Application for Ethics Review

Faculty of Allied Health Sciences

University of Peradeniya

(Postgraduate applicants/Academics/Researchers)

1. Information to Applicants

1.1. Submitting Ethics Review Applications

- 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).
- Two soft copies of all the documents should be prepared as mentioned below and email to ERC email erc@ahs.pdn.ac.lk
  1. **Original copy**: A PDF of the completed Ethics Application form **including section 01** of the application with all other relevant documents mentioned in section 2.2. of the application.
  2. **Blind copy**: A PDF of the completed Ethics Application form **excluding section 01** of the application and with all other relevant documents mentioned in section 2.2. of the application. Do not disclose the investigators' names and designations in this copy. Indicate the investigators' names and designations as "xxxxxxxx" on the proposal, information sheet, consent form or where applicable.
- Rename each copy as "original copy" and "blind copy".
- Indicate only the title of the research topic as the subject of the email.
- To avoid unnecessary delays, please submit your applications for ethical clearance well in advance of the commencement of the research project. The review process of the applications may take a minimum of two months.
- The calendars of dates of ERC's forthcoming meetings are given on the Faculty of Allied Health Sciences website https://ahs.pdn.ac.lk/subcom12. Applications should be submitted **at least 15 working days** before the scheduled meeting of each month to be reviewed in the same month.
- The committee reserves the right to refuse or 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.

1.2. Resubmission of the revised applications

- Indicate all corrections on the revised application. Highlight suggested changes as a tracked version and submit both tracked and clean versions to the committee for further evaluation.
- Resubmission should also accompany a point-by-point response to the reviewer's comments.
- The revised application should be submitted within 6 weeks of the time of the notification. If the revision is not possible by that date, then the application will be considered as a new submission.
- Send the revised document to the same email thread that you received reviewer comments from the ethics review committee as a reply email.

1.3. Payments for Applications

- Payment for an Ethics Review application of external applicants including postgraduate students - **Rs.3000/=**
- Please note that all payments regarding ERC can be paid to the shroff counter of the Faculty of Allied Health Sciences from 9.00 a.m. to 3.00 p.m. during working days, or by direct deposit to the following bank account.
    - **No: 057 1 001 16994228**
    - **Account Name: Faculty of Allied Health Sciences Fund Account**
    - **Bank: People's Bank, Peradeniya Branch**

- Please send the proof of payment with the application.
- The application fee is non-refundable.
- The application fee is exempt if the principal investigator is a staff member of the Faculty of Allied Health Sciences, University of Peradeniya.

2. Guidelines to complete the 'Ethics Review Application.

2.1 General

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.

2.2. Sections of the Ethics Review Application

The documents should be prepared and attached in the following order.

1. ***Cover letter*** addressed to the Ethics Review Committee of Faculty of Allied Health Sciences, University of Peradeniya.
2. ***Letter from the supervisor/s and/or the relevant 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. ***Protocol Assessment Form and Checklist for Reviewer.***
6. ***Study instruments*** in English (if required in languages of Sinhala and Tamil).
7. ***Information sheet(s) and consent form(s)*** in English, and where appropriate, Sinhala and Tamil translations (e.g.: In situations where the study participants' English knowledge is inadequate to understand the nature of the study, instructions, their rights, and consent).

   Consent forms need to be included for:

   - participants if they are over 18
   - parents/legal guardian, if the participants are under 18 years of age*

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

8. ***Assent form(s)*** **in English** and, where appropriate, in Sinhala and Tamil translations.
   ******If applicable in languages of English, Sinhala, and Tamil.
9. Any type of ***data collection form(s*****)** to be used during data collection (study questionnaire(s), checklist(s), interviewer guide(s), etc.) in English and, where appropriate, in Sinhala and Tamil translations.

- 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.)

