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

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Maidan Garhi, New Delhi - 110068

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1. Introduction

The need for Institutional Ethics Committee (IEC) in health, social and behavioural research studies resulted from the realization that affirms human rights as a prerogative of all members of the 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 constituted an Institutional Ethics Committee.

2. Composition of Institutional Ethics Committee (IEC)

The Institutional Ethics Committee shall be multidisciplinary and multi sectoral in nature. In compliance with concerned guidelines issued by regulatory bodies, the composition of the IEC shall be as under:

i.	**Chairperson**	External Expert	Nominated by the VC
ii.	**Members**	Five Internal Members	Nominated by the VC
		External Member(s) not more than three	Proposed by the concerned discipline(s), depending upon the area of Ph.D topic(s), along with the extracts of minutes, duly signed by the concerned PhD Programme coordinator and routed through the Director of the concerned School to VC for approval.
iii.	**Member Secretary**	Director, Research Unit	Ex Officio

3. Scope

The IEC shall deal with the ethical issues involved in the research studies of all registered PhD students of IGNOU as per the recommendations of the DRCs followed by the approval of the respective School Boards or Competent Authority.

4. IEC Meetings:

The process for Ethical Clearance of the Ph.D topic 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.

The quorum of the meeting shall be 50% of external members and a minimum of three internal members. The tenure of the IEC members (excluding external members for a particular PhD topic) is for three years. Whereas for external members their term will be completed once the IEC clearance is completed for their respective topics.

5. Procedure:

i. The DRC shall decide the need of the ethical clearance for the Ph.D topic. In case the Ph.D topic requires ethical clearance, the proposal along with the name(s) of External Expert(s) depending upon the area of topic, proposed by the PhD programme coordinator should be routed through Director of the concerned School to obtain approval of the Vice Chancellor before forwarding to Research Unit for placing it at IEC.

ii. The research scholar and the respective proposed research supervisor must be available in person for presentation before the IEC.

iii. 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 of no consensus is arrived, 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. Decision will be made only in meetings where quorum is complete.

iv. Only members can take a decision. The proposed research supervisor will not be a part of decision making.

v. Decision 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 PhD 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.

vi. Roles and Responsibilities:

i. **PhD Scholar:** The PhD scholar will submit hard and soft copies of the research proposal recommended by the DRC, copy of the Informed Consent (Annexure 1.2) in bilingual, draft tools and PPT with all the required annexures (1.1 to 1.2) along with the SOP application form and covering letter to his / her research supervisor.

ii. **PhD Programme Coordinator:** The PhD programme Coordinator (on behalf of the proposed research supervisor) will submit the research proposal of the research student(s) along with the names of the external experts proposed by the concerned discipline(s) shall be routed through Director of the concerned School for the approval of the Vice Chancellor.

iii. **Director of the School :** After the approval of the external members, the DRC minutes along with the relevant documents and the approved list of experts by the Vice Chancellor, shall be submitted to the Director, Research Unit for placing before the IEC.

iv. **Institutional Ethics Committee (IEC):**

a) To protect the dignity, rights and well being of the potential research participants.

b) To ensure that universal ethical values and international scientific standards are expressed in terms of local community values and customs.

c) 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.

v. **The Research Unit (RU) :**

The RU will communicate the ethical clearance to the School for approval of the School Board. Further, the approval of the School Board will be placed before the RC / RCSC.

Annexure – 1.1

INDIRA GANDHI NATIONAL OPEN UNIVERSITY
RESEARCH UNIT
INSTITUTIONAL ETHICS COMMITTEE (IEC)

FORM – A

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

1. PhD Title:

2. Name of PhD student :

3. Name of Supervisor (s) :

4. Discipline :

5. School :

6. Sponsor if any
   Type of Study : Epidemiological ☐ Basic Sciences ☐ Survey ☐

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

(b) Data Collection: From Records ☐ Using 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 (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, 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.]

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

13. 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) :

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

14. 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)

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

16.Informed Consent: Written Oral

i. Subject consent form - enclose

ii. Who will obtain consent? PhD student ☐ Nurse / Counsellor / staff ☐

17. 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.Is there a benefit

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

18. Are the subjects remunerated for their involvement in the research?

Yes No

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

b. Compensation for travel, Specify amount and type:

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

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

21. 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:

Sponsor ☐

Ethics Committee ☐

22. Is there any conflict of interest?
(financial / non-financial) If yes, specify:

(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.

Annexure – 1.2

Informed consent Form (template)

FORM-B

(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: _____