

**University Level Ethics Committee on Research Involving Human
Subjects
(ULECRIHS)**

Checklist for Submission of Research Protocols

Guidelines to be Followed:

1. The **submission letter must be placed first** and signed by the Principal Investigator/Research Supervisor/Chairman, Doctoral Committee.
 2. The checklist should be duly filled and completed.
 3. Pages must be numbered sequentially.
 4. CVs of the guide and co-guide (with relevant experience) should be included.
 5. Vancouver style or an approved referencing format must be followed.
 6. The student and all guides must sign the documents, with dates.
 7. Include setting permission from the concerned authority.
 8. Literature reviewed should be up to date.
 9. Budget details must include currency (e.g., INR) – applicable only for project proposals.
 10. The guide's complete address, including department, must be provided.
 11. All protocols should be addressed to:
**The Chairperson,
University Level Ethics Committee on Research Involving Human Subjects,
University of Kerala.**
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Order of Documents to be Submitted:

1. Submission Letter
2. Checklist
3. Certificate from Research/Doctoral Committee
4. Setting Permission from the Authority Concerned
5. Addresses and Signatures of Internal Guide, External Guide, and Co-guide (Include CVs)
6. Declaration by the Researcher, signed by student and internal guide
7. Undertaking Letter by the Researcher
8. Declaration by the Student/Researcher
9. Research Proposal (Include Budget, if applicable)
10. Fee for Ethical Committee Clearance : Rs. 1050/- (original chalan)

Note: Protocols must be submitted sufficiently in advance to reach each Ethics Committee member at least **10 days prior to the meeting**.

Submission Letter Format

From
Mr./Ms.(Name of the Scholar)
Department of
.....

To
The Chairman
University Level Ethics Committee on Research Involving Human Subjects
University of Kerala

Respected Sir,

Sub: Submission of Project/Research Protocol for Ethical Approval – reg.

Name of the Research Scholar :
Name of the Research Centre :
Date of Joining for Research:
Session (Jan/July Year) :

As part of my (e.g., Postgraduate/Ph.D. program), I
have selected the research topic entitled
“.....”. I am hereby
submitting the research/thesis protocol, along with the necessary documents as per the
prescribed guidelines, and with a forwarding letter from the Head of the Department, for
your kind approval.

Place:

Date:

Yours faithfully,

Mr./Ms.

Recommended and forwarded by

Name and Signature of Research Supervisor

Name and Signature of Chairman, Doctoral Committee

Declaration by the Principal Investigator/Researcher

I hereby declare that I will not commence my research titled “.....” until ethical clearance and approval have been obtained from the University Level Ethics Committee on Research Involving Human Subjects, University of Kerala. I also affirm that I will not deviate from the approved protocol.

Any modifications required during the study will be submitted in writing for the committee’s approval, and changes will only be implemented upon receiving formal approval. I will provide progress reports to the Committee as specified, for verification.

Place:

Date:

Name and Signature of the Principal Investigator/Researcher
Address:

Name and Signature of Research Supervisor

Name and Signature of Chairman, Doctoral Committee

Certificate of Willingness – Guide/Co-guide

I, (Name),
(Designation), Department of (College/Institution), am
willing to act as the Guide/Co-guide for Mr./Ms. of the
Department of for the research thesis titled
“.....”.

Place:

Date:

Signature:

Name:

Designation & Address:

Certificate of Willingness – Co-Investigator

I, (Name),
(Designation), Department of (College/Institution), am
willing to be the Co-Investigator for Dr. of the
Department of for the research project titled
“.....”.

Place:

Date:

Signature:

Name:

Designation & Address:

Project / Research Proposal Format

1. Title of the Study
2. Rationale: Knowledge gap the study aims to address (in bullet points)
3. Objectives: Primary and Secondary (in bullet points)
4. Study Design, Study Settings
5. Study Population
6. Inclusion and Exclusion Criteria , Sample Size
7. Sampling Method, and Study Duration
8. Study Variables: Exposure and Outcome variables
9. Study Tools & Techniques (in English and Malayalam)
10. Methodology / Study Procedure
11. Plan of Analysis and Statistical Tests
12. Ethical Considerations
13. Participant Information Sheet (English & Malayalam)
14. Informed Consent Form (English & Malayalam)
15. Budget (if applicable)
16. References

INFORMED CONSENT

I. Participant Information Sheet

Title of Research:

Name of Researcher:

Affiliation and Contact:

Other Investigators (if any):

1. Introduction & Purpose:

Provide a simple and clear explanation of the study's purpose in layman's terms.

2. Description of the Research:

Explain what participation entails.

3. Subject Participation:

Example: "Approximately ... participants will be enrolled. Participants must meet the following criteria: ..."

4. Risks and Discomforts:

State any known risks. If none, mention "There are no known risks."

5. Benefits of Participation:

Example: "Participants may gain better understanding and awareness of..."

6. Confidentiality:

Explain how data will be secured and anonymity maintained.

E.g., "Audio recordings will be destroyed after transcription."

7. Compensation:

Mention whether compensation will be provided or not.

8. Voluntary Participation:

Example: "Participation is voluntary and refusal will not affect any services you are entitled to."

9. Withdrawal Rights:

Example: "You may withdraw from the study at any time without any penalty."

Participant's Name and Signature:
Date:

Witness Name and Signature:
Date:

Investigator Name and Signature:
Date:

Note: Copies of the signed consent form must be retained by the Principal Investigator and also provided to the participant.

II. Consent Form

Title of Research:
Name of Researcher:
Affiliation and Contact:
Other Investigators (if any):

Consent Statement:

I have read and understood the information provided. I understand that participation is voluntary and that I can withdraw at any time without penalty. My identity will be kept confidential. I voluntarily agree to participate in this study.

Participant's Name and Signature:
Date:

Investigator's Name and Signature:
Date: