Institutional Ethics Committee (IEC)
Standard Operating Procedure (SOP)

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1. Introduction

The need for Institutional Ethics Committee (IECs) in health, social and behavioral research studies 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 research involving human participants pertaining to precaution and risk minimization. Accordingly, Indira Gandhi National Open University (IGNOU), New Delhi, in accordance with the guidelines of different Regulatory Bodies, has established an Institutional Ethics Committee.

2. Institutional Ethics Committee (IEC)

1. The Institutional Ethics Committee shall be multidisciplinary and multi sectoral in nature.
2. It shall comprise internal and external members from various fields nominated by the Vice Chancellor.
3. One of the internal members shall be the Chairperson nominated by the Vice Chancellor and the Director, Research Unit shall be the convenor.
4. The tenure of the Committee shall be for a period of three years.

The composition of the IEC shall be as under:

- One Director of School -Chairperson (Nominated by VC)
- Two internal members from various fields - Members (Nominated by VC)
- One External Member - Member (Nominated by VC)
- Director, Research Unit – Member Convenor (Ex-officio)

3. Standard Operating Procedure (SOP)

The Research Council at its 31st Meeting held on 15.11.2022 approved the SOP in principle and recommended to include more experts making the IEC multi-sectoral.

4. **Scope:** The IEC shall deal with the Ethical issues involved in the research studies of all registered research scholars of IGNOU as per the recommendations of their DRCs/ SBs.

5. **IEC Meetings:** The Chairperson of IEC will conduct all meetings of the IEC. The Member Secretary/ Convener 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 Chairperson before communicating to the researchers.

6. **Expert Committee for Ethical Clearance (EEC):** The Institutional Ethics Committee in its second meeting held on 17.5.2023 decided to have a discipline / area specific expert committee on case-to-case basis.

A) Composition of ECC:

The composition of the committee shall be as under:

1. For disciplines/proposals covered under different Regulatory Bodies like ICMR, Animal Committee of Govt. of India etc, the Chairperson of the expert committee shall be external / non- affiliated to the organization / institution
2. For disciplines/proposals not covered under the above-mentioned Statutory Bodies, Director of the Schools (in case of disciplines like Hindi, English, Economics etc not covered under any specific Regulatory Body) shall be the Chairperson of the Expert Committee.
3. Two or three external experts in the respective fields related to the research area proposed by the Research Supervisor.
4. Concerned Research Supervisor of the PhD Scholar.
5. Any other internal faculty members related to the area of study recommended by the Supervisor (Gender specialist, Legal Expert, Social Scientist and members from the Community as per requirement etc.)
6. The research scholar.
7. Member Secretary (IEC)

B) Procedure to be followed for the clearance by ECC:

1. The PhD scholar will submit the research proposal approved by the DRC with all the required annexures along with covering letter to the Research Supervisor. Research Supervisor with the list of proposed external experts will forward the research proposal to the Director of the School. The Director of the School shall forward the proposal to the Research Unit. The Research Unit shall examine the proposal and if proposal is in order, obtain the approval of the Chairperson of IEC and communicate the approval of the Chairperson to the Director of the concerned School for further necessary action.
2. A PhD scholar will present the proposal before the Expert Committee for Ethical Approval.

3. Expert Committee for Ethical Approval will follow the guidelines of the regulatory bodies for reviewing the proposals.
4. Expert Committee for Ethical Approval with its decision duly signed by the Chairperson of the Expert Committee will submit the report to the Research Unit.
5. Research Unit will place the proposal before the IEC for its approval.
6. In case required, the IEC may call a PhD scholar for clarification on his / her research proposal.
7. The decision of IEC shall be communicated to the concerned School and PhD scholar by the Member Secretary.

C) Decision-Making procedure of IEC:

1. Members of IEC will discuss the various issues involved in the Research proposal before arriving at a consensus.
2. When consensus is not arrived, at the decision will be made by voting procedure.
3. 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.
4. Decision will be made only in meetings where quorum is complete.
5. Only members can make the decision. The expert or Supervisor will not be a part of decision.
6. Decision may be to approve, reject or revise the proposals. Specific suggestions for modifications and reasons for modifications and reasons for rejection will be given.
7. In cases of conditional decisions, clear suggestions for revision and the procedure for having the application revised will be specified.
8. Modified proposals will be reviewed by an expedited review through identified members.
9. Procedures for appeal by the researchers will be clearly defined.

