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Biomedical Ethics Perspectives in the Indian Context

Vol. 1



Editors

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JAYPEE

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CHAPTER

5

Research Ethics in Participants with Mental Illness

Sunita Simon Kurpad

ABSTRACT

As persons with mental illness (PMI) are a vulnerable group, it is vital that all involved in mental health research are aware of the ethical issues involved. Following the letter and the spirit of the Indian Council of Medical Research (ICMR) National Ethical Guidelines for research involving human participants will ensure that ethical research is done in PMI too. All researchers as well as ethics committee (EC) members need to understand why participants with mental illness and their caregivers are considered to be a vulnerable group. Mental illnesses constitute a diverse group of illnesses, some of which have a relapsing course. The personal integrity of the researcher is paramount. However, as participants and caregivers will not automatically grasp that the researcher–participant relationship is not the same as the doctor–patient relationship, the onus is on researchers and research proposal reviewers to ensure that systems are in place to protect the rights and safety of participants. In this chapter, issues ranging from the diagnosis of mental illness; informed consent when the capacity to make the judgment about participation in a study is impaired; benefit–risk assessment around design of certain types of studies; voluntariness; the role of nominated representatives; psychiatric research in the COVID-19 pandemic; and other relevant issues are discussed.

INTRODUCTION

Mental health issues, directly and indirectly, are among the leading causes of disability and mortality across the world including India.[1] In 2016, depressive disorders ranked number 13 in WHO's list of the global top 20 causes of DALYs (disability adjusted life years), accounting for 1.7% of the DALYs.[2] In India, it has been reported that 1 in 7 persons is affected by mental illness of varying severity. Mental disorders contribute to 4.7% of DALYs in India, with depressive disorders contributing to 33.8% of the DALYs due to mental disorders.[3] There is a need to generate and understand evidence on clinical, biological, social, and psychological aspects of mental illness, its treatment, and outcomes. This would make research in mental illness an ethical requirement as persons with mental illness (PMI) also need evidence-based healthcare.

Research involving PMI raises ethical issues, which are relevant to any participant of medical research—from confidentiality to post-research benefit sharing as discussed comprehensively in the ICMR guidelines.[4] In addition, most mental illnesses at certain time points of the course of the illness confer particular vulnerabilities to the PMI. The ICMR National Ethical Guidelines, 2017, recognize the vulnerability of individuals with mental illness in section 6.8[4] and in its Handbook, 2018, in section 6.9.[5] This chapter will discuss the research participant as the PMI, a vulnerable group in research, and some of the ethical challenges that could stem from certain fundamental aspects of mental illness. It is hoped this understanding will help both researchers and EC members to ensure that the participation of PMI in research will not lead to exploitation or violation of their human rights. Understanding how mental illness and its treatment impact ethical considerations is not to prevent research involving PMI, but rather to facilitate ethical research involving them, and thus not discriminate against them.

THE ROLE OF NATURE OF ILLNESS, ITS COURSE, AND SETTING OF RESEARCH

Mental illness covers a spectrum of disorders. The ethical issues raised in a person with a psychotic illness would be different from that with a mood disorder, substance use or personality disorders. This would again be different if the person is acutely symptomatic, improving or in remission (in psychotic illnesses patients may experience a degree of disconnect with reality due to experiences, such as delusions and hallucinations). Participants may also have comorbid physical and other psychiatric illnesses. Sometimes, issues may be picked up on screening "normal" populations. This means that the ethical challenges faced by researchers in a psychiatric institution would be somewhat different from

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those faced in an outpatient clinic in a general hospital, in a community setting, in a rehabilitation center or in a college counselor's office. In addition, advances in mental healthcare have led to an improved prognosis and change in understanding about some mental illnesses. In addition to medications, there are ethical issues with the psychosocial interventions that are provided in mental healthcare.[6,7]

THE THREE CENTRAL AREAS OF VULNERABILITY

In PMI, three issues have long been recognized as particular concerns.[8] They are:

1. Ability of mentally ill participants of research to give an informed consent ("capacity")
2. Issues around the benefit–risk ratio
3. Voluntariness in providing the consent

Trained mental health professionals (which include clinical psychologists, psychiatric social workers, psychiatric nurses, trained occupational therapists as well as psychiatrists) will be aware of the issues around this vulnerability, as it is not fundamentally different from issues that arise during the clinical practice of psychiatry. This makes it particularly important to ensure that all research protocols also have a subject expert to review it, not just for the scientific validity, which is critical, but to also ensure that this vulnerability is not exploited, as can happen even inadvertently. While in the developed countries, some researchers have felt that ECs have overemphasized the specific vulnerability of PMI and been overly restrictive,[9] it is extremely important that everyone involved in research understands how the vulnerabilities in PMI can impact several arenas.

