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**APPLICATION FOR ETHICS REVIEW**

**Faculty of Medicine, University of Jaffna**

***Please read the GUIDE TO APPLICANTS before filling the application form***

**For office use only**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Reference**  **number** | **J/** | **ERC/** |  |  |  |  |  |  |  | **Date**  **received** |  |  | **/** |  |  | **/** |  |  |  |  |

|  |  |
| --- | --- |
| **Reviewer 1 (Name and field of expertise)** |  |
| **Reviewer 2 (Name and field of expertise)** |  |
| **Reviewer 3 (Name and field of expertise)** |  |

|  |  |
| --- | --- |
| **ERC decision** |  |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **ERC Meeting Date** |  |  | **/** |  |  | **/** |  |  |  |  | **ERC decision informed on** |  |  | **/** |  |  | **/** |  |  |  |  |

**Part I – Project Information**

1. **Title of the project**

|  |
| --- |
| ……………………………………………………………………………………………………….  ………………………………………………………………………………………………………. |

1. **Type of project**

Undergraduate

Postgraduate degree (specify) ………………………………….. …………………………………..

Clinical trial

Other (specify) ………………………………….. …………………………………..

1. **Investigators** 
   1. **Principal investigator**

|  |  |
| --- | --- |
| Name |  |
| Qualification/s |  |
| Area of specialisation |  |
| Designation |  |
| Institution |  |
| Contact Address |  |
| Contact number |  |
| E-mail |  |
| Signature |  |

* 1. **Co-investigator / Supervisor (indicate the status)**

|  |  |
| --- | --- |
| Name |  |
| Qualification/s |  |
| Area of specialisation |  |
| Designation |  |
| Institution |  |
| Contact Address |  |
| Contact number |  |
| E-mail |  |
| Signature |  |

* 1. **Co-investigator / Supervisor (indicate the status)**

|  |  |
| --- | --- |
| Name |  |
| Qualification/s |  |
| Area of specialisation |  |
| Designation |  |
| Institution |  |
| Contact Address |  |
| Contact number |  |
| E-mail |  |
| Signature |  |

* 1. **Co-investigator / Supervisor (indicate the status)**

|  |  |
| --- | --- |
| Name |  |
| Qualification/s |  |
| Area of specialisation |  |
| Designation |  |
| Institution |  |
| Contact Address |  |
| Contact number |  |
| E-mail |  |
| Signature |  |

**Attach extra sheet if necessary.**

1. **Proposed date of commencement and completion of the study**

Date of commencement Date of completion

1. **Proposed data collection period (from the initial recruitment of participants / data collection until the completion of all data collection)**

Date of commencement Date of completion

1. **Has this study been submitted to any other ERC or similar committee for ethical clearance?**

Yes No

If yes,

|  |  |
| --- | --- |
| Name of the committee |  |
| Decision \* |  |
| Date |  |

\* Attach documentary evidence.

1. **Has this project been subjected to scientific review?**

Yes No

If yes,

|  |  |
| --- | --- |
| Name and address of committee/board of study |  |
| Decision \* |  |
| Date |  |

\* Attach the copy of communication of the above decision.

1. **Funding**

|  |  |
| --- | --- |
| Name and address of funding agency |  |
| Amount |  |

1. **Have you submitted any application to this ERC before? (attach extra sheets if necessary)**

Yes No

If yes,

|  |  |
| --- | --- |
| Title |  |
| Reference number of project |  |
| Decision \* |  |
| Date |  |
| Current status of the project |  |

\* Attach copy of communication of the above decision.

**Attach additional sheet if required**

1. **If yes to 9, have you submitted the progress / completion report/s for the above project/s**

YesNo\*

**\* If you have not submitted the progress / completion reports, this application will be processed by the ERC after the progress / completion reports are received.**

1. **Collaborative research** Not applicable
   1. Does the project involve international (non-Sri Lankan citizens/residents) researchers?

