

Institutional Ethics Committee (IEC) Policy



**Directorate of Research and Innovation
Uttarakhand Open University
Haldwani-263 139, Uttarakhand, India**

Approved by the Executive Council at its 45th Meeting held on 13th March 2026

1. Introduction

Research Ethics refers to moral principles and actions guiding and shaping research from inception through to completion, the dissemination of findings and the archiving, future use, sharing and linking of data. While research ethics has a long history, originating with medical ethics and then extending to other forms of research with humans, it also has a history of evolution and development. Research ethics in the social sciences initially drew on the 'patient protection' model of medical research but has more recently broadened in scope to cover all areas of research and include consideration of benefits, risk and harms to all persons connected with and affected by research, as well as the broader responsibilities of researchers to publics and society (Ethics principles for research with human participants)¹.

1. (<https://ethics.ncdirindia.org/asset/pdf/ICMRNationalEthicalGuidelines.pdf>, last accessed on 2/2/2026). This SOP will help researchers to design their protocol in a scientific manner and members of IEC to adopt a scientific approach when reviewing the protocols for ethical issues. In this background Uttarakhand Open University, Haldwani hereby establishes an Institutional Ethics Committee in compliance with several regulatory bodies' rules.

2. Scope

The Institutional Ethics Committee (IEC) shall examine and address ethical issues arising from research studies conducted by registered Ph.D. students of the University, based on the recommendations of the respective Research Degree Committees (RDCs) and research proposals submitted by researchers for IEC approval.

3. Aim

The following represents aim of the Institutional Ethical Committee (IEC);

- i) To protect the dignity, rights and wellbeing of the potential research participants.
- ii) To ensure that universal ethical values and international scientific standards are expressed in terms of local community values and customs.
- iii) To review the research proposals involving human subjects to ensure that rights are protected according to international, national and local guidelines as well as to monitor

the progress of the study till the end so that human rights are not violated at any point of time during research.

4. IEC Meetings

The process for Ethical Clearance of the Ph.D topic/ Research Proposal should be initiated as and when the proposal is received from the school (s) and completed at the earliest but not later than 30 days in each case. Accordingly, the Member Secretary will initiate the meeting in consultation with the Chairperson. The Member Secretary will prepare the minutes of the meetings and circulate the same to the members for their consent. After receiving the consent from the members, the Member Secretary shall place it for approval of the Chairperson. The approved Minutes of Meeting will be issued by the Member Secretary.

5. **Procedure:**The RDC shall decide the need of the ethical clearance for the Ph.D topic/Research Proposal. In case the Ph.D. topic/title requires ethical clearance, the proposal along with the name of Co supervisor(s), (External Expert), if required, depending upon the area of topic, proposed by the Ph.D. Programme Coordinator/Principal Investigator should be forwarded through the Director of the concerned School to obtain approval of the Vice Chancellor before forwarding to Directorate of Research and Innovation for placing it at IEC. In the case of Ph.D. research proposals, the research scholar and the proposed Research Supervisor/Co-Supervisor, and in the case of other research projects, the Principal Investigator and Co-Investigator(s), shall be required to be present in person for presentation before the Institutional Ethics Committee (IEC), as and when called. IEC will follow the guidelines of the respective regulatory bodies of various disciplines for reviewing the proposals as per the requirement.

6. Decision-Making by the IEC

- i. The Committee will discuss the ethical issues involved in the research proposal to arrive at a consensus. In case no consensus is reached, the decision will be made by voting.
- ii. 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.

- iii. Decisions will be made only in meetings where quorum is complete.
- iv. Only members can make a decision. The proposed research supervisor will not be a part of decision making.
- v. Decisions may be made only with regard to the ethical aspects of the proposals. Suggestions for modifications (if any) or reasons for rejection on ethical grounds will be recorded and provided to the Ph.D. student within a week of the meeting. In case of modifications suggested, the modified proposal shall be submitted later by the research scholar within a maximum period of 15 days from the date of issue of the recorded suggestions. The modified / revised synopsis will be reviewed by the IEC with the same external members.

