



KARNATAKA STATE OPEN UNIVERSITY
Mukthagangothri, Mysuru – 570 006



Standard Operating Procedures (SOP)

For

Institutional Human Ethics Committee for Human Research

INSTITUTIONAL HUMAN ETHICS COMMITTEE (IHEC)

Institutional Ethics Committee (IECs) in medical and research establishments resulted from the awareness that asserts human rights as a prerequisite of all members of society. It is mandatory, as per the Chapter II of the ICMR Ethical Guidelines for Clinical Research/Biomedical Research on Human Participants that all proposals be cleared by an appropriate the Institutional Human Ethics Committee in order to safeguard the welfare and the rights of the participants.

The IHEC is entrusted not only with the initial review of the proposed research protocols prior to initiation of the projects but also have a continuing responsibility of regular monitoring of the approved programmes to foresee the compliance of the ethics during the period of the project. The basic responsibility of the IHEC is to ensure a competent review of all ethical aspects of the project proposals received by it in an objective manner. IHEC will provide advice to the researchers on all aspects of the welfare and safety of the research participants after ensuring the scientific soundness of the proposed research through appropriate Technical Review Committee.

The Karnataka State Open University (KSOU), in accordance with the ICMR guidelines, has established such an Institutional Ethics Committee.

Scope – Applicable to KSOU & other collaborated institutes/ colleges where there is no independent Human Ethics Committee.

RESPONSIBILITY OF IHEC

1. To protect the dignity, rights and wellbeing 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.

COMPOSITION OF IHEC AT KSOU IN PAR WITH THE ICMR GUIDELINES ARE AS FOLLOWS

| Sl. No. | Members of EC | Proposed Members |
|----------------|-------------------------|---|
| 1 | Chairperson | Prof. Asna Urooj Professor Food Science and Nutrition Department, University of Mysore, Mysuru |
| 2 | Basic Medical Scientist | Dr. Nataraju Angaswamy Chairman, Biochemistry Department, Karnataka State Open University, Mysuru |
| 3 | Clinician | Dr. S. Chandrashekar Surgeon, Department of General Surgery, Mysore Medical College and Research Centre, Mysuru |
| 4 | Legal Expert | Dr. Janhavi S. Assistant Professor, Department of Political Science, Karnataka State Open University, Mysuru |
| 5 | Social Scientist | Dr. Shalvapillai Iyengar Chairperson, Ancient History and Archeology, Karnataka State Open University, Mysuru |
| 6 | Lay Person-1 | Deputy Registrar Dean Academic Section Karnataka State Open University, Mysuru |
| 7 | Lay Person-2 | Deputy Registrar General Section Karnataka State Open University, Mysuru |
| 8 | Member Secretary | Dr. Hemalatha M.S. Chairperson, Food Science and Nutrition Department, Karnataka State Open University, Mysuru |

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 Research investigators are also responsible for implementing this SOP.

- The Principal Investigator has to submit an application (2 hard copies & soft copy) in a prescribed format whichever is applicable provided 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, KSOU, 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.
- 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 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 ethics 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 earlier. 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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Member Secretary, IHEC

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