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| **Faculty of Medicine, University of Colombo****Application for Ethics Review (Part I) – Basic Information** |
| *for official use* |  |  |
| Application No: |  |  |  |  |  |  |  |  |  |  | Date Received: |  |  | */* |  |  | */* |  |  |
|  |  |  |  |
| Reviewed By: |  |  |  |  |  |  |  |  |  |  | ERC Meeting Date: |  |  | */* |  |  | */* |  |  |
|  |  |  |  |
| Decision: |  | Date Informed: |  |  | */* |  |  | */* |  |  |
|  |  |  |  |

**1. Title of Project**

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**2. Investigators**

Applications from investigators based overseas will only be considered if the project is done in collaboration with investigators based in institutions in Sri Lanka who take equal responsibility for the conduct of the study and who will appear as co-authors in any publication arising out of the study.

|  |  |  |  |
| --- | --- | --- | --- |
| **Title, Name, Designation and Affiliation of Investigators** | **Role** |

|  |
| --- |
| **Signature** |

 |
|       | Principal Investigator |  |
|       |       |  |
|       |       |  |
|       |       |  |
|       |       |  |
|       |       |  |

Please note that a short curriculum vitae of all investigators should be attached to the application.

**3. Contact Details of the Principal Investigator**

|  |  |
| --- | --- |
| Address: |       |
| Telephone numbers: |       |
| Fax number: |       |
| Email address: |       |

**4. Funding**

|  |  |
| --- | --- |
| Name and Address of Funding Source(s) | Amount |
|       |       |

**5. Proposed starting / ending dates \*‡** **and Study Setting:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Start Date |       |  | End Date |       |

|  |  |
| --- | --- |
| Study Setting  |       |

\*From initial recruitment of participants until completion of all data collection.

**‡**Retrospective approval will not be given for projects already started or completed.

**6. Has ethics approval for this study been requested earlier from Colombo/ERC or another similar committee?**

 Yes [ ]  No [ ]

 If yes, give details (names of committees and outcome of review)

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Please note that for studies sponsored by foreign funding agencies or sponsors ethics review and approval is

required from the country of the funding agency or the sponsor.

**7. Scientific review**

 Has this research proposal been subjected to scientific review by any other committee?

 Yes [ ]  No [ ]

 If yes, give details (names of committees and outcome of review)

 What is the name of the committee?

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**8. Clinical trials**

8.1. What phase clinical trial is being conducted?

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

 If OTHER specify:

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8.2. Is it a multicentre trial?

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| --- | --- | --- | --- |
| Yes | [ ]  | No | [ ]  |

 If yes, list the other trial sites

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

8.3. Is the clinical trial registered with a clinical trials registry?

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| Yes | [ ]  | No | [ ]  |

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

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 8.4. Data Safety Monitoring Board (only if available)

|  |  |
| --- | --- |
| Name and Designation of Members | Role |
|       |       |
|       |       |
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Please attach the curriculum vitae of all members of the DSMB.

8.5. Details of Indemnity and Insurance coverage for participants, investigators and ethics committee

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**9. Conflict of Interest**

 **9.1. Do you believe this project has a Conflict of Interest:**

Commercially

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 Financially

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 Intellectually

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 Other (explain)**:**

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 **9.2 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?**

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| --- | --- | --- | --- |
| Yes | [ ]  | No | [ ]  |

 **If yes, please explain:**

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 **9.3 If there is a duality of interest identified above describe the interest and state whether it constitutes a**

 **potential conflict of interest.**

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| **Faculty of Medicine, University of Colombo****Ethics Review Application (Part II) - Protocol Checklist** |
| *for official use* |  |  |
| Application No: |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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**1. Title of Protocol**

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**2. Name of Principal Investigator**

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**3. A List of Documents Submitted for Review**

|  |  |  |
| --- | --- | --- |
| **Title of Document** | **Version** | **Date** |
|       |       |       |
|       |       |       |
|       |       |       |
|       |       |       |
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|       |       |       |
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**4. Protocol Checklist**

 Please indicate the following:

|  |  |  |  |
| --- | --- | --- | --- |
| **Collaborative partnership** | **Applicable** | **Protocol****Section Number** | **Reviewer****checked** |
|  | **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 | [ ]  | [ ]  |       |       |

 Reviewers’ comments:

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| **Social Value** | **Applicable** | **Protocol****Section Number** | **Reviewer****checked** |
|  | **Yes** | **No** |  |  |
| 1. | The beneficiaries of your research and the benefit to them | [ ]  | [ ]  |       |       |
| 2. | The plan for dissemination of study findings | [ ]  | [ ]  |       |       |

 Reviewers’ comments:

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| **Scientific Validity** | **Applicable** | **Protocol****Section Number** | **Reviewer****checked** |
|  | **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 your study is a replication study. | [ ]  | [ ]  |       |       |
| 3. | How the sample size was calculated | [ ]  | [ ]  |       |       |

