

## ETHICS OF ETHICS COMMITTEES

# Accreditation of ethics committees in India: experience of an ethics committee

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### Abstract

Many ethics committees (ECs) approving clinical trials in India have got themselves registered with the Drugs Controller General of India as per regulatory requirements. However, there is still scope to improve their functioning. Accreditation, which entails adherence to national and international standards, helps an EC to protect the rights, safety and well-being of research participants. The National Institute for Research in Reproductive Health (NIRRH) ethics committee for clinical studies has received recognition, or accreditation, from the Strategic Initiative for Developing Capacity in Ethical Review (SIDCER). An EC receives recognition from SIDCER if it meets five standards related to its structure and composition; adherence to specific policies; completeness of the review process; after-review process; and documentation and archiving. The extent to which these standards have been met is assessed in various ways, such as review of the EC's records, interviews of selected EC members and observation of a full board meeting of the EC. This paper describes the experiences of the NIRRH EC during and after the process of receiving recognition.

### Introduction and background

During the past decade, many irregularities were reported in the conduct of clinical trials in India. Having a central registration system for ethics committees (ECs), which would ensure the quality of the conduct of clinical trials, became an issue of prime importance. Considering the situation, the Drug Controller General of India (DCGI), under the Central Drugs Standard Control Organisation (CDSCO), made registration mandatory for ECs which approve clinical trials (1). This will definitely ensure quality control during the conduct of clinical trials. Since registration was made mandatory, approximately 850 ECs have registered themselves with the DCGI. This signals

that they will meet the basic standards with respect to efficient functioning and the protection of human research participants. This will also ensure that the reviews made by the ECs and the research conducted by the investigators are of requisite quality. However, the government needs to go further than this mandatory regulation so as to ensure ethical conduct of other research studies involving human participants (such as clinical, genetic, stem cell, operational and socio-behavioural research). The accreditation of ECs plays a vital role in building their capacity in this regard. ECs can strive towards improving their quality through the process of accreditation and thus meet the international as well as national standards. It is formally recognised that an organisation which has received accreditation can carry out certain tasks of a specified scope, meeting the highest possible ethical and professional standards (2). While accreditation is voluntary, it is now accepted worldwide as an important aspect of an organisation's internal activities pertaining to the improvement of quality (3).

Currently, India does not have a government-approved accreditation system to look after quality assurance and control of the conduct of clinical trials and other types of research. Few institutions have sought accreditation from international agencies, such as the Association for the Accreditation of Human Research Protection Programme (AAHRPP) and Strategic Initiative for Developing Capacity in Ethical Review (SIDCER).

The Association for the Accreditation of Human Research Protection Programme is an independent, non-profit body, established in 2001. It uses a voluntary, peer-driven, educational model to ensure that human research protection programmes meet rigorous standards of quality and protection. To earn accreditation, organisations must provide tangible evidence—in the form of policies, procedures and practices—of their commitment to scientifically and ethically sound research and to continuous improvement. The primary purpose of AAHRPP accreditation is to strengthen protections for research participants (4). A unique feature of the AAHRPP is the integrative nature of the programme, in which the protection of research participants is the common goal of the sponsors of the trial, investigators, EC members and institutions (5). Only four institutes in India are registered with the AAHRPP.

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As for SIDCER, it was established under the World Health Organisation–Tropical Disease Research (WHO-TDR) as a public–private partnership project. It provides the international community with not only a means of building in-country human participant protection programmes, but also a way of measuring the quality and effectiveness of ethical review and of providing accountability in this respect. The Forum for Ethical Review Committees in the Asian and Western Pacific Region (FERCAP) has taken a lead role in conducting the recognition process in the Asia Pacific region and has been actively engaged in this work during the last decade. The Forum for Ethics Committees in India (FERCI) makes contributions to this initiative and assists FERCAP. An EC is recognised if it meets five standards, ie standards related to its structure and composition, adherence to specific policies, completeness of the review process, after-review process, and documentation and archiving. An EC that meets the five criteria is issued a certificate of recognition and granted recognition for a maximum period of three years.

