**Annexure: (UOR/03-001)**

Ethics review application form for human research

|  |  |
| --- | --- |
| ETHICS REVIEW COMMITTEE  **Faculty of Medicine, University of Ruhuna,**  **P.O Box: 70, Galle, Sri Lanka**  **Email:** |  |

*Office use only*

**Unique Identification No** …………….…………….. **Date received \_\_\_\_/\_\_\_\_/\_\_\_\_\_\_\_**

**Version:**

**Name of Applicant: (Prof/Dr/Mr/Ms) ……………………………………………………..**

**APPLICATION FORM – HUMAN RESEARCH**

This form should be filled and **signed** by the principal investigator who requests ethical approval for a research project involving **human subjects**. All entries should be typed. **Hand written forms will not be accepted.** **No cages should be left blank.**

*The spaces in this form are expandable as you type.*

Please read the **instructions carefully when completing the application** and ensure all relevant documents as per the document checklist are submitted.

**PART 1 (Administrative details)**

**1**. **Title of Research Project:**

**2. Details of Principal Investigator**

|  |  |  |
| --- | --- | --- |
| Title(Prof./Dr./Mr/Ms): | Name: | |
| Current designation and name and address of institution where the applicant is attached: | | |
| Highest educational qualification of applicant: | | |
| Mailing address: | | |
| Phone no for contact: | | e-mail: |

**3. Is this study a requirement for a postgraduate degree/requirement by PGIM for Board**

**Certification, Faculty of Graduate studies (FGS)?** Yes  No

**3.1 Have you already registered for this degree?** Yes  No

|  |  |  |
| --- | --- | --- |
| Type of degree (MSc/PhD/MD/MS/other): | | |
| Awarding University: | | |
| Date of registration : | Date of protocol approval by Board of Study : | Letter annexed |

***Please append letter of approval from Board of Study of University/PGIM.***

**4. Are there supervisors for this project?** Yes  No

**4.1 Details of Supervisors:**

|  |  |  |
| --- | --- | --- |
| Title: | Name: | |
| Institutional affiliations: | | |
| Highest educational qualification : | | |
| Mailing address: | | |
| Phone: | | e-mail: |

|  |  |  |
| --- | --- | --- |
| Title: | Name: | |
| Institutional affiliations: | | |
| Highest educational qualification : | | |
| Mailing address: | | |
| Phone: | | e-mail: |

***Please append additional pages with Supervisors names if necessary***

**5. Are there Co-investigators for this project?** Yes  No

**5.1 Details of co-investigators:**

|  |  |  |
| --- | --- | --- |
| Title: | Name: | |
| Institutional affiliations: | | |
| Highest educational qualification : | | |
| Mailing address: | | |
| Phone: | | e-mail: |

|  |  |  |
| --- | --- | --- |
| Title: | Name: | |
| Institutional affiliations: | | |
| Highest educational qualification : | | |
| Mailing address: | | |
| Phone: | | e-mail: |

***Please append additional pages with co-investigators names if necessary***

1. **Location(s) where the research will be conducted:**
   1. Is this a multi-site study? Yes  No
   2. Specify all study sites

If the research is to be conducted at a site requiring administrative approval/consent (e.g., in a hospital/school), it is the responsibility of the researcher to obtain approval prior to starting the project.

|  |  |
| --- | --- |
| Type of site (hospital/clinic/school/community etc.) | Details |
|  |  |
|  |  |

***Please append the letter drafted to seeking the permission from the relevant authorities.***

1. **Other Research Ethics Committee approval(s)**
   1. Has any other ERC approved this project? Yes  No

*If Yes, please attach a copy of the approval letter.*

1. **Funding of this project**

|  |  |
| --- | --- |
| Funding Status | Source and amount |
| Funded | Agency:       Total Budget : SLR |
| Applied for funding | Agency:       Total Budget : SLR |
| Unfunded  If unfunded, please explain why no funding is needed: | |

