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| **Image result for pgimlogo** | **Ethics Review Committee**  **Postgraduate Institute of Medicine**  **University of Colombo**  **Application Form for Scientific**  **and Ethical Review** | **Image result for colombo university logo** |

**For Office Use Only:**

Application Number: PGIM/ERC/20\_\_\_/\_\_\_\_\_\_ Date Received: \_\_\_/\_\_\_/20\_\_\_

Name of the Applicant: Rev/Prof/Dr/Mr/Ms\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**This application should be forwarded by the principal investigator who requests ethical approval for a research project. All the co-investigators should provide signed consent to submit the application to ERC, PGIM/UOC. Application guidelines are available at PGIM website. Only the trainees, trainers, extended faculty and staff of the PGIM/UOC are eligible to apply for ERC approval from PGIM/UOC.**

**Part A – Administrative Details**

1. **Title of the Research Project:** Enter title of the research project here

1. **Details of the Investigators:**

|  |  |  |
| --- | --- | --- |
| Title, Name, Designation and Affiliation | Role | Signature |
|  | Principal Investigator |  |
|  |  |  |
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1. **Contact Details of the Principal Investigator:**

|  |  |
| --- | --- |
| 3.1 Postal Address | Enter the name of Principal Investigator |
| 3.2 Email Address | Enter the name of Principal Investigator |
| 3.3 Telephone | Enter the name of Principal Investigator |

1. **Nature of the study:**

Observational/non-interventional  Clinical trial (investigator initiated) Research database/information system  Sponsored clinical trail Other

1. **Proposed starting (initial date of enrolment of participants) and ending (completion of data collection) dates** (retrospective approval will not be given to the projects already started)

Start Date:       End Date:

1. **Has the relevant Board of Study/Specialty Board approved the research project (if applicable)?**

Yes :  No:

If Yes, Board of Study/Specialty Board:

Details:

1. **Has ethics approval for this study been requested earlier from ERC, PGIM/UOC or another ERC?** (if you have received ethics approval already, please attach a copy of the approval)

Yes :  No:

Details:

1. **Funding (if any)**

Name and Address of the funding source:

Amount:

1. **Do you believe the proposed project has conflicts of interest?**

Yes :  No:

If Yes, Details:

**Part B – Protocol Check List**

Under each category, indicate the protocol section of the research proposal. If a particular category in not relevant to your study, indicate it as ‘NA’

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|  | **Scientific validity** | Protocol page/s | **Reviewer Evaluation** | | | |
| Acceptable | | | Comments |
| Yes | No | N/A |
| 1 | Title |  |  |  |  |  |
| 2 | Research problem |  |  |  |  |  |
| 3 | Research questions/hypothesis |  |  |  |  |  |
| 4 | Objectives |  |  |  |  |  |
| 5 | Study setting |  |  |  |  |  |
| 6 | Study design |  |  |  |  |  |
| 7 | Study population (giving inclusion exclusion criteria) |  |  |  |  |  |
| 8 | Sample size |  |  |  |  |  |
| 9 | Sampling method |  |  |  |  |  |
| 10 | Measurements / variables |  |  |  |  |  |
| 11 | Study instruments |  |  |  |  |  |
| 12 | Procedures to ensure quality of data |  |  |  |  |  |
| 13 | Plan for analysis |  |  |  |  |  |
| 14 | Ethical considerations |  |  |  |  |  |
| 15 | Budget (if relevant) |  |  |  |  |  |
| 16 | Work plan and time frame |  |  |  |  |  |
| 17 | Justification for a replication study, if your study is a repl.. |  |  |  |  |  |

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|  | **Social Value** | Protocol page/s | **Reviewer Evaluation** | | | |
| Acceptable | | | Comments |
| Yes | No | N/A |
| 1 | Benefits of the study to the community/society |  |  |  |  |  |
| 2 | Plan for dissemination of study findings |  |  |  |  |  |
| 3 | Scientific importance of the study |  |  |  |  |  |

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|  | **Risk Benefit Assessment** | Protocol page/s | **Reviewer Evaluation** | | | |
| Acceptable | | | Comments |
| Yes | No | N/A |
| 1 | Potential risks to the participants |  |  |  |  |  |
| 2 | Potential benefits to the participants |  |  |  |  |  |
| 3 | Justification for risks against benefits |  |  |  |  |  |
| 4 | Steps taken to minimize risks |  |  |  |  |  |
| 5 | Support provided to participants (medical, educational, other) |  |  |  |  |  |