Yes**\*** No

**\* For projects involving international researcher/s, attach the agreement between the local and international collaborators on the following;**

* 1. Fate of data and, if applicable, samples/ specimens.
  2. Ownership of data, publication and intellectual property rights.
  3. Nature of benefits and their distribution.

**(For further information refer the SOP 7 / V4)**

* 1. List the collaborating institutions

|  |  |
| --- | --- |
| 1. |  |
| 2. |  |
| 3. |  |
| 4. |  |
| 5. |  |

* 1. Has this study been submitted to any ERC / similar body in the country/ countries of the international collaborator/s?

Yes No

If yes,

|  |  |  |
| --- | --- | --- |
| Name and address of the committee(s) | Decision\* | Date |
|  |  |  |
|  |  |  |

\* Attach evidence of the above decision.

If no, give reason/s

|  |
| --- |
|  |

* 1. What is the relevance of this study to this country?

|  |
| --- |
|  |

**11.5.** Are biological samples to be transferred abroad?

Yes No

**If yes, attach the material transfer agreement.**

1. **Clinical trials**  Not applicable
   1. Which phase of the trial is being conducted?

Phase I

Phase II

Phase III

Phase IV

Others (specify) …………………………………………………

* 1. Is the clinical trial registered with a clinical trial registry?

Yes No

If yes\*,

|  |  |
| --- | --- |
| Name of the registry |  |
| Registration number |  |

\* Attach evidence.

* 1. Is the drug/ product/device registered in Sri Lanka?

****Yes No

**If no, submit the approval from the National Medicines Regulatory Authority**

* 1. Is the new intervention, or any intervention that is to be tested outside its approved use, registered and approved by the Sub-committee of Clinical Trials of the Ministry of Health?

 Yes No

**If, yes attach the copy of the approval.**

**If, no please obtain the approval before submitting to ERC.**

* 1. Is this a multicenter trial?

Yes No

If yes, list the other centers.

|  |
| --- |
|  |

* 1. Are the participants to be compensated for participation?

Yes No

If yes, compensation per participant in Sri Lanka Rupees.

|  |
| --- |
|  |

* 1. Are the investigators to be paid?

Yes No

If yes, by whom?

|  |
| --- |
|  |

* 1. Please provide details of the Trial Monitoring Committee / Data Safety Monitoring Board (if applicable).

|  |  |  |
| --- | --- | --- |
| **Name of member** | **Designation** | **Role** |
|  |  |  |
|  |  |  |
|  |  |  |

* 1. Please provide details of insurance coverage for participants, investigators and the ERC.

|  |
| --- |
|  |

1. Conflicts of interest (please declare)**.**

|  |
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|  |

1. Declare any objection you have for this protocol to be sent for review to any particular reviewer/s with reasons**.**

………………………………………………………………………………………………

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**Part II – Protocol Checklist**

