



**UNIVERSITY OF MYSORE**



**Standard Operating Procedures (SOP)**

**For**

**Institutional Human Ethics Committee for Human Research**

## **About Institutional Human Ethics Committee (IHEC)**

The need for Institutional Ethics Committee (IECs) in medical and research establishments resulted from the realization that affirms **human rights** as a prerogative of all members of society. This has been emphasized under the Statement of General Principles in Biomedical research involving human participants ([http://icmr.nic.in/human\\_ethics.htm#Guidelines](http://icmr.nic.in/human_ethics.htm#Guidelines)) pertaining to precaution and risk minimization. It is mandatory that all proposals on biomedical research involving human participants should be cleared by an appropriately constituted Institutional Ethics Committee (IEC), also referred to as Institutional Review Board (IRB).

The University of Mysore, in accordance with the ICMR guidelines, has established such an Institutional Ethical Committee.

**Scope** – applicable to University of Mysore & other affiliated institutes/ colleges where there is no independent Human Ethics Committee.

## **RESPONSIBILITY**

The responsibilities of IHEC are :-

1. To protect the dignity, rights and well being of the potential research participants.
2. To ensure that universal ethical values and international scientific standards are expressed in terms of local community values and customs.
3. To assist in the development and the education of a research community responsive to local health care requirements.

The Chairman and Member Secretary are responsible for implementing these SOPs.

## **COMPOSITION OF IHEC**

IECs should be multidisciplinary and multisectorial in composition. Independence and competence are the two hallmarks of an IEC.

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. 1-2 basic medical scientists.
3. 1-2 clinicians from various Institutes
4. One legal expert or retired judge
5. One social scientist / representative of non-governmental voluntary agency
6. One philosopher / ethicist / theologian
7. One lay person from the community
8. Member-Secretary

**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.

### **IEC MEETINGS**

The Chairperson will conduct all meetings of the IEC. 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.

### **SUBMISSION OF APPLICATION**

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 .
- All research proposals must be submitted in English language only.
- Application can be submitted to the office of the Member Secretary, IHEC, UOM, Mysore on any working day.
- PhD research – only registered candidates are eligible to apply.
- Sponsored projects - Only approved projects are eligible for clearance by the committee. However, a no objection letter for the purpose of seeking funds from various funding sources will be issued by the Sub-committee
- All the proposals and documents must be submitted at least three weeks in advance from the scheduled date of IEC meeting.
- Copies of informed consent form to be enclosed.
- Incomplete applications will be rejected.

### **SCRUTINY OF PROPOSALS**

All members of IHEC are responsible for reviewing the proposals

- The Member-secretary or secretariat shall screen the proposals for their completeness and depending on the risk involved, categorize them into three types, namely, exemption from review, expedited review and full review.
- They will evaluate them on ethical issues, scientific soundness and technical excellence of the proposed research.
- All the Members will evaluate the possible risks to the study participants with proper justifications, the expected benefit and adequacy of documentation for ensuring privacy, confidentiality and justice issue.
- The IHEC review will be done through formal meetings and will not resort to decision through circulation of proposal. The investigators shall make a presentation before the committee.
- Expert opinion of additional members would be obtained, if necessary.
- A decision of the IHEC will be communicated to the applicant in writing, within 15 days of the meeting at which the decision was taken in the specified format.
- 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.

#### **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 quorum is complete.
- Only members can make the decision. The expert consultants will only offer their opinions.
- 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.

#### **COMMUNICATING THE DECISION**

- Decision will be communicated by the Member Secretary in writing.
- Suggestions for modifications, if any, should be sent by IEC.
- Reasons for rejection should be informed to the Researchers.

#### **FOR MORE DETAILS CONTACT:**

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