2.3. Disclosure of study investigator's identity

Do not disclose the **investigators' names and designations in the blind copy of the application.** Please indicate the investigators' names and designations **as "xxxxxxxx" on proposal, information sheet, consent form or where applicable.**

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 supervisor/institute (if relevant)* *Required for **all postgraduate and external** applicants	☐	☐
3.	Completed and signed application form	☐	☐
4.	Protocol Assessment Form and Checklist for Reviewer	☐	☐
5.	Study instruments		
	English	☐	☐
	Sinhala	☐	☐
	Tamil	☐	☐
6.	Information Sheet		
	English	☐	☐
	Sinhala	☐	☐
	Tamil	☐	☐
7.	Consent forms		
	English	☐	☐
	Sinhala	☐	☐
	Tamil	☐	☐
8.	Assent forms (if applicable)		
	English	☐	☐
	Sinhala	☐	☐
	Tamil	☐	☐
9.	Data collection forms		
	English	☐	☐
	Sinhala	☐	☐
	Tamil	☐	☐
10	Others (specify)	☐	☐

PLEASE NOTE:

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

……

Signature of Principal Investigator

Date : _____

Application for Ethics Review-Application Form

Faculty of Allied Health Sciences, University of Peradeniya

For official Use

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

Section 01- Basic Information

1.1 Title of the Project:

1.2 Investigators:

1.2.1 Principle Investigator/Supervisor:

Title: Mr. ☐ Ms./Mrs. ☐ Dr. ☐ Prof. ☐

Name:

Qualifications:

Designation:

Place of Work:

Address:

Contact NOs:

Email Address:

Signature:

	Yes	No
1.2.1.1 Is this study part of a/requirement for a postgraduate degree?	☐	☐
1.2.1.2 Have you already registered for this degree?	☐	☐

Type of degree (MSc/M.Phil/PhD)		
Awarding University		
Date of Registration:		Letter annexed:

Include all supervisors, and co-investigators in this application

1.2.2 Investigator 1:

Title: Mr. ☐ Ms./Mrs. ☐ Dr. ☐ Prof. ☐

Name:

Qualifications:

Designation:

Place of Work:

Address:

Contact NOs:

Email Address:

Signature:

1.2.3 Investigator 2:

Title: Mr. ☐ Mr./Mrs. ☐ Dr. ☐ Prof. ☐

Name:

Qualifications:

Designation:

Place of Work:

Address:

Contact NOs:

Email Address:

Signature:

1.2.4 Investigator 3:

Title: Mr. ☐ Ms./Mrs. ☐ Dr. ☐ Prof. ☐

Name:

Qualifications:

Designation:

Place of Work:

Address:

Contact NOs:

Email Address:

Signature:

1.2.5 Investigator 4:

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:

Where will the study take place? ……

Is this a multi-site study? Yes ☐ No ☐

Specify all study sites

If the research is to be conducted at a site requiring administrative approval/consent (e.g., in a hospital/school), it is the responsibility of the researcher to obtain approval prior to starting the project.

Type of site (Hospital/Clinic/School/Community…etc.)	**Details**

2.2 Proposed starting and ending dates:

Start Date: ☐ End Date: ☐

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

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

Yes ☐ No ☐

* Where? ☐

* When? ☐

* Result: ☐

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

Submit a detailed protocol separately

3.1 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 < 1000 words)

3.2 Is all or part of your application a pilot study?

Yes ☐ **No** ☐

A pilot study is an **initial** investigation to give information that will be necessary when designing a future trial or study.

SECTION 04- SAFETY OF SUBJECTS AND INVESTIGATOR/S, RISKS, ETHICAL PROBLEMS

4.1 Are there any potential hazards/risks to the human subjects, their relatives, and investigator/s?

1. Possible Risks

Please indicate all potential risks to participants that may arise from this research:

Risks	**Yes**	**No**
Physical risks (E.g. any bodily contact or administration of any substance)		
Psychological/emotional risks (E.g. feeling uncomfortable, embarrassed, upset)		
Social risks (E.g. loss of status, privacy and/or reputation)		
Legal risks (E.g. apprehension or arrest, subpoena)		

If yes to any of the above, please describe.

State measures employed during the procedure/study to remove or minimize these risks

2. Possible Benefits

- Describe any potential direct benefits to participants from their involvement in the project
- Describe any potential direct benefits to the community (e.g., capacity building)
- Comment on the potential benefits to the scientific/scholarly community or society that would justify the involvement of participants in this study

3. Compensation

3.1 Are there any financial incentives for the subject?

Yes ☐ *If Yes, please give details.*

No ☐

3.2 Will participants receive compensation for participation?

Compensation	**Yes**	**No**
Financial		
In-kind		
Others		

If **yes**, please provide details and justification for the amount or the value of the compensation offered.

