



Application for Ethics Review
Faculty of Allied Health Sciences
University of Peradeniya
(Undergraduate applicants)

Information to Applicants

- Please read the guidelines before completing the "Ethics Review Application" form. Please ensure all relevant documents are in order.
- 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.
- Undergraduate students must obtain approval from their respective departments before applying for ethical clearance and the application must be forwarded with the signature of the head of the department.
- The review process of the external (non-faculty) applications may take a minimum of three months. Therefore, please submit your applications for ethical clearance well in advance before the due date of the commencement of the research project.
- Applications are to be submitted before 10.00 am, of the third Wednesday of each month to be reviewed in the same month.
- The committee reserves the right to refuse or to accept applications for projects that are due to commence within three months of the date of the receipt of applications.
- The committee does not review applications for already commenced projects.
- The status (approval/ revision/ rejection) of your application will be notified via e-mail.
- During the resubmission:
 - indicate all corrections on the revised application using a highlighter pen/ track changer.
 - original previous reviewed application should be also submitted.

Guidelines to complete the ‘Ethics Review Application’

- ❖ The researcher requesting ethical clearance from the Ethics Review Committee (ERC), Faculty of Allied Health Sciences, University of Peradeniya is advised to submit following documents to avoid delays in processing the application.

PLEASE NOTE:

- ✓ **Undergraduate applicants** should be submitted only **one copy** of the below documents (except item 2 and 5), unless otherwise advised by a member of the ERC upon your submission.
- ✓ **One copy** of all the below documents 1 to 9 should be submitted by **all External undergraduate applicants**.
- ✓ **Two copies** of all the below documents 4 to 9 (one copy from item 1, 2 and 3) should be submitted by **all postgraduate and other research applicants**.
- ✓ In addition to above documents, **seven copies** of 2 page research summary without references should be submitted by all the applicants.
- ✓ **A digital copy** of the ethical clearance application form with all the annexures excluding section 1 should be emailed to ercahspdn@gmail.com as one pdf file. (Mention the research title as the email subject).

1. **Cover letter** addressed to the Ethics Review Committee of Faculty of Allied Health Sciences, Peradeniya
2. **Letter from supervisor and institute** (if relevant)*
* required for all postgraduate, external and other research applicants.

(For postgraduate study proposals; a letter is required from the relevant institute/board/committee OR the supervisor stating that the research proposal has been evaluated and has been found to be satisfactory for the purpose of postgraduate research.)

3. **Completed and signed submission checklist**
4. **Completed and signed Application form**
5. **Completed Proposal Protocol Checklist with the proposal**

6. *Study instruments* (English, Sinhala, Tamil)
7. *Information sheet(s) and consent form(s)* in English, and where appropriate, Sinhala and Tamil translations (e.g: when the study sample/population's knowledge in English may be inadequate to understand the nature of the study, their rights, etc).

Please note:

Consent forms need to be included for:

- participants if they are over 18
- parents, if participant is under 18/a child*

* A verbal or written assent is required from children at the time of participation, and this needs to be mentioned in the procedures.

8. *Assent form(s)*<if applicable> (English, Sinhala, Tamil)
9. Any type of *data collection form(s)* to be used during data collection (study questionnaire, check lists, interviewer guide, etc) in English, and where appropriate in Sinhala and Tamil translations as explained before.

- ❖ Documents of 3, 4, 5 and 7 in the above list are attached below.
- ❖ Attach both section 1 and 6 of the **Ethics Review Application form** as separate documents in the file.
- ❖ Do not disclose the **investigators' names and designations except in section 1 of the application form**. Please indicate the investigators' names and designations as "**xxxxxxx**" **on proposal, information sheet, consent form or where applicable**.
- ❖ If available, additional documentation regarding consent should be provided such as: screening materials, introductory letters, letters of administrative consent or authorization.(e.g., if the research is conducted at a hospital/hospital, letter(s) of permission from the hospital director(s), regional/provincial director(s); if the research is done at a school/schools, letter(s) of permission from the provincial directors, divisional secretariats and principals etc.)