ARENAS OF ETHICAL CONCERNS

The following paragraphs will discuss some of the ethical aspects surrounding issues that impact research. These are not mutually exclusive, as one aspect can affect another.

The Diagnosis of Mental Illness

While the biological treatments of depression and anxiety disorders, or psychotic illnesses, such as schizophrenia and bipolar disorder, involve the use of medication that alters neurotransmitter levels or functioning, the diagnosis of mental illness is still based on the description of a constellation of symptoms and signs and the degree of distress and/or dysfunction experienced by the patient or by others due to the patient's behavior. While diagnostic criteria elucidated in WHO's ICD-10 (International Classification of Diseases, 10th revision) and American Psychiatric Association's DSM-5 (Diagnostic and Statistical Manual, 5th revision) are accepted as the gold standards in clinical care, improved understanding of what constitutes mental illness and what is not has led to diseases being included or excluded over time.[10,11] For example, in ICD-11, which is expected to be functional in January 2022, gaming addiction has been added, while gender incongruence has been taken out from the mental health section and placed in sexual health.[12]

We need to be aware that some PMI, early in the course of illnesses, may have a degree of denial, or a sense of stigma about their diagnosis. In India, a psychiatric diagnosis can impact issues ranging from marriage to job prospects. So, it would be best if the PMI are approached for recruitment into a study only with the permission of the treating psychiatrist and confidentiality strictly maintained.

In addition, while the clinical impression of trained psychiatrists using specific criteria may be used for research, validated scales, such as the Mini International Neuropsychiatric Interview (MINI PLUS), are generally used to generate diagnosis.[13] Sometimes research diagnostic criteria are used. Other scales that have been used in the past are Schedules for Assessment in Neuropsychiatry (SCAN) and the Composite International Diagnostic Interview (CIDI).

The MINI version 5.0, SCAN, and CIDI are based on ICD-10 and DSM-4, while MINI version 7.0 is based on new DSM-5.[13-16] It is important that the right person uses the right tool for the right purpose. For example, sometimes a scale used to screen for depression would be different from the one used to diagnose depression, while another one is used to measure its severity. This is important as some symptoms of mental illness, such as insomnia, anxiety, and feeling sad, can be part of the normal experience of life. Often it is the context, duration, severity of symptoms and dysfunction, which will distinguish normality from mental illness. The training of the person administering the scale is also important to address issues of reliability. While many scales are freely available, others are copyrighted. Researchers would need to check the usage rights, follow the process to either pay for the scales used or contact the publishers/copyright holder, and request a waiver (which is sometimes granted for small unfunded/low-funded studies). The ethical concerns about the medicalization of some behaviors, such as bereavement—the "medicalization of normality"[17] and the influence of pharmaceutical industry, place a greater ethical responsibility on researchers and EC members to ensure the measures used are appropriate to the research question. This is where a review by a subject expert in clinical practice would be additionally invaluable for the EC to arrive at a decision.

It would be useful to understand the meaning of certain terminologies and their context **(Table 1)**.

Informed Consent Process

The emphasis on informed consent is the bedrock on which one is able to ensure ethical research in medicine. Informed consent implies not only that all the relevant information has been given, but that the research participant has understood all of it and is able to make an informed decision as to whether to participate in the research or not. In PMI, the

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TABLE 1: Meaning of terminologies and their context.