If **No**, please explain why compensation is not possible or inappropriate.

If participants choose to withdraw, how will compensation be affected?

4. Feedback/ Debriefing/ Referral/ After-Care

Please describe what information/feedback/services will be provided to participants and/or communities after their participation in the project is complete (e.g., health education, referral to clinic/hospital, etc.)

5. Do you, the applicant, or any of the co-investigators, including supervisors, have any conflict of interest related to this project?

Conflict of interest	**Yes**	**No**
Financial		
Commercial		
Intellectual		
Other		

If you state 'yes' for any of the above, please describe.

6. Does any member of the research team have any affiliation with the provider(s) of funding/support, or a financial interest in the outcome of the research?

Yes ☐ No ☐

If yes, please explain:

ONLY COMPLETE APPENDICES **A**, **B, C** AND **D** IF RELEVANT TO YOUR STUDY

SECTION 05: DECLARATION OF APPLICANT

- As the principal investigator of this project, I will ensure that all procedures performed under the project are conducted in accordance with all relevant national and international policies and regulations that govern research involving human participants.
- I understand that if there is any deviation from the project as originally approved, I must submit an amendment to the ERC for approval prior to its implementation.
- I declare that I am not seeking approval for a study that has already commenced or has already been completed.
- I will submit progress reports/reports of adverse events and side effects as requested by the ERC/FAHS.
- I will submit the final reports at the completion of the study.
- I understand that at least two months are required for ethics review and granting of ethics clearance.

…….. ……

Signature of Principal Investigator Date

……..

Full name of Principal Investigator

Consent from all Investigators

We, the undersigned hereby confirm that we have consented to be co-investigators of the project titled '……'

Name	Qualifications	Institutional Affiliations	Signature

ONLY COMPLETE APPENDICES **A**, **B, C** AND **D** IF RELEVANT TO YOUR STUDY

Appendix A — Radioactivity

A.1 Radioactive substances

a) Details of substances to be administered.

b) Estimated effective dose (effective dose equivalent) (mSv).

Please supply source of reference or submit calculation.

c) Absorbed dose to organ or tissues concentrating radioactivity (mGy)

Please supply source of reference or submit calculation.

A.2 X-rays

a) Details of radiographic procedures.

b) Estimated effective dose (effective dose equivalent) (mSv).

Please supply source of reference or submit calculation.

I have delegated authority to administer the radioactive substance(s) in this project to Rev/Prof/ Dr/Mr/Ms…… and I approve the arrangements that have been made.

……
Signature of Consultant/Head Radiology or Nuclear Medicine or oncology.

Date: ……..

Appendix B	**Medicinal Products**

B.1 Will the medicinal product be:

- **unlicensed?** **Yes** ☐ **No** ☐
- **a licensed product to be used outside the terms of its product license?** **Yes** ☐ **No** ☐

B.2 Details of medicinal product

Please submit the data sheet for licensed products.

Approved name:

Strength:

Dosage, form and frequency:

Route of administration:

B.4 Safety, stability and purity data relevant to the protocol usage.

Please provide information on the following, including references where appropriate.

a) Toxicity:

b) Purity:

c) Stability:

B.5 Who will administer the product? (Name/Designation, Address?)

B.6 Manufacturing information.

a) Who is the supplier?

b) What manufacturing license(s) do they hold?

B.7 Have arrangements for dispensing been made with the pharmacy?

Yes ☐ *If **Yes**, state who your advisor is.*

No ☐ *If **No**, explain why not.*

C.1 Will the medical device/item of medical equipment be:

* **a prototype/currently un-marketed product?** **Yes** ☐ **No** ☐

* **a new application of an existing product?** **Yes** ☐ **No** ☐

C.2 Details of Medical Devices/Equipment

Please attach any details of the manufacturer's recommended usage for existing products.

Approved name:

Intended study usage:

C.3 Safety data relevant to the protocol usage.

a) Is there any quality approval mark for this product? **Yes** ☐ **No** ☐

*If **No,** please indicate the classification of a company manufactured device under the EC Directive. It relates to the level of risk attached to the product and can be obtained from the manufacturer.*

b) Please give details of relevant safety data, including references where appropriate.