D) Procedure for communicating the Decision of IEC:

1. Decision of the meeting on the proposals will be communicated by the Member Secretary of IEC in writing to the Research Scholar within 10 working days after the meeting. Scholar must get his or her proposal reapproved after any change in methodology.

2. The communication of the decision will include:

a. Name and address of IEC

b. The date, place and time of decision

c. The name and designation of the applicant

d. Title of the research proposal reviewed

e. Clear identification of protocol no., version no., date

f. Protocol, other documents reviewed- Clear description of these documents

g. List of EC members who attended the meeting- clear description of their role, affiliation and gender

h. Clear statement of decision reached

i. Any advice by the EC to the applicant

j.In case of conditional decision, any requirement by EEC, including suggestions for revision, and the procedure for having the application re-reviewed

k. In case of rejection of the proposal, reason(s) for the rejection will be clearly stated.

l. Signature of the Chairperson of EC with date

7. Roles and Responsibilities:

A. Responsibilities of PhD Scholar: The PhD scholar will submit hard and soft copies of the research proposal along with the approval of the DRC, Informed Consent, draft tools and PPT with all the required annexures along with the covering letter to his / her research supervisor.

B. Responsibilities of Supervisor: The Research Supervisor with the list of proposed external experts of EEC, proposed budget for convening the meeting will forward the research proposal with annexures related to SOP/Informed consent, tools to the Director of the School.

C. Responsibilities of the Director of the School: The Director of the School will forward the proposal with annexures, list of experts, budget, date of approval of the competent authority to the Research Unit.

D. Responsibilities of Research Unit:

- Research Unit will verify the list of Expert Committee of the School for Ethical Approval in accordance with the guidelines of the regulatory bodies for reviewing the proposals and forward it to the Chairperson of IEC for approval.

- After getting approval from IEC Chairperson, RU will intimate the School to constitute an Expert Committee Meeting and to invite the members of the EC .

- Director, Research Unit will attend the expert committee meeting in the capacity of convenor of the IEC.

E. **Responsibilities of IEC:** The responsibilities of IEC are :-

- To protect the dignity, rights and well being of the potential research participants.
- To ensure that universal ethical values and international scientific standards are expressed in terms of local community values and customs.
- To assist in the development and the education of a research community responsive to local health care requirements. The Chairperson and Member Secretary/Convener are responsible for implementing these SOPs.
- Accord approval to form EEC and approve the list of experts of ECC.
- To consider the recommendations of the EEC and approve the Minutes of EEC.
- The convener of IEC will place the recommendations of the IEC before the Chairperson of IEC for issuance of Ethical Clearance Certificate.

Note: **After ethical clearance there will be no change in topic or title of thesis. In case of Change of Topic by Expert Committee for Ethical Clearance/Approval,** all the statutory approvals like DRC, SB and RC / RCSC to be sought again for the Ethical Clearance/Approval.

8. Procedure to place the research proposal for re-approval:

a. To be initiated by the Supervisor to Programme Coordinator and Director of the School for DRC with revised Proposal, Tools, SOPs/Informed Consent
b. Scholar will present the proposal for approval of DRC.
c. Thereafter, approval of the School Board will be sought.
d. Proposal with minutes and agenda to be submitted to RC/RCSC for approval of change in the topic.
e. On the recommendations of ECC and IEC, issuance of Ethical Clearance Certificate (ECC) by Chairperson, IEC, IGNOU

9. Annexures

Annexure – 1.1

INDIRA GANDHI NATIONAL OPEN UNIVERSITY
RESEARCH UNIT
INSTITUTIONAL HUMAN ETHICAL COMMITTEE (IHEC)
FORM – A

APPLICATION FOR PHD STUDENTS FOR OBTAINING PERMISSION TO STUDY ON HUMAN SUBJECTS

1. Title:

2. Submitted by (Name of Research Scholar)

3. Name of Supervisors

4. School

5. Sponsor if any

6. Type of Study : Epidemiological ☐ Basic Sciences ☐ Survey ☐

(a) Clinical : Single centric ☐ Multicentric ☐ Behavioral ☐

(b) Data Collection: From Records ☐ Questionnaire ☐

(c) Any other, specify:

7. Duration of the study :

8. Probable date of initiation : Completion :

9. Pre-clinical studies done, if any : (in brief)

10. Publications, if any :

11. **Study design**

[Brief description of the proposal – Introduction, aim (s) & objectives, justification for study, methodology describing number of subjects, Inclusion / exclusion criteria, dosages of drug, duration of treatment, potential risks & benefits, outcome measures, statistical analysis and whether it is of national significance with rationale. Attach sheet with maximum 500 words.]

