Editorial

Status of Ethical Review and Challenges in India

Research on human participants raises ethical concerns because of it's inherent potential to cause any harm, but the willingness of the participants to accept the risks and inconvenience to contribute to the cause of scientific knowledge and benefit to others necessitates a third party evaluation of the intended research to minimize such harms. The two pillars of ethically conducted research are a competent ethical review and a well placed informed consent process. The purpose of an ethical review is to ensure that the research is ethically acceptable and the welfare and rights of the research participants are well protected. To achieve this, a well informed, multidisciplinary team comprising of physicians, scientists, philosopher, legal expert, and theologian knowledgeable about ethical issues concerning research are expected to examine, evaluate and approve the conduct of any research before the same can be initiated. Hence, the role of an Institutional ethics committee (IEC) or Institutional review board (IRB) as it is known in many countries is crucial in the implementation of any research venture.

The concept of minimal risk to research participants plays a key role in the decision making process by the IECs. Apart from examining that the risks are minimal, which is defined as those "ordinarily encountered in daily life or during the performance of routine physical or psychological tests" the committee has also to examine that the risks are reasonable in relation to anticipated benefits and the importance of the generalisable knowledge that is expected to be gained through such research process. Further it has also to ensure that the selection of participants is equitable, no undue coercion is employed during recruitment, informed consent is sought from the participants or their legally authorized representatives wherever needed and the confidentiality is being maintained during and after the research. Hence, the IEC has to ensure that all the ethical principles–non-malificense, bene-ficence; autonomy and justice are well observed during the conduct of any research.

However, since bioethics education is not part of any curriculum, be it medical or nursing courses or life science courses in Universities, many IECs lack the expertise to adequately fulfill the mission of protecting the research participants. In most instances the ethics approval can be regarded only as a minimal ethical standard for research. The commitment and sensitivity of the investigators to adhere to ethical principles still remains the most essential element for ensuring that the research is ethically conducted. A recent survey by the Indian Council of Medical Research amongst over 200 institutions reveals the ground reality that many IECs are far from satisfactory in structure and function defined by the Council in it's revised guidelines of 2000, "Ethical guidelines for biomedical research on human subjects".

There are no Standard Operating Procedures (SOP) for these committees which may or may not meet regularly and have

varied methods of evaluation and decision taking process. They end up doing scientific review of the research proposals and scrutinize the consent forms as the only proof of ethical requirement. Actual discussion on risk-benefit analysis, compensation and inducement, protection of the vulnerable, issue of distributive justice, provision of Standard of care and post trial benefits are beyond the scope of most committees. Hence the ethics review mechanisms currently in position need drastic improvement, if India has to face the challenge of being projected as a "global hub" for clinical trials by the pharmaceutical industry. Newer issues are cropping up in the recent times such as conflict of interest, use of stored tissue, involvement of vulnerable groups *etc*. in addition to use of newer technologies with their ethical implications.

Amongst the vulnerable groups with diminished autonomy, research on children takes a central role in the modern times. While it is an accepted norm that for information that could be generated in adults, children should not be used for research, it is also argued that for specific diseases of children, it is necessary to include the pediatric population as they are a category by themselves and not merely small adults. While consent is to be taken from the legal guardian, it is also necessary to obtain the assent of the child depending on their maturity level and the refusal to participate should be respected. The growing use of DNA analysis in clinical research poses many ethical concerns related to confidentiality, inadequate genetic counseling, disclosure of results without any therapeutic intervention, intellectual property rights and patent issues *etc*. Do the IECs have enough capacity to identify these issues is a moot question. There is a great need for large scale capacity building exercises for IEC members, investigators, sponsors, policy makers, community members *etc*. if we want to instill confidence in the public that all research undertaken in this country takes care of the safety and welfare of the research participants who play the central role in any clinical research.

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