**Ethics Review Committee
Faculty of Graduate Studies**

**Application Form for Ethical Review**

**For Office Use Only:**

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

|  |  |  |
| --- | --- | --- |
| Review Type: |  | Exempted/Expedited Review/Full Committee Review |
| Reviewers: | 1. |  | 2. |  |
| IS/ICF Reviewers: | 1. |  | 2. |  |
| Decision: | Approve/Conditional Approval/Resubmit/Reject |
| ERC Meeting Date: |  |  |

**This application should be filled and signed by the principal investigator who requests ethical approval for a research project. All the co-investigator should provide consent to submit the application to ERC/FGS by signing the application. Please read the guidelines for application available at FGS website carefully before filling the application. Please note that ERC/FGS accepts applications only from students enrolled in FGS and the Academic Staff Members/visiting Lecturers attached to the FGS.**

**Part A – Basic Information**

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 |  |
|       |       |  |
|       |       |  |
|       |       |  |
|       |       |  |

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. **Study Setting:**
2. **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 approved the research project (if applicable)?**

Yes : [ ]  No: [ ]

If Yes, Details:

1. **Has ethics approval for this study been requested earlier from ERC, FGS/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 – Reviewer Check List**

**(Applicant should indicate the number of the protocol section where each issue is addressed in their research proposal. If a particular issue in not relevant to your study indicate that as ‘NA’)**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **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 |       | [ ]  | [ ]  | [ ]  |       |

|  |  |  |  |
| --- | --- | --- | --- |
|  | **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.. |       | [ ]  | [ ]  | [ ]  |       |

|  |  |  |  |
| --- | --- | --- | --- |
|  | **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 |       | [ ]  | [ ]  | [ ]  |       |
|  | Steps taken to minimize risks |       | [ ]  | [ ]  | [ ]  |       |
| 4 | Support provided to participants (medical, educational, other) |       | [ ]  | [ ]  | [ ]  |       |

|  |  |  |  |
| --- | --- | --- | --- |
|  | **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 |       | [ ]  | [ ]  | [ ]  |       |

|  |  |  |  |
| --- | --- | --- | --- |
|  | **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 |       | [ ]  | [ ]  | [ ]  |       |

|  |  |  |  |
| --- | --- | --- | --- |
|  | **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 |       | [ ]  | [ ]  | [ ]  |       |

|  |  |  |  |
| --- | --- | --- | --- |
|  | **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 |       | [ ]  | [ ]  | [ ]  |       |
|  | Provision of medical / psychological care to the participants |       | [ ]  | [ ]  | [ ]  |       |
| 5 | Qualifications of the research team to handle the research study |       | [ ]  | [ ]  | [ ]  |       |

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Foreign funded studies** | Protocol Page/s | Reviewer Evaluation |
| Acceptable | Comments |
| Yes | No | N/A |
| 1 | Justification for conducting the study in SL |       | [ ]  | [ ]  | [ ]  |       |
| 2 | Relevance of the study to SL |       | [ ]  | [ ]  | [ ]  |       |
| 3 | Post research benefits to SL |       | [ ]  | [ ]  | [ ]  |       |
| 4 | The sharing of intellectual property rights |       | [ ]  | [ ]  | [ ]  |       |
| 5 | How the results will be conveyed to authorities in SL |       | [ ]  | [ ]  | [ ]  |       |

|  |  |  |  |
| --- | --- | --- | --- |
|  | **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 | Appropriate translation of the information sheet |       | [ ]  | [ ]  | [ ]  |       |
| 12  | Appropriate translation of the consent form |       | [ ]  | [ ]  | [ ]  |       |

**For Office Use Only - To be filled by the Reviewers:**

|  |  |  |
| --- | --- | --- |
| Decision of the Reviewer: | Approved | [ ]  |
|  | Conditional Approval (please mention the conditions below) | [ ]  |
|  | Resubmit | [ ]  |
|  | Reject | [ ]  |

Comments of the Reviewer: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of the Reviewer Signature Date