Conferences

Ethical Issues in Health Research in South Asia, Thiruvananthapuram, *29 January–1 February 2001*

THE NEED FOR FUNCTIONING ETHICAL REVIEW BOARDS

Research involving humans contributes significantly to the improvement of human health.[1] Biomedical and social science research must conform to certain ethical guidelines in order to be accepted by both the scientific community and the public. International guidelines concerning ethical issues for biomedical and social science research are updated frequently. The Indian Council of Medical Research (ICMR) has recently revised its own *Ethical Guidelines for Biomedical Research on Human Subjects.*[2] The National Committee for Ethics and Social Research in Health (NCESSRH) has published the first *Ethical Guidelines for Social Science Research in Health* for India.[3] The Achutha Menon Centre for Health Science Studies of the Sree Chitra Tirunal Institute for Medical Sciences and Technology, Thiruvananthapuram, organized a four-day workshop on 'Ethical Issues in Health Research in South Asia'. Some of the important issues discussed in the workshop are presented here.

There is agreement among various stakeholders regarding the general principles of biomedical research. These are the principles of essentiality; voluntariness, informed consent and community agreement; non-exploitation; privacy and confidentiality; precaution and risk minimization; professional competence; accountability and transparency; maximization of public interest and distributive justice; institutional arrangements; public domain; totality of responsibility; and compliance. Although these principles seem to be self-explanatory, their interpretations differ. Implementation of these principles is extremely challenging in the developing country context because of a lack of proper 'architecture'. The role of ethical review boards and the need for incorporating the teaching of ethics in professional colleges is discussed below.

Ethical review boards (ERBs) should be constituted to provide independent, competent and timely review of the ethics of proposed studies. Also, ERBs need to have freedom from political, institutional, professional and market influences. It has been argued that ERBs should review the proposal and study design because any improperly designed study is by definition unethical. Therefore, ERBs should have study design experts and epidemiologists as members. Though there are some excellent ERBs in India, many research institutions do not have ERBs or have them in name only. The World Health Organization (WHO) through the Tropical Diseases Research Programme has recently published *Operational Guidelines for Ethics Committees that Review Biomedical Research*, which provides an excellent overview of establishing an ERB and making it a viable and functioning unit. The guidelines address questions such as: Who should be members of review boards? One important suggestion is that ERBs should have multidisciplinary representation. A representation from the community is another requirement. The recruitment policy for an ERB should make it clear whether the selection will be made by consensus, by majority vote or by direct appointment. Quorum requirements should be decided in advance. A proper gender mix is necessary for ERBs. How many members should there be and what should they do? What should be the process by which proposals are reviewed? What should be the training of ERB members? How long should members serve? How should ERBs be supported financially? Is it appropriate to charge a modest fee for the conduct of an ethical review for each proposal? How should the fees be decided? It may be necessary to conduct a small study to identify the answers to these important questions. Again, the most important principle for ERBs is that they are '... responsible for acting in the full interest of potential research participants and concerned communities, taking into account the interests and needs of the researchers, while having due regard for the requirements of relevant regulatory agencies and applicable laws'.[4] Monitoring and follow up of research is another issue. How can ERBs take up the responsibility of following the research and ensuring that their recommendations are actually implemented? ? Ethical review boards should establish a follow up procedure for all studies for which a positive decision has been reached, from the time the decision was taken until the termination of the research. Follow up is necessary because of the following reasons:

1. To see whether there was any amendment in the protocol after approval which may adversely affect the study participants;
2. To assess the possibility of serious and unexpected adverse events related to the conduct of the study and the response of investigators, sponsors and regulatory agencies; and
3. To utilize the availability of new information that may affect the benefit/risk ratio of the study.

It is important to avoid unreasonable delays in reviewing the research proposal and follow up; ERBs should be conscious of the researcher's time lost due to repeated revisions.

One of the recommendations of the workshop was to include and improve the teaching of medical and research ethics to health professionals, including social scientists who might be engaged in health-related research. Medical ethics is not taught as a separate subject in Indian medical colleges except at St John's Medical College.[5] Professional colleges do not have enough teachers trained in ethical issues in health research. This could be taken up as a priority in all teacher-training programmes in professional colleges. A curriculum for such multidisciplinary courses should be developed in collaboration with other institutions including national law schools. The role of professional associations, such as the Indian Medical Association, would be critical in the teaching and dissemination of ethical principles for research.

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