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 provided.
- 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 two months. Therefore, please submit your applications for ethical clearance well in advance before the due date of the commencement of the research project.
- 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.
- **During the resubmission:**
    - Indicate all corrections on the revised application using a highlighter pen/ track changer.
    - Original previous reviewed application should also be submitted.
    - Revised application should be submitted within 6 weeks of time of the notification. If the revision is not possible by that date, then the application will be considered as a new submission.

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 the following documents to avoid delays in processing the application.

PLEASE NOTE:

- ✓ **Undergraduate applicants** should submit only **one copy** of the documents given below (see the next section), unless otherwise advised by a member of the ERC upon your submission.

- ✓ **A single PDF file** of the ethical clearance application form with all annexures **excluding section 1** should be emailed to erc@ahs.pdn.ac.lk . In addition to the above documents, a two-page research summary without references and section 1 should be attached as separate documents (mention the research title as the email subject).

- ✓ The summary should consist of:
    - Brief introduction/literature review
    - Objectives
    - Methodology
    - Ethical concerns
    - How to address/overcome the ethical concerns

Documents to be submitted:

1. ***Cover letter*** addressed to the Ethics Review Committee of the Faculty of Allied Health Sciences, University of Peradeniya
2. ***Letter from the supervisor/s and institute*** (if relevant)*
   * required for all external applicants.
3. ***Completed and signed submission checklist***
4. ***Completed and signed Application form***
5. ***Study instruments*** (English, Sinhala, Tamil)
6. ***Information sheet(s) and consent form(s)*** in English, and where appropriate, Sinhala and Tamil translations (eg.: 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.

7. ***Assent form(s)*** <if applicable> (English, Sinhala, Tamil)

8. Any type of ***data collection form(s)*** to be used during data collection (study questionnaires, check lists, interviewer guides, etc.) in English, and where appropriate translations in Sinhala and Tamil as explained before.

- Do not disclose the **investigators' names and designations except in section 1 of the application form**. Please indicate the investigators' names and designations **as "xxxxxxxx" 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(s), letter(s) of permission from the hospital director(s), regional/provincial director(s); if the research is done at a school(s), 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

		To be marked by the applicant	To be marked by ERC office
1.	Cover letter signed by the applicant	☐	☐
2.	Letter from the supervisor/s and institute (if relevant)* * required for all **external** applicants	☐	☐
3.	Completed and signed application form	☐	☐
4.	Study instruments **English**	☐	☐
	Sinhala	☐	☐
	Tamil	☐	☐
5.	Information Sheet **English**	☐	☐
	Sinhala	☐	☐
	Tamil	☐	☐
6.	Consent forms **English**	☐	☐
	Sinhala	☐	☐
	Tamil	☐	☐
7.	Assent forms (if applicable) **English**	☐	☐
	Sinhala	☐	☐
	Tamil	☐	☐
8.	Data collection forms **English**	☐	☐

	Sinhala	☐	☐
	Tamil	☐	☐

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 : _____

Application for Ethics Review-Application Form

Faculty of Allied Health Sciences, University of Peradeniya

Application No: …….. Date Received:……

For office use only

……

SECTION 01- BASIC INFORMATION

1.1 Research Project Title:

1.2 Name of the Student (s): (Indicate **Mr/Ms**)

1.3 Registration Number (s):

1.4 Contact Number:

1.5 Email:

1.6 Nature of Project: Group ☐ Individual ☐

1.7 Supervisors:

1.7.1 Principle Supervisor:

Title: Mr. ☐ Ms./Mrs. ☐ Dr. ☐ Prof. ☐

Name:

Qualifications:

Designation:

Place of Work:

Address:

Contact NOs:

Email Address:

Signature:

1.7.2 Co-Supervisor 1:

Title: Mr. ☐ Ms./Mrs. ☐ 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 until completion of data collection.*

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

2.3 Site of data collection:

(specify community/hospital/clinic/field…etc.)

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

Yes ☐ No ☐

If yes, provide a copy of the communications/certificates

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

SECTION 03- RESEARCH PROPOSAL AND METHODOLOGY

3.1 What is your research question? (Give a brief description of the Hypothesis, Objectives and clear justification for the study in < 500 words)

3.2 Scientific background of the study :

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

If "Yes", please give reasons why you wish to repeat it.

3.2.2. 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 study design and measurements to be made and all data to be collected in < 500 words)

Recruitment of Participants

Will consent be sought? **Yes** ☐ **No** ☐ **Not Required** ☐

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

Nature of the consent: **Oral** ☐ **Written** ☐

Describe the consent procedure (who will obtain the consent and how?)

Are there any subjects included with special considerations such as vulnerable group/children less than 18 years? **Yes** ☐ **No** ☐

If yes, how will consent be sought (briefly describe)

If subjects with age group 12-18 are included, in addition to parent consent, assent form should be signed. How would you seek the assent?

Please attach the assent from ☐

SECTION 04- DESCRIPTION OF THE RISKS AND BENEFITS

a) Risks

- Possible risks should be described including physical (body damage or administration of substances…etc.), psychological/emotional (feeling upset, embarrassment…etc.), social (privacy, loss of status…etc.) and legal risks.

- How would you minimize the risks stated above?

b) Benefits

- Describe the potential benefits for the study participants, community and scholarly community.

c) Compensation:

- Describe whether participants will receive any form of compensation or not.

d) Feedback

- Describe the feedback participants/community will receive.

e) Give statement on how you would handle data security, retention and access.

Declaration of Applicant

- I/we do hereby declare that all the procedures mentioned in this application will be followed according national and international policies governing the research involved in human subjects.
- I/we ensure that any amendments to this proposal will be immediately informed to the committee and approval will be sought prior to implementation.
- I/we declare that any form of data collection has not been started and not seeking approval for the completed studies.
- I/we understand that it will take at least 2 months to process the application.
- I will also ensure that any serious adverse events will be reported to the committee immediately.

Name of the student(s)	Signature	Date

SECTION 05- COMMENTS AND OBSERVATIONS OF THE SUPERVISOR

As a supervisor of this study, I confirm that I have read and approve the scholarly merit of this research and will provide necessary supervision throughout the research. I will ensure that the national and international policies governing research involved in human subjects will be followed.

Comments/Observations by the supervisor:

Name of the supervisor(s)	Signature	Date

Signature of the Head of the Department

I……..as the Head of the department confirm that this research proposal was presented during the proposal presentation and the department agrees with the proposed study.

Signature of the Head of the Department and stamp: ……

Date: ……

(Print section 06 on a new page)

SECTION 06- COMMENTS AND OBSERVATIONS OF THE REVIEWER

Name of Reviewer **:……**

Signature **:……**

Date **: ……**

For official Use

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

Template for Information Sheet and Consent Form

PLEASE NOTE: Do not duplicate the sample consent form below.

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 may 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 clarifications. 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 any assessments, tests, measurements that will be performed. Please indicate which procedures are routine and which are experimental or investigational.

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 are unable to reimburse you for your participation in this research either monetarily or by 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 the following contact details."

Please provide details of ALL researchers that can 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, University of Peradeniya.

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 _____

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 _____

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 investigator……..……..Date…….

Name (BLOCK CAPITALS)……