Application for Ethics Review-**Submission Checklist**

Faculty of Allied Health Sciences, University of Peradeniya

NOTE:		To be marked by the applicant	To be marked by ERC office
<ul style="list-style-type: none"> • Undergraduate applicants should be submitted only one copy of the below documents (except item 2 and 4), unless otherwise advised by a member of the ERC upon your submission. • Two copies of all the below documents 3 to 9 (one copy from item 1 and 2) should be submitted by all postgraduate and other research applicants. 			
1.	Cover letter signed by the applicant	<input type="checkbox"/>	<input type="checkbox"/>
2.	Letter from supervisor and institute (if relevant)* * required for all postgraduate and external applicants	<input type="checkbox"/>	<input type="checkbox"/>
3.	Completed and signed application form	<input type="checkbox"/>	<input type="checkbox"/>
4.	Completed proposal protocol checklist with the proposal	<input type="checkbox"/>	<input type="checkbox"/>
5.	Study instruments		
	English	<input type="checkbox"/>	<input type="checkbox"/>
	Sinhala	<input type="checkbox"/>	<input type="checkbox"/>
	Tamil	<input type="checkbox"/>	<input type="checkbox"/>
6.	Information Sheet		
	English	<input type="checkbox"/>	<input type="checkbox"/>
	Sinhala	<input type="checkbox"/>	<input type="checkbox"/>
	Tamil	<input type="checkbox"/>	<input type="checkbox"/>
7.	Consent forms		
	English	<input type="checkbox"/>	<input type="checkbox"/>
	Sinhala	<input type="checkbox"/>	<input type="checkbox"/>
	Tamil	<input type="checkbox"/>	<input type="checkbox"/>
8.	Assent forms (if applicable)		

	English	<input type="checkbox"/>	<input type="checkbox"/>
	Sinhala	<input type="checkbox"/>	<input type="checkbox"/>
	Tamil	<input type="checkbox"/>	<input type="checkbox"/>
9.	Data collection forms		
	English	<input type="checkbox"/>	<input type="checkbox"/>
	Sinhala	<input type="checkbox"/>	<input type="checkbox"/>
	Tamil	<input type="checkbox"/>	<input type="checkbox"/>

PLEASE NOTE:

Your application will not be processed until all required documents are received by the ERC office.

.....

Signature of Principal Investigator

(or the first author, if a group project).

Date : _____

(DD/MM/YYYY)



Application for Ethics Review- **Application Form**

Faculty of Allied Health Sciences, University of Peradeniya

Section 01- Basic Information

1.1 Research Project Title:

1.2 Name of the Student:

(Indicate **Mr/Ms**)

1.3 Registration Number:

1.4 Contact Number:

1.5 Email:

1.6 Nature of Project:

Group

Individual

1.7 Investigators:

1.7.1 Principle Investigator/Supervisor:

Title: Mr. Ms. Dr. Prof.

Name:

Qualifications:

Designation:

Place of Work:

Address:

Contact NOs:

Email Address:

Signature:

1.7.2 Co-Supervisor 1:

Title: Mr. Ms. Dr. Prof.

Name:

Qualifications:

Designation:

Place of Work:

Address:

Contact NOs:

Email Address:

Signature:

(Start section 02 on a new page)

Section 02- Nature of Research (Please indicate with a “√” appropriately)

2.1 Title of the project:

2.2 Proposed starting and ending dates:

Start Date:

End Date:

* From initial recruitment of animals until completion of data collection.

‡Retrospective approval will not be given for projects already started or completed.