Terminology and context	*Meaning*
Mental illness—clinical practice of psychiatry	The clinical impression of psychiatrists, doctors or trained mental health professionals based on listing of illness and symptoms as per International Classification of Diseases 10th version (ICD-10) or Diagnostic and Statistical Manual-5 (DSM-5).[10,11]
Mental illness—research	Diagnosis generated by psychiatrists or trained professionals by using validated scales. The caveats with use of these scales need to be borne in mind, as already discussed in paragraph on diagnosis.
Mental illness—Mental Health Care Act, 2017 (MHCA)	"Mental illness" means a substantial disorder of thinking, mood, 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, but does NOT include mental retardation, which is a condition of arrested or incomplete development of mind of a person, especially characterized by subnormality of intelligence.[18] (Due to the negative connotations associated with the term "mental retardation", the term "intellectual disability" is now the more socially acceptable term.)
Person with disability (The Rights of Persons with Disability Act, RPWD Act, 2016)	Person with disability means a person with long-term physical, mental, intellectual or sensory impairment, which, in interaction with barriers, hinders his full and effective participation in society equally with others.[19]
Intellectual disability (The Rights of Persons with Disability Act, RPWD Act, 2016)	"A condition characterized by significant limitation both in intellectual functioning (reasoning, learning, problem solving) and in adaptive behavior which covers a range of everyday social and practical skills including specific learning disabilities and autism spectrum disorders"[19] (Note that the term mental retardation is not used here).
Cognition and cognitive impairment	Cognition broadly refers to our ability to think, understand, remember, and plan. It is a function of the brain and includes mental processes by which we acquire, retain, and use information. Cognition is critical in decision-making. While cognitive impairment is a broad term, it is often used to denote attention and memory difficulties.

challenge is in that some illnesses can fundamentally affect cognition—the ability to think, understand, remember, and plan **(Table 1)**, and this in turn will impact their capacity to give informed consent.

Cognitive Impairment and Capacity

Cognitive impairment can be due to a range of disorders, and can be temporary or permanent. For example, attentional difficulties in delirium or acute state of confusion can be due to physical disorders, such as alcohol withdrawal, from which persons can recover completely. Dementia can cause a cognitive decline with forgetfulness, which depending on the cause, may be permanent. Cognitive impairment can also occur with intellectual disability, while mental illnesses, such as depression and psychosis, can temporarily influence cognition. It is not only attention and memory that influences thinking and decision-making, but experiences like delusions (false beliefs) can also affect a PMI's ability to give an informed consent.[20]

The best way to practically ensure ethical recruitment into a study is to remember that assessing capacity and taking informed consent should not be a one-time event, but an iterative process.[21] Depending on whether the patient has the capacity to give informed consent or not, the correct process should be followed as given below:

- When the participant is capable of giving informed consent to participate in the study: In this situation, informed consent from participant (PMI) should be obtained. Generally, most PMI in India would have one or more trusted family members or a friend involved in their clinical care—a primary caregiver. While the choice to inform them or not about the research should reside with the PMI, the potential research participants should be encouraged to discuss it with them. Including a PMI, who does not want to inform any friend or family, into a research protocol needs to be carefully reviewed, as the issues of vulnerability may crop up later during the research. In India, unlike countries like the UK, healthcare is not routinely linked to a general health practitioner or a national health service, which would raise the question of who could be involved in taking care of the patient should the clinical need arise during research or should the PMI drop out during the research period or what happens after the research period. In addition, costs of healthcare are often borne by PMI and family. All this points to the fact that it would be important for researchers to document discussion with the PMI and key caregivers during the informed consent process. Sometimes researchers worry about giving all required details to the PMI. For example, in a randomized control trial (RCT), disclosing rare side effects of medication to a patient with depression or anxiety is difficult but nonetheless it has to be done. Informed consent refusals may be high, but some participants would still take part in the interests of science if they are convinced of the safety nets in place for the study.
- When the participant is not capable of giving informed consent to participate in the study: In certain illnesses like dementia or some intellectual disabilities, the

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person may be unable to understand and process all the information given in order to make an informed decision about participation in research. In conditions like acute psychosis, this may be a temporary inability.

