The Strategic Initiative for Developing Capacity in Ethical Review

SIDCER
Globalizing Ethics for Health Research

in collaboration with the

FERCAP

Forum for Ethical Review Committees in Asia and the Western Pacific Region

hereby renews recognition of the

Yenepoya Ethics Committee-1,
Yenepoya (Deemed to be University)
(Mangalore, India)

for its compliance with the
Declaration of Helsinki, International Council for Harmonisation (ICH) Guidelines, Good Clinical Practice (GCP) Standards, Council for International Organizations of Medical Sciences (CIOMS) Guidelines, World Health Organization (WHO) Standards and Operational Guidance for Ethics Review of Health-Related Research and Surveying and Evaluating Ethical Review Practices, EC/IRB Standard Operating Procedures (SOPs), and Local Regulations and Standards in Ethical Review

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The SIDCER-FERCAP Foundation

Promoting the development of human research ethics

SIDCER Recognition Program

About the Program

There has been widespread discussion on the conduct of biomedical research in developing countries in the past several years and much of the concern is focused on developing capacity for ethical review in these countries to ensure the rights and safety of persons and communities participating in clinical research. In recognition of the need for the international community to measure and provide accountability regarding the quality and effectiveness of ethical review worldwide, SIDCER has initiated the SIDCER Recognition Program. The objective of the Program is to survey and recognize the quality of EC/IRBs based on 5 Standards:

Standard I. STRUCTURE AND COMPOSITION OF THE ETHICS COMMITTEE
Structure, composition and skills of the EC/IRB and staff are appropriate to the amount and nature of research reviewed

Standard II: ADHERENCE TO SPECIFIC POLICIES
EC/IRB has appropriate management and operational procedures for optimal and systematic conduct of ethical review

Standard III: COMPLETENESS OF ITS REVIEW PROCESS
EC/IRB review protocols and its supporting documents in a timely fashion according to an established procedure to protect the interest of research participants

Standard IV: AFTER APPROVAL REVIEW PROCESS
EC/IRB should adequately and effectively communicate its decision to investigators as well as have a clear process for continuous review. Procedures for reviewing other after-protocol approval reviews should also be properly documented and followed.

Standard V: DOCUMENTATION AND ARCHIVING
EC/IRB systematically documents and archives its activities for a good time period

The survey will be conducted by qualified surveyors who have undergone a full training course delivered by SIDCER, using the SIDCER Recognition Tools: (1) Operational Guidelines for Ethics Committees That Review Biomedical Research (2000) by World Health Organization (WHO/TDR); (2) Surveying and Evaluating Ethical Review Practices (2002) by World Health Organization (WHO/TDR); (3) Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants (2011) by World Health Organization (WHO); (4) SIDCER Self-Assessment Tool; and (5) FERCAP Standard Operating Procedures (SOPs) for Ethics Committees (ECs)/Institutional Review Boards (IRBs).

The Assessment and Recognition Process

The assessment and recognition process will be carried out in 4 stages:

1. **SELF ASSESSMENT OF ETHICS COMMITTEE (EC/IRB)**
   An EC/IRB seeking recognition will make an application. A copy of the SIDCER Assessment Tool will be sent to and completed by the EC/IRB. The completed Assessment Tool will be reviewed to determine if the applicant is ready for a site visit (survey). If the tool reflects a need for improvements, written suggestions will be provided in preparation for the survey.
2. **SURVEY**
   An EC/IRB, having gone through the self-assessment, will then be surveyed for SIDCER recognition. The site Survey will be performed by Regional Forum surveyors (trained by SIDCER). The survey includes interviews, assessment of documents and procedures, observation of the facilities and observation of an

EC/IRB full committee meeting. The survey will be followed by a written report with a recommendation regarding recognition of the surveyed organization. Copies of relevant documents will be attached to the report.

3. **RECOGNITION**
   If the 5 standards are met, the EC/IRB will be recognized by the SIDCER and the respective regional fora, and a certificate of recognition will be issued to the EC/IRB. Recognition will be granted for an initial maximum period of three years. SIDCER and the respective regional fora will have the discretion of awarding recognition for a shorter period and can withdraw recognition at any time if it is established that recognition criteria are no longer being met. An EC/IRB with recognition pending is not entitled to a certificate.