 Reviewers’ comments:

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| **Assessment of Risks/Benefits** | **Applicable** | **Protocol****Section Number** | **Reviewer****checked** |
|  | **Yes** | **No** |  |  |
| 1. | The risks to research subjects | [ ]  | [ ]  |       |       |
| 2. | Benefits to research subjects | [ ]  | [ ]  |       |       |
| 3. | Steps taken to minimize risks | [ ]  | [ ]  |       |       |
| 4. | Steps taken to enhance benefits | [ ]  | [ ]  |       |       |
| 5. | Justification of the potential benefits against the risks | [ ]  | [ ]  |       |       |
| 6. | Support provided to the research participants (medical, psychological and other) | [ ]  | [ ]  |       |       |

 Reviewers’ comments:

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| **Consent** | **Applicable** | **Protocol****Section Number** | **Reviewer****checked** |
|  | **Yes** | **No** |  |  |
| 1. | The procedure for approaching the relevant community | [ ]  | [ ]  |       |       |
| 2. | The information (written/oral) provided to the community | [ ]  | [ ]  |       |       |
| 3. | The procedure for initial contact of participants | [ ]  | [ ]  |       |       |
| 4. | The information (written/oral) provided to participants | [ ]  | [ ]  |       |       |
| 5. | The procedure for obtaining informed consent | [ ]  | [ ]  |       |       |
| 6. | The procedure for ensuring that participants have understood the information provided | [ ]  | [ ]  |       |       |
| 7. | The procedure for obtaining proxy consent | [ ]  | [ ]  |       |       |
| 8. | The procedure for obtaining assent | [ ]  | [ ]  |       |       |
| 9. | The procedure for consenting if the child reaches consenting age during the study | [ ]  | [ ]  |       |       |
| 10. | The procedure for consenting if the participant acquires capacity to give consent during the study | [ ]  | [ ]  |       |       |
| 11. | The procedure for re-consenting if data or specimens that have been collected are to be used for other research projects that may be in the same (Extended Consent) or a different (Unspecified Consent) field of study | [ ]  | [ ]  |       |       |
| 12. | The procedure for withdrawing consent | [ ]  | [ ]  |       |       |
| 13. | The justification for waiver of consent or waiver of written consent | [ ]  | [ ]  |       |       |
| 14. | Incentives/rewards/compensation/reimbursement provided or not provided to participants and their accompanying persons | [ ]  | [ ]  |       |       |
| 15. | The procedure for re-consenting if the research protocol changes during the course of research | [ ]  | [ ]  |       |       |

 Reviewers’ comments:

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| **Confidentiality** | **Applicable** | **Protocol****Section Number** | **Reviewer****Checked** |
|  | **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 | [ ]  | [ ]  |       |       |

Reviewers’ comments:

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| **Rights of the participants** | **Applicable** | **Protocol****Section Number** | **Reviewer****Checked** |
|  | **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 | [ ]  | [ ]  |       |       |

 Reviewers’ comments:

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| **Fair participant selection** | **Applicable** | **Protocol****Section Number** | **Reviewer****checked** |
|  | **Yes** | **No** |  |  |
| 1. | The justification for the selection of the study population | [ ]  | [ ]  |       |       |
| 2. | The inclusion and exclusion criteria | [ ]  | [ ]  |       |       |

 Reviewers’ comments:

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| **Responsibilities of the researcher** | **Applicable** | **Protocol****Section Number** | **Reviewer****Checked** |
|  | **Yes** | **No** |  |  |
| 1. | The provision of medical services to research participants | [ ]  | [ ]  |       |       |
| 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. | [ ]  | [ ]  |       |       |

 Reviewers’ comments:

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| **Vulnerable populations** | **Applicable** | **Protocol****Section Number** | **Reviewer****Checked** |
|  | **Yes** | **No** |  |  |
| 1. | Justification for conducting the study in this population | [ ]  | [ ]  |       |       |

 Reviewers’ comments:

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| --- | --- | --- | --- |
| **Research funded by foreign agencies/companies** | **Applicable** | **Protocol****Section Number** | **Reviewer****Checked** |
|  | **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 | [ ]  | [ ]  | PleaseAttach |       |
| 9. | The materials transfer agreement, if biological material is to be transferred abroad | [ ]  | [ ]  | PleaseAttach |       |

 Reviewers’ comments:

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| **Community based research** | **Applicable** | **Section in Protocol** | **Reviewer****Checked** |
|  | **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 | [ ]  | [ ]  |       |       |

 Reviewers’ comments:

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| **Clinical trials** | **Applicable** | **Section in Protocol** | **Reviewer****Checked** |
|  | **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. | Provisions for safety monitoring | [ ]  | [ ]  |       |       |
| 7. | Provisions/criteria for termination of the trial | [ ]  | [ ]  |       |       |
| 8. | Previsions for making the trial drug available to participants after the trial if found to be effective | [ ]  | [ ]  |       |       |

 Reviewers’ comments:

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| **Information Sheet (IFS)/Informed Consent Form (ICF) Check List** | **Section IFS/ICF** | **Reviewer****Checked** |
|  |  |  |
| List the sections in IFS/ICF where you have dealt with the following: |       |       |
| 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 |       |       |

 Reviewers’ comments:

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| --- | --- | --- | --- |
| Yes | [ ]  | No | [ ]  |

 Are the investigator’s qualifications and experience appropriate to conduct the study?

