GUIDE TO APPLICANTS

Ethics Review Committee

Faculty of Medicine, University of Jaffna

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1. Research projects involving human subjects conducted by students and staff of the University of Jaffna and other projects conducted in the Northern Province are eligible to be submitted for ethical clearance to the Ethics Review Committee (ERC), Faculty of Medicine, University of Jaffna.
2. The Application for Ethics Review may be downloaded from the Faculty of Medicine website at this link.

   Sections of the application form that are not applicable to the proposal may be skipped.
3. Along with the completed original application form, a hard copy of the project summary, protocol, and annexures should be submitted to the Office of the Ethics Review Committee, Faculty of Medicine, University of Jaffna. Except the application form, soft copies of all documents should be emailed to ercmed@univ.jfn.ac.lk
4. If the application form contains erroneous information OR progress/completion reports are pending from the Principal Investigator (PI), new applications will be processed once corrections are made and/or the relevant report(s) is/are submitted.
5. The summary should not exceed 500 words and should include an introduction (with justification for the research), objectives, methods, and any anticipated ethical concerns. The protocol should cover all applicable areas in the 'Protocol Checklist' in the application form, and be formatted according to ERC requirements (Times New Roman, 12 pt, 1.5 spacing). Please use double-sided printing and normal binding.
6. Protocols that involve electronic informed consent procedures and/or data collection will be assessed for risk on a case-by-case basis. The sensitivity of the topic, the researcher's experience, whether identifiable data are to be collected, data security, and the possibility of coercive data collection (such as requiring responses for questions in online questionnaires) will be considered in the risk assessment. Researchers should outline the measures taken to minimize these risks and cover these aspects in the information sheet.

Screen shots of all pages of the web interface, including those to obtain informed consent and elicit data, must be annexed.

7. The authorized copy of the completed paying in voucher (available at the Faculty website at this link) should be handed over along with the application. Payment can be made by cash/money order/postal order/ cheque (in favour of the **Ethics Review Committee, University of Jaffna**) at the Shroff Counter of the University of Jaffna or at any branch of People's Bank (in favour of the **Ethics Review Committee, University of Jaffna**) to the credit of the account number in the paying in voucher.
8. Undergraduate student proposals should be submitted through the relevant Head of the Department.
9. Proposals for postgraduate degrees should be submitted under the responsibility of a qualified supervisor (unless the researcher is exempted from working under a supervisor) with a covering letter indicating:
    - 8.1 Degree to be obtained
    - 8.2 Institution where the candidate is registered and, if scientific review has been undertaken, a letter from the relevant postgraduate institute / Board of Study stating that the research proposal has been approved for postgraduate study.
10. Applicants for ethical review of protocols involving research with international collaborators are directed to the instructions in the application form and the SOP available at the Faculty of Medicine website at this link (Section 8.4.15 of SOP8 / V4).
11. Completed applications submitted before the close of business of the last working day of the month will be taken up at the next scheduled meeting and the ERC's decision will be communicated to the PI/ Head of the Department. This process will take a minimum of 6 weeks.
12. The ERC will disapprove all projects that have already started participant recruitment, data collection, or any projects that are completed before obtaining ethical clearance.
13. If the protocol is to be amended after submission for review or after obtaining ethical clearance, such amendments should be communicated to the ERC and effected only after ERC approval.

14. After obtaining ethical clearance, researchers are responsible for adhering to the protocol. The ERC has the right to withdraw clearance if there is evidence of non-compliance with an approved protocol and/or ERC guidelines.
15. All researchers whose projects have been granted ethical clearance are obliged to send progress reports every 6 months (or more frequently if requested to do so by the ERC) and a completion report on completing the project, in the format prescribed by the ERC in its Standard Operating Procedures.
16. Please quote the reference number assigned to the project in all future communications.
17. For further information, refer the Standard Operating Procedure (SOP) available on the Faculty of Medicine website at this link.
18. If you need any further clarifications, please call 021 2222073; extension 342.
19. If you want to make any complaints about the ERC, please write to the Chairperson, ERC, Faculty of Medicine, University of Jaffna.
20. Details of application fees for protocols submitted for ethical clearance:

Personal research	***Payment to ERC***
Grants less than (Rs. 300,000.00)	**Rs. 2500.00**
Grants more than (Rs. 300,000.00)	**Rs. 5000.00**
Research with international collaboration	
Sri Lankan PI	**Rs. 10,000.00**
Non-Sri Lankan PI	**Rs. 50,000.00**
Sponsored clinical trials	**USD 1000**
Undergraduate projects of others universities	**Rs. 500.00**
Undergraduate projects of the UJ	**No fee**

GUIDANCE FOR PREPARATION OF INFORMED CONSENT FORM

The informed consent form(s) should cover the following areas:

- Introduction to the Principal Investigator (name, designation, affiliated institution) and the research project, including the objective(s) and research setting
- Reasons for selecting the participant
- Statement regarding voluntary participation
- Study duration
- Study procedures (including details of data collection methods or interventions)
- Risk-benefit assessment
- Reimbursements (if any)
- Measures to protect privacy and confidentiality
- Data security concerns (if any)
- Contact details of research team for additional information
- Contact details of ERC for complains (if any)
- Consent forms, and, if applicable, assent forms, including, for illiterate participants (if necessary)

Please note: Separate informed consent forms must be developed if a study protocol includes: 1) several research activities that involve different groups of participants (e.g., participants of surveys, interviews, and focus groups in a mixed methods study) or 2) recruitment of minors when informed consent/assent needs to be obtained from parents and minors.

A sample informed consent form is provided below. Some sections of this form may not be relevant to your project. Please include only the sections that are applicable to your project.