C.5 Who will fit the device/use the equipment?

C.6 Who is the supplier and how do they ensure appropriate manufacturing quality?

Please supply certification or registration numbers.

Appendix D	Research involving Genetic Modification

D.1 Have you considered Genetic Modification Safety in performing this work?

Yes ☐ **No** ☐

If Yes, please give details

Application for Ethics Review
Faculty of Allied Health Sciences
University of Peradeniya

Protocol Assessment Form and Checklist for Reviewer

(Applicant must fill all the relevant sections and submit)

For official Use

Application No:								

For the Reviewer

Section 01- Declaration (Mark your response appropriately)

- I have conflicts of interest in reviewing this research proposal ☐
- I have no conflict of interest in reviewing this research proposal ☐

Title of the Research Project:

- **Indicate the type of the study:** Postgraduate/Not related to a degree

  ……..
  (If a postgraduate study, indicate the name of the degree and registered university)

- **Please include the following information as given in your research proposal, indicating the page number(s) relevant to each section in the box, which will help the reviewers.**

		Yes	**No**	**N/A**	**Section & Page**	*Reviewer checked/ Comments (For the Reviewer)*
1.	**Collaborative partnership**					
1.	Collaborations established with institutions where the					

		Yes	No	N/A	Section & Page	*Reviewer checked/ Comments (For the Reviewer)*
	study is to be conducted	☐	☐	☐		
2.	Collaborations established with the community where the study is to be conducted	☐	☐	☐		
3.	Benefits to institutions, communities and participants in your research	☐	☐	☐		
Reviewer's comments						
2.	**Social Value**					
1.	Beneficiaries of the research and the benefits to the participants and others	☐	☐	☐		
2.	Plan for dissemination of study findings	☐	☐	☐		
Reviewer's comments						
3.	**Scientific Validity**					
1.	Scientific importance of the study in relation to improving health care and/or knowledge on the subject	☐	☐	☐		
2.	Justification if the study is a replication study	☐	☐	☐		
3.	How the sample size was calculated?	☐	☐	☐		
Reviewer's comments						

		Yes	No	N/A	Section & Page	*Reviewer checked/ Comments (For the Reviewer)*
4.	**Confidentiality**					
1.	How the data and samples will be obtained?	☐	☐	☐		
2.	How long data and samples will be kept?	☐	☐	☐		
3.	Justification for collection of personal identification data	☐	☐	☐		
4.	Who will have access to personal data of the research participants?	☐	☐	☐		
5.	How confidentiality of participants will be ensured?	☐	☐	☐		
6.	Procedure for data and sample storage	☐	☐	☐		
7.	Procedure for data and sample disposal	☐	☐	☐		
Reviewer's comments						
5.	**Rights of the participants**					
1.	Procedure for subjects to withdraw from the research at any time	☐	☐	☐		
2.	Procedure for subjects to ask questions and register complaints	☐	☐	☐		
3.	Procedure to register complaints	☐	☐	☐		

		Yes	No	N/A	Section & Page	*Reviewer checked/ Comments (For the Reviewer)*
4.	Contact person for research subjects	☐	☐	☐		
5.	Provisions for participants to be informed of results	☐	☐	☐		
6.	Provision to make the study product available to the study participants after research	☐	☐	☐		
Reviewer's comments						
6.	**Fair participant selection**					
1.	Justification for the selection of the study population	☐	☐	☐		
2.	Inclusion and exclusion criteria	☐	☐	☐		
7.	**Responsibilities of the researcher**					
1.	Provision of medical care to research participants	☐	☐	☐		
2.	Provisions for continuation of care after the research is completed	☐	☐	☐		
3.	Declaration of conflicts of interests and how the investigators plan to manage the conflicts	☐	☐	☐		
4.	Ethical/legal/social and financial issues relevant to the study.	☐	☐	☐		
Reviewer's comments						