1. ***For Clinical Trials only***
   1. **What is the phase of the clinical trial that is being conducted?**

|  |  |
| --- | --- |
| Phase I |  |
| Phase II |  |
| Phase III |  |
| Phase IV (post marketing) |  |
| Other |  |

If OTHER specify:

|  |
| --- |
|  |

**9.2 Is it a multi-centre trial?**

|  |  |  |  |
| --- | --- | --- | --- |
| Yes |  | No |  |

If yes, list the other trial sites

|  |
| --- |
|  |

Please attach ethics approval from the sponsoring country or country of the overseas principal investigator (if any)

**9.3 Is the clinical trial registered with a clinical trials registry?**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Yes |  | No |  | Pending |  |

If yes, give details (name of register and registration number)

|  |
| --- |
|  |

If No, give reasons

|  |
| --- |
|  |

**9.4** ***Has this study been approved by the SCOCT (Subcommittee on Clinical Trials) at***

***the Ministry of Health***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Yes |  | No |  | Pending |  |

If yes, give details of Approval Number

|  |
| --- |
|  |

If No, give reasons

|  |
| --- |
|  |

**9.5 Data Safety Monitoring Board (DSMB) (only if available)**

|  |  |
| --- | --- |
| **Name and Designation of Members\*** | **Role** |
|  |  |
|  |  |
|  |  |

**\*** Please attach the curriculum vitae of all members of the DSMB.

**9.6 Details of Indemnity and Insurance coverage for participants, investigators and**

**ethics committee**

|  |
| --- |
|  |

**PART 11 (Research Proposal)**

**10. Project start and end dates**

Estimated start date that involves human participants or data:

Estimated completion date of involvement of human participants or data for this project:

