# APPICATION FORM FOR ETHICAL CLEARANCE

***For Office Use***

Application Number: ……Date Received: ……..

Nature of Investigator: FHCS Student/PG Trainee/EUSL Staff/Any others

Payment: Received/Not Received/NA

Name of Reviewer 1: .....

Name of Reviewer 2: .....

Date of ERC Meeting: ..... Decision: .....

Date of ERC Meeting: ..... Decision: .....

Date of ERC Meeting: ..... Decision: .....

Certificate Issued Date.....

Received Signature .....

**Check List (Please mark all the documents attached)**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Two copies of Proposal | | | | | | | |
| Two copies of Study instruments | | English | | Tamil | | Sinhala | |
| Two copies of Information Sheet | | English | | Tamil | | Sinhala | |
| Two copies of Consent Form | | English | | Tamil | | Sinhala | |
| Letter from the Supervisor* | | | | | | | |
| Eight copies of one Page Summary of the study | | | | | | | |
| Approval from relevant institution | | | | | | | |

* Only for Undergraduate & Postgraduate Study

## SECTION 1: GENERAL INFORMATION

### 1.1 Title of Research project:

### 1.2 Investigators Information:

1.2.1. Principal Investigator/s

| | |
|---|---|
| Name | |
| Qualifications | |
| Designation | |
| Official Address | |
| Telephone | |
| E-mail address | |
| Signature | |

1.2.2. Co-Investigator/Supervisor

| Name | Designation | Affiliation | E-mail address | Signature |
|---|---|---|---|---|
| | | | | |
| | | | | |
| | | | | |
| | | | | |

*Please append additional pages with co-investigators' names if necessary.*

### 1.3 Where will the study take place? *(If the study will take place in more than one center please indicate which other research ethics committees have been approached and what the outcome to the date is)*

**1.4 If this is a student project, please give details of your academic supervisory arrangements**.

Course:

Faculty & Institution:

Supervisor:

## SECTION 2: DESIGN OF PROJECT

**2.1 Has any work similar to this been undertaken before?** If yes, please explain why you wish to conduct it again and give the results of previous work.

**2.2 Is all or part of your application a pilot study?**

| **Yes** | | **No** | |
|---|---|---|---|

| | **Description** | **No** | **Yes** | ***if yes, please complete appendix*** |
|---|---|---|---|---|
| **2.3** | Will any ionizing radioactive substances or X-rays be administered which are additional to those which would normally be administered to these subjects as part of their routine clinical care? | | | ***A*** |
| **2.4** | Will any medicinal products be administered as part of the research which are additional to those which would normally be administered to these subjects as part of their routine clinical care? | | | ***B*** |
| **2.5** | Will any medical devices/items of medical equipment be used as part of the research which are additional to those which would normally be used with these subjects as part of their routine clinical care? | | | **C** |
| **2.6** | How many subjects (and controls, if appropriate) will be recruited? | | | **D** |
| **2.7** | Is the research a clinical trial? | | | **E** |

**2.8 What are the inclusion and exclusion criteria?**

**2.9. If you took statistical advice on the overall design and analysis, please state from whom such advice obtained**

Name:

Institution:

## SECTION 3: RISKS AND ETHICAL PROBLEMS

**3.1 Who will approach subjects/controls/parents etc. in the first instance?**
*(Please submit any advertisements/letters to employers or schools. etc that will be used.)*

**3.2 Who will explain the study?**

**3.3 Will there be a written information sheet or letter?**

| | | |
|---|---|---|
| **Yes** | | if **yes**, please attach copies of any to be used |
| **No** | | if **No**, please explain why? |

**3.4 Will consent be sought?**

| | |
|---|---|
| **Yes** | if **yes**,<br>1. From whom will consent be sought(i.e. Subjects, parents etc.)<br>2. Will consent be written or oral (oral consent should be justified below)?<br>*please attach copy of consent form* |
| **No** | if **No**, please explain why? |

**3.5 What special arrangement have been made for subjects who can communicate only through their native language?**

**3.6 Are there any ethical problems or issues that the investigators consider to be important or difficult with the proposed study?**

| | | | |
|---|---|---|---|
| Yes | | No | |

If yes, please give details

**3.7 Are there any potential hazards/risks to the subjects, their relatives or the investigators?**

| | | | |
|---|---|---|---|
| Yes | | No | |

If Yes, please give details, including an estimated probability of occurrence and a description of precaution/s taken to meet them and arrangements to deal with adverse events

**3.8 Could the procedures being used in this study cause discomfort/distress/ inconvenience to subjects?**

| | | | |
|---|---|---|---|
| Yes | | No | |

If yes, please give details

SECTION 4: FINANCES, CONFIDENTIALITY AND INDEMNITY

**4.1 Are there any financial incentives for the subject?**

| | | | |
|---|---|---|---|
| Yes | | No | |

If yes, please give details

**4.2 Are there financial interests for the applicants over and above those detailed on the registration from?**

| | | | |
|---|---|---|---|
| Yes | | No | |

If yes, please give details

**4.3 Will any expenses incurred by the subject be refunded?**

| | | | |
|---|---|---|---|
| Yes | | No | |

If yes, please give details

**4.4 Who besides the named investigators will have access to the subjects' medical records?**

**4.5 Is there any Indemnity, insurance and liability cover for the project?**

| | | | |
|---|---|---|---|
| Yes | | No | |

If **No** who would take responsibilities in the event of a claim?