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			
Questionnaire + Sampling			
Observational Only			
Interventional Study			
Involving Animal Subjects (If “Yes”, specify)			
Involving Human Subjects (If “Yes”, specify the age group)			
Others (Please specify)			

2.5 Will Consent be sought? Yes No Not Required

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

2.6 Nature of the consent: Oral Written

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)

3.3 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)

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

- Absolutely necessary to use animal/Human subjects Yes No
- Minimum required number of Animal/Human subjects are used Yes No
- Animals are housed/looked after properly Yes No

Investigation/Intervention	Routine Procedure		Additional Procedure		Will cause additional discomfort / distress / inconvenience to subjects		Please specify when required
	Yes	No	Yes	No	Yes	No	
Local/General anesthesia							
Venepuncture							
Arterial puncture							
Biopsy							
Other tissue/Body Sample							
Ionizing Radioactive Substances/X-rays **							
Non-radioactive imaging investigations							
Other medicinal products **							
Medical Devices/Equipment / Procedures **							
Other instrument / Procedures **							
Hospitalization of Animal/Human Subjects							
Longer inpatient stays							
Additional outpatient attendance							
Other investigations / Procedures not part of routine care							

****** If additional procedures are done, please give details of the product / procedure / device / equipment and the quality and safety of the procedure / product with the estimated effective dosage / recommended usage.

Section 04- Safety of Subjects and Investigator/s

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

4.2 What are the Ethical concerns of your study?

(a)

(b)

(c)

(d)

(e)

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

(a)

(b)

(c)

(d)

(e)

**** 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.

(Print section 06 on a new page)

Section 06- Comments and Observations of the Reviewer

1.

2.

3.

4.

5.

Name of Reviewer :

Signature :

Date :

For official Use

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

Template of Information Sheet and Consent Form

PLEASE NOTE:

- **Do not duplicate the below sample consent form.**
Use it as a guide to prepare the consent form for your own research study.

Introduction:

I am Dr./Mr./Mrs./Ms. working in the (Department/Faculty/Institute).....
..... as (your designation).....**(OR)** We are (final year/fourth
year/etc.) students of the (Department/Faculty/Institute). I/We am/are doing a research on (topic of
research)..... This form provides you information and invites you to be part of this research.
You do not have to decide whether or not you will participate in the research today/now. You
may discuss the research with anyone you are comfortable with before making a decision to
participate or not.

This form may contain certain words that you not clearly understand. Please do not hesitate to stop
me/us to inquire from me/us at any point if you have any questions or need clarification. If any
questions/doubts arise at a later time, you may inquire from me/us at any time during this research.

Part 1: Information sheet

Title of the research:
.....
.....

Version Number:

Date:

Purpose of the research:

Briefly describe background of the problem, justification and the objectives of the research in
layman's terms.

Procedures of Research:

In layman's terms, give a concise description of the exact procedures in the exact order in a step by
step manner. Include information on many assessments, tests, measurements that will be performed.
Please indicate which procedures are routine and which are experimental or research.

Participants should understand clearly what to expect and what is expected of them. Use
active language, such as "we will ask you to...." instead of conditional language, such as "we would
like to ask you to....".

In clinical trials where randomization or blinding is involved, the participants should be told in
clear language what that means and what chance they have of getting which drug. Where an inactive
drug or placebo is involved, it is important to ensure that the participants understand what is meant
by a placebo or inactive drug.

In clinical research, explain that there are standards/guidelines that will be followed for the treatment of their condition. If blood samples are to be taken, explain how many times and how much of blood will be drawn. If the samples are to be used only for this research, then clearly mention that the biological samples obtained during this research procedure will be used only for this research, and will be destroyed after ____ years, when the research is completed. If the tissues/blood samples or any other human biological material will be stored for a duration longer than the research purpose, or is likely to be used for a purpose other than mentioned in the research proposal, then provide information about this and obtain consent specifically for such storage and use in addition to consent for participation in the study.

Participant selection and voluntary participation:

Briefly describe how and from where participants are selected for your study. Justify if needed. To inform about the voluntary participation, you may use the following format with necessary modifications as needed:

“Your participation in this research is entirely voluntary. It is your choice whether to participate or not. (Your decision will not affect any services you may receive at this facility). If you choose not to participate in this research project, please do not hesitate to let me/us know of your decision. You can change your mind at any time during this research and stop participating even if you agreed to participate now.”