7. Role and Responsibility of Institutional Ethical Committee (IEC)

- i. The basic responsibility of an Institutional Ethical Committee (IEC) is to ensure protection of the dignity, rights and well-being of the research participants and therefore members should be aware of local, social and cultural norms and emerging ethical issues.
- ii. The IEC must ensure ethical conduct of research by the Scholars.
- iii. The IEC is responsible for declaration of conflicts of interest to the chairperson, if any, at each meeting and ensuring these are recorded in the minutes.
- iv. The IEC should perform its function competent initial and continuing review of all scientific, ethical, medical and social aspects of research proposals received by it in an objective, timely and independent manner by attending meetings, participation in discussion and deliberations.
- v. The IEC must ensure that universal ethical values and international scientific standards are followed in terms of local community values and customs.
- vi. The IEC should ensure that privacy of the individual and confidentiality of data including the documents of EC meetings is protected.

8. Composition of an IEC

The composition, affiliations, qualifications and roles and responsibilities of members are:

Table 1 Composition, affiliations, qualifications, member specific roles and responsibilities of an IEC

S.N.	Members of E.C		Definition/Description
1.	Chairperson	External Expert Nominated by the Hon'ble Vice Chancellor	<ul style="list-style-type: none"> • Conduct IEC meetings and be accountable for independent and efficient conduct. • Ensure active participation of all members(particularly non-affiliated, non-medical/ non- technical) in all discussions and deliberate • Ratify minutes of the previous meetings. • In case of anticipated absence of both chairperson at a planned meeting, the Chairperson should nominate a committee member as Acting Chairperson or the members present may elect an Acting Chairperson on the day of the meeting. • Seek Conflict of Interest (COI) declaration from members and ensure quorum and fair decision making. • Handle complaints against researchers, IEC members, conflict of interest issues and requests for use of IEC data, etc.
2.	Members	Five Internal Members, 02 Directors 01Associate Director 02 Assistant Professor Nominated by the Hon'ble Vice Chancellor	Evaluate and provide recommendations on research proposals submitted by registered students and faculty of the University to ensure compliance with ethical standards.
3.	Member Secretary	Director, Research and Innovation /	<ul style="list-style-type: none"> • Organize an effective and efficient procedure for receiving, preparing,

	/Alternate Member Secretary Affiliated	Additional Director, Research and Innovation	<p>circulating and maintaining each proposal for review</p> <ul style="list-style-type: none"> • Schedule IEC meetings, prepare the agenda and minutes • Organize EC documentation, communication and archiving • Ensure training of IEC members • Ensure SOPs are updated as and when required • Ensure adherence of EC functioning to the SOPs • Ensure completeness of documentation at the time of receipt and timely inclusion in agenda for IEC review. • Assess the need for expedited review/exemption from review or full review.
4.	<p>Research Expert/ Social Scientist Non Affiliated(External Expert not associated with UOU)</p> <p>Minimum 10 years of teaching and/or research experience</p> <p>Demonstrated experience in: Research methodology (quantitative, qualitative, mixed methods)</p>	Nominated by the Hon'ble Vice Chancellor	<p>Familiarity with:</p> <p>Ethical issues in research</p> <p>UGC / ICMR /national & international ethical guidelines</p> <p>Ethical Review of Research Proposals</p> <p>Evaluating research designs involving:</p> <ul style="list-style-type: none"> • Surveys, interviews, focus groups, case studies • Behavioral, educational, and management research • Community-based and participatory research <p>Assessing scientific merit vis-à-vis ethical soundness</p> <ul style="list-style-type: none"> • Reviewing: • Sampling techniques • Data collection tools • Research design <p>Research involving:</p> <ul style="list-style-type: none"> • Vulnerable groups (women, children, elderly, marginalized communities)

	Supervision of Ph.D./M.Phil. scholars Publication in peer-reviewed journals		<ul style="list-style-type: none"> • Sensitive topics (income, health, caste, religion, behavior) • Assess impact on community involvement, socio-cultural context
5.	<p>Medical Expert Demonstrated experience in clinical research, public health research, or biomedical research, as applicable. Minimum 3 years of professional experience in medical practice, teaching, research, or clinical administration. External Expert not associated with UOU)</p>	Nominated by the Hon'ble Vice Chancellor	<ul style="list-style-type: none"> • Provide expert guidance on medical, clinical, and health-related aspects of research proposals. • Review medical care, facility and appropriateness of the principal investigator, provision for medical care management and compensation. • Offer expert opinion on research involving vulnerable populations from a health and welfare standpoint. Assist the IEC in monitoring approved studies for medical or safety-related concerns.