If a person is not able to give informed consent due to mental illness or cognitive impairment **(*see* Table 1)**, it has been discussed in the section on vulnerability in ICMR National Ethical Guidelines (2017) that the informed consent of the legally authorized/acceptable representative (LAR) should be taken. ICMR National Ethical Guidelines for Biomedical Research in Children (2017) emphasize that in children the consent has to be taken from parents or the LAR stating that "a LAR is an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective participant to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure as per research protocol".[22]

As India had been a signatory to the United Nations Convention for the Rights of Persons with Disabilities (UNCRPD), there was an effort to ensure that the recent Mental Healthcare Act (MHCA) of 2017 was harmonized with the UNCRPD.[18,19,23] In the UN "Mental Health and Human rights" report by the High Commissioner for Human Rights at the UN General Assembly in 2017, the gap in research on mental health was noted. This was in the context of the discrepancy in valuing physical versus mental health, in particular to research on human rights aspects of mental healthcare.[24] However, it has been noted that (in principle) the Indian Mental Healthcare Act of 2017 has good concordance with WHO's checklist on mental health legislation on research.[25,26]

The Indian Mental Healthcare Act (MHCA, 2017) uses the term nominated representative (NR) for the person who is involved in "supported decision-making" when the capacity of the PMI to take decisions regarding own healthcare is affected. The entire Chapter IV of the MHCA is devoted to the definition of who can be construed as NR, the procedure for selecting the NR and their role. In principle, the PMI can nominate someone as their NR, as someone who can support them in making decisions. The MHCA specifies that the presence of a NR should not make one assume that the PMI does not have the capacity to make decisions. The term LAR as legally acceptable representative in the context of research described in ICMR National Ethical Guidelines of 2017 is not used in the MHCA, 2017.[18] However, the two terms NR and LAR are synonyms used for clinical care and research, respectively. If the PMI has not nominated an NR, the MHCA specifies an order of precedence of people who can be accepted as NR for the purpose of advance directives, as relative, caregiver, person appointed by the State Mental Health Board, and finally the Director of Social Welfare or their representative as appointed by the Board. For a minor (person with age <18 years), the legal guardian is considered to be the NR, unless a concern is communicated to the Board that the legal guardian is not acting in the best interest of the child or does not have the capacity to be the child's NR. In this situation, the Board will appoint a suitable person or appoint the Director of Social Welfare or their representative to act as NR. While the challenges in using NR in clinical care in India have been noted, it is probably easier when the primary caregiver is also the NR.[27]

Section 99 of the MHCA requires that several criteria be fulfilled before any interventional ("psychological, physical, chemical or medicinal" interventions) research can be undertaken if the PMI is incapable of giving informed consent.[18] These criteria include informed consent from the NR of the PMI, permission from the State Mental Health Authority; ethics approval from the EC where the research is going to be conducted; following all local, national, and international guidelines on ethical research; and declaration of no conflict of interest by researchers. The fundamental requirement should be that the research question is relevant and useful, and can *only* be answered by taking such patients into the study. And importantly, no research should be conducted if the PMI is unwilling for it. Even if the NR has given the informed consent for a PMI who is not capable of informed consent, no research activity should be performed if the PMI does not at least "assent" (as in "agree") to it, for example, to take a blood sample without the assent would amount to assault. On a practical level, to even ask questions for a rating scale, which involves cooperation, would not be possible if there is no assent. If the PMI is experiencing a condition like acute psychosis, then as soon as the patient's clinical condition improves and the patient becomes capable of giving informed consent that should also be taken (of course, assuming that the NR had "consented", as well as the PMI had "assented" at the start of the research). Like in any other research, the PMI and NR should be aware that they are free to withdraw their assent/consent at any time. It is important to follow the procedure as laid out by the prevailing law of the land to ensure that the rights of the PMI are protected, and ECs and research investigators do not get into difficulties later.

- Use of audio-visual recording of consent process: In the new regulations for clinical trials in India (New Drugs and Clinical Trials Rules, 2019), there is a requirement for audio-visual recording of the informed consent process when vulnerable patients are recruited for participation in a trial involving a new chemical or molecular entity.[28] While there could be understandable concerns about confidentiality, this step is considered necessary to ensure that the consent is truly informed and voluntary.