For clinical trials only: (Omit this section if this is not a clinical trial)

Information on the Trial Drug [Name of Drug]

- give the phase of the trial and explain what that means. Explain to the participant why you are comparing or testing the drugs.
- provide as much information as is appropriate and understandable about the drug such as its manufacturer or location of manufacture and the reason for its development.
- explain the known experience with this drug
- explain comprehensively all the known side-effects/toxicity of this drug, as well as the adverse effects of all the other medicines that are being used in the trial

Duration:

Mention the estimated duration of your project; specify dates if possible. You may use the following format with necessary modifications as needed:

“The research takes place over ____ (number of) days/ or ____ (number of) months in total. During that time (please explain what the person is expected to do for the research briefly).”

Risks/Hazards/Discomforts:

If there are any risks/hazards/discomforts involved in your research study, please mention all clearly.

Potential Benefits:

If there are any potential benefits to the participants, to the researchers, and/or to the society as a whole as a result of your research study, all benefits should be mentioned.

You may use the following format with necessary modifications as needed:

“If you participate in this research, you will have the following benefits:”

.....
.....

(OR)

There are no (direct) benefits for you by participating in this research, but your participation is likely to help us find the answer to the research question. There may not be any benefit to the society at this stage of the research, but future generations are likely to benefit.

Reimbursement:

If the participants are reimbursed either monetarily or otherwise (e.g., gifts), please mention the details, including any payment to the participant indicating the amount or details of the gift(s) if necessary, when it would be paid/given and any conditions attached to it.

If no reimbursements will be given, please mention this as well.

You may use the following format with necessary modifications as needed:

“We will pay you Rs..... to pay for your travel/time as a token of appreciation for participating in this research **(OR)** We will give you (gift/s) as a token of appreciation for participating in this research.

(OR)

“We unable to reimburse you for your participation in this research either monetarily or any other form of gift(s). We are grateful for your participation.”

Confidentiality:

Briefly describe what measures are taken to ensure the participants’ confidentiality by participating in your research study.

You may use the following format with necessary modifications as needed:

“The information that we collect from this research project will be kept confidential. Information about you that will be collected during the research will be put away and no-one but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone except (name who will have access to the information:)”

Right to Refuse or Withdraw:

Include a statement informing about their right to withdraw from participation or refuse to participate. You may use the following format with necessary modifications as needed:

“You do not have to take part in this research if you do not wish to do so (and your decision will not affect any services you may receive at this facility/by me/by us as part of routine care). You may also stop participating in the research at any time you choose. It is your choice and all of your rights will still be respected.”

Whom to Contact:

Include a statement such as “If you have any questions, you may ask us now or later, even after the study has started. If you wish to ask questions later, you may contact any of us or our supervisor(s) through following contact details.”

Please provide details of ALL researchers that should be contacted in the following format.

Name with title:-

Address:-

Telephone number/e-mail:-

This research proposal has been reviewed and approved by the Ethics Review Committee of the Faculty of Allied Health Sciences.

PART II: Certificate of Consent

To be completed:

A. By the participant

The participant should complete the whole of this sheet himself/herself.

1. Have you read the information sheet? (Please keep a copy for yourself) YES/NO
2. Have you had an opportunity to discuss this study and ask any questions? YES/NO
3. Have you had satisfactory answers to all your questions? YES/NO
4. Have you received enough information about the study? YES/NO
5. Who explained the study to you?
6. Do you understand that you are free to withdraw from the study at any time, without having to give a reason and without affecting your future medical care? YES/NO
7. Sections of your medical notes, including those held by the investigators relating to your participation in this study may be examined by other research assistants. All personal details will be treated as **STRICTLY CONFIDENTIAL**. Do you give your permission for these individuals to have access to your records? YES/NO
8. Have you had sufficient time to come to your decision? YES/NO
9. Do you agree to take part in this study? YES/NO

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Name of Participant _____

Signature of Participant _____

Date _____

(DD/MM/YYYY)

If illiterate:

A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb-print as well.

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness _____ AND Thumb print of participant

Signature of witness _____

Date _____

(DD/MM/YYYY)

B. By the investigator

I have explained the study to the above volunteer and he/ she has indicated her willingness to take part.

Signature of investigatorDate.....

Name (BLOCK CAPITALS).....