6.	Legal Expert Affiliated/ non-affiliated Qualifications- • Should have a basic degree in Law from a recognized university, with experience (Internal Expert/External Expert)		Interpret and inform IEC members about new regulations, if any Examine research proposals to ensure compliance with applicable laws, statutory provisions, and regulatory frameworks, including those related to data protection, privacy, intellectual property rights, and participant consent.
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The quorum should be as specified in Box 1.

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| <ol style="list-style-type: none"> 1. A minimum of five members present in the meeting room. 2. A minimum of 2 members from the internal committee. 3. The quorum should include the presence of a medical expert. 4. No decision is valid without fulfilment of the quorum. |
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The IEC can also have a set of alternate members for Legal Expert and Medical expert who can be invited as members with decision-making powers to meet the quorum requirements. Only in case of special circumstances, such members shall have the same Terms of Reference (ToRs) as regular members and may attend meetings in place of regular members in their absence.

The IEC can maintain a panel of subject experts who are consulted for their subject expertise, if any requirement is noticed. They may be invited to attend the meeting to give an expert opinion on a specific proposal but will only give his/her opinion or advice. However, permission for the same shall be required from the Hon'ble Vice-Chancellor.

9. Terms of reference for IEC members

- i. The Hon'ble Vice Chancellor shall appoint all IEC members.
- ii. The tenure of the IEC members (including external members) is for three years.
- iii. The appointment letter issued to all members should specify the Term of Reference. The letter issued by the Chairperson after due approval from the Vice Chancellor should include, at the minimum, the following:
 - Role and responsibility of the member in the committee
 - Duration of appointment
 - Conditions of appointment
- iv. Honorarium to external members shall be made in the accordance with university norms.
- v. External Experts shall provide their acceptance in writing, either through email or through a duly signed acceptance letter.

10. Convention and Conduct of IEC meetings

The Chairperson will conduct all meetings of the Uttarakhand Open University-IEC. In the absence of the Chairperson an alternate Chairperson will be elected from the other members on the day of meeting (or Chairperson should nominate a committee member as Acting Chairperson for that meeting) by the members present, who will conduct the meeting. The alternate or acting chairperson should have the powers of the chair person and should be a non-affiliated person. The Member Secretary is responsible for organizing the meetings, maintaining the records and communicating with all concerned. The Member Secretary will prepare the minutes of the meetings and get it approved by the Chairperson and all the members. In the absence of Member Secretary alternate Member Secretary among the members, will organize the IEC meeting.

All proposals will be received at least 3 weeks before the meeting and after initial scrutiny by the Member Secretary the proposals will be circulated to the IEC members.

The recommendations by the IEC will be communicated to all the PIs and guides/HODs in case of student's proposals. If required additional review meetings can also be conducted with a short notice period.

11. Details of Documents to be submitted for IEC review

The following documents should be placed before the IEC Committee;

- i. Cover letter to the Member Secretary (Annexure 1)

- ii. Application form for initial review (Annexure 2)
- iii. Brief CV of all Investigators (Annexure 3)
- iv. Copy of the detailed proposal (Annexure 4)
- v. Participant/ Respondents information sheet (Annexure 5)
- vi. Informed Consent Form (English/s Hindi) (Annexure 6&7)
- vii. Performa/Questionnaire / Case Report Forms (CRF)/ Interview guide Focused Group Discussions (FGDs) / Structured Interview Schedule etc.

12. Administration and Management

- i. Directorate of Research and innovation will serve as secretariat for the IEC for maintaining safe archival of records and conduct of meetings.
- ii. The Research Officer shall assist the IEC Member Secretary in carrying out the functions of the Institutional Ethics Committee, including maintaining records and documentation, coordinating meetings, facilitating communication with researchers, processing proposals, and supporting other administrative and operational activities of the IEC.
- iii. An expedited review shall be conducted by the committee members designated by the Chairperson, in consultation with the Member Secretary, after payment of the fee as prescribed by the University.
- iv. The Member Secretary would communicate the decision in writing to the Principal Investigator/ Research Supervisor in prescribed format.

13. Procedure for Documentation and Archiving of Documents

- i. All documents, communication of IEC will be dated, filed and achieved in a secure place.
- ii. Only persons who are authorized by the chairman of IEC will have access to various documents.
- iii. All documents will be archived for a minimum period of three years in the University following completion or termination of project.
- iv. All the agenda and minutes of the meeting will be filed and archived.

