Are registered ethics committees empowered to ensure human research protection?

Protection of the rights, safety, and well-being of clinical trial participants is the fundamental tenet of clinical research. All stakeholders – regulatory authority, ethics committee (EC), investigator, and sponsor – are responsible for ensuring this human research protection. However, as the EC is responsible for ethical review of clinical research and is closest to the scene of action – clinical trial conduct in an institute, the EC has to play a vital role in providing the assurance of human protection to the clinical trial participants. In India, most ECs were established after the Schedule Y 2005 and Indian Good Clinical Practice (GCP) defined the roles and responsibilities of ECs. However, there was hardly any focus on functioning of ECs till 2013, when the EC registration came into vogue. In this issue of the journal, Bhide *et al.* have reported on the quality of over 800 EC registration approval letters issued by Drugs Controller General of India (DCGI).[1] The study found wide variation in time to approval, and in regulatory directives on functioning, composition, and training of the EC members. The authors recommend the need for uniformity in the regulatory directives to registered ECs. However, the unanswered question is: Are registered ECs empowered to ensure human research protection?? Do they function as per regulatory requirements and ethical guidelines? These issues become all the more important as ECs have been made responsible for several regulatory and ethical issues, for example, compensation for serious adverse event, continuing oversight, academic clinical trials, number of trials per investigator, and site infrastructure. Hence, it is crucial to review EC performance and consider strategies for empowering the ECs.

Several studies on performance of Indian ECs have reported deficiencies in EC functioning,[2,3] for example, inappropriate composition and functioning, inadequate training, conflict of interest, lack of standard operating procedures, deficiencies in approval letters. However, these studies were conducted before the registration of ECs. It was expected that DCGI office would review/audit the registered ECs and ask them to correct deficiencies. However, in 2016, the ECs have been asked to apply for re-registration, without any need for DCGI audit.

The US Office for Human Research Protections (OHRP), which registers Institutional Review Boards (IRBs), mentions on its website that IRB registration is not a form of accreditation or certification and registration does not mean compliance to human research protection regulations. OHRP regularly evaluates compliance of IRBs to regulations, and has cited deficiencies in Indian IRBs registered with OHRP.[4] Some of the findings were:

- Failure to meet quorum requirement
- Subjects not adequately informed of the alternative procedures or courses of treatment
- Failure to conduct continuing review of research at least once per year
- Minutes of meetings not available for some meetings or not in sufficient detail.

The Indian scenario is not likely to be different. If a thorough evaluation of registered ECs is conducted, not many would be found compliant to regulations. Studies of EC functioning from low- and middle-income countries, which included India, have revealed several deficiencies - insufficient diversity of membership, lack of institutional financial support and resources, limited

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competence of EC members for review and monitoring of research study protocols, inadequate training, and lack of independence.[5] Hence, it would be premature to assume that registered ECs are compliant to regulations and can aspire for accreditation. The process of accreditation of ECs is not a solution for problems or a quick fix, but a long-term strategy.[6,7] Forum for Ethical Review Committees in the Asian and Western Pacific Region through its Strategic Initiative for Developing Capacity in Ethical Review recognition has accredited 9 ECs in India. In comparison to India, other Asian countries have more accredited ECs – China 71, South Korea 29, Philippines 28, Taiwan 24, and Thailand 21.[8] The long and arduous accreditation process and awareness or concerns about deficiencies in functioning probably deter the Indian ECs from making efforts to obtain accreditation. This could also be a reflection of lack of competence of EC and inadequate training in ethical, scientific, and regulatory issues.

CDSCO registration requires a certificate or training record of evidence that EC members are conversant with the provisions of clinical trials as per the provisions of Drugs and Cosmetics Rules and GCP Guidelines. Hence, most EC members attend short 1–2-day workshops focusing on Indian regulations, GCP, and EC responsibilities. However, these workshops are not adequate to make ECs prepared to meet accreditation standards. The accreditation standards that EC is adequately qualified, experienced, and knowledgeable in ethical issues and applicable rules and regulations for conduct of clinical trials ensuring scientific integrity and protection of subject rights, safety, and well-being. Furthermore, the registration requirements for training of EC members cater only to regulatory clinical trials. However, ECs have to review variety of clinical research – epidemiology, public health, social and behavioral science, clinical trials, genetics, biological materials, humanitarian disasters, and emergencies – which have diverse and challenging ethical and human protection issues. Hence, there is a need to provide training and education to EC members by in a holistic manner.

For the EC training, the World Health Organization recommends following content:[9]

1. Roles and responsibilities of the EC and its role vis-à-vis other relevant entities, according to relevant international guidelines national laws, and institutional policies
2. Ethical considerations relevant to research with human participants
3. Application of such ethical considerations to different types of research
4. Basic aspects of research methodology and design
5. Impact of different scientific designs and objectives on the ethics of a research study
6. Various approaches for recognizing and resolving the tensions that can arise among different ethical considerations and modes of ethical reasoning.

Independence and competence are hallmarks of a well-trained EC. The training and education of EC should focus on encouraging the EC to attain these benchmarks. The training programs for EC may range from short-term 1–2-day orientation workshops on fundamental science, ethics, and regulations to intensive longer programs of 1 week. Each EC should have a training plan for each EC member for orientation/induction training within 1 month of joining EC, followed by ongoing updates and annual refresher program. As the regulatory and ethical environment is dynamic, it would be desirable to include an update as part of every EC meeting. The EC can organize long-term train-the-trainer program of 6–12 months for some members of new ECs, who can serve as faculty for regular training of EC members.

At present, the EC training in India is fragmented. Several different organizations organize short workshops. However, there is no uniformity in these programs. Furthermore, there is no centralized resource available to respond to queries on regulatory and ethical issues. It is desirable that Indian government – CDSCO and ICMR – should facilitate development of a central EC training resource using expertise of "senior" ECs, which have long experience and deep expertise in providing on the ground training and education to new ECs or inexperienced ECs. The central organization can emulate the education and training approach of the international bodies, for example, OHRP. The OHRP offers online training, webinars, videos, tutorials, workshops for IRBs, and also offers consultation to answer questions and provide guidance on Human Research Protections.[10]

Indian ECs will require support from institutional management and regulators to develop capabilities to function independently with competence, and cooperation from the investigators and sponsors to perform their functions. It is also important to acknowledge that ECs are professional organizations rather than amateur bodies served by honorary volunteer members.

The current approach of regulatory authorities to delegate some of the powers to ECs is commendable. Unless the ECs are empowered, they will not be able to fulfill their responsibilities. An independent and a competent EC is an empowered EC. Only empowered ECs can elevate the standards of ethical review and ensure human research protection.

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