7. Will any advertising be done for recruitment of Subjects? (posters, flyers, brochure, websites – if so kindly attach a copy)

8. 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) Other (specify).
(f)

If answer is Yes to (b) & (c) mention the tests

9. **Intervention Studies**- Oral

(a) Product evaluation : Yes / No
(b) Dietary : Yes / No
(c) Synthetic : Yes / No
If Yes, is toxicological evaluation carried out.
(d) Known medication : Yes / No

If yes, give a brief summary of dosage, administration, Contra indications (if any)

10. Use of biological/hazardous material : Yes No
(If the answer is Yes, give details)

11. **Informed Consent :** Written Oral
i. Subject consent form - enclose

ii. Who will obtain consent ? PI/Co-PI ☐ Nurse/Counsellor Any other ☐
Research staff

12. Risks & Benefits:

i. Is the risk reasonable compared to the anticipated benefits to subjects / community / country? Yes No

ii. Is there physical / social / psychological risk / discomfort? Yes No

iii.iii.Is there a benefit

a) to the subject ? Direct Indirect
b) Benefit to society Direct Indirect
c) if yes, explain

13. i. Are the subjects remunerated for their involvement in the research?
YES No

ii. If yes, is this remuneration provided irrespective of their social and economic conditions?

iii. Compensation for travel, Specify amount and type:

14. Data Collection Requirement (Brief) if required attach separate sheet

15. Data Management (Brief) if required attach separate sheet

16. Data Monitoring

i. Is there a data & safety monitoring committee

ii. Is there a plan for reporting of adverse events ?

If Yes, reporting is done to :

Sponser ☐

Ethics Committee ☐

15 Is there any conflict of interest?

(financial / non-financial) If Yes, specifiy :

(Signature, Name of the Applicant)

(Signature / Name of the Research Supervisor)

Official Stamp forwarded by the Director of the School

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

INDIRA GANDHI NATIONAL OPEN UNIVERSITY

RESEARCHUNIT

INSTITUTIONAL HUMAN ETHICAL COMMITTEE

(IHEC)

FORM - B

APPLICATION FOR SPONSORED PROJECTS FOR OBTAINING PERMISSION TO STUDY ON HUMAN SUBJECTS

	Name & Designation /Qualification	Address Tel & Fax no Email	Signature
Name of PI/			
Co-PI, if any			
Research fellow (if any)			
Place where study will be conducted			
Date of commencement& duration of Study			
Funding agency / sponsor			

Investigator's Declaration

Certified that

1. The research proposal is not duplicative of previously reported research
2. All investigators working on this proposal are aware of the ICMR ethical guidelines
3. I / we have reviewed the pertinent scientific literature
4. I/we will obtain approval from IEC before initiating any deviation/changes in the study
5. The study shall be initiated only upon review & approval of IEC
6. I /we shall maintain all the records as per format
7. Informed consent will be obtained & confidentiality of the subjects will be maintained

Place:
Date

Principal Investigator

For Office use only

Proposal number
Date of receipt | Date received after revision
Approval date | Expiry date

Secretary / convener | Chairman

Annexure – 1.3

Informed consent Form (template)

FORM-C

(may be typed on plain sheet and may be translated to Hindi and other regional languages, if required)

Study Title: _____

Study number: _____

Subject initials: _____

Age: _____

Subject Name: _____

I confirm that I have read and understood the information sheet dated _____ for the above study. I have had the opportunity to ask questions and all the questions were answered to my satisfaction. I understand that my participation in the study is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. I understand that the investigator and the ethics committee will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However I understand that my identity will not be revealed in any information released to third parties or published. I agree not to restrict the use of any data or results that arise from this study provided that such a use is only for scientific purpose.

I agree to take part in the above study.

Signature (or thumb impression) of the subject_____

Date: _____

Signatory name: _____

Signature of the Legally Accepted Representative _____

Date: _____

Signatory name: _____

Signature of the investigator _____ Date

Study investigator name: _____

Signature of the witness: _____ Date: _____

Name of the witness: _____