Until now, eight ECs in India have received recognition from the SIDCER/FERCAP. These include the King Edward Memorial Hospital, Mumbai, the Tata Memorial Hospital, Mumbai, the Indian Council of Medical Research (ICMR) institutes (National Institute for Research in Tuberculosis and National Institute for Epidemiology, Chennai, and National Institute for Research in Reproductive Health (NIRRH), Mumbai), the YR Gaitonde Centre for AIDS Research and Education, Chennai, and the Sanjay Gandhi Post Graduate Institute of Medical Sciences, Lucknow. The number of institutions that have received recognition in India is less than that in neighbouring countries, such as China, South Korea, Indonesia and the Philippines. China leads in the region, with 63 ECs having received recognition till 2014. The important question is why India is lagging behind? Indeed, the reasons behind the slow response of the Indian ECs need to be investigated. One of these could be lack of awareness. Also, many ECs are reluctant to adhere to the stringent quality control standards required by the recognition process as this has not been made mandatory by the Indian authorities.

However, the ECs should realise that they ought to make an extra effort to obtain international recognition as going through this process has various advantages. An essential component of the process is capacity-building of the EC members, which helps them to improve the quality of reviewing protocols. This leads to a reduction in the turnover time of the review of proposals, and also ensures the protection of the rights, interests and dignity of the participants. Further, it reduces the investigators' resistance to abiding by the rules and regulations when submitting protocols to ECs which, in turn, makes for smoother functioning of the ECs. Another advantage of obtaining recognition is that it improves the reputation of the institute globally, which indirectly helps the investigators of the institute to receive funding for extramural and good-quality research studies. Research approved and conducted by internationally recognised ECs is more likely to be published in international journals and is of greater benefit to a wider group of scientists.

Improving the quality of review of an EC also safeguards the investigators and sponsors in case of serious adverse events (SAEs), as well as in matters of compensation and insurance for the study participants. This article shares the experiences of the NIRRH EC for clinical studies and aims to encourage other ECs in India to go through the process of accreditation so that the quality of review of ECs may be improved.

### **Experiences on the path to recognition**

The NIRRH, one of the premier institutes of the ICMR, has a team of basic, clinical and operational research scientists. The NIRRH EC for clinical studies was established in 1994. The committee reviews multidisciplinary research, such as basic, clinical, operational, socio-behavioural, genetic and stem cell research. The committee has varied expertise to review the wide range of research and a dedicated member secretary. It has been registered with the DCGI since April 2013. It is also registered with the Office of Human Rights and Protection (OHRP), which provides leadership in the protection of the rights, welfare, and wellbeing of subjects involved in research conducted or supported by the US Department of Health and Human Services (HHS).

As it is, the NIRRH EC was functioning efficiently and was particular about adhering to national and international guidelines and standards since its inception. Over the years, the committee improved in line with the guidelines and policies formulated in this field. In 2013 the EC planned further improvements, including training in research ethics and good clinical practice (GCP) for all its members and scientists in an ICMR-funded workshop. A committee was formed for drafting and finalising the Standard operating procedures (SOPs) in 2013.

It was decided that the EC should go through the process of SIDCER/FERCAP accreditation to improve its quality of review and to ensure that the highest ethical standards were met to protect research participants. The SIDCER/FERCAP programme would achieve its main aim (assisting the EC in developing its quality) by reviewing its ethical review practices and appraising its performance vis-à-vis the SIDCER criteria for recognition. Recognition that entails strict adherence to specific standards ensures greater uniformity and systematic review of research protocols. At first, the NIRRH EC completed a self-assessment form and sent it to FERCAP. The form was based on the five standards mentioned earlier (6).

The process of filling the self-assessment form presented the EC with an opportunity to review each aspect of its functioning and identify gaps which needed to be addressed. The self-assessment indicated that the EC had an appropriate structure and composition, and standard processes and SOPs were already in place. It also had a separate office with its own staff. However, certain gaps were identified under each standard and these needed to be addressed. The EC members tried to take remedial measures under the leadership of the chairperson. The committee had a preparatory period of about two months to work on the gaps identified in the self-assessment form. The

member secretary, affiliated members and secretariat were entrusted with the responsibility of ensuring that all the issues were addressed.

In accordance with the standard procedures of FERCAP, the FERCAP accreditation team made a site visit to the NIRRH, lasting four days. During the visit, the protocol files of the preceding three years were reviewed. The accreditation team also visited the EC office, observed the full board meeting and interviewed the chairperson, member secretary, selected EC members and the secretarial assistant. The team then made certain recommendations. After the site visit, the secretariat including member secretary, affiliated members and the secretarial assistant deliberated on the recommendations and prepared a report on the action to be taken on these. A full board meeting was called to discuss this plan of action. This proved very fruitful. After the report was finalised and endorsed by the chairperson and member secretary, it was sent to the FERCAP office.

