

Application for Ethics Review

Teaching Hospital Jaffna

Information to Applicants

- Your application will not be processed until all required documents are received by the Ethics Review Committee (ERC).
- All documents submitted must be bound in a file.
- Approval from their respective departments and head of the institution before applying for ethical clearance and the application must be forwarded with the signature of the head of the department/s concerned along with the signature of head of the institution
- The review process would take a minimum a month duration or longer if resubmission required, please make sure to apply in advance well before planned commencement of the study.
- Applications are to be submitted before 10.00 am, 9th of each month to be reviewed in the following month.
- The status (approval/ revision/ rejection) of your application will be notified via e-mail.
- During the resubmission: Proposed correction should be highlighted clearly and submitted along with original paper.
- A digital copy of the ethical clearance application should be forwarded along with the study proposal to erc.thjaffna@gmail.com, in a .pdf format single file.

Submission Checklist

		To be marked by the applicant	To be marked by ERC office
1.	Cover letter signed by the applicant	<input type="checkbox"/>	<input type="checkbox"/>
2.	Completed and signed application form- 4 copies	<input type="checkbox"/>	<input type="checkbox"/>
3.	Structured study proposal along with protocol-4 copies	<input type="checkbox"/>	<input type="checkbox"/>
4.	Study instruments		
	English	<input type="checkbox"/>	<input type="checkbox"/>
	Sinhala	<input type="checkbox"/>	<input type="checkbox"/>
	Tamil	<input type="checkbox"/>	<input type="checkbox"/>
5.	Information Sheet		
	English	<input type="checkbox"/>	<input type="checkbox"/>
	Sinhala	<input type="checkbox"/>	<input type="checkbox"/>
	Tamil	<input type="checkbox"/>	<input type="checkbox"/>
6.	Data collection forms		
	English	<input type="checkbox"/>	<input type="checkbox"/>
	Sinhala	<input type="checkbox"/>	<input type="checkbox"/>
	Tamil	<input type="checkbox"/>	<input type="checkbox"/>
7.	Is the study proposal forwarded to the ERC email address along with application in a pdf format?		

Application for Ethics Review-Application Form

Section 01-

Research Project Title:

1.1 Name of the Applicant:

1.2 Registration Number:

1.3 Contact Number:

1.4 Email:

1.5 Nature of Project:

Group

Individual

1.6 Investigators:

1.6.1 Principle Investigator/Supervisor:

Title: Mr. Ms. Dr. Prof.

Name:

Qualifications:

Designation:

Place of Work:

Address:

Contact NOs:

Email Address:

Signature:

1.6.2 Co-Supervisor 1:

Title: Mr. Ms. Dr. Prof.

Name:

Qualifications:

Designation:

Place of Work:

Address:

Contact NOs:

Email Address:

Signature:

Section 02

2.1 Title of the project:

2.2 Proposed starting and ending dates:

Start Date:

End Date:

2.3 Has ethics review for this study been requested earlier from this committee or another similar committee?

Yes No

* Where?

* When?

* Result:

2.4 Nature	Yes	No	Specification
Questionnaire only	<input type="checkbox"/>	<input type="checkbox"/>	
Questionnaire + Sampling	<input type="checkbox"/>	<input type="checkbox"/>	
Observational Only	<input type="checkbox"/>	<input type="checkbox"/>	
Interventional Study	<input type="checkbox"/>	<input type="checkbox"/>	
Others (Please specify)	<input type="checkbox"/>	<input type="checkbox"/>	

2.5 Would consent be sought? Yes No Not Required

(If "Yes", attach a copy of the consent form)

Section 03- Methodology

3.1 What is your research question? (Give a brief description of the Hypothesis / Objectives in < 100 words)

3.2 Scientific background study:

3.2.1. Has similar type of studies been done before? Yes No

3.2.2 If “Yes”, give the results of the previous study briefly.

3.2.3 If “Yes”, please give reasons why you wish to repeat it.

3.2.4 Brief literature review of your study. (< 250 words)

3.2.5 What investigations and/or interventions will the subjects have?

3.3 Sample Size (justify whenever necessary):

3.4 Brief research design of the study (Describe the method in lay person's terms including the measurements to be made and all data to be collected in < 500 words)

Section 04- Safety of Subjects and Investigator/s

4.1 Briefly explain the precautions taken for the safety of the Subjects and Investigator/s.

4.2 What are the Ethical concerns of your study?

(a)

(b)

(c)

4.3 How do you address the above ethical issues in your study?

(a)

(b)

(c)

Please note that Clinical Trials need Trial Registration in an acceptable database before commencing the project.

Section 05- Comments and Observations of the Supervisor

- 1.
- 2.
- 3.
- 4.

Approval and signature:

Section 06 – Comments and Observation of Department head where the proposed study would take place.

- 1.
- 2.
- 3.
- 4.

Approval and signature:

Section 07 – Comments and Observation of the Head of the Institution where proposed study would take place

- 1.
- 2.
- 3.
- 4.

Approval and signature:.....

Section 06- Comments and Observations of the Reviewer

1.

2.

3.

	Satisfactory	unsatisfactory
Safety of study participants and the environment		
Scientific validity and reliability		
Compliance with customs, ethics and laws		
Technical and methodological coherence, integrity and scientific validity		
Relevance to clinical healthcare and national health care delivery		

Outcome

- Ethical clearance could be granted without any modification
- Ethical clearance could be granted with minor modifications
- Ethical clearance could be granted on resubmission with modification
- Ethical clearance could not be granted

Name of Reviewer :

Signature :

Date :

For official Use

Application No:										Date Received:			/			/		
Reviewed By:										Meeting Date:			/			/		
Decision:										Date Informed:			/			/		

