VIEWPOINT

Concerns about ethical review of health research in India

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This essay presents a brief discussion on ethical review of biomedical research in India, and problems that need to be addressed. Given the paucity of published material on this subject, it depends on informal exchanges with researchers, academicians and members of ethics committees during various training sessions on research ethics.

Limitations of ethical review in India

The Indian Council of Medical Research (ICMR), the apex agency guiding biomedical research involving human participants in India, has published detailed guidelines on the composition and responsibilities of Institutional Ethics Committees or IECs (1). Despite these guidelines, more than 50% of institutions conducting research in India reportedly lack formal IECs (2). It is apparently difficult to get external members to volunteer, especially from among trained legal scholars and ethicists. Most medical schools do not offer bioethics courses. Typically, well-known people are nominated as IEC members. Finally, in the Indian context, 'lay persons' can be intimidated by the presence of more powerful scientific members.

Institutional budgets seldom allocate resources for IECs. Many IECs do not have sufficient office space. There have been instances of protocols disappearing after the project's approval. The IEC secretary can be a middle or lower level staff or faculty member for whom this responsibility is in addition to a full workload. There are no post-approval monitoring systems in place, and IECs' responsibilities tend to end with approval. Without standard operating procedures, the IECs may follow different methods for submission, approval and follow up of research.

The politics of research

For medical researchers the world over, publishing research in peer-reviewed journals is a vehicle for career advancement. When ethical review and monitoring are weak, researchers may be under pressure to cut corners. Pharmaceutical companies hire practising doctors as researchers for their prescribing potentials. Hyder, Kass and Dawson note that 'the majority of developing country researchers were middle-aged males who were physicians employed by educational institutions, carrying out research on a part-time basis' (3). Gulhati observes that 'many investigators who conduct clinical trials are, or have been, beneficiaries of largesse from the pharmaceutical manufacturers (4).' Institutional members in the IEC may be junior to these researchers. Since no overt conflict of interest is apparent to IECs, the indirect benefits and mutual arrangements between companies and doctors often go unnoticed. Institutions' need for resources may also put subtle pressure on IECs to approve research.

Moreover, the ICMR lacks the authority to take action against unethical IECs. There exists no mechanism for accreditation of IECs and quality control of ethics review is practically impossible. There is no comprehensive database on either IECs or research participants.

India is also witnessing the birth of unaffiliated Ethics Committees to review protocols for institutions with no IECs, supported by fees from the pharmaceutical industry. In the West, there is an 'uneasy alliance' between such bodies and the industry (5). The problem is likely to be worse in India.

The Indian Council of Medical Research

The ICMR has implemented several interventions in the past few decades to improve the ethical review of research. In addition to developing general research guidelines, it has started work on guidelines for specific areas of research. It has constituted a 'Bioethics Cell' under senior staff trained in bioethics. It hosts a website with links to leading bioethics journals (6). It is preparing standard operating procedures for IECs and standard formats for ethics review across IECs. It has supported the formation of a forum for ethics review committees in India, is working with similar bodies in the Asia-Pacific

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region, and is putting together a database on IECs in the country. To enhance ethics capacity, the ICMR identifies mid-career professionals to be trained in bioethics through fellowships. It also conducts training sessions for researchers, academicians, IEC members and students within India.

Future directions

Various initiatives are on to strengthen the capacity of bioethics in India, with the help of the US National Institutes of Health and global bodies such as the World Health Organization and UNESCO. However, current efforts may be limited, given the number of research institutions and the volume of research. The following suggestions may be considered:

India needs more professionals trained in bioethics. Bioethics training should figure strongly in the medical curriculum, and researchers need to be trained in research ethics. When professionals such as lawyers cannot be attracted to work voluntarily for IECs, their time may need to be compensated for adequately. IEC member secretaries must be compensated fairly for their additional work. A portion of every research institute's budget should be earmarked for IECs. Databases on IECs and trial participants will have to be created. State-level IECs should be created to monitor IECs and review protocols of institutions without IECs. Standards must be prepared and made available to all IECs. The ICMR must be given more legal authority.

Institutional mechanisms for ethical reviewing of research involving human participants in India are weak and vulnerable. A concerted effort is required to strengthen them to fulfil their stated missions.

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