

## Ethical issues in psychiatry research: Special concerns for India

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In this issue of the journal, Avasthi *et al.* provides an overview of ethical issues in research.<sup>[1]</sup> The ethics of medical research in India, including psychiatric research, have been much debated.<sup>[2-13]</sup> With specific reference to psychiatric research in India, we wish to address two of the principles that Avasthi *et al.* lists in his overview because we believe that these are important yet neglected in this country (and surely in many other parts of the world, as well!). These two principles are non-exploitation of research subjects and release of the results of the research into the public domain.

### EXPLOITATION OF RESEARCH SUBJECTS

Avasthi *et al.*<sup>[1]</sup> provides a broad description of what non-exploitation entails. With specific regard to medical or hospitalization costs and insurance claims when adverse events occur, we make the following observations:

- Patients in India seldom have the financial resources to settle their medical or hospitalization expenses and wait for the insurance claims to be settled in order to obtain their reimbursements. Thus, if the study concludes without the patients requiring additional medical attention, no ethical issues arise. However, if special outpatient or inpatient expenses are incurred as a result of adverse events, and if patients have to settle these expenses through their personal resources, they have effectively been exploited. What is the solution? A novel approach is one that had been adopted by the National Institute of Mental Health and Neurosciences (NIMHANS), Bangalore, for many years. The NIMHANS Ethics Committee required clinical trial sponsors to provide an undertaking in the informed consent form that interim relief would be provided to patients and their families in the event of misadventure. The interim relief would cover all expenses related to investigation and treatment of the adverse event, and would include compensation in

case of death. These benefits would help the family cope until the insurance claims were settled.

- Patients in India do not have the ability to file claims with an international insurance company and defend these claims, if the claims are contested. Again, NIMHANS innovated by insisting that local insurance be obtained, so that claims could be filed in the city in which the study was conducted.
- The lives of patients in India are valued at far lower levels than those of patients in Western countries. This is an unfortunate consequence of local insurance, and more attention needs to be paid to ensure that Indian subjects are treated at par with subjects recruited from other sites.

There are other ways, as well, in which research subjects may be exploited in India. For example, in some private medical institutions, research subjects pay for investigations the results of which are included as major or minor variables in the dissertations of postgraduate students. Clearly, actual or potential exploitation of research subjects exist in many garbs.

### NON-PUBLICATION OF RESEARCH

There are hundreds of psychiatry postgraduate students who submit dissertations each year in part fulfillment of their course obligations. Scores of research papers are presented in state, zonal, and national conferences attended by psychiatrists. Much of this research is not published, judging from the contents of psychiatry journals published in this country and elsewhere. There are two possible reasons for non-publication of completed research: The research may not be publication-worthy, or the investigators may not be making the effort to prepare and submit their manuscripts. Either way, the subjects who participated in the research stand betrayed because

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they have suffered inconvenience related to the study procedures, or even risks, without the scientific discipline or future patients benefiting.

Part of the problem lies in the fact that faculty and students in psychiatry departments across the country are inexperienced in statistics and research methodology. Just one significant shortcoming in a study may compromise the conclusions of the entire work; in consequence, the study becomes unpublishable; or if it is published in a journal of low rank, it has no effect whatsoever in the scientific field. As a result, the participation of the research subjects remains wasted, rendering the study unethical.

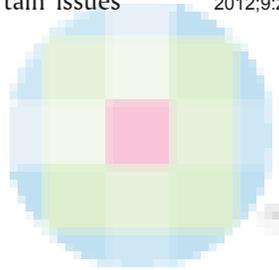
### THE WAY FORWARD

The Indian Council of Medical Research has published schedule Y, which is a locally relevant version of guidelines for good clinical practice and ethical research. The Medical Council of India and many universities have mandated research publications criteria for the selection and promotion of medical faculty. There is a gradual increase in the emphasis on training in statistics and research methods. We hope that by bringing to the forefront certain issues

related to ethical research, awareness will result in self-correction.

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