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

(Checklist)

Form-I B

Research protocols for submission to IEC – Guidelines to be followed

1. The submission letter should be kept first with signature of Principal Investigator/Research Supervisor
2. Checklist should be filled and responded
3. There should be page number
4. CV of guide and co-guide with experience
5. Vancouver style/approved format of referencing to be followed
6. Signature of student and guides with date
7. Setting permission
8. Studies reviewed to be recent
9. Student/ Investigator's CV
10. Budget (indicate unit of currency ie. INR.) (**for Project Proposals only**)
11. There should be correct address of guide including department
12. All the protocols should be addressed to the Chairman/Chairperson, University Level Ethics Committee on Research Involving Human Subjects, University of Kerala
13. **Fee for Ethical Committee Clearance – Rs. 1050/-**

Order of arranging documents

1. Submission Letter
2. Checklist
3. Certificate from Research/Doctoral Committee
4. Setting permission from Medical Superintendent of concerned authority
5. Setting permission from HoD
6. Address and signature of internal guide, external guide and co-guide (CV of guide, co-guide & researcher)
7. Declaration by the researcher with signature of students and internal guide
8. Undertaking letter by the researcher
9. Declaration by student / researcher
10. Research proposal with work plan (and budget for project proposal)
11. Tools in English
12. Tools in Malayalam
13. Informed Consent – English
14. Informed Consent – Malayalam
15. Participant information sheet – English
16. Participant information sheet - Malayalam

Note: Protocols should be submitted sufficiently early so as to reach this to each member of Ethics Committee one week prior to the meeting.

Checklist

Title of the Research/Project-					
Name of the Principal Investigator/Research scholar					
	LIST OF DOCUMENTS	Yes	No	Not Applicable	Page Number
1	Submission letter form Principal investigator/Research Scholar				
2	Covering letter from HoD/Research Superviosr				
3	Certificate from Research / Doctoral committee				
4	Setting permission				
	Setting permission-1				
	Setting permission-2				
	Setting permission-3				
	Setting permission-4				
5	Declaration / Undertaking by Principal investigator/ Researcher				
6	Details of study team				
7	Willingness certificate from guide				
8	CV of the Guide				
9	Willingness certificate from co-guide (if any)				
10	CV of the Co-guide (if any)				
11	Willingness certificate from co-investigator (if any)				
12	CV of the co-investigator (if any)				
13	Research/Project Protocol/Proposal				
14	Tool in English				
15	Tool in Malayalam/Local language				
16	Participant information sheet in English				
17	Participant information sheet in Malayalam/Local language				
18	Consent form in English				
19	Consent form in Malayalam/Local language				
20	Budget and details of funding agency **for Project Proposals**				

Signature

Name of Principal investigator/Researcher

Verified by Research Supervisor (Name and Signature)

From

Mr/Mrs ……..
Department of ……
……..

To

The Chairman
The University Level Ethics Committee on Research involving Human subjects.

Respected Sir,

Sub: Submission of Project/Research protocol for approval

As a part of …… ……. I have selected the topic for Research titled ……..……..……
I am submitting the thesis protocol with necessary documents as per the guidelines with the forwarding letter from the Head of the Department……, for submitting before the University Level Ethics Committee on Research Involving Human Subjects.

Date

Place

Yours faithfully,

Mr/Mrs ……...

From

Dr…… …….

Department of ……..….

……..

To

The Chairman

The University Level Ethics Committee on Research Involving Human Subjects.

University of Kerala.

Respected Sir,

Sub: submission of thesis protocol for approval

I am hereby forwarding thesis/ Project protocol named "…… ……...…….…… by ……... (name of the Principal investigator/research scholar)" before the University Level Ethics Committee on Research involving Human subjects.

Yours faithfully,

Dr……...

Professor and HoD.

Department of……..

…….

Certificate from Research / Doctoral Committee

Setting Permission

Declaration by Principal Investigator/ Researcher

Declared that I will not start my Research titled…….. until the ethical clearance and approval is obtained for the study and will not deviate from the protocol submitted for approval. If any modification is required during the course of study or before commencement of the study, it will be intimated in writing, to the University Level Ethics Committee on Research involving Human subjects, University of Kerala , for approval and these changes will be applied only after the approval by the committee and is officially intimated. Progress of my research will be intimated to the University Level Ethics Committee on Research involving Human subjects, University of Kerala, as specified, for verification of progress.

