**Faculty of Medicine, Sabaragamuwa University of Sri Lanka**

**ETHICS REVIEW COMMITTEE**

**APPLICATION FOR ETHICS REVIEW**

*For official use only*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Application No: | ERC/SAB/YEAR/000 | | Date of Received: |  |  | / |  |  | / |  |  |  |  |
| Reviewed by: |  | | ERC Meeting Date: |  |  | / |  |  | / |  |  |  |  |
| ERC Discussion: | No Risk / Minimal Risk / Greater than Minimal Risk | | | | | | | | | | | | |
| ERC Recommendation: | Exempt from Ethic Review / Expedited Review / Full Committee Review | | | | | | | | | | | | |
| Decision: | Approved |  | Date Informed: |  |  | / |  |  | / |  |  |  |  |
| Approved with corrections |  |
| Resubmission |  |
| Rejection |  |

**PART I – BASIC INFORMATION**

1. **Title of Research Project**
2. **Investigators**
   1. **Details of Principal Investigator**

|  |  |
| --- | --- |
| Title | Mr / Ms / Rev / Dr / Prof |
| Name |  |
| Current designation |  |
| Institute where the applicant is attached |  |
| Highest educational qualification of the applicant |  |
| Telephone (office) |  |
| Telephone (home) |  |
| Telephone (mobile) |  |
| E mail (main method of communication) |  |
| Address for correspondence |  |
| Signature |  |

* 1. **Details of Other Investigator**

|  |  |  |  |
| --- | --- | --- | --- |
| Co-Investigator |  | Supervisor |  |

|  |  |
| --- | --- |
| Title | Mr / Ms / Rev / Dr / Prof |
| Name |  |
| Current designation |  |
| Institute where the applicant is attached |  |
| Highest educational qualification of the applicant |  |
| Telephone (office) |  |
| Telephone (home) |  |
| Telephone (mobile) |  |
| E mail (main method of communication) |  |
| Address for correspondence |  |
| Signature |  |

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| --- | --- | --- | --- |
| Co-Investigator |  | Supervisor |  |

|  |  |
| --- | --- |
| Title | Mr / Ms / Rev / Dr / Prof |
| Name |  |
| Current designation |  |
| Institute where the applicant is attached |  |
| Highest educational qualification of the applicant |  |
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| Telephone (home) |  |
| Telephone (mobile) |  |
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| Signature |  |

* 1. **Details of Other Investigator**

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| --- | --- | --- | --- |
| Co-Investigator |  | Supervisor |  |

|  |  |
| --- | --- |
| Title | Mr / Ms / Rev / Dr / Prof |
| Name |  |
| Current designation |  |
| Institute where the applicant is attached |  |
| Highest educational qualification of the applicant |  |
| Telephone (office) |  |
| Telephone (home) |  |
| Telephone (mobile) |  |
| E mail (main method of communication) |  |
| Address for correspondence |  |
| Signature |  |

* 1. **If this is a student project** **(undergraduate or post graduate)** please give details of your academic supervisory arrangements.

|  |  |
| --- | --- |
| Course/degree |  |
| Faculty/ Institution |  |
| Academic supervisor/s  (*name, affiliation and qualifications*) |  |

1. **Nature of Research Project**
   1. Is it for an academic degree: Yes No
   2. If yes, specify:

Post graduate degree Undergraduate degree

Diploma Other

1. **Proposed commencing and concluding dates**

*[From initial recruitment of participants until completion of all data collection]*

D D M M Y Y Y Y

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Date of commencement |  |  |  |  |  |  |  |  |  |  |
| Date of conclusion |  |  |  |  |  |  |  |  |  |  |

1. **Study Type** *(you may tick more than one box)*

|  |  |
| --- | --- |
| Case-control study |  |
| Cohort study |  |
| Cross-sectional study |  |
| Health system research |  |
| Implementation research |  |
| Interviews, focus group |  |
| Laboratory study not using animals |  |
| Laboratory study using animals |  |
| Laboratory study using stored human biological material |  |
| Other type of qualitative study |  |
| Participant observation |  |
| Phase 1 or 2 of trial using a experimental drug or device |  |
| Randomized Controlled Trial not using experimental drug or device |  |
| Randomized Controlled Trial using experimental drug or device |  |
| Research on medical records or other personnel information |  |
| Social science research |  |
| Other type of study (please describe) |  |

1. **Previous ethical review**

Has ethical review for this study been sought earlier from this or another similar Ethics Review Committee (ERC)? Yes No

* 1. If yes Reference number No: ...….…….……………...
  2. Results of that review (if relevant) ………………………………………………………….

1. **Funding**
   1. Source of Funding: ………………………………………………………………………
   2. Do the study subjects have to incur any expenses by being participants in the study?