**11. Please include the following information as given in your project proposal indicating the page number(s) relevant to each section in the box**.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **11. 1 Collaborative partnership** | | **Applicable** | | **Section in Protocol & page** |
|  | | **Yes** | **No** |  |
| 1. | The collaborations you have established with institutions where the study is to be conducted |  |  |  |
| 2. | The collaborations you have established with the community where the study is to be conducted |  |  |  |
| 3. | The benefits to institutions, communities, and participants in your research |  |  |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **11.2 Social Value** | | **Applicable** | | **Section in Protocol & page** |
|  | | **Yes** | **No** |  |
| 1. | The beneficiaries of your research and the benefit to them |  |  |  |
| 2. | The plan for dissemination of study findings |  |  |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **11.3. Scientific Validity** | | **Applicable** | | **Section in Protocol & page** |
|  | | **Yes** | **No** |  |
| 1. | The scientific importance of your study in relation to improving healthcare and/or knowledge on the subject. |  |  |  |
| 2. | The justification for a replication study, if your study is a replication study. |  |  |  |
| 3. | How the sample size was calculated? |  |  |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **11.4 Confidentiality** | | **Applicable** | | **Section in Protocol & page** |
|  | | **Yes** | **No** |  |
| 1. | How the data and samples will be obtained? |  |  |  |
| 2. | How long data and samples will be kept? |  |  |  |
| 3. | Justification for collection of personal identification data |  |  |  |
| 4. | Who will have access to the personal data of the research participants? |  |  |  |
| 5. | How the confidentiality of participants will be ensured? |  |  |  |
| 6. | The procedure for data and sample storage |  |  |  |
| 7. | The procedure for data and sample disposal |  |  |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **11.5 Rights of the participants** | | **Applicable** | | **Section in Protocol & page** |
|  | | **Yes** | **No** |  |
| 1. | Procedure for subjects to withdraw from the research at any time |  |  |  |
| 2. | Procedure for subjects to ask questions and register complaints |  |  |  |
| 3. | The contact person for research subjects |  |  |  |
| 4. | Provisions for participants to be informed of results |  |  |  |
| 5. | Provision to make the study product available to the study participants after research |  |  |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **11.6 Fair participant selection** | | **Applicable** | | **Section in Protocol & page** |
|  | | **Yes** | **No** |  |
| 1. | The justification for the selection of the study population |  |  |  |
| 2. | The inclusion and exclusion criteria |  |  |  |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **11.7 Responsibilities of the researcher** | | | | **Applicable** | | | **Section in Protocol & page** |
|  | | | | **Yes** | | **No** |  |
| 1. | | The provision of medical services to research participants with special reference to research/trial related injuries | |  | |  |  |
| 2. | | The provisions for continuation of care after the research is completed | |  | |  |  |
| 3. | | Declaration of conflicts of interests and how the investigators plan to manage the conflicts | |  | |  |  |
| 4. | | The ethical/legal/social and financial issues relevant to the study | |  | |  |  |
| **11.8 Vulnerable populations** | | | | **Applicable** | | | | **Section in Protocol & page** |
|  | | | | **Yes** | | **No** | |  |
| 1. | | Justification for conducting the study in this population | |  | |  | |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **11.9 Research funded by foreign agencies/companies** | | **Applicable** | | **Section in Protocol & page** |
|  | | **Yes** | **No** |  |
| 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 steps taken to take into account cultural and social customs, practices, and taboos in Sri Lanka |  |  |  |
| 5. | The sharing of rights to intellectual property |  |  |  |
| 6. | The fate of data and biological samples including whether they will be transferred abroad and what will happen to them after the conclusion of the study |  |  |  |
| 7. | How the results of research will be conveyed to relevant authorities in Sri Lanka? |  |  |  |
| 8. | The agreement between the sponsor/funding agency and the investigator |  |  | Please  Attach |
| 9. | The materials transfer agreement, if biological material is to be transferred abroad |  |  | Please  Attach |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **11.10 Community based research** | | **Applicable** | | **Section in Protocol & page** |
|  | | **Yes** | **No** |  |
| 1. | The impact and relevance of the research on the community in which it is to be carried out |  |  |  |
| 2. | The steps taken to consult with the concerned community during the design of the research |  |  |  |
| 3. | The procedure used to obtain community consent |  |  |  |
| 4. | The contribution to capacity building of the community |  |  |  |
| 5. | The procedure for making available results of research to the community |  |  |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **11.11 Clinical trials** | | **Applicable** | | **Section in Protocol & page** |
|  | | **Yes** | **No** |  |
| 1. | Justification for withdrawing any therapy from participants to prepare them for the trial |  |  |  |
| 2. | Justification for withholding standard therapy from trial participants (e.g. control group) |  |  |  |
| 3. | Justification for providing care which is not the standard of care |  |  |  |
| 4. | Procedure for dealing with adverse events |  |  |  |
| 5. | Procedure for reporting adverse events |  |  |  |
| 6. | Measures in place for management of trial related injuries |  |  |  |
| 7. | Provisions for safety monitoring |  |  |  |
| 8. | Provisions/criteria for termination of the trial |  |  |  |
| 9. | Provisions for making the trial drug available to participants after the trial if found to be effective |  |  |  |

|  |  |  |
| --- | --- | --- |
| **11.12 Information Sheet (IFS)/Informed Consent Form (ICF)**  **Checklist**  (List the sections in IFS/ICF where you have dealt with the following) | | **Section IFS/ICF** |
|
| 1. | Purpose of the study |  |
| 2. | Voluntary participation |  |
| 3. | Duration, procedures of the study and participant’s responsibilities |  |
| 4. | Potential benefits |  |
| 5. | Risks, hazards and discomforts |  |
| 6. | Reimbursements |  |
| 7. | Confidentiality |  |
| 8. | Termination of study participation |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **11.13 Consent** | | **Applicable** | | **Section in Protocol & page** |
|  | | **Yes** | **No** |  |
| 1. | The procedure for initial contact of participants\* |  |  |  |
| 2. | The procedure for obtaining informed consent  Verbal |  |  |  |
|  |  |  |  |  |
|  | Written |  |  |  |
| 3. | The information (written/oral) provided to participants |  |  |  |
| 4. | The procedure for ensuring that subjects have understood the information provided. |  |  |  |
| 3. | The procedure for obtaining proxy consent. |  |  |  |
| 4. | The procedure for withdrawing consent. |  |  |  |
| 5. | Incentives/rewards/compensation provided to participants. |  |  |  |
| 6. | The procedure for re-consenting if the research protocol changes during the course of research. |  |  |  |
| 7. | The procedure for consenting if vulnerable groups / children under 18 years of age are being recruited. |  |  |  |
| 8 | The procedure for consenting if children aged 12 - 18 years of age are being recruited (for children aged 12-18 years in addition to parental consent, children’s assent must be sought)\*\* |  |  |  |

