**Participation information leaflet**

**Annexure 04**

**Institute/University**

**Name of the project**

**Sample Participant information sheet**

We would like to invite you to participate in a research project. Please read this leaflet carefully, and if you have any questions about the survey do not hesitate to ask from the researcher. Feel free to discuss the project with your family or friends before you make a decision on participating.

**Introduction**

This is a study about \_\_\_\_\_\_\_\_.

This research project is a collaboration between \_\_\_\_\_\_\_\_.

This research project is funded by the \_\_\_\_\_\_\_\_.

This project has been approved by the Ethics Review Committee of GWUIM, Sri Lanka.

**Why have I been invited?**

You have been selected for this study because \_\_\_\_\_\_\_\_.

**Do I have to take part?**

No. Participation is entirely voluntary. There is no obligation for you to take part, and if you do not want to take part, this will have no effect on your medical care, or affect you in any other way. It is also possible for you to withdraw from the interview or withdraw data at any point without giving any reasons and without any penalty. As we are conducting this research to improve knowledge about the \_\_\_\_\_\_\_\_ in Sri Lanka, we would greatly appreciate your participation.

**What will the research involve? *(the procedure needs to be explained)***

We will ask you to take part in an interview, carried out in private, by a trained research assistant. The interview includes questions on demographic information, \_\_\_\_\_\_\_\_. Interview process will take approximately 2 hours and to compensate for time we will pay you Rs \_\_\_\_\_\_\_\_. We will also check your height, weight, waist circumference and blood pressure.

A fully qualified trained nurse will carry out physical examinations and draw 25ml of blood (standard amount of blood drawn for investigations) and 15ml of urine will be required for clinical investigations of which a report of the results will be given to you.

**Are there any risks?**

Drawing blood for biochemical investigations has a minimal risk. We ensure that all possible preventative measures according to the current standards and guidelines will be strictly adhered to prevent any risks of blood drawing. All personnel conducting the research will be trained specifically to detect and handle complications of blood drawing and a medical officer will be on duty for medical assistance. No one except the investigators will have the access to the blood and urine samples and they will be disposed after each day according to the current standards. *(Indicate any psychological stress)*

**Are there any benefits?**

You will be paid/will not be benefited by participating in this study. However, information gathered from this study would help to develop new interventions in the community in future.

**Will the information I give stay confidential?**

**Yes. All information you provide is strictly confidential**

If we find that you may be having a significant problem, we will suggest and direct you to the necessary health care providers with your permission. The information you give may be used for a research report or publications, but it will not be possible to identify you in any way from this.

If you have any further questions please ask:

Investigators: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Telephone : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

If you have any complaints about this research or its conduct please contact:

Secretary, Ethics Review Committee, Gampaha Wickramarachchi University of Indigenous Medicine, Sri Lanka

Phone number: +94(033)2238206

(please contact during working hrs 8 am – 4 pm)

E-mail: erc@gwu.ac.lk

**Annexure 05**

Annexure 05

**Name of the study**

**Sample Participant’s consent form**

|  |  |  |
| --- | --- | --- |
| **Investigators** | **Telephone number** | **Address** |
|  |  |  |
|  |  |  |

**Please circle your answer**

Have you read the information sheet? Yes/No

Did you have an opportunity to ask questions and Discuss about the study?

Yes/No

Have you received satisfactory answers to the questions you asked about the project? Yes/No

Who explained the study to you? ……………………………………………………….

Do you understand that you are free to leave the study without giving any reason? Yes/No

Did you agree to take part on your own wish? Yes/No

I understand that the information I give is confidential. Yes/No

I give my consent to take part in the study and this will include an interview lasting approximately \_\_\_\_ hours, and a blood sample of about 20ml (about four teaspoonfuls) will be taken. Yes/No

I understand that my waist circumference, weight, height and blood pressure will be measured. Yes/No

I understand that if I may be selected for an additional test to measure the heart rate that will involve wearing a light monitoring device for a period of 5 minutes. Yes/No

I understand that if I may be approached in later stage of the study to wear an actigraphy watch for one week which will record my activity levels and sleep. Yes/No

If you are detected as having any significant problems with depression, anxiety or any other health issue, we may refer you to a doctor, but we will only do this with your permission.

**Do you agree?** Yes/No

Name ……………………………………………………….

Signature ……………………………………………………….

Date ……………………………………………………….

Name of the witness ………………………………………………….

Signature ………………………………………………….

Date …………………………………………………..

**Additional genetic consent**

• I give my consent for my blood to be stored for this study.

• I understand that I will not receive any results about my own genotype.

**Participant’s statement:**

I agree that the genetic component of the research project named above has been explained to me

to my satisfaction and I agree to take part in the study. I have read both the notes written above and the Information Sheet about the project, and understand what the research study involves.

Name ……………………………………………………….

Signature ……………………………………………………….

Date ……………………………………………………….

**If you have any complaints about this research or its conduct, please contact:**

Secretary, Ethics Review Committee, Gampaha Wickramarachchi University of Indigenous Medicine, Sri Lanka

Phone number: +94(033)2238206 (please contact during working hrs 8 am – 4 pm)

E-mail: erc@gwu.ac.lk

**Annexure 06**

**ETHICS REVIEW COMMITTEE**

Annexure 06

**Gampaha Wickramarachchi University of Indigenous Medicine, Sri Lanka**

**Proposal Evaluation Form**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **ERC No:** | | **PI name:** | **Date received:** | | | |
|  | | | **Yes** | **No** | **NA** | **Comment** |
| **Background and social value (Refer background and justification sections of the protocol)** | | | | | | |
| 1 | Background and justification – sufficient? | |  |  |  |  |
| 2 | Literature review – adequate? | |  |  |  |  |
| 3 | Need for human participation justified? | |  |  |  |  |
| 4 | Has the protocol been approved by a competent body? | |  |  |  |  |
| 5 | Should the study be referred to a technical or statistical expert? | |  |  |  |  |
| **Scientific value (Refer methodology section of the protocol)** | | | | | | |
| 6 | Objectives – clear? | |  |  |  |  |
| 7 | Methodology – clear? | |  |  |  |  |
| 8 | Study design – appropriate? | |  |  |  |  |
| 9 | Sample size – adequate? | |  |  |  |  |
| 10 | Statistics used – appropriate? | |  |  |  |  |
| **Subject selection (Refer methodology section of the protocol)** | | | | | | |
| 11 | Inclusion criteria – appropriate? | |  |  |  |  |
| 12 | Exclusion criteria – appropriate? | |  |  |  |  |
| 13 | Voluntary, non-coercive recruitment of participants | |  |  |  |  |
| 14 | Inducement for participation | |  |  |  |  |
| 15 | Vulnerable populations involved?  If yes, is it justifiable? | |  |  |  |  |
| **Assessment of risk/benefits** | | | | | | |
| 16 | Researcher qualifications, competence and experience suitable for safe conduct of research? | |  |  |  |  |
| 17 | Risks: benefits assessment acceptable? | |  |  |  |  |
| 18 | Medical and psychological support for participants – adequate? | |  |  |  |  |
| 19 | Provision for treatment in study related injuries? | |  |  |  |  |
| 20 | Provision for compensation (where applicable)? | |  |  |  |  |
| **Informed consent** | | | | | | |
| 21 | Procedures for obtaining informed (written/verbal) consent – appropriate? | |  |  |  |  |
| 22 | Information sheet and consent form contain clear and adequate details? | |  |  |  |  |
| 23 | Translations of all sheets/forms consistent? | |  |  |  |  |
| 24 | Contact details of PI available for participants on the information sheet? | |  |  |  |  |
| 25 | Arrangements for proxy consent –appropriate? (where applicable) | |  |  |  |  |
| 26 | Incentives offered – approved? | |  |  |  |  |
| **Respect for participants and confidentiality** | | | | | | |
| 27 | Privacy and confidentiality of the participants – safeguarded? | |  |  |  |  |
| 28 | Participants’ right to dissent, unconditional withdrawal safeguarded? | |  |  |  |  |
| 29 | Data/ sample storage and disposal procedures appropriate? | |  |  |  |  |
| **Independent review** | | | | | | |
| 30 | Disclosure or declaration of potential conflicts of interest | |  |  |  |  |
| **Is all the documentation provided?** | | |  |  |  |  |
| **Recommendation** | | | Approve /Approve with corrections / Re-submit/  Reject | | | |

**Additional comments:**

**………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………**

**Name of the reviewer:**

**Signature :**

**Date :**

**Annexure 07**

Annexure 07

**Ethics Review Committee**

**GAMPAHA WICKRAMARACHCHI UNIVERSITY OF INDIGENOUS MEDICINE**

**YAKKALA, SRI LANKA**

Date:

……………………………..