Yes No

If yes, Please specify……………………………………………………………………………………………………….

…………………………………….......................................................................................................................................

1. **Multi-Centre research**
   1. Has the research project been approved by an ERC/IBD in the sponsoring / other country?

Yes No

If yes, please attach documentary evidence. If No, why?

………………………………………………………………………………………………………………………………………………………………………………………………………………

* 1. Are any of the data or biological samples to be transferred overseas?

Yes No

If yes, describe the fate of the data or biological samples at the conclusion of the study?

………………………………………………………………………………………………………………………………………………………………………………………………………………

1. **Scientific importance & validity**
   1. What is the scientific importance of your study in relation to improving healthcare in Sri Lanka? ………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………
   2. Are the investigator’s qualifications and experience appropriate to conduct the study?

Yes No

* 1. Are the facilities at study site adequate to support the study?

Yes No

* 1. How will the results of the study be disseminated?

………………………………………………………………………………………………………………………………………………………………………………………………………………

* 1. Is your study an original or a replication of a previous study?

Original Replication

1. **Assessment of risk / benefit**
   1. Is the involvement of human subjects necessary to obtain the required information?

Yes No

* 1. Are there any risks (physical, psychological, social, economical and legal) to the study participants?

Yes No

If yes, identify them and state how you propose to mitigate such risk(s):

………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………..

* 1. Justify the potential benefits against risks:

……………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………..

* 1. What is the procedure for reporting and dealing with adverse events?

………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………..

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1. **Informed consent**
   1. Is it written or verbal consent?

Written Verbal N/A

* 1. Who will obtain consent?

…………………………………………………………………………………………………………………………………

* 1. How will you ensure that the research participant is adequately informed?

…………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………

* 1. How will you ensure your information is understood and queries answered?

………………………………………………………………………………………………………………………………………….…………………………………………………………………………………………………………………………….

* 1. Are you offering financial or other rewards / inducements to study participants?

Yes No

If yes, identify them and provide justification

………………………………………………………………………………………………………………………………….

* 1. Will you obtain fresh informed consent if procedures are changed during the research?

Yes No

* 1. How will you ensure participant’s right to unconditional withdrawal from the study at any time?

………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………..

* 1. Write briefly your procedure for obtaining informed consent

………………………………………………………………………………………………………………………………………..………………………………………………………………………………………………………………………………….………………………………………………………………………………………………………………………………..

**PART II**

**Please include the following information in the project proposal.**

**Indicate page number(s) relevant to each section in the boxes provided in this application form.**

1. **Project title**
2. **Introduction**

* Literature review
* Justification for the study

1. **Objectives of the study**
   * General Objectives
   * Specific Objectives
2. **Methodology**

* Study design
* Study setting
* Sample size and sampling technique
* Definition of Exposures/intervention and Outcome measures
* Plan for data analysis
* Time frame

1. **Participant characteristics**

* What is the target population?
* Indicate exclusion and inclusion criteria as relevant.
* Indicate the recruitment procedures.

1. **Identification of potential risks/benefits**

* Describe all invasive procedures.
* Is there any risk to participants? If yes please specify.
* If there is any risk to participants, how would you intend to minimize/prevent harm?
* What are the post research benefits to participants/community?
* If participants are patients under your care, describe how you would ensure they would not feel obliged to participate.
* Do you plan to withhold or withdraw standard therapies for research?

If yes, please justify.

* If study subjects are medical students indicate how you would prevent students from feeling pressurized to participate.

1. **Informed consent**

* Is it written or verbal consent?
* If participant is not capable of giving consent, indicate who will give consent on behalf of the participant.
* Attach the consent form (with English, Sinhala/Tamil translations where relevant). If consent is verbal describe the procedure.
* Describe how you would deal with findings of the research which are relevant to the participants.
* Describe how you would manage any adverse effects that may arise related to the research.
* What steps will be taken to ensure the validity of your results if participants voluntarily withdraw during the course of the research.

1. **Describe storage of data, disposal procedures and measures taken to ensure confidentiality of personal information**
2. **Summary of the Project**

*Project summary (of no more than 500 words) with PIs name, title of the research project on top and a word count in this form.*

*A structured project summary should include the rationale/ background (2-3 sentences), objectives of the proposed study and the methods. Study design, sample and sampling procedure, measurements and data collection, time frame and data analysis with outcome measures should be included in the methods section of the summary.*

*Title of the research*

*PI name*

|  |  |  |  |
| --- | --- | --- | --- |
| *Word count* |  |  |  |

1. **Declaration**

I certify that the information given above is true and correct to the best of my knowledge. If there is change in the protocol or the research project is terminated before completion I will inform the ethics review committee. I will also inform if there are any serious adverse events to the human participants during the research project.

**Date:** DD/MM/YYYY **Applicants signature: ……………………………………………….**