\* **Attach a copy of all posters, advertisements, flyers, letters, to be used for recruitment.**

**\*\* Please attach an assent form for children aged 12-18 years**

**12. Data Collection**

12.1 What is the procedure to be carried out on these subjects **(give** **details of all study instruments** to be used, collection of samples/blood/application of tests/administration of drugs etc, in detail).

|  |  |
| --- | --- |
| Page Number/s |  |
| Section/s |  |

**13. Experience of Investigators with this type of research**

13.1 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 trained/prepared.

**PART III – (Description of the risks and benefits)**

**14. Possible Risks**

14.1 Please indicate all potential risks to participants 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 (feeling uncomfortable, embarrassed, 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

14.2 If Yes to any of the above, please describe.

14.3 State measures employed during the procedure/study to remove or minimize these risks

**15. 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

**16. Compensation**16.1 Will participants receive compensation for participation?

FinancialYes  No  In-kind Yes  No

Other Yes  No

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

16.3 If **No**, please explain why compensation is not possible or inappropriate.

16.4 If participants choose to withdraw, how will compensation be affected?

**17. Feedback/debriefing/referral/after care**

Please describe what information/feedback/services will be provided to participants and/or communities after their participation in the project is complete (e.g., health education, referral to clinic/hospital, etc.)

**18. Do you have any conflict of interests with regards to this project?**

Yes  No

If yes, please state below.

18.1 Commercially

18.2 Financially

18.3 Intellectually

18.4 Other (Explain)

**19. 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?**

|  |  |  |  |
| --- | --- | --- | --- |
| Yes |  | No |  |

**If yes, please explain:**

|  |
| --- |
|  |

**20. If there is a duality of interest identified above describe the interest and state whether it constitutes a potential conflict of interest.**

|  |
| --- |
|  |

**21. Declaration of applicant**

1. As the Principal Investigator of this project, my signature confirms that I will ensure that all procedures performed under the project will be conducted in accordance with all relevant national and international policies and regulations that govern research involving human participants.
2. I understand that if there is any deviation from the project as originally approved I must submit an amendment to the ERC for approval prior to its implementation.
3. I have submitted all significant previous decisions by this or any other ERC and/or regulatory authorities relevant for the proposed study.
4. I declare that I am not seeking approval for a study that has already commenced or has already been completed.
5. I understand that at least two months are required for ethics review and granting of ethics clearance.
6. I will submit progress reports/reports of adverse events and side effects as requested by the ERC. FM, UR.

………………………………………………..

Signature of Principal Investigator Date: \_\_\_ /\_\_\_\_/\_\_\_\_\_\_

Full name of Principal Investigator:

**22. Consent from all Investigators**

We, the undersignedhereby confirm thatwe have consented to be co-investigators of the project titled:

|  |  |  |  |
| --- | --- | --- | --- |
| Name | Qualifications | Institutional Affiliations | Signature |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**23. Acknowledgement (***Office use only)*

**Name of Applicant: (Prof/Dr/Mr/Ms)** …………………………………………………………….

**Unique identification No ………………………………. Date received \_\_\_\_/\_\_\_\_/\_\_\_\_\_\_\_**

**Version:**

Thank you for submitting the above research proposal. The proposal has been assigned the protocol number stated above. It will be considered by the Ethics Review Committee at its meeting in …………………………………and will be assigned to three principal reviewers. The ERC may contact you in due course if any clarifications; additional documentation; or revisions are required.

……………………………………….

Administrative Officer/Convenor/Secretary

ERC,FM, UOR