Standard Operating Procedure (SOP)
for Institutional Ethics Committee for Human Research
at Mount Carmel (Deemed to be University) Bengaluru

1. Objective

The objective of Standard Operating Procedure (SOP) is to ensure quality and consistency in review of clinical research proposals and to follow the ICMR and national ethical guidelines for biomedical research on human subjects.

2. About IHEC

IHEC will review and approve all types of research proposals involving human participants with a view to safeguard the dignity, rights, safety and well- being of all actual and potential research participants. The goals of research, however important, should never be permitted to override the health and well-being of the research subjects/participants. The IHEC will take care that all the cardinal principles of research ethics viz Autonomy, Beneficence, Non - malfeasance and Justice are taken care of in planning, conduct and reporting of the proposed research. For this purpose, it will look into the aspects of informed consent process, risk benefit ratio, distribution of burden and benefit and provisions for appropriate compensations wherever required. It will review the proposals before the start of the study as well as monitor the research throughout the study until and after completion of the study through appropriate well documented procedures, such as annual reports, final reports and site visits etc. The committee will also examine compliance with all regulatory requirements, applicable guidelines and laws. The mandate of the IHECs will be to review all research projects involving human subjects including human biological materials and human biological data to be conducted at the Institute, irrespective of the funding agency.

3. Composition of the IHECs

IHECs shall be multidisciplinary and multi-sectorial in composition. The number of members in the committee shall be kept small (7-11 members) as a large committee makes it difficult in reaching consensus and in having the presence of all the members.

The external members shall be in the majority to ensure the independence of the committee. The Chairperson of the Committee should preferably be from outside the Institution and not head of the same Institution to maintain the independence of the Committee. The Member Secretary who generally belongs to the same Institution, should conduct the business of the Committee. Other

members should be a mix of medical / non-medical, scientific and non-scientific persons including at least one representative of common man to reflect the differed viewpoints.

The composition is as follows:-

1. Chairperson
2. Basic medical scientists
3. Clinicians
4. Legal expert
5. Social scientist/representative of non-governmental voluntary agency
6. One philosopher / ethicist / theologian
7. One lay person from the community
8. Member-Secretary

4. Ethics Sub-Committee

All expedited approvals will be given in a meeting of the Sub-Committee of three members (nominated by the Chairman). All the three members, including the Member Secretary should be present for the meeting.

5. Membership Duration and Responsibilities

1. The duration of the membership will be 3 years

2. There will be no bar on the members serving for more than one term but it is desirable to have around one third fresh members.

3. A member can be replaced in the event of long-term non-availability (three consecutive meetings). The authority to replace the member shall be with the Director.

4. Members should maintain confidentiality of all discussions during the meeting and sign a confidentiality form at the start of their term. Each member of the committee will submit a declaration to maintain the confidentiality of the documents submitted to them during their membership period.

5. Conflict of interest if any shall be declared by members of the IHEC at the beginning of every meeting.

6. Institutional Human Ethics Committee (IHEC) Meetings

The Chairperson will conduct all meetings of the IHEC. The Member Secretary is responsible for organizing the meetings, maintaining the records and communicating with all concerned. He/she will prepare the minutes of the meetings and get it approved by the Chairman before communicating to the researchers with the approval of the appropriate authority.

7. Submission of application

1. All investigators are also responsible for implementing this SOP. The Principal Investigator has to submit an application (2 copies & soft copy) in a prescribed format (form A & B or A & C) along with study protocol and other related documents necessary for review of the IHEC.
2. All research proposals must be submitted in English language only.
3. Application can be submitted to the office of the Member Secretary, IHEC, Mount Carmel College, on any working day.
4. Ph.D. research – only registered candidates are eligible to apply.
5. Sponsored projects - Only approved projects are eligible for clearance by the committee.
6. However, a no objection letter for the purpose of seeking funds from various funding sources will be issued by the Sub-committee
7. All the proposals and documents must be submitted at least three weeks in advance from the scheduled date of the IHEC meeting.
8. Copies of informed consent form to be enclosed.
9. Incomplete applications will be rejected.

8. Review Procedure

1. Meetings of IHEC shall be held on scheduled intervals as prescribed (once in 6 months, for which the dates will be decided at the end of previous meeting).
2. Additional meetings will be held as and when necessary.
3. The proposals will be sent to members at least 2 weeks in advance.
4. Decisions will be taken by consensus after discussions
5. PI should be available during the meeting and may be invited to offer clarifications.
6. Independent consultants/Experts may be invited to offer their opinion on specific research proposals.

7. The decisions of the meeting shall be recorded in the minutes book and shall be confirmed during the next meeting with the signature of the Chairperson on each page.
8. A certificate of approval will be issued to the applicant. All the approvals will be valid for only 3 years or for the duration of the project, whichever is less. Investigator has to get his or her project re-approved after three years, if necessary.

9. Expedited Review

Proposals which are recommended for minor revisions will be reviewed by a sub-committee appointed by the IHEC for clearance and approved by the Chairperson. The approvals will be reported in the next IHEC meeting by Member Secretary. The revised form of proposals requiring major changes will be reviewed at the next ethics committee meeting. Rejected proposals may be reconsidered only if a very strong background is there.

10. Decision making

Members will discuss the various issues before arriving at a consensus decision. A member should withdraw from the meeting during the decision procedure concerning an application where a conflict of interest arises and this should be indicated to the chairperson prior to the review of the application and recorded in the Minutes. Decisions will be made only in meetings where the quorum is complete. Only members can make the decision. The expert consultants will only offer their opinions. The decision may be to approve, reject or revise the proposals. Specific suggestions for modifications and reasons for rejection should be given. In cases of conditional decisions, clear suggestions for revision and the procedure for having the application re-reviewed should be specified. Modified proposals may be reviewed by an expedited review through identified members.

11. Communicating the decision

The decision will be communicated by the Member Secretary in writing. Suggestions for modifications, if any, should be sent by IHEC. Reasons for rejection should be informed to the Researchers.

12. Record Keeping and Archiving

1. Curriculum Vitae (CV) of all members of IHEC.

2. Minutes of all meetings duly signed by the Chairperson. Copy of all correspondence with members, researchers and other regulatory bodies.

3. Copy of existing relevant national and international guidelines on research ethics and laws along with amendments.

4. All study related documents (study protocols with enclosed documents, progress reports, and SAEs.) should be archived for a minimum of ten years after the completion of study. A copy of the filled CRF shall remain with the PI for minimum of fifteen years.

5. Final report of the approved projects.

13. Updating IHEC Members

1. All relevant information on ethics will be brought to the attention of the members of IHEC by the Member Secretary.

2. Institute Members will be encouraged to attend national and international training programs/conferences/seminars in the field of research ethics to help in improving the quality of research protocols/ethics committee submissions and review.

For more details Contact:

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