The FERCAP office approved the report and informed the NIRRH that the EC would obtain accreditation during the FERCAP conference in November 2014.

The details of the action taken by the EC, standard-wise, are as follows.

### ***Standard I – structure and composition***

The NIRRH EC had an adequate number of members, with the requisite gender/age balance. The members were also balanced in terms of affiliated versus non-affiliated, community members and legal experts. They had been trained in research ethics and GCP the year before in an ICMR-funded workshop. All EC members and all scientists and investigators had undergone this training. The EC had a dedicated member secretary and a fully equipped office with institutional support.

In keeping with the experts' recommendations, legal experts/social scientists/affiliated statisticians were appointed as alternative members, since this would help the committee fulfil the quorum requirements when regular members were absent from meetings. As multidisciplinary research is conducted at the NIRRH, independent consultants in the fields of proteomics, stem cell research, genetic research and public health were appointed. A roster of their names was maintained so that the EC could refer to it when in need of subject expertise for a particular protocol. Initially, the credentials of all members of the EC were recorded in a single file. However, this was replaced by individual files on all members, in accordance with the recommendations. Thus the structure and composition of the EC were strengthened.

### ***Standard II – adherence to specific policies***

The committee had a comprehensive set of SOPs. These SOPs, numbering 24, were in writing and were operational. They had been prepared by a SOP committee and reviewed by all the members. They were revised when necessary. The committee followed national and international guidelines, which were

available in its office, for this purpose. The procedure for submission and review was firmly established. For review of the participant information sheet (PIS) and informed consent form (ICF) in local languages, a full board meeting was held to grant approval for English version followed by a separate meeting of community members. The PIS and ICF in local languages was discussed in detail and approved during this meeting.

Though the procedures for submission and review were in place, an assessment form for the review of studies had not been prepared. In accordance with the recommendations, such a form was prepared. It would be given to the assigned reviewers who would fill it before the full board meeting. The elements of science, ethics and informed consent were incorporated into the form to improve the review of the protocol by the committee's members. The inclusion of a checklist in this form ensures that the protocol is reviewed critically and that attention is given to the necessary scientific and ethical issues.

Before the recognition process, a meeting of community members used to be held after the approval of a research protocol with a PIS and ICF in English. This meeting was held to review the PIS and ICF in local languages and the principal investigator (PI) and community members would discuss how to simplify the terms used, to make them easier for lay people to understand. However, this used to lead to considerable delays in the approval of projects and the initiation of studies by the investigators. Hence, this task was integrated with the initial review, wherein the PI simultaneously submits the PIS and ICF both in English and the local language to the EC.

### ***Standard III – thorough review process***

The good practices noted by the experts during their observation of the full board meeting were quite encouraging. The agenda of the meeting had been prepared and was followed, conflicts of interest were addressed and the quorum was achieved. The discussion at the meeting was comprehensive and scientific. The chairperson did a good job of facilitating the meeting, the non-affiliated members participated actively and inputs were given to the investigators.

In accordance with the recommendations, the following points were kept in mind with regard to the conduct of future meetings: Confirmation of the previous meeting minutes in the agenda; to improve the sequence of the discussion, which should start with protocol-related issues, followed by ethical issues and those related to informed consent; to assess the local version of the ICF, at the same time as the protocol and the ICF in English, during the full board meeting; to encourage more active participation by the affiliated and community members; to prepare a comprehensive assessment form for the protocol and ICF for the reviewers to fill in; and to ensure that the EC does not grant "in-principle approval". In-principle approval would be given in certain circumstances, such as when the protocol involved no major issues.

### **Standard IV – after-review process**

The recommendations in this area concerned the implementation of SOPs with respect to the reporting of SAEs, site visits, deviations from the protocol and the final report. The experts had also made recommendations on keeping track of reports that were due and sending reminders to the investigators to submit their annual reports and final reports.

### **Standard V – documentation and archiving**

The existing good practices included the presence of permanent staff, appropriate location of the office, sufficient space for the office and proper equipment. Further, information on the EC and the SOPs was available on the institute's website. The protocols were numbered in chronological order and all details were available both in hard and soft copies in the EC office.

The following corrective actions were taken in keeping with the recommendations. Clear indicators were used to separate ongoing and completed study files. An index was made of all the documents in each protocol file. The necessary steps were taken to update the database regularly and to track and send reminders for progress reports.