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(Of course, the participant needs to consent to the audiovisual process too.) As there is a statutory requirement that study material be preserved for a certain number of years, investigators and ECs need to ensure that adequate steps are taken to protect the privacy of the data, including that of the audio-visual recording.

- The assessment of capacity to give informed consent: Mental illnesses encompass a range of disorders, which affect the thinking or cognition of persons differently **(*see* Table 1)**. Lack of insight (awareness and acceptance that they have a mental illness) can also be a fundamental part of the experience of psychoses for some patients. In addition, insight can change during the course of illness and its treatment with relapse of illness or during the research period itself. There may not be a one-to-one relationship between insight and capacity. Capacity for informed consent in PMI is task- and time-specific. For example, a participant in partial remission of schizophrenia, who is still hearing voices, might be able to give informed consent to participate in a study that involves the use of rating scales to assess illness experience. However, a PMI in a manic episode is unlikely to have the judgment to understand the risks involved in a placebo control study. The PMI might know of the risks, but might feel it is not applicable to them, as being unduly confident can be part of the illness experience of mania.

  Across the world, there are tools, such as MacCAT-CR (the McArthur assessment of competence tools for clinical research), which have been described for the assessment of decisional making capacity in schizophrenia.[21] As informed consent can be context driven, objective measures of insight and capacity might not always be useful.[29] If one is conducting research in acutely ill psychotic patients, some degree of diminished capacity might be inevitable. So it would be vital to get informed consent from the NR/LAR and the assent of the PMI, and follow the process laid down in the Mental Healthcare Act of India (2017) as described earlier.[30] In PMI with impaired decisional capacity, an iterative consent process using simple language to convey the participant information has been found to be useful.[21] Empirical research in India has shown that the capacity of the NR/LAR should not be presumed to be present. It would appear that assessment of the capacity of the NR/LAR who is giving proxy consent on behalf of the research participant is also warranted.[29] It has been suggested that the person who assesses capacity to consent should be independent of the research recruiting team.[31] It is possible that this might come across as logistically tedious in India, but it would be a good practice to avoid conflict of interest in the inclusion of PMI in research. This is particularly important till further evidence on matter of objective tests of capacity is available, as the clinical opinion of the treating mental health professional may be more useful in ascertaining if the PMI has the capacity to consent for a particular research study.

Benefit–risk Assessment

An RCT would be indicated only when there is clinical equipoise (i.e., a genuine uncertainty as to which treatment arm is better). Nearly 40 years ago, Helmchen and Müller-Oerlinghausen discussed an ethical dilemma in the "paradox of the clinical trial", summarizing the conundrum as "First, it is unethical to use treatment, the efficacy of which has not been tested scientifically; second, it is also unethical to examine the efficacy of treatment scientifically".[32] This need not be too much of a dilemma, if the pros and cons are understood and weighed carefully. "Therapeutic misconception" does exist, that is, participants tend to think the research would be of therapeutic benefit for them. It would obviously be important to ensure that the benefits and risks are clearly communicated both to the PMI and their caregivers and/or NR/LAR. In clinical interactions, trust in the doctor–patient relationship is important with many patients and caregivers understanding and expecting that clinicians take decisions in the patient's best interest. While the researcher is expected to conduct the research ethically, the researcher–participant relationship is not exactly the same as the doctor–patient relationship.[31] When researchers plan potentially risky protocols, such as an RCT with placebo control, wash out of treating medication or challenge studies where there is risk of precipitating mental illness[33], the PMI and family members may not fully appreciate the risk, despite it being written in the participant Information Sheet. While one would expect that participants are not wrong is trusting researchers, there should be adequate safety nets in place, which would be important for ECs to decide whether benefits outweigh risks and there are adequate procedures in place to detect risk situations, such as nonimprovement or early clinical worsening, in which case it will be ensured that the PMI will be taken out of the study and offered appropriate treatment.

