Strengthening ethics of ethics committees in India

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It is often said that the ethics committees (ECs) in India are mushrooming in numbers, but not all are functioning properly. Chatterjee1 referred to the existence of less than 40 ethics committees that function properly in India. There are only two institutional ethics committees in the country (Ethics Committees of Seth G. S. Medical College and Tata Memorial Hospital in Mumbai) accredited by the Forum for Ethical Review Committees in the Asian and Western Pacific Region (FERCAP) under its Strategic Initiative for Developing Capacity in Ethical Review (SICER) recognition programme. Recently, the Indian Council of Medical Research (ICMR), New Delhi, in collaboration with FERCAP organized a symposium on human subject protection course followed by a training programme on developing standard operating procedures for ethics committee members at the Sanjay Gandhi Post Graduate Institute of Medical Sciences (SGPGIMS), Lucknow, where 13 ECs participated, indicating a rise in their number. This exercise was undertaken as a part of the programme to accord recognition to the ethics committee at SGPGIMS and questions raised were related to how its functioning can be monitored, whether the selection of members was done in conformity with the ICMR guidelines2, and whether it was monitoring clinical research projects efficiently. It is being gradually realized that unless proper monitoring is done an EC will not ensure compliance of an approved protocol. While questions are being raised about the functioning of ECs in developed countries3 and reforms are being proposed4, it is time for introspection in developing countries as well. This has been further necessitated by a recent report on the criticism of ethics surrounding the human papillomavirus (HPV) vaccine project6.

ICMR guidelines consider competence and independence as the hallmarks of institutional ethics committees (IECs). The competence relates to expertise of the committee and in its role, concerned with freedom needed to take decisions free from any coercion. In India, the required structured forms are available on these aspects of ECs. The European Forum for Good Clinical Practice (EFGCP) has brought out a report on research ECs in Australia, Brazil, Canada, China, India, Japan and USA, now available on its website7. This report was uploaded in July 2010 and addresses information regarding 12 carefully planned questions on the functioning of ECs in the countries mentioned above. There are two major aspects of ECs, namely constitution and mode of functioning. In India, there is no collective information about ECs in the public domain. A recent report from Clinical Trial Registry India (CTRI) revealed that there is lack of awareness on regulatory processes, especially related to ethical review and many institutes have no ECs8. ICMR, in collaboration with the World Health Organization, conducted a survey of ongoing clinical research/trials in 71 institutes in 2002. Thirty-six institutes responded and each reported having IECs and 24 also had separate scientific review committees. Standard operating procedures were in place for review procedures in 23 IECs and 14 claimed that they had trained members in research bioethics9. The expertise requires having members with training in identifying and resolving the ethical issues that are becoming complex with newer scientific advances. Therefore, it is a need to define minimum level for such labelling of expertise. The following questions remain unanswered and need immediate attention in the light of the controversy surrounding ethical issues of the HPV vaccine study: what should be the minimal expertise level? Is certification by attending an ethics workshop sufficient for complexities encountered in ethics review or continued updating is essential? How does one decide on updating modalities? Are such facilities available to EC members easily and do they have enough interest to devote their time?

The Drugs Controller General of India (DCGI) has stake in adequate EC functioning and depends primarily on ECs for implementing ethical standards in clinical trials. Schedule Y implemented by the DCGI is proposed to be further amended – with the introduction of Schedule Y3, wherein research ECs overseeing clinical trials in the country will have to be registered with the office of the DCGI, as also reported in the EFGCP report (www.efgcp.eu).

Streamlining the ethics review

Each country should have its own mechanism to improve the functioning of ECs, and the institutes involved in health research must send a strong message to