**Ethics Review Application Form**

**Common Application Format-FERCSL**

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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 needed  1.3. Contact details of the Principal Investigator | | | | | | | | | | | | | | Address for communication | | | |  |  | | | |  | | | Telephone No(s) | | | |  | | | | | | Fax No | | | |  | | | | | | Email Address | | | |  | | | | |  | | | 1.4. Is this a post graduate protocol   |  |  |  |  |  | | --- | --- | --- | --- | --- | | 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 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| Outcome of the review and date | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| 1.6. Funding | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Is this project funded | | | | | | | | | | | | | | | | | Yes |  |  | | | | No | | | |  | |  | | | | | | | | |
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|  | Name & Address of the Funding Source (s)† | | | | | | | | | | | | | | | | | | | | | | | | | | Amount | | | | | | | | | |  |
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| †*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 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| 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) | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | |
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| 1.10. Conflict of interest   1. Does any member of the research team have any Conflict of | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | |
| Yes | | |  | |  | | | | No |  | |
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|  | | | 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 study  Survey/Audit  Clinical trial (*Please complete Annexure-2*)  field Trial/Community Trial  Case study  Qualitative study  Health System Research  Implementation Research  Complementary and alternative medicine (CAM) research  Experimental study  Other (please specify) |
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| 2.2. Nature of the Protocol (mark all appropriate with a "") | | |
|  |  | Research with Human Participants  Research using stored human biological material  Research involving medical devices  Research using Medical Records, Registers or Databases  Establishment 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 |  | |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | | 3.5. Vulnerability and Inducement | | Applicable | | Section in Protocol & page | | Yes | No | | 1) | Justification for including vulnerable populations |  | |  | | 2) | Compensation provided to participants. |  | |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | | 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. |  | |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | | 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 |  | |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | | 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 |  | |  | |
| |  |  |  |  |  | | --- | --- | --- | --- | --- | | 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 |  | |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | | 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) |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | | **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 bee  Completed.  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.   |  |  |  |  |  | | --- | --- | --- | --- | --- | |  | Date: |  |  |  |   Signature of Principal Investigator  Full name of the Principal Investigator   |  | | --- | |  | | |