The placebo trials in mental illness have invited criticism (and some support), both abroad and in India.[34] On one hand, it would arguably be unethical to offer placebo in illnesses where gold standard treatment is available, yet in some illnesses with a strong placebo response, some researchers feel it may be important to compare the new drug to a placebo. In July 2018, the World Medical Association adopted the Declaration of Helsinki (version amended in 2013). It has a paragraph on the use of placebo. It states that "The benefits, risks, burdens, and effectiveness of a new intervention must be tested against those of the best proven intervention(s), except in the following circumstances". It goes on to list these circumstances. These range from a situation where no proven intervention exists to ensure that patients who receive a less effective treatment should

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not experience irreversible or serious harm.[35] Those in favor of placebo control studies opine that it is methodologically superior, cheaper, and efficient due to the requirement of smaller sample sizes. Those against placebo control studies feel it violates the principle of equipoise when a standard treatment is available. They also feel it risks the deontological ethical principle as the possibility of benefit to society is at the risk of harm to a participant.[36] A detailed discussion of arguments for and against placebos would be outside the purview of this chapter, but readers could refer to the articles listed above. It is the considered opinion of this author that if placebo response data is available, and the protocol still proposes a comparison of a new drug (or old drug for a new indication) to a placebo, there should be a convincing reason as to why the comparison should not be to the gold standard treatment available. However, gold standards may have a lot of adverse events in comparison to the new drug. Another option would be to first compare the new drug to placebo to see if it is effective, or compare to placebo and the gold standard simultaneously. However, it would be important for EC reviewers not be influenced by stakeholders and be convinced for themselves about the ethics of the use of placebo or not in a particular study. What is important is that the use of placebo, method of randomization, and other relevant details are clearly discussed in the participant information sheet and informed consent form, in a language that the PMI and NR/LAR can understand. It would be important that the PMI and NR understand not only the potential risks/benefits but practical issues like the possibility of a longer stay in hospital if there is a nonresponse to placebo. The consent process should be clearly documented and witnessed.

Sometimes, the existence of independent Data safety and monitoring boards (DSMB) would be useful as its members are independent of the research team. It has also been pointed out that a default position of not allowing persons with severe mental illness to participate in research can be unhelpful because best practice evidence needs to be generated for that group too.[37]

Some Issues in Psychotherapy Research

There is evidence that placebo response not only occurs with medications, but also with medical interventions like procedures.[38] This would imply that the placebo response also needs to be accounted for in psychotherapy research. Sham interventions are one way of ascertaining placebo response in interventions. In order to perform a sham intervention arm of research ethically, it is important to inform the study participant *beforehand* that they could receive the sham treatment and get their consent.[39] The placebo response in psychotherapy exists, but is complex and challenging to measure.[40] Psychotherapy is sometimes studied alone, or in combination with medication. If controls like "waitlist controls" or "treatment as usual (TAU)" are used, its scientific validity and limitations should be borne in mind.[41] Informed consent in these situations should also include information about handling any undue distress while awaiting intervention/worsening of symptoms during the waitlist time, including accessing treatment/stopping participation in the study.

In the rare situation where an informed consent would undermine the rationale of the study, then ICMR Guidelines (point 5.11) discuss the role of deception in research and that EC may give permission with the consent as a two-stage procedure with a debriefing of the participant as soon as feasible.[4]

Researchers and EC members are also reminded that psychotherapy, while effective, is not immune to adverse effects.[42] Safety monitoring systems should be in place even for social and behavioral intervention studies.[43]

Voluntariness

Enthusiastic researchers may have blind spots in their drive/pressure to recruit patients. It is important that their enthusiasm does not result in or come across as coercion. The doctor–patient relationship is important in the care of a PMI as it has therapeutic value by itself and this needs to be protected. As the researcher–participant relationship is different, there could be a conflict of interest (COI) if the treating doctor is also a researcher involved in the study and tries to recruit the PMI into the study. This is yet another reason why it would be good practice to obtain the permission of the treating psychiatrist beforehand, as they might be in a good position to reiterate that if the PMI decides not to participate in the study, the doctor is not going to get annoyed and there would be no repercussions to their clinical care. The best way to ensure no COI is to ensure that one does not recruit patients under one's clinical care into one's own research. If that is impossible, at a minimum, someone else in the research team undertakes administration of the consent process and its documentation. This is particularly important in India as research has suggested that trust in the doctor and the institution can influence patients and family members to participate in clinical trials.[44]

Research in Relatively More Vulnerable Groups

It is important that researchers are made aware of PMI who are in relatively more vulnerable position like children and adolescents,[22,45] persons with substance use and high risk sexual behavior,[46] the elderly and prisoners among others. ICMR Guidelines for research in children[22] also mention about parents being particularly vulnerable to therapeutic misconception while consenting to their child's participation in research.

