**The Teaching Hospital-Peradeniya**

**ETHICS REVIEW COMMITTEE**

**APPLICATION FOR ETHICS REVIEW**

**PART - I**

*For official use only*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Application No: | ERC/THP/YEAR/000 | | Date of Received: |  |  | / |  |  | / |  |  |  |  |
| Version : |  | | ERC Meeting Date: |  |  | / |  |  | / |  |  |  |  |
| Reviewed by: |  | |
| ERC Discussion: | No Risk / Minimal Risk / Greater than Minimal Risk | | | | | | | | | | | | |
| Decision: | Approved |  | Date PI Informed: / / | | | | | | | | | | |
| Recommend a revision |  |
| Rejected |  |
| Exempted from Ethic Review |  |
| Full Committee Review |  |

**PART II – BASIC INFORMATION**

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

|  |  |
| --- | --- |
| Title | Dr./Prof./Mr. / Ms. |
| 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 Investigators/ Supervisors**

**Copy and paste this table and fill for each and every other investigator/ Supervisor**

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

|  |  |
| --- | --- |
| **Title** | **Dr./Prof./Mr. / Ms. /Ven.** |
| 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

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

1. **Study type:**

Cross - sectional Cohort

Case – control Randomized controlled trial

Other (specify)

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 of this project**

**(a)**

|  |  |  |  |
| --- | --- | --- | --- |
| **Funding status** | **Source and Type** | **Details (number)** |  |
| **Funded** | **Agency:** |  |  |
| **Agency:** |  |  |
| **Applied for funding** | **Agency:** |  |  |
| **Agency:** |  |  |
| **Sponsored** | **Agency:** |  |  |
| **Agency:** |  |  |
| **Unfunded / Self-funded** | | | |

(b) If one protocol is to cover more than one grant, please include all grant identification numbers.

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 not, why?

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* 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?

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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. **Data Security, retention and access**
2. Describe how data (including written records, video/audio recordings, artifacts and questionnaires) will be protected during the conduct of the research and dissemination of results.

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1. Explain how long data will be retained. (If applicable, referring to the standard data retention practice for your discipline) Provide details of their final disposal or storage. Provide a justification if you intend to store your data for an indefinite length of time. If the data may have archival value, discuss how participants will be informed of this possibility during the consent process.

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c) If participant anonymity or confidentiality is not appropriate to this research project, please explain.

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d) If data will be shared with other researchers or users, please describe how and where the data will be stored and any restrictions that will be made regarding access.

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|  |

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

Yes No

* 1. Are there any risk (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):

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* 1. Justify the potential benefits against risks:

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

Yes No

If yes, identify them and provide justification

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* 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?

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* 1. Write briefly your procedure for obtaining informed consent

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1. **Declare conflicts of interest**

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