MOTHERHOOD UNIVERSITY, ROORKEE

Institutional Clinical Ethics Committee

IEC-HANDBOOK

Vision

The SOP will ensure the quality and consistency in review of clinical research proposals and to follow the ICMR ethical guidelines for biomedical research on human subjects.

Activity

As per ICMR, the Ethical Committee should provide independent, competent and timely review of the ethics of proposed studies before the commencement of a study and regularly monitor the ongoing studies.

It will review and approve all research proposals involving human participants with a view to safeguard the rights, safety and well-being of research participants. The goals of research, however important, should never be permitted to override the health and well-being of the research subjects. It will look into the aspects of informed consent process, risk benefit ratio.

Application process

1. All proposals should be submitted in the prescribed application form, copies of which will be available with the Member Secretary.
2. All relevant documents should be enclosed with application.
3. The required number of copies of the proposal along with the application and documents in prescribed format duly signed by the PI and Co-investigators/Collaborators.
4. The Member Secretary will acknowledge the receipt and indicate any lacunae.
5. The date of meeting will be intimated to the PI who should be available to offer clarifications if necessary.
6. The decision of IEC will be communicated in writing. If revision is to be made, the revised document in required number of copies should be submitted within a stipulated period of time as specified in the communication.
7. PI/Co-PI/PhD student should apply through proper channel with covering letter mentioning the type of review requested for the submitted project.

Review Procedure

1. Meetings shall be held on scheduled intervals (once in 4 months, for which the dates will be decided at the end of previous meeting). Additional meetings will be held as and when necessary.
2. The proposals will be sent to members at least 2 weeks in advance.
3. Decisions will be taken by consensus after discussions, and voting will be done if necessary.
4. PI should be available during the meeting and may be invited to offer clarifications.
5. Independent Experts may be invited to offer their opinion on specific research proposals.
6. The decisions of the meeting shall be recorded in the minute's book and shall be confirmed during the next meeting with signature of Chairperson at each page.
7. All the applicants, whose proposal has been approved, need to submit annual progress report and completion report as per prescribed format.

A. Exemption from review

Proposals with less than minimal risk where there are no linked identifiers, for example; research conducted on data available in the public domain for systematic reviews or meta-analysis;

- Observation of public behaviour when information is recorded without any linked identifiers and disclosure would not harm the interests of the observed person;
- Quality control and quality assurance audits in the institution;
- Comparison of instructional techniques, curricula, or classroom management methods;
- Consumer acceptance studies related to taste and food quality; and
- Public health programmes by Govt agencies such as programme evaluation where the sole purpose of the exercise is refinement and improvement of the programme or monitoring (where there are no individual identifiers).

B. Expedited review

Proposals that pose no more than minimal risk may undergo expedited review, for example; research involving non-identifiable specimen and human tissue from sources like blood banks, tissue banks and left-over clinical samples; research involving clinical documentation materials that are non-identifiable (data, documents, records); modification or amendment to an approved protocol including administrative changes or correction of typographical errors and change in researcher(s);

- Revised proposals previously approved through expedited review, full review or continuing review of approved proposals;
- Minor deviations from originally approved research causing no risk or minimal risk;
- Progress/annual reports where there is no additional risk, for example activity limited to data analysis. Expedited review of SAEs/unexpected AEs will be conducted by SAE subcommittee; and

C. Full Review

All research presenting with more than minimal risk, proposals/ protocols which do not qualify for exempted or expedited review and projects that involve vulnerable population and special groups shall be subjected to full review by all the members. While reviewing the proposals, the following situations may be carefully assessed against the existing facilities at the research site for risk/benefit analysis:

Collection of blood samples by finger prick, heel prick, ear prick, or venipuncture:
Collection of data through noninvasive procedures routinely employed in clinical practice.
Research involving clinical materials (data, documents, records, or specimens) that will be collected solely for non-research (clinical) purposes.
research involving vulnerable populations, even if the risk is minimal;

- research with minor increase over minimal risk;
- studies involving deception of participants

- research proposals that have received exemption from review, or have undergone expedited review/undergone subcommittee review should be ratified by the full committee, which has the right to reverse/or modify any decision taken by the subcommittee or expedited committee;
- amendments of proposals/related documents (including but not limited to informed consent documents, investigator's brochure, advertisements, recruitment methods, etc.) involving an altered risk;
- major deviations and violations in the protocol;
- any new information that emerges during the course of the research for deciding whether or not to terminate the study in view of the altered benefit–risk assessment;
- research during emergencies and disasters either through an expedited review/ scheduled or unscheduled full committee meetings. This may be decided by Member Secretary depending on the urgency and need;

Element of Review

- ✓ Scientific design and conduct of the study.
- ✓ Assessment of predictable risks/harms and potential benefits.
- ✓ Procedure for selection of subjects including inclusion/exclusion, withdrawal criteria and other issues like sample size and advertisement details.
- ✓ Management of research related injuries, adverse events and compensation provisions.
- ✓ Availability of products to the trial subjects after the study, if applicable.
- ✓ Requirements of Patient information sheet
- ✓ Informed consent either verbal or written form in English/Bengali /Hindi and local language.
- ✓ Protection of privacy and confidentiality of subjects.
- ✓ Involvement of the community, wherever necessary.
- ✓ Plans for data analysis and reporting.
- ✓ Adherence to all regulatory requirements and applicable guidelines.
- ✓ Competence of investigators, research and supporting staff.
- ✓ Facilities and infrastructure.

Decision making

1. A member shall withdraw from the meeting during the decision procedure concerning an application where a conflict of interest arises. This shall be indicated to the chairperson prior to the review of the application and recorded in the minutes.
2. Only members will make the decision. The decisions shall be taken in the absence of investigators, representatives of sponsors, consultants.
3. Decision may be to approve, reject or revise the proposals. Specific suggestions for modifications and reasons for rejection should be given.
4. Revised proposals may be subjected to an expedited review.
5. All approved proposals will be subject to the following standard conditions.

Communicating the Decision

1. Decision will be communicated to PI by the Member Secretary in writing.
2. Suggestions for modifications and reasons for rejection shall be communicated to the PI.

Record keeping and archiving

1. Curriculum Vitae (CV) of all members of IEC.
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 minimum of ten years after the completion of study. A copy of filled CRF shall remain with the PI for minimum of fifteen years.

*** ** ***

Documentation

All research proposals should be submitted with the following documents:

Checklist for the required documents for EC review of the research project /proposal
1. Cover letter to the member secretary through proper channel mentioning type of review requested (Annexure A)
2. Prescribed application form (Annexure B)
3. Information sheet in English and local languages (Annexure C [Part I & Part II])
4. Consent document in English and local languages (Annexure D [Part I & Part II])
5. Case record form/ questionnaire
6. Synopsis of the study
7. One merged (point 2 to 6) soft .pdf copy submitted to the e-mail: icec@mhu.edu.in
8. Permission letter /endorsement letter from the organization involved in the study.
9. Declaration of undertaking as per prescribed format. (Annexure E)
10. Any other document as per applicable.
11. Two hard copies of the form should be submitted to the Member secretary, Institutional Clinical Ethics Committee (IEC). Dept, of Science, MHU.