Post-research Benefit in Psychiatric Illnesses

This aspect of post-research benefit needs careful assessment by EC when reviewing research submissions. Psychiatric

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illnesses invariably need longer term treatment beyond the acute phase to reduce risk of relapse. This duration can last from 6 months to several years. It depends on various factors, for example, the nature of illness and past episode history. If the participant has responded best to the experimental drug, then changing or discontinuing the medication post-trial risks relapse. This can be a particular problem if there is delay in the drug being available in the market or is expensive. ICMR recommends in point 2.11.3 that EC ensures that these issues are discussed by the sponsor when the research is submitted for ethics consideration.[4]

Confidentiality and Data Privacy

Privacy of data is important and data should be stored and retrieved appropriately through controlled access.[47] Confidentiality has to be maintained unless information about a mandatorily reportable crime is obtained, for example, information pertaining to risk of homicide or the sexual abuse of minors as elucidated in the POCSO Act (Protection of Children from Sexual Offences Act), 2012. Retrospective research using case records need to be planned appropriately, needing EC approval for assured anonymity[48,18] and waiver of consent. An undertaking by the researcher should be submitted that the data will be anonymized by a third person.

Innovative Practices and Technological Advances in Psychiatry

The opinion of a mental health expert should be sought to ensure that the study is scientifically valid. This is particularly important in evaluating research using relatively newer methods, such as telepsychiatry, online therapy, app-based interventions, use of artificial intelligence, and other technological advances in psychiatry.

Some Ethical Issues with Use of the Internet

Ensuring privacy of research data is obviously important for any research, but it is particularly important in online mental health research due to the nature of the information requested.[49] As the internet is a public forum, both researchers and EC members need to consider steps such as data/email encryption and restricted access to data. The data security measures in place should be spelt out. As with any research, sometimes the participant's clinical condition can worsen and the need for specific intervention arise during the course of the study. Researchers need to be alert to adverse events, as they can occur with online interventions too. Safety nets in place to pick up "red flags" during online research and the process to refer such participants for intervention should also be clear.[50]

There are challenges in ensuring informed consent when there is no face-to-face interaction between the researcher and participant. If verbal consent is used, a script is advisable and signature of witness required. If information about the research and consent is being done online, steps to protect privacy should be taken and EC approval obtained before the study.[4] If cloud computing is likely and involvement of researchers across the globe, it would be important to know the terms of service providers and ensure there is no data access by others like advertisers. For work on "big data", the scientific and ethical pitfalls of use of algorithms and predictive models borne in mind. As the internet can be both a tool as a well as a space for research, readers can access a more detailed discussion on the ethical challenges involved.[51] As technology evolves, so would the ethical and legal challenges. Till specific guidelines are available in India on this issue, readers might find the ethics guidelines for internet research brought out by the Association for Internet Researchers an additional useful resource.[52]

Research During Pandemic and Disaster Situations

In 2009, the WHO technical consultation on research ethics in international epidemic response highlighted the point that while the essence of the general principles of research ethics and protection of human rights remain the same in a public health emergency situation, there are some key differences.[53] EC members need to be alert to issues pertaining to changing perception of risk, benefits, need to "fast track" ethics review, yet ensure organizational accountability and transparency to ensure that substandard research or any unethical practices are flagged quickly.

In disaster situations, whether natural or man-made, the scale of healthcare requirements overwhelms the locally available resources. While mental stress can be understandable in these situations, it can precipitate mental illness in a vulnerable person or a person made vulnerable by extreme circumstances.

Research During the COVID-19 Pandemic

Research during the COVID-19 pandemic poses several additional challenges, both as a pandemic situation and, at times, a disaster situation. As discussing pandemic ethics and disaster ethics is beyond the scope of this section, readers are referred to WHO's training manual on this subject.[54] However, a few key points relevant to psychiatric research during the COVID-19 pandemic are briefly discussed below. The experience and lessons from the current COVID-19 scenario could be relevant to future epidemic/pandemic/disaster situations.

