, Great Britain, the Netherlands, Poland, Sweden, and the United States).). He identified three basic principles across all psychiatric research guidelines: (1) protection from physical harm; (2) protection from psychological harm; and (3) confidentiality of data.[314]

Comparisons of ethical principles and standards across various countries should be further encouraged. They help to determine consistencies between ethical codes in various countries. By determining consistencies and finding common values across cultures, core ethical principles, and standards can be derived by international psychological associations.

The conundrum of Researchers' commitment to Psychiatry: The more the researchers are committed to research and the more self-interests' are connected with the research results, the more likely they are to balance their 'first contract' at the expense of their 'second contract'. The first contract refers to the researchers' commitment to the research community and the organizations backing their research. The second contract refers to their commitment to the welfare of the research participants. As the two parties to either contract lack equal power, the researchers/ scientists can impose increased costs on their subjects to finance the increased benefit anticipated from the other contract.

Moreover, less benefit is expected by the public and researchers from psychological research than from medical research. This could be responsible because psychological experiments rarely result in severe danger and harm to the subjects compared to medical experiments. The benefits from psychiatric research are not expected to be significant enough to balance high costs. This impression may also arise from the fact that it is harder to prove mental damage than physical damage.[315]

6.3. Suggestions

[314] HEINZ SCHULER, ETHICAL PROBLEMS IN PSYCHOLOGICAL RESEARCH (1982).

[315] Paul G. Stiles, Monica Epstein et. al., *Protecting people who decline to participate in research: an example from a prison setting* 34 IRB ETHICS AND HUMAN RESEARCH 15 (2012).

Several psychiatric bodies and associations in India aim to improvise psychiatric practice and treatment in India. Some of them include the Indian Psychiatric Society (IPS)[316], the Indian Association of Clinical Psychologists (IACP), [317] and the Indian Association of Private Psychiatry (IAPP)[318]. However, the stark reality is that there is no ethical code in psychiatric research or a general psychiatric code in India despite the numerous psychological associations and bodies in place. It is high time to prepare a comprehensive ethical code of psychiatry that distinguishes when and when not to use specific treatments, conduct research, etc. For this purpose, the National Ethical Guidelines of 2017 will not be alone sufficient. Some of the suggestions that can be incorporated to improvise psychiatric research and mental healthcare would include:

i. The need for a strong mental health policy and plan: There is an urgent need for a robust mental health policy and plan in the country. A 'mental health policy' can be defined as "*an official statement of a government that conveys an organized set of values, principles, objectives, and areas for action to improve mental health*.[319]" A policy without a strategic plan would remain a dream and, a plan without policy is an aimless and disorganized set of activities.[320]

ii. Formulation of more sound 'Constitution committees' that involve diverse groups: In order to formulate well-round guidelines on ethics in psychiatric research, the Committees entrusted in preparing the norms must have multidisciplinary expertise on guideline workgroups; organizing guidelines around focused clinical questions rather than broad categories of illness; obtaining input on the questions from patient

[316] Indian Psychiatric Society was established in 1929 and is credited to be the largest association of Indian Psychiatrists. The organisation, inter alia, aims to promote the subject of Psychiatry and allied science, advance the mental health of the people and mental health education, and promote the prevention, control, and treatment of psychiatric disabilities.

[317] Indian Association of Clinical Psychologists is the national association of clinical psychologists in India and was established in the year, 1968. It is noteworthy for the publication of its journal, Indian Journal of Clinical Psychology (IJCP).

[318] Indian Association of Private Psychiatry (IAPP), established in 2000, is one of the largest organisations of privately practicing psychiatrists in India.

[319] Mental Health Policies and Action Plans, World Health Organisation, 2007 (*https://www.who.int* › 1_MHPolicyPlan_Infosheet, accessed on 20 August 2021).

[320] Supra.

and family representatives; using independent raters to screen literature search results.[321]

iii. The researcher should be aware of the cultural ethos and values of people in India. It differs based on several factors like geographic location, religion, and caste. So, when conducting research, the researchers should respect the participant's beliefs, perceptions, limitations, and decisions that tend to affect the research at hand.

iv. In India, psychiatric epidemiology[322] remains a challenge. While conducting cross-cultural comparisons in mental disorders, the researcher has to be extra cautious due to external factors like culture and environmental differences. Carstairs and Kapur noted succinctly in 1976 that researchers engaged in such comparisons face two significant problems: (i) establishing comparable definitions of psychiatric symptoms across cultures and (ii) the paucity of suitable techniques for measuring the relevant socio-cultural parameters.[323]

v. Genetic researches on psychiatric illnesses are increasing. Research on the genetic basis of mental disorders is rapidly increasing. Research on the genetic basis of mental disorders is rapidly increasing. Psychiatrists involved in genetic research must be mindful that the implication of genetic information is not restricted to the individual from whom it was obtained alone. Moreover, its disclosure can have disruptive effects on the families and communities of the individuals concerned. Psychiatrists involved in genetic research should ensure that the subjects who participate in genetic research do so with fully informed consent.