		Yes	No	N/A	Section & Page	*Reviewer checked/ Comments (For the Reviewer)*
8.	**Vulnerable populations**					
1.	Justification for conducting the study in this population	☐	☐	☐		
Reviewer's comments						
9.	**Research funded by industry**					
1.	Justification for conducting the study in Sri Lanka	☐	☐	☐		
2.	Relevance of the study to Sri Lanka	☐	☐	☐		
3.	Post research benefits to Sri Lanka	☐	☐	☐		
4.	Steps taken to take into account cultural and social customs, practices, and taboos in Sri Lanka	☐	☐	☐		
5.	Sharing of rights to intellectual property	☐	☐	☐		
6.	Fate of data and biological samples including whether they will be transferred abroad and what will happen to them after the conclusion of the study	☐	☐	☐		
7.	Agreement between the sponsor/funding agency and the investigator	☐	☐	☐		
8.	Materials transfer agreement, if biological material is to be transferred abroad	☐	☐	☐		

		Yes	No	N/A	Section & Page	*Reviewer checked/ Comments (For the Reviewer)*
Reviewer's comments						
10.	**Community based research**					
1.	Impact and relevance of the research to the community in which it is to be carried out	☐	☐	☐		
2.	Procedure used to obtain consent from the community leader	☐	☐	☐		
3.	Contribution to capacity building of the community	☐	☐	☐		
4.	Procedure for making available results of the research to the community	☐	☐	☐		
Reviewer's comments						
11.	**Clinical trials/other clinical studies**					
1.	Justification for withdrawing any therapy from participants to prepare them for the trial	☐	☐	☐		
2.	Justification for withholding standard therapy from trial participants (e.g. control group)	☐	☐	☐		
3.	Justification for deviating from the accepted standard procedure	☐	☐	☐		
4.	Procedure for dealing with adverse events	☐	☐	☐		

		Yes	No	N/A	Section & Page	*Reviewer checked/ Comments (For the Reviewer)*
5.	Procedure for reporting adverse events	☐	☐	☐		
6.	Provisions for safety monitoring	☐	☐	☐		
7.	Provisions/criteria for termination of the trial	☐	☐	☐		
8.	Provisions for making the trial drug available to participants after the trial, if found to be effective	☐	☐	☐		
Reviewer's comments						

12.	**Information Sheet (IFS)/Informed Consent Form (ICF) Check List** (List the sections in IFS/ICF where you have dealt with the following)	**Section IFS/ICF**	**Reviewer checked/ Comments**
1.	Purpose of the study		
2.	Voluntary participation		
3.	Duration of the study		
4.	Procedures of the study		
5.	Participant's responsibilities		
6.	Potential benefits		
7.	Risks, hazards and discomforts		
8.	Reimbursements		
9.	Confidentiality		
10.	Termination of study participation		
Reviewer's comments			

		Yes	No	N/A	Section & Page	Reviewer checked/ Comments
13.	**Consent** (List the sections in consent form where you have dealt with the following)					
1.	Procedure for initial contact of participants*	☐	☐	☐		
2.	Procedure for obtaining informed consent - Verbal/Written	☐	☐	☐		
3.	Information (written/oral) provided to participants	☐	☐	☐		
4.	Has the understanding of the subjects verbally verified (making sure subjects understand the intended message)	☐	☐	☐		
5.	Procedure for obtaining proxy consent	☐	☐	☐		
6.	Procedure for withdrawing consent	☐	☐	☐		
7.	Incentives/rewards/compensation provided to participants	☐	☐	☐		
8.	The procedure for re-consenting if the research protocol changes during the course of research	☐	☐	☐		
9.	The procedure for consenting if vulnerable groups / children under 18 years of age will be recruited	☐	☐	☐		
10.	The procedure for consenting if children aged 12 - 18 years of age will be recruited. (for children aged 12-18 years, in addition to parental consent, children's assent must be sought)**	☐	☐	☐		
Reviewer's comments						

*** Attach a copy of all posters, advertisements, flyers, letters to be used for recruitment.**

**** Attach an assent form for children aged 12-18 years.**

For official Use

14. Overall Comments of the Reviewer:

Final Decision: (PLEASE TICK ✓)

Accepted without any modifications	
Accepted with minor modifications	
Accepted with major modifications	
Not Accepted	

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 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 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 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 _____

(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 investigator……..……..Date…….

Name (BLOCK CAPITALS)……