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|  | **Participants rights and consent** | Protocol page/s | **Reviewer Evaluation** | | | |
| Acceptable | | | Comments |
| Yes | No | N/A |
| 1 | Procedure for recruiting the participants |  |  |  |  |  |
| 2 | Information provided to the participants |  |  |  |  |  |
| 3 | Procedure for obtaining informed consent |  |  |  |  |  |
| 4 | Procedure for obtaining proxy consent |  |  |  |  |  |
| 5 | Procedure for obtaining assent |  |  |  |  |  |
| 6 | Procedure for withdrawing consent |  |  |  |  |  |
| 7 | Incentives provided to participants |  |  |  |  |  |
| 8 | Procedure for participants to ask questions / register complaints |  |  |  |  |  |
| 9 | Participants right to decline consent without losing entitled benefits |  |  |  |  |  |

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|  | **Confidentiality and Privacy** | Protocol page/s | **Reviewer Evaluation** | | | |
| Acceptable | | | Comments |
| Yes | No | N/A |
| 1 | Steps to ensure confidentiality of data |  |  |  |  |  |
| 2 | Justification for collecting personal identification data |  |  |  |  |  |
| 3 | Steps taken to ensure privacy during data collection |  |  |  |  |  |
| 4 | How long data and samples will be kept |  |  |  |  |  |
| 5 | Who will have access to the data |  |  |  |  |  |
| 6 | Procedure for storage of data and samples |  |  |  |  |  |
| 7 | Procedure for disposal of data |  |  |  |  |  |

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|  | **Fair participant selection and vulnerability** | Protocol page/s | **Reviewer Evaluation** | | | |
| Acceptable | | | Comments |
| Yes | No | N/A |
| 1 | Justification for selection of study population |  |  |  |  |  |
| 2 | Justification for conducting the study in a vulnerable population |  |  |  |  |  |

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|  | **Responsibilities of the researcher** | Protocol page/s | **Reviewer Evaluation** | | | |
| Acceptable | | | Comments |
| Yes | No | N/A |
| 1 | Ethical, legal, financial issues related to the study |  |  |  |  |  |
| 2 | Any conflicts of interest and how the researcher plans to manage them |  |  |  |  |  |
| 3 | Permissions from relevant institutions / authorities |  |  |  |  |  |
| 4 | Collaborations with the relevant stakeholder |  |  |  |  |  |
| 5 | Provision of medical / psychological care to the participants |  |  |  |  |  |
| 6 | Qualifications of the research team to handle the research study |  |  |  |  |  |

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|  | **Foreign funded studies** | Protocol page/s | **Reviewer Evaluation** | | | |
| Acceptable | | | Comments |
| Yes | No | N/A |
| 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 | The sharing of intellectual property rights |  |  |  |  |  |
| 5 | How the results will be conveyed to authorities in Sri Lanka |  |  |  |  |  |

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|  | **Information Sheet / Consent Form** | Section in Info. sheet consent form | **Reviewer Evaluation** | | | |
| Acceptable | | | Comments |
| Yes | No | N/A |
| 1 | Purpose of the study |  |  |  |  |  |
| 2 | Voluntary participation |  |  |  |  |  |
| 3 | Duration of the study and responsibilities of the participants |  |  |  |  |  |
| 4 | Potential benefits |  |  |  |  |  |
| 5 | Risks, Hazards, Discomforts |  |  |  |  |  |
| 6 | Incentives / Reimbursements |  |  |  |  |  |
| 7 | Confidentiality |  |  |  |  |  |
| 8 | Contact person for the participants |  |  |  |  |  |
| 9 | Understanding of information provided by the researcher |  |  |  |  |  |
| 10 | Agreement of the participant to provide information / samples |  |  |  |  |  |
| 11 | Consent for dissemination of research findings |  |  |  |  |  |
| 12 | Appropriate translation of the information sheet |  |  |  |  |  |
| 13 | Appropriate translation of the consent form |  |  |  |  |  |

**Decision of the reviewer:**

Approved

Conditional approval

Approve with revisions

Reject

**Comments of the Reviewer**:

Name of the Reviewer:

Signature of the Reviewer: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: