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Case Report

Experiences on the path to achieving SIDCER recognition of an Ethics Committee

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Abstract: Ethics Committees (ECs) are endowed with the responsibility of ensuring ethical conduct of biomedical research and human research participants' protection. Although mandating its registration with central regulatory agency/agencies like Department of Health Research or Central Drugs Standard Control Organisation helps to improve its quality of functioning, further progress in achieving highest standards of ethical review is facilitated by undergoing various recognition/accreditation programs. One such is the Strategic Initiative for Developing Capacity in Ethical Review (SIDCER) recognition program, which was established under the World Health Organization–Tropical Disease Research (WHO-TDR) as a public-private partnership project in the year 2005. An EC is recognized by SIDCER after assessing five standards namely its structure and composition; adherence to specific policies; completeness of its review process; after review process; and documentation and archiving. This review describes the experiences of an EC of Sri Manakula Vinayagar Medical College and Hospital (SMVMCH), on the path to receiving SIDCER recognition and way beyond.

Keywords: Ethics committee, accreditation, recognition, capacity building of ethics committee

Introduction: Any research to be undertaken on human participants should be scrutinized and approved by an independent body of experts, constituting the ethics committee (EC). In order to ensure the quality of functioning of the ECs, they were mandated to register with a central regulatory agency under the Ministry of Health and Family Welfare. As

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per the New Drugs and Clinical Trials Rules 2019, ECs approving biomedical and health research must be registered with the Department of Health Research (DHR). ECs approving clinical trials and bioavailability and bioequivalence studies should be registered with the Central Licencing Authority (CLA) [also called the Drug Controller, India] under the Central Drugs Standard Control Organisation (CDSCO)[1]. The capacity of ECs can be further strengthened by undergoing various recognition or accreditation programs[2,3]. This review describes the experiences of our EC on the path to receiving SIDCER recognition and way beyond.

Strategic Initiative for Developing Capacity in Ethical Review (SIDCER) recognition program: SIDCER recognition program was established under the World Health Organization–Tropical Disease Research (WHO-TDR) as a public-private partnership project in the year 2005. This initiative by the WHO was formulated to aid in capacity building of the EC members in ethical review of research proposals and thus helping in protection of dignity, rights, safety and wellbeing of human participants in biomedical research. SIDCER has established a framework for surveying and evaluating the functioning of the ECs through a recognition (or accreditation) program. It evaluates the ethical review practices of an EC and grants accreditation which is valid for a period of 3 years [4].

SIDCER was formulated as a network of independently established regional fora for ECs, in five regions of the world [4]. They are:

1. Forum for Ethics Committees in the Confederation of Independent States (FECCIS)
2. Foro Latino Americano de Comites de Etica en Investigacion en Salud [Latin American Forum of Ethics Committees in Health Research] (FLACEIS)
3. Pan-African Bioethics Initiative (PABIN)
4. Forum for Institutional Review Boards [IRBs]/Ethics Review Boards [ERBs] in Canada and the United States (FOCUS)
5. Forum for Ethical Review Committees in the Asian and Western Pacific Region (FERCAP)

FERCAP is involved in conducting the SIDCER recognition program in the Asian and Western Pacific region. Its main objectives are "capacity building of stakeholders and quality improvement of ECs in the Asia-Pacific region" [5]. In India, a separate registered society was established as the national chapter of FERCAP and was named "Forum for Ethics Review Committees in India" (FERCI). FERCI operates in association with the WHO, Indian Council of Medical Research (ICMR), CDSCO, and FERCAP. It is involved in assisting FERCAP in conducting SIDCER recognition program in India [6].

Evaluation Standards for Recognition of an EC by SIDCER [7]: An EC will be granted recognition/accreditation after a thorough assessment based on the following 5 standards:

- Standard I: Structure and composition of EC
- Standard II: Adherence to specific policies
- Standard III: Completeness of its review process
- Standard IV: After review process
- Standard V: Documentation and archiving

Experiences on the path to recognition: Sri Manakula Vinayagar Medical College and Hospital (SMVMCH) is a 900-bedded multi-specialty tertiary care teaching hospital located in rural area of Puducherry, India. Every year, it admits 150 undergraduate medical students and around 60 postgraduate medical students. It has a well-established central research laboratory. Medical students and faculty members of the institute are actively engaged in biomedical research. Every year, around 100-120 research proposals are reviewed by the EC of SMVMCH.

The EC of SMVMCH was constituted in the year 2007. The Standard Operating Procedure (SOP) of the committee on "Protecting research participants and guiding investigators" was first developed in the year

2013. The SOP booklet had 50 pages and contained 12 SOPs with supporting forms and documents. The committee was registered with the CDSCO in the year 2014 and since then it was named as SMVMCH ethics committee (SMVMCH–EC). It was re-registered with the CDSCO in the year 2017 after completion of the three-year validity period. The committee reviews multidisciplinary research, such as basic, clinical, socio-behavioural and genetic research. The mission of the committee is to safeguard the rights, safety and wellbeing of the research participants, researchers and the institution. It also ensures that research is conducted as per the Indian regulations, national as well as international ethical guidelines [8].