4. **ANNUAL REPORTS**
   A recognized EC/IRB will be required to produce annual reports for review and monitoring by SIDCER and the respective regional fora. This should include all the relevant activities of the EC/IRB in the past year, any amendments to SOPs and guidelines and any new SOPs or guidelines that have been developed within the one year period and any changes in the administrative staff or procedures.

Categories of Recognition

There are various categories of recognition, depending on whether the survey was performed for a first time applicant or for an EC/IRB seeking renewal of recognition.

FIRST-TIME APPLICANTS

First-time applicants may be recognized under one of three categories, including "full recognition," "preliminary recognition," or "recognition pending."

1. **Full Recognition**
   A fully recognized EC/IRB meets all the standard requirements specified in the recognition requirement.

2. **Preliminary Recognition**
   An EC/IRB placed in this category meets a substantial amount of the standard requirements, but there are issues that require corrective actions. The EC/IRB will commit to addressing outstanding issues within a reasonable time period, to be determined in a case-by-case basis.
   If the corrective actions are completed within the specified time frame the EC/IRB will be upgraded to a full recognition.

If the EC/IRB is unable to address the outstanding issues within the specified time frame, the EC/IRB may submit a written request for an extension. The request should include a plan for completing the required corrective actions. The EC/IRB will be notified if the extension is granted. If the corrective actions are completed in the newly allotted time, the EC/IRB will be upgraded to full recognition.

If the EC/IRB does not address outstanding issues and does not submit a written request for additional time or if a request for additional time is denied, the EC/IRB will be downgraded to recognition pending.

Notification of upgrade or downgrade will be sent to the EC/IRB following the respective regional forum committee meeting where the change is noted.

3. **Recognition Pending**

   The EC/IRB in this category does not meet a substantial standard of the specified requirements. The EC/IRB may not be able to address the outstanding issues within a specified time frame. In this case the EC/IRB can reapply for recognition at its own discretion after it believes it has taken corrective action and is now ready for recognition.

RENEWING APPLICANTS

Five (5) months before the end of the 3-year recognition period, the EC/IRB will reapply and be revisited. Based on the outcome of the surveyor's re-visitation, SIDCER and the respective regional fora makes a decision on the renewal of recognition.

1. **Full Recognition**

   The EC/IRB continues to meet the entire required standard.

2. **Recognition Withdrawn**

   The earlier given recognition can be withdrawn when SIDCER and the respective regional fora believes that the EC/IRB no longer meets the criteria for preliminary recognition and demonstrates inability or unwillingness to take effective corrective actions.

3. **Re-Recognition Pending**

   An EC/IRB is placed in this category when it does not meet the criteria for full recognition, but is willing and able to take corrective measures to meet the criteria for full recognition within a specified time frame. Based on the corrective actions a full recognition will be given.

Specific Recognition Requirements for EC/IRBs

Generally an EC/IRB will be recognized based on the quality of the EC/IRB, its adherence to specific policies for ethical review, the completeness of its review process, the after review process and documentation.

1. STRUCTURE AND COMPOSITION

1.1 Membership Requirements

1.1.1. Members: at least 5

1.1.2. Gender: Balance

1.1.3. Experience and knowledge: balance in ethics, science and social science (alternatives to cover the topic of review should be in place)

1.1.4. Non-scientific or lay person

1.1.5. Non-affiliated person (independent of the institution/research site)

1.1.6. Terms and conditions of appointment, including policy and duration of appointment, disqualification, resignation and replacement procedures

1.2. Administrative Requirements

The EC/IRB should have:

1.2.1. Administrators that oversee the day-to-day activity of the EC/IRB;

1.2.2. Documentation of the functions and activities of the staff;

1.2.3. The Adequate number of administrative staff; and

1.2.4. Terms and conditions of appointments of members.

1.3. Membership Initial and Continuous Training

The provisions available for EC/IRB members to receive introductory as well as continuous education need to be stated and observed.

1.4. EC/IRB Office

The EC/IRB should have an office space with necessary equipments and staff for good functioning.

1.5. Management of Conflicts

EC/IRB should have a policy to address conflicts of interest and obligations.

2. ADHERENCE TO SPECIFIC POLICIES

2.1. Management of EC/IRB

The EC/IRB should document and make publicly available a term of reference, which should include its purpose, scope, objectives, activities, organization and management.

2.2. Availability of Standard Operating Procedures (SOPs)

The EC/IRB should have a written SOP with which they comply. The reasons for any non-compliance should be stated.