14. Review of Proposals from External Research Scholars

External research scholars/ External Principal, Investigator shall submit their research proposals to the Institutional Ethics Committee (IEC) through the prescribed format and along with all necessary documents, including consent forms, protocols, and supporting

approvals from their home institution, if applicable within the specific time frame. The research scholar and the proposed Research Supervisor/Co-Supervisor shall be available in person or via authorized hybrid/online mode for presentation before the IEC, as scheduled by the Committee. Once approved, the research scholar shall also submit the final research proposal or thesis to the IEC/University within the prescribed timeline, ensuring compliance with all ethical, procedural, and regulatory requirements. Payment to all IEC members, whether internal or external, for attending meetings, reviewing research proposals, or participating in expedited reviews, shall be made as per the University-prescribed sitting fee and norms.

All expenditures, including those incurred for the organization and conduct of the meeting, shall be the responsibility of the respective Research Scholar or Principal Investigator not associated with the University.

UTTARAKHAND OPEN UNIVERSITY

Directorate of Research and Innovation

INSTITUTIONAL ETHICS COMMITTEE (IEC)

APPLICATION FORM FOR PH.D. STUDENTS/ RESEARCHES FOR OBTAINING PERMISSION TO STUDY ON HUMAN SUBJECTS

1. Ph.D. Title/ Research Proposal Title:
2. Name of Ph.D. Student:
3. Name of Supervisor (s):
4. Department:
5. School:
6. Type of Study:
7. Duration of the study:
8. Probable date of initiation: Completion:
9. Pre-clinical studies done, if any:(in brief)
10. Publications, if any (attach the list) :
11. Study design:
[Brief description of the proposal – Introduction, aim (s) & objectives, justification for study, methodology describing number of subjects, Inclusion / exclusion criteria, duration of treatment, potential risks & benefits, outcome measures, statistical analysis and whether it is of national significance with rationale].
12. Detail of Intervention Studies
13. Detail of Informed Consent
14. Social Risks and Benefits
15. Data Collection Requirement
16. Data Management
17. Does the study involve;
(a) Anthropometric Measurements: Yes / No

- (b) Blood Samples:** Yes / No
- (c) Urine Analysis:** Yes / No
- (d) Lifestyle Modification:** Yes / No
- (e) Dietary Assessment / Nutritional Evaluation:** Yes / No
- (f) Clinical / Physical Examination:** Yes / No
- (g) Yoga / Physical Exercise Intervention:** Yes / No
- (h) Psychological / Behavioural Assessment:** Yes / No
- (i) Collection of Biological Samples :** Yes / No
- (j) Use of Medical Devices / Monitoring Instruments:** Yes / No
- (k) Radiological / Imaging Procedures (if any):** Yes / No
- (l) Use of Biological / Hazardous Material:** Yes / No
- (m) Drug / Supplement / Therapeutic Intervention:** Yes / No
- (n) Any Other Procedure (Specify):** _____ :

18. Data Monitoring

19. Is there any conflict of interest?

20. Details of Funding

(Signature / Name of the Research Supervisor/ Principal Investigator)

Official Stamp

Forwarded by the Director of the School

Note: It is compulsory to provide all the required information, incomplete applications will be rejected.

Cover Letter

To

Dated.....

The Member Secretary

Institutional Ethics Committee

Uttarakhand Open University, Haldwani

Sub: Submission of research proposal for ethical approval

Sir/ Ma'am

A research proposal is enclosed with this letter for your approval titled

“ _____ ” and

required information is made available with the proposal.

I am hopeful of getting your approval to do this research work.

Thank you

Name of Researcher: _____

Signature: _____

Designation & Department: _____

Acknowledgement Letter

IEC has received research proposal
entitled.....
.....
.....
for placing the same for IEC

Member Secretary

Ethics Committee Approval Certificate

INSTITUTIONAL ETHICS COMMITTEE (IEC)

Uttarakhand Open University

Ref.No.: _____

Date: _____

This is to certify that the Institutional Ethics Committee (IEC) of **UOU** has reviewed and approved the research proposal entitled:

“.....
.....”

submitted by **Mr./Ms./Dr.** _____,

Designation/Affiliation: _____,

Department/Institution: _____.

The proposal was reviewed in the IEC meeting held on _____ (**date**). The Committee has found the study to be ethically acceptable subject to adherence to the approved protocol and guidelines issued by the Institutional Ethics Committee.

- a) Any deviation, modification, or amendment in the research protocol must be reported to and approved by the IEC prior to implementation.
- b) The researcher shall also submit periodic progress reports and a final report upon completion of the study.

This approval is granted for research purposes only.

Member Secretary