|  |  |  |  |
| --- | --- | --- | --- |
| **No.** |  | **Page No.** | **NA\*** |
| 1 | Summary of the project |  |  |
| 2 | Introduction/ background |  |
| 3 | Justification |  |
| 4 | Review of literature |  |
| 5 | Objectives |  |
|  | **Methodology** |  |
| 6 | Study design |  |
| 7 | Study setting |  |
| 8 | Study duration (and data collection period) |  |
| 9 | Study population |  |  |
| 10 | Sample size and calculation of sample size |  |  |
| 11 | Inclusion criteria |  |  |
| 12 | Exclusion criteria |  |  |
| 13 | Study instrument/s |  |  |
| 14 | Pilot study |  |  |
| 15 | Sampling/ recruitment procedure |  |  |
| 16 | Data collection |  |
| 17 | Data analysis |  |
| 18 | Budget |  |
| 19 | Timeline |  |
|  | **Ethical issues** |  |  |
| 20 | Assessment of risks/ benefits |  |  |
| 21 | Procedure for obtaining consent |  |  |
| 22 | Informed consent form |  |  |
| 23 | Justification for including a vulnerable population |  |  |
| 24 | Procedures to protect the rights of participants |  |  |
| 25 | Confidentiality |  |  |
| 26 | Maintenance and fate of data |  |  |
| 27 | Safety monitoring |  |  |
| 28 | Provision of medical and psychological support to participants |  |  |
| 29 | Dissemination of results |  |  |
|  | **Biological Samples** |  |  |
| 30 | Justification for using biological sample/s |  |  |
| 31 | Procedures for collection, storage and disposal of biological sample/s |  |  |
| 32 | Consent for collecting biological sample/s |  |  |
|  | **Collaborative research** |  |  |
| 33 | Justification and benefits of collaboration with foreign investigators |  |  |
| 34 | Protection of the rights of local collaborator and participants |  |  |
| 35 | Justification for transfer of data and /or biological/ genetic materials to the country of foreign collaborator |  |  |
| 36 | Fate of transferred data and biological/ genetic material |  |  |
|  | **Clinical trials** |  |  |
| 37 | Criteria for termination of participants from the trial |  |  |
| 38 | Criteria for termination of the trial |  |  |
| 39 | Adverse event monitoring, management and reporting |  |  |
| 40 | Justification for withholding/ withdrawing standard therapy |  |  |
| 41 | Provision for making the trial drug available after completion |  |  |

**\* NA – Not applicable**

**Part III – Application Checklist**

**I declare that I have attached the following documents.**

**(Please tick the appropriate check box)**

|  |  |  |
| --- | --- | --- |
| **No.** | **Document** | **Check**  **box** |
| 1 | Application form – 1 copy |  |
| 2 | Signed and dated CV of PI and postgraduate research supervisor/s – 1copy |  |
| 3 | Summary of the project – 1 copy |  |
| 4 | Research protocol – 1 copy |  |
| 5 | Informed consent form (should be provided in English and local language of participants i.e. Tamil / Sinhala/ both Tamil and Sinhala) – 1 copy each |  |
| 6 | Questionnaire (should be provided in English and local language of participants i.e. Tamil / Sinhala/ both Tamil and Sinhala) – 1 copy each |  |
| 7 | Data record booklet/ event record diary/data record sheet or form (should be provided in English and local language of participants i.e. Tamil / Sinhala/ both Tamil & Sinhala, if self-administered by participants) – 1 copy each |  |
| 8 | Approval from National Drug Regulatory Authority (for clinical trials) |  |
| 9 | Approval from SCOCT (to test new interventions/ interventions outside approved use in clinical trials) |  |
| 10 | Insurance coverage (for clinical trials) |  |
| 11 | Ethical clearance from the country of international collaborator(s), if applicable |  |
| 12 | Evidence of scientific review, if available |  |
| 13 | Soft copies of all documents other than the application form (by email) |  |
| 14 | Receipt for payment of application fee to Shroff Counter, University of Jaffna or any branch of the People’s Bank |  |
| 15 | Administrative approval/s, if available (permission letters from heads of institution or authorized officers/ in-charge of the study site(s), etc.).  Specify ………………………………………….. |  |
| 16 | Material transfer agreement |  |
| 17 | Font size -12pt |  |
| 18 | Line space between sentences- 1.5 |  |
| 19 | Other  (Specify ………………………………) |  |

**I understand that the application for ethics clearance will not be accepted unless all necessary documents are submitted and that at least 6 weeks are required for ethics review.**

I declare that:

* I am not seeking approval for a study that has commenced or been completed.
* all the information given is correct to the best of my knowledge.

……………………………………………… Date:

Signature of Principal Investigator

………………………………………………. Date:

Signature of Chief Supervisor

(If applicable)

………………………………………………. Date:

Signature of Head of the Department/ Unit

(If applicable)

………………………………………………. Date:

Signature of Dean/Head of the Institution

(if applicable)