### **Discussion**

In India, some institutes have experienced the process of AAHRPP and FERCAP- SIDCER recognition. If these experiences are shared, they will be useful for other organisations that are willing to go through this process. A report prepared by the Institute of Medicine, US, entitled "Preserving public trust: accreditation and human research participant accreditation programmes", has outlined various considerations for setting up an accreditation system outlined various considerations for setting up an accreditation system.. The EC reviewed and considered the available draft standards developed independently by Public Responsibility in Medicine and Research and the National Committee for Quality Assurance, which is under contract to the US Department of Veterans Affairs. The EC presented a series of findings and recommendations on the use of performance standards to improve the system for protecting human research participants (3). Though the report is relevant to the US, it can be a useful reference for setting up an accreditation system in India.

Accreditation raises the standards employed by ECs to review protocols and protect research participants. Auditing and accreditation programmes encourage research ethics committees (RECs) to develop standardised policies and procedures, which helps to promote the consistent application of ethical principles. They also provide a means of checking whether RECs are actually adhering to the policies and procedures that they claim to be following. Self-assessment makes ECs aware of their weaker aspects. Both accreditation and certification are likely to enhance the status of an REC within its own institution, which may make it easier for it to gain access to the necessary institutional resources (7).

Also, accreditation is helpful in that investigators submitting proposals to the REC are more particular and adhere to the guidelines and SOPs.

Each country should have its own mechanism to improve the functioning of ECs. Institutes involved in health research must send a strong message to society and individuals that they are committed to conducting research of the highest quality, and that protecting research participants is a top priority (8). In the light of the reported scams in the conduct of clinical trials in India during the last few decades, the process of accreditation would benefit the government and research participants as it would play an important role in protecting the research participants. Accreditation also helps to build trust in research and bridges the gap between researchers and the public (lay people). The people are assured that the rights and interests of participants in research studies/clinical trials are protected (9). An important issue which needs to be addressed is that investigators should not feel that ECs pose an obstacle to research. It should be explained to them that the ECs are striving to protect both the participants and the researchers.

The National Accreditation Board for Hospitals and Healthcare Providers, Quality Council of India, in consultation with various stakeholders, has prepared draft accreditation standards for clinical trial sites, ECs and investigators with a mind to starting a new accreditation programme, which may be initiated soon (10). However, this would be applicable only to clinical trials. As for ethical regulation in other types of research, the bill prepared by the ICMR, the "Biomedical Research on human subjects (regulation, control and safeguards) bill", is pending in the Health Ministry. The scope of the bill includes the promotion and regulation of biomedical and behavioural research on human subjects, ensuring the safety and well-being of research subjects, controlling and monitoring the application of new technologies (stem cell research, therapeutic cloning, ART, genomics), and keeping a check on unscrupulous clinical trials. It also envisages the creation of a national biomedical research authority, as well as the establishment of a national ethics committee on human research (11).

Now that it has obtained SIDCER accreditation, the NIRRH EC has a responsibility to adhere to the highest ethical standards. The committee is striving to maintain these standards, which is an ongoing process. Although it has received accreditation only six months ago, there are already visible signs of improvement in its functioning.

Some of the SOPs have been modified in accordance with the SIDCER recommendations. For example, the duration of the full board meeting has been reduced. This has been made possible by the fact that the project review assessment form is filled by the reviewers for each project so the discussion can be completed in a shorter time and conducted in an organised manner. The submission of the PIS and ICF in the local language together with the English version, and doing away with the meeting of community members (the meeting which earlier used to be held to simplify the PIS for

lay people) has reduced the overall turnaround time for the approval of projects. The mandatory requirement for PIs/clinical collaborators to submit a valid GCP certificate along with the project proposal is now being met. This ensures that the study is conducted properly, in an ethical fashion and with a commitment to protecting the rights and interests of the participants. The EC updates its database and sends regular reminders to the PIs about the submission of the annual/final reports. Since the last few months, the PIs have been prompt in submitting the annual/completion reports. The committee does not review the annual/completion reports of the PIs unless they submit their pending reports. All these steps have resulted in proper compliance with the guidelines and SOPs of the NIRRH EC.

The experiences of the NIRRH EC during and after the process of accreditation may prove to be valuable to other ECs that wish to adopt the standard procedures and improve their quality of work. It may help them adhere to international and national standards and ultimately, serve to protect the rights and interests of study participants.

### Declaration

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