vi. Furthermore, in India, ethics is still not part of the existing teaching curriculums in medical and non-medical streams. This prejudicially affects both the quality of output in biomedical and health research and the protection of human participants.

vii. There should be a system for checking whether the Guidelines are complied with or not. Despite the ICMR guidelines on biomedical research, India does not have any vital data on compliance (or lack thereof) by research organisations or companies of these regulations. The mere existence of guidelines does not ensure that they are

[321] Andorno R., *Human dignity & human rights as a common ground for a global bioethics*, 34 J MED PHILOS. 223, 231 (2009).

[322] Psychiatric epidemiology studies the causes and prevalence of mental disorders in society. It is a sub-field of the more general epidemiology.

[323] CARSTAIRS G. M., KAPUR R.L., THE GREAT UNIVERSE OF KOTA 42 (1976).

being followed. More importantly, India's lack of a psychiatric research code means even the evidence of violations is low.

viii. The National Ethical Guidelines 2017 have indeed highlighted the need for payment of compensation in case of research-related injury and suggested mechanisms for putting a system in place to make such payments. However, at present, only sponsored clinical trials may have the provision for paying compensation for research-related injury since that is mandated by law. Also, there is a total lack of clarity regarding compensation payment in academic, investigator-initiated, or non-funded research. [324]

ix. India needs to have specific guidelines or new provisions on the conduct of psychiatric research in particular groups like women, mentally ill prisoners, and the homeless with mental illness, just like there are specific guidelines for their clinical treatment. There is no doubt that unethical medical research has increased over the decades. Psychiatric research has several issues which need to be taken care of, and researchers need to be trained specifically for these issues. The issues that affect psychiatric research in special sub-groups (homeless, linguistically distinct, fetal, maternal, pediatric, geriatrics) differ from those issues faced in sub-areas (genetic, addiction, internet-based, telepsychiatry). So, a comprehensive law addressing all these aspects should be framed.

x. Psychiatrists conducting research should be entrusted with the obligation to disclose their financial and contractual obligations to the concerned Ethics Review Board and their research subjects. The benefits accruing to the sponsor of the study should also be revealed. The process of research funding must be transparent too. Every effort should be made to establish review boards composed of researchers, ethicists, and community representatives to ensure that research subjects' rights are protected.

xi. Despite the guidelines, there should be proper communication and awareness. Proper enforcement requires not just proper monitoring but also engagement with the public. People have a right to be aware of what they can expect from a particular research and what they are, by law, entitled to from the research. A failure to interact with

[324] Roli Mathur, Soumya Swaminathan, *National ethical guidelines for biomedical & health research involving human participants, 2017: A commentary,* 148 IJMR 279, 282 (2018).

public interest groups results in the spread of rumours, misconceptions, and distrust in science.

xii. In situations where providing comprehensive information before the experiment would be harmful to the experiment's objectives, special measures must be adopted to ensure that their participation in no way harms experimental subjects. Experimental subjects must be informed in general terms about the reasons for not providing comprehensive information regarding the research. The same should be followed in cases of concealed observation.

6.4.Conclusion

Conducting psychiatry studies can be quite a challenging task. The field of mental health is witnessing growth, and the milieu in India has unique challenges, beginning with the lack of an ethical code in psychiatric research.[325] Lessons derived from experience with other therapy area studies are not always directly valuable to psychiatry studies. The need of the hour includes a deep understanding of psychiatric patient/ research subject's vulnerabilities, ethical issues, and methodological difficulties. The successful conduct of clinical and research studies in psychiatry necessitate addressing these concerns.

India should have a comprehensive training system for research ethics committees to ensure that committee members receive systematic training in research ethics and related laws and regulations. In this regard, continued education and knowledge update services should regularly be catered to committee members, which can be done through domestic academic symposiums and medical ethics workshops. Such programs would be an eye-opener for the researcher regarding domestic and international frontier issues in ethical review and to improve their ethical review capability. The researchers who have not attended such training and knowledge update programs should not conduct new research.

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Effective healthcare would require health professionals to take a human approach, which actively involves patients, instead of making them recipients of what may be considered a pre-occupation with impersonal, high-tech processes. The human approach to the treatment of both body and mind is the crucial message of medical ethics. It is the man that counts primarily and not the machine or the method.[326] Therefore, psychiatric research should confirm with sound medical ethics principles.

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APPENDIX

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