The informed consent form must be translated in the local language/s of the participants based on their language preferences and competencies.

SAMPLE INFORMED CONSENT FORM

Part I: Information sheet

Title:……
…….

Part I – Information sheet

1. **Introduction**

   I/We *(name of PI/investigators)* attached to *(institute)* as *(designation)* are doing research on *(field/discipline)* at (*site of the study*) to (*aim of the study*). I wish to give you information about the research and invite you to participate in this research.

   If you do not understand any words, you can stop me and ask for explanation. You need not necessarily decide now whether to participate or not. Before you decide you may talk to anyone you feel comfortable with about the research. If you have any questions /doubts about the research/ procedures, you may ask me or anyone from the research team you are comfortable with now or later.

2. **Participant selection**

   The reason for considering you suitable for this research is ……

3. **Voluntary participation**

   You are free not to participate or withdraw from the study at any time *(of the study/during data collection)* without any loss of or compromise in *(medical care/other services)* to which you are otherwise entitled. If you decide to participate, you are not required to provide any information, and may skip any part of the research that makes you feel uncomfortable.

4. **Duration of the study**

   The study will begin on *(DD/MM/YYYY)* and ends on *(DD/MM/YYYY)*. Data will be collected from *(DD/MM/YYYY)* to *(DD/MM/YYYY)*.

5. **Procedures of the study and participant responsibilities**

(Explain what is expected from the participants in relation to research and the time that the participant would need to dedicate towards the research. If a questionnaire is to be used, the nature and purpose of questions, and the information and data to be collected. If any intervention study, explain how it differs from routine medical care / procedures).

6. Intervention

7. *(Explain the type of intervention to be studied and currently available established standard intervention/treatment and other alternatives, if any).*

8. Clinical trial (if applicable)

The following need to be clearly explained:

a. Phase of the trial with detailed description of procedures.
b. Reason for development of a new drug
c. Treatment and manufacture information of drug/device
d. Known experience with the new drug, if any.
e. Known and potential adverse effects of the drug/device and other drugs/devices.
f. Unfamiliar procedures such as randomization, blinding, placebo etc. Participants should be informed about the meaning of placebo, the chances of getting the test/standard drug/placebo and that they may not know whether they will be receiving the test/standard drug/placebo till data collection is over.

9. Nature of benefits, risks/hazards/discomforts, and risk-benefit assessment

(Mention actual and potential benefits, any potential or actual risks, hazards and/or discomforts, including any sensitive questions/topics; weigh the benefits of the study against its risks for the individual and / or community in simple language).

10. Reimbursements

You will be paid for expenses incurred as a result of participation, including *(travel costs, money for wages lost, etc.)*

11. Privacy

I will make sure that data will be collected discreetly so that your privacy is not compromised in any way.

(Mention the measures taken to ensure privacy).

12. Confidentiality

The information collected will be kept confidentially. Personal details, if collected, and any information that may identify you will not be disclosed or published.

13. Data storage and security

(If data or biological samples are to be stored for some time or are likely to be used for another purpose, provide information and obtain consent specifically for such storage and use; mention possibilities of third-party use of electronic data, if applicable)

14. Additional information regarding this research

Please feel free to contact any member of the research team to obtain additional information regarding this research.

(List name and contact details of PI and other members of the research team)

15. Complaints

If you have any complaints regarding the conduct of this research, please inform…

(Provide the contact information of the ERC for participants who may want to express their concerns or make complaints regarding the study.)

Part II –Consent Form

Title: ……

I have read the above information / the above information has been read to me and I understand it thoroughly. I have been allowed to ask questions regarding this study and all the questions have been answered satisfactorily. I am aware of the benefits and risk of this study and the confidentiality of my details. I voluntarily give my consent to participate in this study and understand that I have the right to withdraw from the study at any time without loss of benefit to which I am otherwise entitled.

……. Date:

Signature of the participant

Name of the participant:

I confirm that the participant was given an opportunity to ask questions about the study and all the questions asked by the participant have been answered to the satisfaction of the participant. I confirm that consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

……. Date:

Signature of the investigator

Name of the investigator:…….

Format for assent from a child/minor (<18 years)

I have read this information (or have had the information read to me). I have had my questions answered and know that I can ask questions later if I have any.
I agree to take part in the research.

Print name of the child …….
Signature of the child: ……
Date:…….

Format for consent form from parent or legally acceptable representative

I have read the above information / the above information has been read to me and I understand it thoroughly. I was allowed to ask questions regarding this study and all the questions have been answered satisfactorily. I voluntarily give my consent for my child (name of the participant) to participate in this study and understand that I have the right to withdraw her/his participation from the study at any time without loss of benefit to which he/ she is otherwise entitled.

……. Date:

Signature of the parent/ legally acceptable representative

Name of the parent/ legally acceptable representative:……..

Relationship to the participant: ……

Format for consent from illiterate participants

I have witnessed that the above information are clearly and accurately read to the participant and he/ she has understood it thoroughly. The participant was allowed to ask questions and all the questions have been answered to the satisfaction of the participant. I confirm that the participant has given the consent voluntarily to participate in this study and has understood that that he/ she has the right to withdraw from the study at any time without loss of benefit otherwise he/ she is entitled.

……. Date:

Signature of the witness

Name of the witness:

Name of the participant: Thumb print of participant

I have read the information sheet to the participant clearly and accurately. I confirm that the participant was given an opportunity to ask questions about the study and that all the questions have been answered to the satisfaction of the participant. I confirm that consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

……. Date:

Signature of the investigator

Name of the investigator: