Annexure 15

**APPLICATION FOR ETHICS REVIEW OF STUDENT PROJECTS- PART 1**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| *for official use* | | No; ERC | |  | Checked by |  | |
| ERC Discussion | | | | No Risk / Minimal Risk / Greater than Minimal Risk | | | |
| ERC Recommendation | | | | Exempt from Ethics Review / Expedited Review / Full Committee Review | | | |
| Reviewer 1 | |  | | | Reviewer 2 |  | |
| PIL and ICF reviewer | | | |  | | | |
| Received date | | |  | | Meeting Date | |  |
| Decision | Approved/ Approved with corrections/Resubmission/Rejection | | | | Date Informed | |  |

* 1. Title of Research Project: descriptive and short

|  |
| --- |
| Descriptive title: |
| Short title: |

* 1. Principal investigator/ applicant (*please attach CVs*)-if you have more than one PI please duplicate this form

|  |  |
| --- | --- |
| Title | Mr/Ms/Rev/Dr/Prof |
| Name |  |
| Current designation |  |
| Institute where the applicant is attached |  |
| Highest educational qualification of the applicant |  |
| Telephone (office) |  |
| Telephone (home) |  |
| Telephone (mobile) |  |
| e mail (main method of communication) |  |
| Address for correspondence |  |
|  |  |

* 1. Names, qualifications and affiliations of the co-investigators.

|  |  |  |
| --- | --- | --- |
| **Name** | **affiliation** | **Qualifications** |
|  |  |  |
|  |  |  |
|  |  |  |

* 1. If this is a student project (undergraduate or post graduate) please give details of your academic supervisory arrangements.

|  |  |
| --- | --- |
| Course/degree |  |
| Faculty/ Institution |  |
| Academic supervisor/s  (*name, affiliation and qualifications*) |  |

* 1. Where will the study take place?

a. Is this a collaborative and multi-center trial?

No

Yes

If yes please describe the other centers and collaborating institutes or universities.

b. Please indicate what other research ethics committees have been approached and what the outcome of the proposal.

* 1. Has this research proposal undergone scientific review

No

Yes

*If yes please give details*

* 1. Please name the source of funding and the amount.
  2. Data collection period (*from the initial recruitment of participants to completion of data collection*)

D D M M Y E A R

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Starting date |  |  |  |  |  |  |  |  |  |  |
| Finishing date |  |  |  |  |  |  |  |  |  |  |

* + 1. Project summary (*of no more than 500 words in non-technical language*) with PIs name, title of the research project on top and a word count in this form. Also submit thirty one copies of the project summary with PIs name, title of the project and word count in a separate file. A structured project summary should include the rationale/ background (2-3 sentences), objectives of the proposed study and the methods. Study design, sample and sampling procedure, measurements and data collection and data analysis with outcome measures should be included in the methods section of the summary.

*Title of the research*

*PI name*

|  |  |  |  |
| --- | --- | --- | --- |
| Word count |  |  |  |

Project summary.

**Application for Ethics Review - PART 11**

**SECTION A**

**RESEARCH PROJECT***-please attach a complete protocol of your research*

All proposals that has not undergone prior scientific review will undergo scientific review (Standards and operational guidance for ethics review of health-related research with human participants World Health Organization 2011)

2.1 **Please indicate study type**– *you may tick more than one box.*

|  |  |
| --- | --- |
|  | Laboratory study not using animals |
|  | Laboratory study using animals |
|  | Laboratory study using stored human biological material |
|  | Participant observation |
|  | Interviews, focus group |
|  | Other type of qualitative study |
|  | Social science research |
|  | Research on medical records or other personnel information |
|  | Health system research |
|  | Implementation research |
|  | Cross-sectional study |
|  | Case-control study |
|  | Cohort study |
|  | Randomized Controlled Trial not using experimental drug or device |
|  | Randomized Controlled Trial using experimental drug or device |
|  | Phase 1 or 2 of trial using a experimental drug or device |
|  | Other type of study (please describe) |

2.2 What are the Hypotheses or objectives of the research project?

2.3 How will the participants in the study be selected? What inclusion and exclusion criteria will be used?

**SECTION B**

**PARTICPANT RISK**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | *Yes* | *No* | *Yes* | *No* |
| Self completed questionnaires |  |  |  |  |
| Structured interviews/researcher completed questionnaires |  |  |  |  |
| Venepuncture |  |  |  |  |
| Arterial puncture |  |  |  |  |
| Biopsy |  |  |  |  |
| Other tissue/ body sample |  |  |  |  |
| Ionizing radioactive substances/X-rays |  |  |  |  |
| Non-radioactive imaging investigations |  |  |  |  |
| Non-invasive tests (eg. ECG) |  |  |  |  |
| Anesthesia, sedation |  |  |  |  |
| Other medicinal products |  |  |  |  |
| Medical devices/ equipment |  |  |  |  |
| Hospitalization |  |  |  |  |
| Longer inpatient days |  |  |  |  |
| Additional outpatient attendances |  |  |  |  |
| Other investigations not part of routine care |  |  |  |  |

*Please fill the table below*

***Investigation******Routine Procedure******Additional Procedure***

3.2 Description of the procedure to be carried out on these participants (administration of a questionnaire/drug/collection of blood/ samples/ investigation/surgery)

3.3 Safety measures employed during the procedure.

3.4 Are there any potential hazards/ risks/discomfort / distress/ inconvenience to the participants, their relatives or the investigators? *Please describe.*

3.5 How this will be minimized? *Please describe.*

3.6 Potential benefits to the participants and the community and any steps taken to enhance these benefits. *Please describe.*

3.7 Justification of potential benefits over the risks. *please discuss.*

**SECTION C**

**RECRUITMENT AND CONSENT**

4

4.1 Who will approach the participants initially? *Please submit any letters / advertisements to employers/ schools etc. or newspaper advertisement that will be used. Please explain the training and educational qualification of the people who will obtain consent.*

4.2 Will there be a participant information sheet?

Yes

No

*If no please justify. If yes, please attach copies in English and in the language of the participant*

4.3 Will informed consent be sought?

Yes

No

*If Not please justify*

4.4 Will consent be written or oral? *Oral consent should be justified below. Please attach written consent form in English and in the language of the participant.*

4.5 Incentive or compensation if any offered to the participants

No

Yes

*Please justify if yes, or no and if yes describe the incentive*

4.6 Describe any steps to ensure whether participants have understood the information procedure

4.7 Please describe the procedure of obtaining consent (*describe the time interval between providing information to the participants and obtaining consent, the space given to discuss with their significant others about participating, any special considerations to vulnerable groups etc*)

4.8 Please describe the procedure if the participant wishes to withdraw from the study

4.9 Will there be proxy consent (in acutely ill patients, patients with cognitive impairment, and in children) please describe and justify

4.10 What data will be collected from the participants who refuse consent?

4.11Describe procedure for participants to ask questions and register complaints

**SECTION D**

**CONFLICTS OF INTREST, INTELLECTUAL PROPERTY AND CONFIDENTIALITY**

5.1 Are there any financial or other incentives for the participants or recruiting physicians, mid wives or any other official?

No

Yes

*If yes, please give details*

5.2 Are there any interests for the investigators over and above those detailed in this form?

No

Yes

*If yes, please give details*

5.3 Are there any conflicts of interest or duality of interests such as that between providers of funding and the investigators?

5.4 Who besides the named investigators will have access to the participants’ medical/ personal records? Please describe the procedure to ensure confidentiality of data

5.5 Will the proposed research use technology, materials or other invention that, as far as you are aware, are subject to any patents or other form of intellectual property protection?    Please give details (no more than 200 words)

5.6 Is the proposed research, (in whole or in part) subject to any agreements with commercial, academic or any other organizations?   If yes Please give details (no more than 200 words)

5.7 Is the proposed research likely to lead to any results that could be patented or commercially exploited? Please give details (no more than 200 words)

5.8 Will any potentially commercially exploitable results be based upon tissues or samples derived from human participants?   Please confirm that there has been appropriate informed consent for such use.

**SECTION E**

**DISSEMINATION OF THE FINDING, PUBLIC ENGAGEMENT & COMMUNITY CONSIDERATIONS**

6. 1 Please describe if relevant the steps taken to consult with concerned community when designing the research and during the course of research (no more than 200 words)

6.2 Please describe briefly how you address or engage the community and the collaborations you have built with the community. (No more than 200 words)

6.3 Please outline your plans, for engaging non-academic public audiences. Particularly the way you intend to make the results of your research available to the participants and to the concerned community (no more than 200 words)

6.4 Please describe briefly the plan for dissemination of findings (no more than 200 words)

**7. Declaration**

I certify that the information given above is true and correct to the best of my knowledge. If there is change in the protocol or the research project is terminated before completion I will inform the ethics review committee. I will also inform if there are any serious adverse events to the human participants during the research project *(please see the notes below).*

**Date: Applicants signature: ……………………………**