

Appendix - 1

Application for Ethical Review

Below is a framework/ template of Application for researchers to submit their proposals to the IEC EDPA for Ethical review of research study proposals:

Section 1: Basic Information

1. Title of Research Proposal:

- Provide a concise, descriptive title for the study.

2. Principal Investigator:

- Name:
- Designation:
- Institution/Organization:
- Contact Information (Email/Phone):

3. Co-Investigators:

- Name(s) and Designation(s):
- Institution(s)/Organization(s):
- Contact Information (Email/Phone):

4. Study Sponsor/Funding Agency:

- Name of funding source:
- Type of funding:

5. Submission Date:

- Date of application submission.

Section 2: Study Details

6. Brief Introduction and Background:

- Summarize the background, significance, and rationale for the study.

7. Objectives:

- State the primary and secondary objectives of the research.

8. Study Design:

- Clearly describe the methodology, including type of study (e.g., observational, clinical trial).

9. Study Participants:

- Define inclusion and exclusion criteria.
- Describe participant recruitment and enrollment methods.

10. Study Duration:

- Provide the estimated start and end dates.

Section 3: Ethical Considerations

11. Informed Consent Process:

- Attach the informed consent form template.
- Describe how informed consent will be obtained and documented.

12. Risk-Benefit Analysis:

- Describe potential risks and benefits to participants.

13. Confidentiality Measures:

- Detail how participant privacy and data confidentiality will be protected.

14. Vulnerable Populations:

- Specify plans for ethical handling of vulnerable populations, if applicable.

Section 4: Documentation and Attachments

15. Documents Submitted for Review:

- Research Protocol (mandatory)
- Participant Information Sheet (PIS)
- Consent Form Template

- Investigator's CV(s)
- Ethical Risk Assessment Form
- Budget Details (including funding sources)

16. Additional Attachments:

- Any supplementary documentation, as required.

Section 5: Declaration

17. Investigator's Declaration:

"I hereby declare that the information provided in this application is accurate to the best of my knowledge. I agree to abide by the ethical principles and guidelines set forth by the Institutional Ethics Committee (IEC), EDPA, and commit to safeguarding the rights and welfare of research participants during the study."

Signature of Principal Investigator:

- Name:
- Date:

Signatures of Co-Investigators:

- Name(s):
- Date(s):

Section 6: Processing Fee Details

18. Payment Information:

- Details of payment of the application processing fee, if applicable.