Place

Mr/Mrs……..

Address

Date

STUDY TEAM	
Principal Investigator/Research Scholar	Mr/Mrs
Address	
Phone	
email	
Guide	Dr
Address	
Phone	
email	
Co-Guide 1	Dr/Mr/Smt
Address	
Phone	
email	
Co-Guide 2	Dr/Mr/Smt
Address	
Phone	
email	
Co - investigator	Dr/Mr/Smt

CERTIFICATE OF WILLINGNESS

(GUIDE/Co GUIDE)

I, (Name) ……..……, (designation) Department of ……..…….. (College/institution), am willing to be the guide/co guide(if any) for Mr/Mrs ……..…….. in the Department of ……..……. for the Research project/ thesis / Dissertation named "……..……."

Signature

Place

Name

Date

Designation

Address

CV of Guide / Co-Guide (if any)

CERTIFICATE OF WILLINGNESS

(Co-investigator)

I, ……...(name) ……... (designation) Department of ……...……..(College/institution), am willing to be the co-investigator for Mr/Mrs ……..…….. in the Department of ……..……. for the Research project Dissertation named "……"

Signature

Place

Name

Date

Designation

Address

C V of Co – investigator

Research Protocol/ Proposal

Tool English

Tool Malayalam

Participant Information Sheet - English

Participant Information sheet - Malayalam

Informed Consent English (format shown below)

Informed Consent Malayalam

Budget (for Project Proposals

(In separate sheets)

INFORMED CONSENT

I. PARTICIPANT'S INFORMATION SHEET

Title of Research:
Principal Investigator, Affiliation and Contact Information:
Additional Investigators and Affiliations if any:

1. Introduction and Purpose of the Study

Include a brief overview of the study on a level of understanding for the person who will be signing the form. Remember that the general population might not understand what you consider basic terminology. A general rule is to keep the wordings at the standards of an ordinary man.

2. Description of the Research

Include a description of what participation in the study entails.

3. Subject participation

Give an overview of what participant characteristics are needed for the study.
Example: I estimate that a total of about …… participants will enrol in this study. Participants must have (describe inclusion criteria). Your participation will involve …… interviews approximately …….. minutes in length.

4. Potential Risks and Discomforts

In this section include a statement about potential risks or discomforts if any and how those risks will be addressed. If you believe there are no risks involved, state that there are "no known risks".

5. Potential Benefits

Include a statement about potential benefits for participating in the study.
Example: People who participate in this study may have a better understanding that enable individuals to experience and increase their overall sense of well-being.

6.Confidentiality In this section let the participant know the level of identity protection of any personal information collected for this study and whether their identity will be fully protected, and if so how.

Example: *All information taken from the study will be coded to protect each subject's name. No names or other identifying information will be used when*

discussing or reporting data. The investigator will safely keep all files and data collected in a secured locked cabinet in the principal investigators office. Once the data has been fully analysed it will be destroyed.

If the researcher will be collecting audio or video recordings, there must be a statement explaining how the recording will be handled and at what point destroyed.

Example: Once audio recordings are coded and transcribed they will be destroyed.

Authorisation: In this section you may state that by signing this form, the participant authorise the investigator to their records, observations or comments without disclosing their identity and subject to the confidentiality clause.

7.Compensation In this area you may state if there is, or no compensation.

8. Voluntary Participation and Authorization Participants need to be made aware that they do not have to participate in the study, and that it is fully voluntary.

***Example*:** Your decision to participate in this study is completely voluntary. If you decide to not participate in this study, it will not affect the care, services, or benefits to which you are entitled.

9. Withdrawal from the Study and/or Withdrawal of Authorization Participants also need to know that they can withdraw at any point if they choose not to continue.

***Example*:** If you decide to participate in this study, you may withdraw from you participation at any time without penalty.

Name of Participant: _____

Signature: _____ Date:

Name of Witness : _____

Signature: _____ Date:

Name of Investigator: _____

Signature: _____Date:

Note: A copy of the signed, dated information sheet and consent form must be kept by the Principal Investigator(s) and a copy must be given to the participant.

II. CONSENT FORM

I have read and understood the provided information and have had the opportunity to ask questions. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving a reason and without cost. I have been assured that my identity will not be disclosed at any point of time. By signing this form I voluntarily agree to participate in the study.

Participant's name and signature _____Date____

Investigator's name and signature _____Date_____