 *Recommendation: Approve* [ ]  *Reject* [ ]  *Conditional Approval (please state the conditions)* [ ]

 Reviewers’ comments:

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Reviewer:…………………………………………..Signature: ………………………… Date:……. /……./…….

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| --- |
| **Faculty of Medicine, University of Colombo****Application for Ethics Review – Document Checklist** |
| *for official use* |  |  |
| Application No: |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |

**Application Checklist**

I declare that I have attached the following documents (Please tick the check box and confirm):

1. Application Form: Part I [1 copy] [ ]
2. Application Form: Part II [1 copy] [ ]
3. The complete research protocol including a section on ethics considerations [1 copy] [ ]
4. Information sheet for research participants (Should be provided in all three languages – Sinhala, Tamil, and

 English - if the participant is being interviewed or is filling up the form). [1 copy each] [ ]

1. Consent forms (Should be provided in all three languages: Sinhala, Tamil, and English). [1 copy each] [ ]
2. Assent forms (Should be provided in all three languages: Sinhala, Tamil, and English). [1 copy each] [ ]
3. Data collection booklets/forms/questionnaires. (Should be provided in all three languages – Sinhala, Tamil,

 and English) [1 copy] [ ]

1. Indemnity/Insurance coverage (required for clinical trials) [ ]
2. Clinical Trials Contract (required for clinical trials) [1 copy] [ ]
3. Summary and flowchart (required for clinical trials) [1 copy] [ ]
4. Certificate of GCP training for at least one member of the research study [1 copy] [ ]
5. Materials Transfer Agreement (required for all research involving transfer of biological samples abroad) [1 copy] [ ]
6. Ethics approval from sponsoring country or country of the overseas investigator (if any) [ ]
7. Brief curriculum vitae of all investigators [1 copy] [ ]
8. Curriculum vitae of all DSMB members[1 copy] [ ]
9. Agree to submit soft copies of all documents after receiving the ERC reference number [ ]
10. A receipt for the appropriate payment to the accounts department [ ]

**I understand that the application for ethics clearance will not be accepted unless all documents are submitted. I declare that I am not seeking approval for a study that has already commenced or has already been completed. I understand that at least two months are required for ethics review and granting ethics clearance.**

*………………………………………………………… ……………………………*

Signature of Principal Investigator Date

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| --- |
| **Faculty of Medicine, University of Colombo****Application for Ethics Review – Document Receipt Checklist** |
| *for official use* |  |  |
| Application No: |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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**THIS WILL BE FILLED AND HANDED OVER TO THE APPLICANT BY THE**

**ERC STAFF MEMBER ACCEPTING THE APPLICATION**

The ERC confirms that the following documents were handed in by the applicant:

1. Application Form: Part I [1 copy] [ ]
2. Application Form: Part II [1 copy] [ ]
3. The complete research protocol including a section on ethics considerations [1 copy] [ ]
4. Information sheet for research participants (Should be provided in all three languages – Sinhala, Tamil, and

 English - if the participant is being interviewed or is filling up the form). [1 copy each] [ ]

1. Consent forms (Should be provided in all three languages: Sinhala, Tamil, and English). [1 copy each] [ ]
2. Assent forms (Should be provided in all three languages: Sinhala, Tamil, and English). [1 copy each] [ ]
3. Data collection booklets/forms/questionnaires. (Should be provided in all three languages – Sinhala, Tamil,

 and English) [1 copy] [ ]

1. Indemnity/Insurance coverage (required for clinical trials) [ ]
2. Clinical Trials Contract (required for clinical trials) [1 copy] [ ]
3. Summary and flowchart (required for clinical trials) [1 copy] [ ]
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5. Materials Transfer Agreement (required for all research involving transfer of biological samples abroad) [1 copy] [ ]
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7. Brief curriculum vitae of all investigators [1 copy] [ ]
8. Curriculum vitae of all DSMB members [1 copy] [ ]
9. Agree to submit soft copies of all documents after receiving the ERC reference number [ ]
10. A receipt for the appropriate payment to the accounts department [ ]

The application number appearing on top of this page has been assigned to this application. Please quote the number in all correspondence with the committee.

Please see the website of the ERC – <http://www.med.cmb.ac.lk/index.php/2012-05-16-05-25-21/ethical-review-committee> for the standard operating procedures of the committee.

*………………………………………………………… ……………………………*

Authorized Signatory for ERC Date