



GUIDE TO APPLICANTS

Ethics Review Committee

Faculty of Medicine, University of Jaffna

1. Research projects involving humans to be conducted by the students and staff of University of Jaffna and in the Northern Province could be submitted for ethical clearance.
2. Ethics review application form can be downloaded from the following link;
<http://www.med.jfn.ac.lk/index.php/subcommittees/ethical-review-committee/>
3. With completed original application form, four (04) hard copies of project protocol, four copies of summary of the protocol and all relevant documents along with soft copy of all the documents in a CD should be submitted to the Ethics Review Committee, Faculty of Medicine, University of Jaffna, Adiyapatham Road, Kokuvil. *In the application form, sections that are not applicable to the proposal can be skipped.*
4. The summary should not exceed 500 words and should include the following: background, justification, objectives, methodology and ethical issues.
5. The contents of the protocol should be based on the 'Protocol Checklist' of the application form. The font size and space between sentences should be in 12pt and 1.5 lines respectively. Submit the protocol as Printed in both pages with normal binding.
6. The authorized copy of the completed paying in voucher for the appropriate payment (can be downloaded from the link;
<http://www.med.jfn.ac.lk/index.php/subcommittees/ethical-review-committee/>) should be handed over along with the application. Payment can be made by cash/money order/postal order/ cheque (in favor of **Ethics Review Committee, University of Jaffna**) at the shroff counter of the University of Jaffna or at any branch of People's Bank (in favor of **Ethics Review Committee, University of Jaffna**) to the credit of the account number given in the paying in voucher.

7. Undergraduate student proposals should be submitted through the relevant Head of the Department.
8. 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 the degree to be obtained
 - 8.2 the institution where the candidate is registered and a letter from the relevant postgraduate Institute / Board of Study stating that the research proposal has been approved for postgraduate study.
9. Applications for research with foreign collaborators: please read instructions in the application form and also refer section of SOP 8 / V3 on collaborative research.
10. Completed applications submitted before the close of business of last working day of the month will be taken up at the next schedule meeting and the decision of the ERC will be communicated to the PI/ Head. This process will take minimum of 6 weeks.
11. The ERC will disapprove all projects that have already started recruitment of participants or collection of data and that are completed before obtaining the ethical clearance.
12. If the protocol to be amended after submission or after obtaining ethical clearance, such amendments should be communicated to the ERC and effected only after approval by the ERC.
13. After obtaining ethical clearance, the researchers are responsible to adhere to the protocol and the ERC has the right to withdraw the clearance if there is evidence for not complying with approved protocol and ERC guidelines.
14. All researchers whose projects have been granted ethical clearance are obliged to send progress report every 6 month as requested format by the ERC and at the end a completion report. Please quote the reference number assigned to the project in all future communications.
15. For further information, refer to the Standard Operating Procedure (SOP) at the following link: <http://www.med.jfn.ac.lk/index.php/subcommittees/ethical-review-committee/>
16. If you need any further clarifications, please call 021 2222073; extension 342.
17. If you want to make any complaints about the ERC, please write to the Chairperson, ERC, Faculty of Medicine, University of Jaffna.

18. Details of application fee for proposals submitted for ethical clearance:

Personal research	<i>Payment to ERC</i>
<i>Grants less than (Rs. 300,000.00)</i>	Rs.1500.00
<i>Grants more than (Rs. 300,000.00)</i>	Rs. 3000.00
Research with foreign collaboration	
<i>Sri Lankan PI</i>	Rs. 5,000.00
<i>Non-Sri Lankan PI</i>	Rs. 50,000.00
Sponsored clinical trials	Rs. 200,000.00
Undergraduate projects of others Universities	Rs. 500.00
Undergraduate projects of the UJ	No fee

GUIDANCE FOR PREPARATION OF INFORMED CONSENT FORM (ICF)

We recommend you to use the following format in the preparation of ICF for the projects that are submitted to this ERC. Some sections of this ICF may not be relevant to your project. You can skip the sections that are not applicable to your project. The ICF must be translated in the local language/s of the participants.

INFORMED CONSENT FORM

Part I: Information sheet

Title:.....

Part I – Information sheet

1. Introduction

I (name of PI) attached to (institute) as (designation). I am / we are (state the name and designation of other investigators) doing a research on (field) at (site of the study) to (aim of the study). I wish to give you the 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. You are free not to participate or withdraw from the study at any time of the study without any loss of or compromise in medical care/ other services otherwise you are entitled.

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. (Name and contact details of PI and other members of research team from whom the participant can ask questions and clarify)

2. Participant selection

The reason for considering you suitable for this research is

3. Duration of the study

The study will begin on (DD/MM/YYYY) and ends on (DD/MM/YYYY).

4. Nature of the benefits; Participation in this study may benefit you and/ or others by (mention all the actual and potential benefits).

5. Nature of the risk, potential hazards and discomforts: Any potential or actual risks, hazards and discomforts should be clearly mentioned.

6. Procedures of the study and participants responsibilities

(Explain how it differs from the routine medical care / procedures, nature and purpose of questions to be asked, time needs to be spent for each interview and information and data to be collected. Explain what is expected from the participants in relation to research).

7. Intervention

(Explain the type of intervention and currently available established standard intervention or treatment and other alternatives if any).

8. Reimbursements

You could be paid for expenses incurred as a result of participation in the research e.g. travel costs and money for wages lost, etc.

9. Confidentiality

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

10. Clinical trial

Following need to be clearly explained:

- 9.1 Phase of the trial and its detailed description.
 - 9.2 Reason for development of new drug/ treatment and manufacture information of drug/device
 - 9.3 Explanation on known experience with the new drug if any.
 - 9.4 Explanation on known and potential adverse effects of this drug/device and other drugs used in the trial.
 - 9.5 Explanation of unfamiliar procedures such as randomization, blinding and involving placebo etc. - the participants should be told what that means and what chance they have of getting test/ standard drug or placebo drug and they also should be informed that they may not know the drug they will be on till the data collection is over.
- 11. Risk benefit assessment: explain the risks and benefits (for the individual and / or community at large) of the study in simple language.
 - 12. If data or biological samples will be stored for a duration longer or is likely to be used for another purpose, provide information about this and obtain consent specifically for such storage and use in addition to consent for participation in the study.
 - 13. Contact information (Personal Mobile Number, Office Number and contact Address of the all investigator/s including the PI
 - 14. Contact information of the ERC which approves the project if participants 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 have been read to me and I understand it thoroughly. I have been allowed to ask questions regarding this study and all the questions are being answered satisfactorily. I am aware of the benefits and risk of this study and 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 otherwise I am entitled.

.....
Signature of the participant

Date:

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 the consent has been given freely and voluntarily.

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

.....
Signature of the investigator

Date:

Name of the investigator:.....

Format for Assent from the child

I have read this information (or had the information read to me). I have had my questions answered and know that I can ask questions later if I have them.

I agree to take part in the research.

Print name of child

Signature of child:

Date:.....

Format for consent form from parent or legally acceptable representative

I have read the above information / the above information have been read to me and I understand it thoroughly. I am 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/him from the study at any time without loss of benefit otherwise he/ she is 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 all the questions asked by the participant have been answered to the satisfaction of the participant. I confirm that the consent has been given freely and voluntarily.

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

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Date:

Signature of the investigator

Name of the investigator: \