The committee has 15 members with expertise in various fields including a dedicated Member Secretary and Chairperson. The members undergo periodic training in GCP (Good clinical Practice) and Bioethics. Over the years, our EC showed tremendous improvements/evolved with the changing trends in this field.

In the year 2018, it was decided that the committee should undergo the process of SIDCER recognition to further improve its quality and adhere to the highest ethical standards.

Before SIDCER survey: The first step was to fill up the application form and self-assessment form available from the FERCAP-SIDCER website (http://www.fercap-sidcer.org/selftool.php) [9]. The details required to be filled in the SIDCER application form are enlisted in box. 1.

Box. 1: The details required to be filled in the SIDCER application form [9]:

- Name and address of EC
- Contact details of Member secretary and Chairperson
- List of EC members with male/female ratio
- List of SOPs with titles
- Number of protocols approved through full board
- Common types of protocols reviewed at full board (drug, medical device, investigator initiated, etc.)
- Number of expedited protocols
- Types of protocols in expedited review
- Number of board meetings
- Average number of members who attend meetings
- Ethical issues/challenges

The self-assessment form is a 19 page document which contains the following details [9]:

- Name and address of EC
- Brief introduction of the EC (Year established, frequency of meetings, type and number of protocols reviewed/year)
- Brief introduction of EC staff and members (name, profession and credentials, gender, institute affiliation status)
- Section A on “Structure and composition of EC”
- Section B on “Adherence to specific policies”
- Section C on “Completeness of its review process”
- Section D on “After review process”
- Section E on “Documentation and archiving”

The sections have various subdivisions, each of which contains various questions about the EC, for which either of the four options; A, B, C or D (A-complete/adequate/always; B-partially complete/sometimes/not adequate; C-not complete/never; D- Not applicable) needs to be selected. Also, there is a separate column for writing any comments pertaining to each question, by the EC.

The various sub-divisions of sections A, B and C are summarized in Boxes 2, 3 and 4. Section D on after review process contains questions on whether EC has an effective and timely way of communicating a decision with clearly stated reasons to the investigator. It also assesses meeting minutes, protocol amendments, deviations/violations, Serious Adverse Event (SAE) reports, progress and final reports, and site visit.

Section E on documentation and archiving contains questions to assess whether EC systematically documents and archives its activities for a good time period. It assesses EC office: adequate space & equipment, confidentiality & security protection, comprehensive documentation, orderly filing

system, separation of active from inactive files, archiving, database for tracking and website.

Box. 2: Various sub-divisions of Section A on Structure and composition of EC (structure, composition and skills of the EC and staff are appropriate to the amount and nature of research reviewed) [9]:

- A1 - Membership requirements (at least 5 members, gender balance, experience, non-scientific and affiliated members and terms and conditions of appointment)
- A2 - Administrative requirements (Adequate number of administrators to oversee the EC activities, have documentation of the functions and activities of staff and their terms and conditions of appointment)
- A3 - Training of EC members (EC needs to state and observe the provisions available for its members to receive introductory and continuous education)
- A4 - Management of conflicts (EC should have a policy to address conflicts of interests)

After filling the application form and self-assessment form, they were sent by e-mail to the FERCAP coordinator. The process of filling the self-assessment form which was highly rewarding since it gave us an insight into the

Box. 3: Various sub-divisions of Section B on Adherence to specific policies (EC to have appropriate management and operational procedures for optimal and systematic conduct of ethical review) [9]:

- B1 - EC management (EC to have terms of reference)
- B2 - Availability of SOP (EC should have an SOP that covers its function and activities which they comply with)
- B3 - Submission guidelines and process (EC should have a submission guideline including its requirements and forms)
- B4 - Meeting requirements (EC should have documented meeting requirements which they comply with, quorum and professional requirements)

Box. 4: Various sub-divisions of Section C on Completeness of its review process (EC review protocols and its supporting documents in a timely fashion according to an established procedure to protect the interest of research participants) [9]:

- C1 - Review process (enough time for protocol review, EC to have documented and detailed review process which is complied with)
- C2 - Elements of review (EC to have a policy and procedure for review, elements reviewed should include the scientific design and conduct and ethics)
- C3 - After protocol approval (EC to document and follow procedures of reviews of amendments, continuing, SAE reports)
- C4 - Completeness of EC meeting minutes (minutes should be a complete record and reflect actions taken during the meeting)
- C5 - Decision making process (EC should have a procedure for decision making and members should participate in the process)

functioning of the EC, helped us in identifying the lacuna/ deficiencies in our EC and provided opportunities to address the same. Upon identification of the gaps, the Member Secretary along with a team of EC members and secretariat, under the leadership of Chairperson instituted remedial measures. The team worked for a period of 2 months in order to rectify the deficiencies and ensure that all the issues were addressed.

One week before the survey, the FERCAP coordinator had sent all the necessary documents for printing, the hardcopies of which were to be kept ready in order to assist the surveyors in the survey process. Also, it was informed to arrange for six FERCAP survey trainees who should not be affiliated to the institute in which survey is being conducted.

During SIDCER survey: The SIDCER – FERCAP survey team had 4 members including a lead/foreign surveyor, a survey coordinator and two local surveyors. They were assisted by six survey trainees.

Opening meeting: The survey started with an opening meeting in which the chief coordinator appraised us regarding the rationale for the survey, survey plan, and procedures and schedule of survey activities. The survey team then signed a confidentiality agreement with the EC and worked within the confidentiality document.

Visit to the EC office: The surveyors assessed for availability of adequate space and other facilities for smooth functioning of EC, measures taken to ensure confidentiality, use of computer databases for tracking, use of a separate and exclusive e-mail ID for all communications from the EC, details of EC

functioning and related documents and periodic updating of EC activities in the college website, orderly filing of the research protocols and other EC documents, separation of active protocols from the completed ones, archival mechanisms and methods for confidential disposal of documents after the termination of archival period (e.g. presence of a shredder).

Document review: The following documents for the last three years were reviewed

- Membership and training files
- EC SOPs
- Protocol files
- Agenda, minutes of the meeting
- SAE files, site visit files, annual and final reports
- Other communication records

Procedures reviewed: The various procedures which were reviewed were appointment of members, EC meeting, communicating decisions, continuing review, documentation of EC activities and archival of records. Apart from the EC meeting, which was visualized by the team members, all other procedures were reviewed with the help of documents and/or interview of the EC members.

***Interview of selected members of the EC*:** EC members like the Chairperson, Member secretary, non-medical member, medical member, member handling SAEs and EC secretarial assistant were interviewed to understand their appointment process, knowledge on EC SOP, their perceived roles and responsibilities in the EC and their suggestions for improvement of quality of EC functioning.

Observation of an EC board meeting: The survey team observed an EC board meeting. It was observed whether there was declaration of conflict of interest for any proposals by EC members, adherence to SOP, quality of ethical review of research proposals, group dynamics, participation level of the non-medical EC members, documentation of minutes of the meeting.

Closing meeting: The report prepared by the survey team summarizing the strengths and weakness of the EC along with their recommendations pertaining to each of the 5 SIDCER recognition standards were presented by the survey coordinator in the closing meeting to all the EC members. Also, the survey team sent the survey report within 3 weeks of the survey to the FERCAP secretariat, who reviewed it and sent the final survey report to our EC.

After SIDCER survey: After receipt of the survey report from FERCAP, an EC meeting was organized to discuss the action plan for the survey recommendations. With effective inputs from all the EC members, a corrective action plan was prepared and sent to FERCAP office by e-mail within 30 days. The action plan contained the recommendations by survey team, corrective action taken/to be taken by our EC with the compliance date. After scrutiny, the FERCAP accepted the action plan and granted the SIDCER recognition in the FERCAP conference in Taiwan.

The details of the action taken by the EC are as follows:

Standard I-structure and composition: The SMVMCH EC had an adequate number of members with a dedicated Chairperson and Member Secretary. There were 15 EC members with two support staff. Its composition was diverse and multidisciplinary with 7 medical and 8 non-medical members. Also, it was balanced in terms of affiliation status with 8 affiliated and 7 non-affiliated members. However, the EC had male preponderance (male-11; female-4). Most of the members were trained in GCP and bioethics. The chairperson had a Postgraduate Diploma in Medical Ethics and Law, and two of the EC members had completed their Postgraduate Diploma in Bioethics.

As per the recommendations of the FERCAP, an organogram was made available and displayed in EC office. The committee was re-constituted with appointment of Vice Chairperson, Assistant Member Secretary and alternate members to ensure fulfilment of quorum requirements. It was also ensured that there was appropriate ratio of female members in the committee. A list of independent consultants or subject experts to assist the EC in evaluation of specific research proposals

was prepared. Adequate full-time staffs were appointed to assist in EC office work. Periodic trainings on SOP, GCP, bioethics for EC members and staff are being conducted. The COI declaration by the EC members is being documented in the EC meeting minutes. Thus, the structure and composition of the EC were strengthened following the survey.

Standard II-adherence to specific policies: The EC had functional SOPs, signed and dated by Member secretary and Chairperson. The SOP booklet had 50 pages and contained 12 SOPs with supporting forms and documents. It covered comprehensive chapters including major sections (structure and composition; initial review procedures; vulnerable population, post-approval procedures; expedited review, and documentation and archiving etc) and areas of review (initial review, follow up of research project) with National and International guidelines as references. Also, the SOPs including forms/checklists of SOPs were made available in office and college website.

As per the recommendations of FERCAP, recent versions of regulatory guidelines have been made available in EC office. The SOP was revised based on the model EC SOPs available from FERCI website, by the SOP sub-committee [6]. The revised SOP is a 283-page document consisting of title page, preface, preamble (consisting of vision, mission and history of SMVMCH-EC), names and signatures of members who prepared and approved the SOP, list of EC members, list of independent consultants, abbreviations, glossary of terms and 21 SOPs. Each SOP has annexure, flowchart and updated references (in accordance to the national and international guidelines) at the end of it. Also, the SOP is being updated periodically as and when required. In addition, the circulations of SOPs to EC members are being documented in a separate register.

Standard III - Completeness of its review process: It was inspiring to know that many of the good practices were noted by the survey team during their observation of the EC board meeting. The agenda of the meeting was prepared and followed. The Chairperson conducted the meeting and ensured that quorum requirement was fulfilled (12 out of the 15 EC members were present for the meeting). The chairperson elicited COI among EC members, for any of the proposals being reviewed in the meeting. The previous meeting minutes was reviewed and approved. The Principal investigators along with their guides (in case of undergraduate/postgraduate student's research proposal) presented their protocol. One primary reviewer was assigned for each proposal. There was good deliberation of scientific and ethical issues in each proposal. The comments of the EC members were summarized before taking the decision. The decision was taken by consensus. Most of the members including the non-medical members actively participated in the review process.

The following recommendations were provided by the survey team. The Agenda should be structured as per new studies, annual report, protocol deviations/violations, ratification of SAE, and expedited review. Before the recognition process, there was no practice of assigning a primary reviewer. However, in the EC meeting during the survey and thereafter, for each proposal submitted to the EC, a primary reviewer has been allocated to enhance the quality of the review process. Also, documentation of the review process by the primary reviewers with the help of proposal review forms have been implemented, which makes the review process highly transparent. Before the recognition process, all the proposals were reviewed in the full board meeting. Now, procedures for exempt from review and expedited review of proposals submitted to the EC has been established for rapid review and thus reducing the burden of the main committee. It was made sure that the PI and guide (in case of undergraduate/ postgraduate student's research proposal) were present in the meeting to clarify any issues and that they leave during EC deliberation and decision making process to avoid any conflict. Also, other investigators not involved in the project were not allowed to be present for the EC discussion. It was also ensured that EC approval was given only after determining that the proposal has been refined as per EC suggestion(s).

Standard IV-After review process: The good practice observed was that the meeting minutes had proper EC reference number and was signed by both chairperson and member secretary.

As per the survey team recommendations, the meeting minutes were made still more comprehensive and continued review (protocol amendments, protocol deviation/violation, SAE reporting, progress report and final report) including periodic site visits are being conducted. The EC also implemented measures for tracking of proposals and sending reminders to PI for submission of annual and final reports.

Standard V-Documentation and archiving: The existing good practices included a spacious EC office with sufficient rooms and equipments. The EC SOP and national and international ethical guidelines were available in the EC office for reference. The EC membership and training records were maintained. The protocol files were coded and kept locked. The college website has the EC SOP and forms for investigators to download. Also, a separate e-mail ID has been used for all EC activities.

With regard to the recommendations, the following corrective actions were taken. The computer in EC office has been protected with password to ensure confidentiality. A comprehensive database for classifying the protocols and tracking them for periodic monitoring has been created. The database has been made password protected with creation of adequate backup. Separate register for inward and outward documents of EC has been maintained. Also, a record of all telephone communications related to EC functions/complaints (available round the clock) has been established. An orderly filing system to ensure completeness of documents in the protocol files (version number and date) has been implemented. Mechanism to classify active from inactive files has been created.

Conclusion: Recognition/accreditation programs help an EC to upgrade the quality of its ethical review of research proposals and further strengthen the protection of research participants. It aids in identification of the weakness in the functioning of an EC and suggests remedial measures to strengthen the system. This in turn leads to better protection of human participants in biomedical research and also safeguards the investigators and sponsors in case of SAEs and in matters of compensation. Our EC has gained a lot from undergoing the SIDCER recognition process. It helped in capacity-building of our EC members, streamlining the functioning of our EC and aligning it with the National and International ethical standards. The accreditation has also enabled us in achieving a global recognition status for our EC and the Institution. The authors feel that sharing of our experiences in achieving the SIDCER recognition would aid the other ECs who are planning to undergo the process of SIDCER accreditation.

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