**Ethics Review Application Form**

**Common Application Format-FERCSL**

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| *For office use only* |
| Application No:  |  | Checked By: |  |
| uiguuiuig |
| Date Received: |  |  |  | ERC Meeting Date: |  |  |  |
| Level of Risk: No Risk/Minimal Risk/Greater than Minimal RiskReview Type: Exempted/Expedited Review/Full Board ReviewNames of the Reviewers: |
| 1) |  | 2) |
| 3) | 4) |
| uguyuyg |
|  Date Informed:  |  |  |  |

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| **Part-I: Basic Information**1.1.Title of Project |
|  |
| 1.2. Details of Investigator (s) |
| Name | Qualifications | Designation &Affiliation of | Role | Signature |
|  |  |  | PI, Co-PI, Co-Investigator, Supervisor,\_\_\_\_\_\_\_\_\_ |  |
|  |  |  | PI, Co-PI, Co-Investigator, Supervisor,\_\_\_\_\_\_\_\_\_ |  |
|  |  |  | PI, Co-PI, Co-Investigator, Supervisor,\_\_\_\_\_\_\_\_\_ |  |
|  |  |  | PI, Co-PI, Co-Investigator, Supervisor,\_\_\_\_\_\_\_\_\_ |  |
|  |  |  | PI, Co-PI, Co-Investigator, Supervisor,\_\_\_\_\_\_\_\_\_ |  |
|  |  |  | PI, Co-PI, Co-Investigator, Supervisor,\_\_\_\_\_\_\_\_\_ |  |
|  |  |  | PI, Co-PI, Co-Investigator, Supervisor,\_\_\_\_\_\_\_\_\_ |  |
|  |  |  | PI, Co-PI, Co-Investigator, Supervisor,\_\_\_\_\_\_\_\_\_ |  |
| Attach separate sheet if needed1.3. Contact details of the Principal Investigator  |
| Address for communication |  |  |  |
| Telephone No(s) |  |
| Fax No |  |
| Email Address |  |  |
| 1.4. Is this a post graduate protocol

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| Yes |  |  | No |  |

If yes, give following details |
| Course/degree |  |
| Institution |  |

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| 1.5. Has this protocol been subjected to scientific review by any other institution/board/committee/Boss? |
|  | Yes  |  |  | No |  |  |
| if yes, give derails Name of the institution/board/committee/BoS |
|  |  |  |
|  Outcome of the review and date |
|  |  |  |
| 1.6. Funding |
|  Is this project funded  | Yes |  |  | No |  |  |
|  |
|  | Name & Address of the Funding Source (s)† | Amount |  |
|  |  |
| †*Please complete Annexure-1 for research funded* |
| 1.7. Proposed starting & Ending dates †,‡ |
|  | Starting Date |  |  |  |  | Ending Date |  |  |  |  |
| *† From initial recruitment of participants until completion of all data collection**‡ Retrospective approval will Not be given for the projects already started or completed* |
| 1.8. Location/s where the study would be conducted |
|  |  |  |
| 1.9. Has ethics approval for this protocol been requested from this ERC or another ERC |
|  | Yes  |  |  | No |  |  |
| If yes, give details (name of the committees and outcome) |  |
|  |  |  |  |
| 1.10. Conflict of interest1. Does any member of the research team have any Conflict of
 |  |
| Yes |  |  | No |  |
|  |
|  | If yes, please give details ( investigator, co- investigator, collaborator) |  |
|  | Commercially |  |  |
| Financially |  |
| Intellectually |  |
| Other(explain) |  |
| C. If there is a duality of interest stated above describe how the conflict/s would be addressed. |
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| **Part –II: Project Overview** 2.1. Study type (mark with "") |
|  |  | Epidemiological study/Non-interventional studySurvey/AuditClinical trial (*Please complete Annexure-2*)field Trial/Community TrialCase study Qualitative studyHealth System ResearchImplementation ResearchComplementary and alternative medicine (CAM) researchExperimental studyOther (please specify) |
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| 2.2. Nature of the Protocol (mark all appropriate with a "") |
|  |  | Research with Human ParticipantsResearch using stored human biological materialResearch involving medical devicesResearch using Medical Records, Registers or DatabasesEstablishment and maintenance of research database *(Please complete Annexure 4)* |
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| **Part-III: Scientific Validity and Ethical Conduct**Please include the following information as given in your protocol indicating the page number(s) relevant to each section in the box.  |
| 3.1. Justification | Applicable | Section in Protocol & page |
| Yes | No |
| 1) | The scientific importance of your study in relation to improving health care and/or knowledge on the subject. |  |  |
| 2) | The justification for a replication study, if this is a replication study.  |  |  |
|  |
| 3.2.Scientific validity  | Applicable | Section in Protocol & page |
| Yes | No |
| 1) | Justification for conducting the study in this population |  |  |
| 2) | Study design |  |  |
| 3) | Objectives: General and specific |  |  |
| 4) | The inclusion and exclusion criteria |  |  |
| 5) | How the sample size was calculated  |  |  |
| 6) | Plan for selection of the sample |  |  |
| 7) | Details of data collection tools, methods, investigations, etc. |  |  |
| † Please complete Annexure-3, if this is a community based study |
| 3.3. Consent  |  | Applicable | Section in Protocol & page |
|  | Yes | No |
| 1) | The procedure for approaching the relevant community and initial contact of with the participants+ |  |  |
| 2) | The procedure for obtaining informed consent |  |  |
| 3) | The information (written/oral) provided to participants |  |  |
| 4) | The procedure for ensuring that subjects have understood the information provided. |  |  |
| 5) | The procedure for obtaining proxy consent. |  |  |
| 6) | The procedure for consenting if vulnerable groups / children under 18 years of age are being recruited. (for children aged 12-18 years in addition to parental consent, children’s assent must be sought) |  |  |
| 7) | The procedure for withdrawing consent and withdraw from the research |  |  |
| 8) | The procedure for re-consenting  |  |  |

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| 3.4. 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 be ensured |  |  |
| 6) | The procedure for data and sample storage |  |  |
| 7) | The procedure for data and sample disposal |  |  |

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| 3.5. Vulnerability and Inducement | Applicable | Section in Protocol & page |
| Yes | No |
| 1) | Justification for including vulnerable populations |  |  |
| 2) | Compensation provided to participants. |  |  |

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| 3.6. 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) | Patient and public engagement and involvement (PPEI) in research |  |  |
| 4) | Benefit due to this collaboration to individual, institution, society, etc. |  |  |

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| 3.7. 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 |  |  |

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| 3.7. Rights of the participants | Applicable | Section in Protocol & page |
| Yes | No |
| 1) | Procedure for subjects to ask questions and register complaints |  |  |
| 2) | The contact person for research participants |  |  |
| 3) | Provisions for participants to be informed of results |  |  |

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| 3.8. Assessment of Risks/Benefits | Applicable | Section in Protocol & page |
| Yes | No |
| 1) | The risks to research participants (physical, psychological, etc.) |  |  |
| 2) | Benefits to research participants |  |  |
| 3) | Steps taken to minimize risks |  |  |
| 4) | Support provided to the research participants (medical, psychological and other) |  |  |
| 5) | Risk-benefit analysis/discussion |  |  |

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| 3.9. Responsibilities of the researcher | Applicable | Section in Protocol & page |
| Yes | No |
| 1) | Declaration of conflicts of interests and how the investigators plan to manage the conflicts |  |  |
| 2) | The ethical/legal/social and financial issues relevant to the study |  |  |

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| **Part-IV: Information Sheet (IFS)/Informed Consent Form (ICF) Check List** 4.1. List the sections and page number in IFS/ICF where you have dealt with the following

|  |  |
| --- | --- |
|  | Section in IFS/ICF & page |
| 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) | Collection and fate of biological samples |  |
| 7) | Reimbursements |  |
| 8) | Confidentiality |  |
| 9) | Termination of study participation |  |

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| **Part-V: Document Check List & Declaration****I declare that I have attached the following documents (Please tick and confirm):**

|  |  |  |  |
| --- | --- | --- | --- |
| Document | version/ Date | Application | No. of copies |
|  |
| 1) | Covering Letter |  |  |  |
| 2) | Application Form (Part I, II, III, IV & V) |  |  |  |
| 3) | Annexure-1 (Research funded by foreign agencies/companies) |  |  |  |
| 4) | Annexure-2 (Clinical trials) |  |  |  |
| 5) | Annexure-3 (Community based research) |  |  |  |
| 6) | Annexure-4 (Establishment and maintenance of research database) |  |  |  |
| 7) | The complete research protocol including a section on ethics considerations  |  |  |  |
| 8) | Information sheet for research participants (IFS) |  |  |  |
|  |  | English |  |  |  |
|  | Sinhalese |  |  |  |
|  | Tamil |  |  |  |
| 9) | Informed Consent Form (ICF)  |  |  |  |
|  |  | English |  |  |  |
|  | Sinhalese |  |  |  |
|  | Tamil |  |  |  |
| 10) | Assent Form  |  |  |  |
|  |  | English |  |  |  |
|  | Sinhalese |  |  |  |
|  | Tamil |  |  |  |
| 11) | Data collection booklets/forms/questionnaires |  |  |  |
|  |  | English |  |  |  |
|  | Sinhalese |  |  |  |
|  | Tamil |  |  |  |
| 12) | Approval letter from BOS, institutions |  |  |  |
| 13) | Ethics approval letter (if any) |  |  |  |
| 14) | Indemnity/Insurance coverage (required for clinical trials)  |  |  |  |
| 15) | Clinical Trials Contract (required for clinical trials)  |  |  |  |
| 16) | Certificate of GAP training for relevant member of the research study  |  |  |  |

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| 17) | Materials Transfer Agreement (required for all research involving transfer of biological samples abroad)  |  |  |  |
| 18) | Brief curriculum vitae of all investigators  |  |  |  |
| 19) | A receipt of payment (if applicable) |  |  |  |
| 20) | Soft copies of the documents |  |  |  |
| 21) | Approval letter from BOS, institutions |  |  |  |
| 22) | Ethics approval letter (if any) |  |  |  |

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| **Declaration of applicant** 1) As the Principal Investigator on 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 affirm that I will submit all relevant documents such as progress reports, final reports, Saes, etc. as required by the ERC 5) I declare that I am not seeking approval for a study that has already commenced or has already beeCompleted. 6) I certify that the information given above is true and correct to the best of my knowledge. I understand that if this information is found to be incorrect the ERC approval if given will be withdrawn.

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|   |  Date: |  |  |  |

 Signature of Principal Investigator Full name of the Principal Investigator

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