2.3. Areas and Functions Covered by the SOPs

The areas of review conducted by the EC/IRB should be covered by the SOPs. SOPs should include, but not be limited to:

- How to prepare SOPs,
- REC Framework and Composition,
- Management of Protocol,
- Initial Review: Exempt, Expedited, Full board
- Continuing Review,
- Board Meeting,
- Documentation Management, and
- Process of Site Visit

2.4. Continuous Review of SOPs

The SOPs should be reviewed at least every three years and revised as necessary. EC/IRB should indicate how often this is done and also document and archive copies of the previous versions.

2.5. Guideline for Protocol Submission

The EC/IRB should have a guideline aiding investigators on protocol submission. The guideline should include the requirements of the EC/IRB for the review of the different kinds of protocols. An informed consent document guideline/template should be made available.

2.6. Submission Process

EC/IRB should indicate to investigators when to submit a protocol so as to meet meeting deadlines. Applications by investigators for ethical approval should be made on standard application forms; EC/IRB should also have and make available these different application forms to researchers.

2.7. Meeting Requirements

The EC/IRB should have documented meeting requirements with which they comply. Included in this is the minimum number of members required per meeting, the professional requirements, and the distribution of the various professions.

3. COMPLETENESS OF ITS REVIEW PROCESS

3.1. Completeness of Protocol Sumitted for Review

EC/IRB should ensure the completeness of each protocol reviewed.

3.2. Review Process

Reviewers should be given enough time to review protocols and make comments. EC/IRB should have a documented and detailed review process with which they comply, for full committee and expedited reviews. They should also have and follow a process of establishing independent consultants that may provide special expertise on research protocols. EC/IRB should have a process to determine which protocols are exempt, reviewed expedited and what happens after expedited review and reviewed by a full board.

3.3. Elements of Review

The process and functions of members and staff in this process should be clearly indicated. EC/IRB should state clearly what elements they review in a protocol. Review element should include: value of research, scientific design and conduct, ethics (risk, benefit, informed consent documents and processes, care and selection of participants etc.).

3.4. Decision Making Process

In other for the EC/IRB to function fully they should have a procedure for decision-making and members should be free to participate fully in discussion, debate and voting where the need arises.

4. AFTER APPROVAL REVIEW PROCESS

4.1. Communicating Decision

EC/IRB should have an effective and timely way of communicating a decision. Where protocol approval was denied by the EC/IRB, reasons should be clearly stated. If provisional approval is given areas that need be re-worked should be clearly stated. EC/IRB should have and issue approval/disapproval letters with the conditions of approval or reasons

for disapproval clearly stated. The IRB should have and issue suspension/termination letters with the conditions of lifting suspension and the reasons for suspension or termination clearly stated.

4.2. Continuous and Protocol Amendment Review

EC/IRB should have a process of continuous review of projects based on its degree of risks (at least once per year). A list of documents including project report required for continuous review should also be made available for researchers. EC/IRB should specify the researcher is expected to submit reports and documents for continuous review and indicate in their SOP how such review should be conducted. The EC/IRB should also indicate to researchers that any amendment made on the protocol should not be implemented till it gets the EC/IRB approval; the EC/IRB should also have a process of reviewing amended protocols.

4.3. Other After-Protocol Approval Reviews

EC/IRB should document and follow procedures for reviewing other after-protocol approval reviews, such as site visit reports, Data Safety Monitoring Board progress reports, serious adverse event reports, termination of study reports, and end of study reports.

4.4. Completeness of EC/IRB Meeting Minutes

Minutes should be a complete record of all aspects of the meeting; including time allocated for review is important as this will reveal, among other things, how the EC/IRB functions, and its adherence to its stated procedures. Minutes should accurately reflect actions taken during the meeting and should also indicate which members were present when the actions were taken.

5. ARCHIVING

5.1. EC/IRB Documentation and Archiving

All protocols with a complete set of its supporting materials are maintained by the EC in a file or database till at least 3 years after the end of the study

All documentations on pertinent discussions and decisions on protocols and communication of the EC/IRB should be properly filed and archived for easy access.

All documents pertinent to effective function of the EC including its SOPs, constitutions, regular annual reports, national and international guidelines etc. should be properly kept.

A retrieval procedure should be indicated and complied with. The minimum period of archive should also be stated and complied with.

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