Ethics in biomedical and social science research

When research entails living beings, ethical considerations are paramount. As research is always a result of careful planning, the process must include consideration of the ethical dimension as much as the scientific merit of the project. The contemporary concept of health includes physical as well as social and spiritual dimensions. Therefore the Tata Institute of Social Sciences (TISS) hosted a workshop on ethics in biomedical and social science research on February 12, 1999, in Mumbai, in collaboration with Johns Hopkins University (JHU), USA and International Institute of Population Sciences, Mumbai.

Presentations included a discussion of the four major principles of biomedical ethics: patient autonomy, non-malfeasance, beneficence, and justice. Just as physicians have a *Hippocratic Oath that governs their practice of medicine, researchers must adopt a research code of conduct that incorporates ethical principles and behaviour, spelling out the do's and don'ts with suitable penalties for transgressions.

One study reported on the household and community response to HIV. Other subjects discussed included the practice of informed consent in surveys such as the National Family Health Survey (I & II), vulnerability of low socio-economic groups with their lack of power and dependency. One presenter focussed on research in maternal and child health at the community level and problems resulting from the prevalent practice of the mother returning to her natal family for delivery and subsequent return to her husband creating a break in continuity of care and follow up. Others addressed accountability and sensitivity on the part of the researcher, the double edged role of the media, the inherent conflict between the social activist and the scientific community and balancing the needs of the community versus the individual in research.

Dr HR Juneja from Institute for Research in Reproduction, of ICMR, reviewed the manner in which ICMR guidelines on ethics in biomedical and social science research were developed. He related the process of soliciting comments about the proposed-guidelines including open forums at various sites throughout India with advance media notification and specific invitations. Yet there was widespread criticism from physicians, institutions and NGOs after the guidelines were published (the full guidelines are available on the Internet at http:\\www.healthlibrary.com).

Dr Nancy Kass from JHU discussed the CIOMS guidelines on clinical research focussing on informed consent, the ethical review process, and the obligations of the sponsors of research particularly for multi-national research and differing cultural perspectives in multinational and multicultural research. Dr Bollinger of the JHU reviewed the process of planning and implementing multinational research from formulating a proposal, selecting participating institutions in the target country, local IRB approval, international expert review, governmental review and approval to final implementation of the research protocol. The process, entailing extensive review at every step with feedback and modifications, may take two years or more. This highlights the attention to detail, both technical and ethical.

With the wide range of topics discussed, it was perhaps surprising that the hour-long, open forum at the end of the workshop focussed almost exclusively on issues pertaining to informed consent. Some of the views expressed regarding informed consent had to do with how often the subjects really understand the issues. Some found written informed consent to be primarily an administrative chore, while others felt that consent could be assumed. One participant described her experience of prospective subjects who eagerly discussed the research project and would have participated but would not agree to sign a consent form. This practice appears to be a misperception of what the signature on a consent form implies, and raises the obvious question of how "informed" the "informed consent" really. was! Another described how participants looked on the written consent as a legal obligation to complete the study and pushed themselves to do so when withdrawal from the study would have been more logical.

At the workshop, research teams from the National AIDS Research Institute, Pune and JHU reported some interesting facts related to informed consent. JHU requires a written informed consent from research subjects. When the research team concluded that written consent compromised patient/ participant confidentiality as the consent form was written proof of the disease, they successfully convinced their Institutional Review Board to waive the requirement for the written consent.

Advocate Anand Grover from the Lawyers Collective parsed the word consent as "con" which means an attempt at establishing parity in the unequal relationship between the researcher and the subject. The intense concern with the subject of informed consent suggests that it would be an appropriate topic for a future issue of *IME*.

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