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| *for official use* | | | | | | | | | | | | | | | |  |  | | | |
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| Reviewed By: |  |  |  |  |  |  |  |  |  |  | | ERC Meeting Date: |  |  | */* |  |  | */* |  |  | |
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| Decision: |  | | | | | | | | | | Date Informed: | |  |  | */* |  |  | */* |  |  | |
| Section I |  | | | | | | | | | |  | |  | | | | | | | |

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**Ethics Review Committee of the Faculty of Applied Sciences, Rajarata University of Sri lanka**

**Application for Ethics Review (Part I) – Basic Information**

**1. Title of Project**

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**2. Investigators**

Applications from investigators based overseas will only be considered if the project is done in collaboration with investigators based in institutions in Sri Lanka who take equal responsibility for the conduct of the study and who will appear as co-authors in any publication arising out of the study.

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| **Title, Name and Designation of Investigators** | **Role**  Principal investigator, Co-investigator, supervisor |
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Please note that a short curriculum vitae of all investigators should be attached to the application.

**3. Contact Details of the Principal Investigator**

|  |  |
| --- | --- |
| Address: |  |
| Telephone numbers: |  |
| Fax number: |  |
| Email address: |  |

**4. Funding**

|  |  |
| --- | --- |
| Name and Address of Funding Source(s) | Amount |
|  |  | |

**5. Proposed starting and ending dates: \*‡**

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| --- | --- | --- | --- | --- |
| Start Date |  |  | End Date |  |

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| Study Setting |  |

\*From initial recruitment of participants until completion of all data collection.

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

**6. Has ethics approval for this study been requested earlier from this ERC or another similar committee?**

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| Yes |  | No |  |

If yes, give details (names of committees and outcome of review)

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Please note that for studies sponsored by foreign funding agencies or sponsors ethics review and approval is required from the country of the funding agency or the sponsor.

**7. Scientific review**

Has this research proposal been subjected to scientific review by any other committee?

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| Yes |  | No |  |

If yes, give details (names of committees and outcome of review)

What is the name of the committee?

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**8. Conflict of Interest**

**8.1. Do you believe this project has a Conflict of Interest:**

Commercially

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Financially

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Intellectually

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Other (explain)**:**

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**8.2 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?**

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| Yes |  | No |  |

**If yes, please explain:**

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# Section II:

**Faculty of Applied Sciences,Rajarata University of Sri lanka**

**Application for Ethics Review (Part I) –** **Summary of the Proposed Research**

**1. RATIONALE, RESEARCH QUESTION AND OBJECTIVES.**

Describe the purpose and scholarly rationale for the proposed project. State the hypotheses/research questions to be examined.

Please include references in this section.

(Max 500 Words)

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**2. METHODS**

(a) Please describe all procedures/methods to be used for the study. Describe the data to be collected, where and how they will be obtained and how they will be analyzed.

(Max 500 Words)

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(b) Attach copies of data collection sheets, questionnaires, interview guides, observation guides and/or any other instruments. (Provide the list here)

(c) Include a **list of appendices** here for all additional materials submitted (e.g., Appendix A – Informed Consent; Appendix B – Interview Guide, etc.):

1. Application for ethics review

2. Appendix A –

3. Appendix B –

4. Appendix C –

5. Appendix D –

6. Appendix E -

7. Appendix F -

**3. PARTICIPANTS AND/OR DATA**

(a) Describe the participants to be recruited, or the individuals about whom personally identifiable information will be collected. List the inclusion and exclusion criteria.

Where the research involves extraction or collection of personally identifiable information, please describe from whom the information will be obtained, what it will include, and how permission to access the data is being sought. Where applicable, justify the sample size.

(b) Is there any group or individual-level vulnerability related to the research that needs to be mitigated (for example, difficulties understanding informed consent, history of exploitation by researchers, power differential between the researcher and the potential participant)?

**4. EXPERIENCE OF INVESTIGATORS WITH THIS TYPE OF RESEARCH**

(a) Please provide a brief description of previous experience with this type of research by (i) the principal investigator, (ii) the research team and (iii) the people who will have direct contact with the participants. If there has not been previous experience, please describe how the principal investigator/research team will be prepared.

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(b) For projects that will involve community members (e.g., peer researchers) in the collection and/or analysis of data, please describe their status within the research team (e.g., are they considered employees, volunteers or participants?) and what kind of training they will receive?

**5. RECRUITMENT OF PARTICIPANTS**

* Where there is recruitment, please describe how, by whom, and from where the participants will be recruited
* Where participant observation is to be used, please explain the form of insertion of the researcher into the research setting (e.g., living in a community, visiting on a bi-weekly basis, attending organized functions)
* If relevant, describe any translation of recruitment materials, how this will occur and whether or not those people responsible for recruitment will speak the language of the participants.
* **Attach a copy of all posters, advertisements, flyers, letters, e-mail text, or telephone scripts to be used for recruitment.**

**6. COMPENSATION**(a) Will participants receive compensation for participation?

FinancialYes No

In-kind Yes No

Other Yes No

(b) If **Yes**, please provide details and justification for the amount or the value of the compensation offered.

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| **DESCRIPTION OF THE RISKS AND BENEFITS OF THE PROPOSED RESEARCH** |

**7. POSSIBLE RISKS**

(a) Please indicate all potential risks to participants as individuals or as members of a community that may arise from this research:

(i) Physical risks (e.g., any bodily contact or administration of any substance): Yes No

(ii) Psychological/emotional risks (e.g., feeling uncomfortable, embarrassed, or upset):

Yes No

(iii) Social risks (e.g., loss of status, privacy and/or reputation): Yes No

(iv) Legal risks (e.g., apprehension or arrest, subpoena): Yes No

(b) If there is any, please briefly describe each of the risks noted above and outline the steps that will be taken to manage and/or minimize them.

**8. 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 involvement of participants in this study

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| **INFORMED CONSENT** |

**9. CONSENT PROCESS**  
(a) Describe the process that will be used to obtain informed consent and explain how it will be recorded.  Please note that it is the quality of the consent, not the form that is important. The goal is to ensure that potential participants understand what they are consenting.

(b) If the research involves extraction or collection of personally identifiable information from or about a research participant, please describe how consent from the individuals or authorization from the data custodian (e.g., medical records department) will be obtained.

**10 CONSENT DOCUMENTS**(a) **Attach a copy of the Information Sheet and Consent Form.**

**12. COMMUNITY AND/OR ORGANIZATIONAL CONSENT, OR CONSENT BY AN AUTHORIZED**

**PARTY**

(a) If the research is taking place within a community or an organization which requires that formal consent be sought prior to the involvement of individual participants, describe how consent will be obtained and attach any relevant documentation. If consent will not be sought, please provide a justification and describe any alternative forms of consultation that may take place.

(b) If any or all of the participants are children and/or others who are not competent to consent, describe the process by which capacity/competency will be assessed, and the proposed alternate source of consent.

1. Submit a copy of the permission/information letter to be provided to the person(s) providing the alternative consent
2. Describe the assent process for participants and attach the assent letter.

**13. DEBRIEFING and DISSEMINATION**

(a) If deception or intentional non-disclosure will be used in the study, provide justification. Please provide a copy of the written debriefing form, if applicable.

(b) Please describe what information/feedback will be provided to participants and/or communities after their participation in the project is complete (e.g., report, poster presentation, pamphlet, etc.) and note how participants will be able to access this information.

**14. PARTICIPANT WITHDRAWAL**

(a) Where applicable, please describe how participants will be informed of their right to withdraw from the project and outline the procedures that will be followed to allow them to exercise this right.

Indicate what will be done with the participant’s data and any consequences which withdrawal may have on the participant.

(b) If participants will not have the right to withdraw from the project at all, or beyond a certain point, please explain. Ensure this information is included in the consent process and consent form.

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| **CONFIDENTIALITY AND PRIVACY** |

**15. CONFIDENTIALITY**

(a) Will the data be treated as confidential? Yes No

(b) Describe the procedures to be used to protect the confidentiality of participants or informants, where applicable

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**16. DATA SECURITY, RETENTION AND ACCESS**

(a) 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.

(b) 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.

(c) 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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| **SIGNATURES** |

**18. PRIVACY REGULATIONS**

**My signature as Principal Investigator, in this application form, confirms that I am aware of, understand, and will comply with all relevant laws governing the collection and use of personally identifiable information in research.** I understand that for research involving extraction or collection of personally identifiable information, provincial, national and/or international laws may apply and that any apparent mishandling of personally identifiable information must be reported to the Ethics Review Committee.

As the **Principal Investigator** on this project, my signature confirms that I will ensure that all procedures performed will be conducted in accordance with all relevant University, provincial, national and international policies/guidelines and regulations that govern research involving human participants. I understand that if there is any significant deviation from the project as originally approved I must submit an amendment to the Ethics Review Committee for approval prior to implementing any change.

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| Signature of Principal Investigator: \_  Date: |