- *For continuing research started before the pandemic*: In view of the risks to participants and investigators due to travel or interaction with each other, the best action is to temporarily suspend research, till the risks subside. This would have to be discussed with the EC as well as the sponsors, if it is a funded study. As this could impact

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salaries of research investigators, it is important that everyone involved is kept informed of the uncertainty of the situation. If the study has to be prematurely stopped due to the COVID-19 situation, the impact on numbers recruited, and thereby the power of the study should be noted. Permissions from the EC for necessary amendments, validation of the online or telephone methodology/use of questionnaires should be done before proceeding further. If the research study could be continued with these modifications, then appropriate changes to the informed consent process for verbal or online consent should also be submitted to the EC.

- *For new research started during the pandemic*: From the evidence available till the moment this chapter goes to print, it seems possible that mental illness could be both a risk factor, as well as a complication of COVID-19.[55] In a position paper on COVID-19 and Mental Health, the need for good research practices even during the pandemic has been emphasized, including expedited reviews by ECs, the need for researchers to discuss protocols and questionnaires with patients/those with the lived experience, the need for harmonizing data/measures and global collaboration on the various aspects of mental health research ranging from neuropsychiatry to stigma.[56]

Additional Ethical Challenges in the COVID-19 Pandemic

Both researchers and ECs should keep in mind the fundamental ethical requirement that the research is truly needed and particularly valid during the COVID-19 pandemic. The fact that the pandemic has led to a glut of poor quality research[57] reminds us of the wisdom in Professor Doug Altman's words stated more than 15 years ago, "We need less research, better research and research done for the right reasons".[58] Online surveys can give useful information, if used correctly. Yet, the reality of the "digital divide" that many vulnerable persons will not be able to access online digital media should be borne in mind. One should not settle for poor quality data gathering merely because online surveys now seem easy to do, and some researchers feel the pressure to publish. If necessary, timelines may be fast tracked but scientific integrity and ethical requirements should never be compromised.[56] As discussed in the earlier section, "online" work with research participants (a fallout of the pandemic) requires that researchers and EC reviewers be alert to the ethical challenges surrounding privacy of data.

Research on Non-COVID-19-related Issues

For research on non-COVID-19-related issues during the pandemic, as reiterated earlier, relevant scientific questions should be addressed with appropriate methodology. But the additional requirement is to ensure the safety of research participants as well as research investigators.

Other General Relevant Issues

All other relevant ethical issues, which are relevant in research for persons without mental illness, are also obviously relevant in PMI. All COI should be declared, including any researcher–pharmaceutical company relationship. International collaborations including submissions to Health Ministry's Screening Committee (HMSC), genetic studies, storage of biological samples, insurance cover, contacting the PMI for future studies, and publication of research should all follow National Ethical Guidelines already available in this regard.[4,5,59]

CONCLUSION

This chapter discussed the various ethical issues that the researchers, reviewers, and EC members need to bear in mind while planning and conducting research in PMI. While PMI are a vulnerable group, there is a need to ensure good quality ethical research that will generate useful information on various aspects of mental health, mental illness, and its management. However, the most important "tool" to ensure ethical research is an ethical researcher. Personal integrity ensures safe research.[60,61] Till specific guidelines for PMI are available in India, researchers are also advised to additionally refer to the principles elucidated in the National Ethical Guidelines[4,5] and also addressed in international guidelines.[62]

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Biomedical Ethics Perspectives in the Indian Context

Vol. 1



"There is a higher court than courts of justice and that is the court of conscience. It supercedes all other courts."

—Mahatma Gandhi

Code of Medical Ethics has widely been discussed since ages. It is a common understanding that ethics is defined by a definite set of rules distinguishing matters of right from wrong. The existing codes, policies and principles, rules and regulations may be often conflicting and may require considerable contextual interpretation. All stakeholders in research look for a strong ethical compass to steer them through difficult ethical dilemmas. This necessitates a comprehensive understanding of such issues in the sociocultural milieu of our country to make reasoned decisions during such situations abiding by the existing codes and regulations.

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