# 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**

…….

…….

**2. Type of project**

Undergraduate ☐

Postgraduate degree (specify) ☐ ……..

……..

Clinical trial ☐

Other (specify) ☐ ……..

……..

## 3. Investigators

### 3.1. Principal investigator

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

### 3.2. Co-investigator / Supervisor (indicate the status)

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

### 3.3. Co-investigator / Supervisor (indicate the status)

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

**3.4. 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.**

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

   Date of commencement ☐ Date of completion ☐

5. **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 ☐

6. **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.

7. **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.

**8. Funding**

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

**9. 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**

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

Yes ☐ No* ☐

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

11. **Collaborative research** Not applicable ☐

**11.1.** 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;**

a. Fate of data and, if applicable, samples/ specimens.

b. Ownership of data, publication and intellectual property rights.

c. Nature of benefits and their distribution.

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

**11.2.** List the collaborating institutions

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

**11.3.** 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

| |
|---|
| |

**11.4.** 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.**

**12. Clinical trials** Not applicable ☐

**12.1.** Which phase of the trial is being conducted?

Phase I ☐

Phase II ☐

Phase III ☐

Phase IV ☐

Others (specify) ☐ ……

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

Yes ☐ No ☐

If yes*,

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

* Attach evidence.

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

Yes ☐ No ☐

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

**12.4.** 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.**

**12.5.** Is this a multicenter trial?

Yes ☐ No ☐

If yes, list the other centers.

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

Yes ☐ No ☐

If yes, compensation per participant in Sri Lanka Rupees.

**12.7.** Are the investigators to be paid?

Yes ☐ No ☐

If yes, by whom?

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

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

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

| |
|---|
| |

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

| |
|---|
| |

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

……

……

## 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.).<br><br>Specify …….. | |
| 16 | Material transfer agreement | |
| 17 | Font size -12pt | |

| | | |
|---|---|---|
| 18 | Line space between sentences- 1.5 | |
| 19 | Other<br>(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)