……………………………..

……………………………..

Dear ……………………….

**Reviewers’ comments on the ethical clearance application**

**(Ref. No: ERC/ / )**

Ethics review committee meeting held on ………………………...., granted ethical approval for your application/approved your application with corrections/subjected your application for resubmission/rejected your ethical application.

Therefore, you may obtain the ethical clearance certificate from the ERC office (If approved only).

Thanking you.

Yours sincerely,

Secretary/ ERC

Gampaha Wickramarachchi University of Indigenous Medicine

**Chairperson:**

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**Secretary:**

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**Assistant Secretary:**

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**Committee Members:**

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Address all correspondence to: Secretary, Ethics Review Committee, Gampaha Wickramarachchi University of Indigenous Medicine, Sri Lanka

Tel. +94 003 2238206, E-mail: erc@gwu.ac.lk

**Annexure 08**

Annexure 08

**ETHICS REVIEW COMMITTEE**

**GAMPAHA WICKRAMARACHCHI UNIVERSITY OF INDIGENOUS MEDICINE**

**YAKKALA, SRI LANKA**

**ETHICAL CLEARANCE CERTIFICATE**

*This is to certify that ethical clearance was granted for the research proposal*

**ERC No**

**Title**

*Submitted by*

**Name and Affiliation of Principal investigator**

*And*

**Co-Investigators**

*At the meeting held on*

*This certificate is valid till*

Chairperson, Ethics Review Committee,

Gampaha Wickramarachchi University of Indigenous Medicine

Sri Lanka

**Annexure 09**

Annexure 09

**Ethics Review Committee**

**GAMPAHA WICKRAMARACHCHI UNIVERSITY OF INDIGENOUS MEDICINE**

**YAKKALA, SRI LANKA**

**Ethical Approval Letter**

**Title:**

**Principal investigator:**

**ERC number:**

**Documents approved and version:**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Documents** | **Version** | | | | | |
| Clinical protocol |  | | | | | |
| Participant information sheet | E |  | S |  | T |  |
| Consent form | E |  | S |  | T |  |
| Advertisement | E |  | S |  | T |  |
| Questionnaire | E |  | S |  | T |  |

**Date discussed:**

**Date approved:**

**Conditions of ERC approval:**

**Duration of ERC approval:**

**Progress report:**

**Date of submission of final report:** Final report should be submitted to the ERC within 3 months of completion of the study

Chairperson

Ethics Review Committee

Gampaha Wickramarachchi University of Indigenous Medicine

Sri Lanka

**Chairperson:**

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**Secretary:**

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**Assistant Secretary:**

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**Committee Members:**

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Address all correspondence to: Secretary, Ethics Review Committee, Gampaha Wickramarachchi University of Indigenous Medicine, Sri Lanka

Tel. +94 (033) 2238206, E-mail: erc@gwu.ac.lk

**Annexure 10**

Annexure 10

**Ethics Review Committee**

**GAMPAHA WICKRAMARACHCHI UNIVERSITY OF INDIGENOUS MEDICINE**

**YAKKALA, SRI LANKA**

**Ethical Approval Letter for Amendments/ Extensions**

**Title:**

**Principal investigator:**

**ERC number:**

**Amendments / Extensions approved and version:**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Amendments** | **Version** | | | | | |
| Clinical protocol |  | | | | | |
| Participant information sheet | E |  | S |  | T |  |
| Consent form | E |  | S |  | T |  |
| Advertisement | E |  | S |  | T |  |
| Questionnaire | E |  | S |  | T |  |

**Date discussed:**

**Date approved:**

**Conditions of ERC approval:**

**Duration of ERC approval:**

**Progress report:**

**Date of submission of final report:** Final report should be submitted to the ERC within 3 months of completion of the study

Chairperson

Ethics Review Committee

Gampaha Wickramarachchi University of Indigenous Medicine

Sri Lanka

**Chairperson:**

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**Secretary:**

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**Assistant Secretary:**

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**Committee Members:**

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Address all correspondence to: Secretary, Ethics Review Committee, Gampaha Wickramarachchi University of Indigenous Medicine, Sri Lanka

Tel. +94 (033) 2238206, E-mail: erc@gwu.ac.lk

**Annexure 11**

Annexure 11

**Ethics Review Committee**

**GAMPAHA WICKRAMARACHCHI UNIVERSITY OF INDIGENOUS MEDICINE**

**YAKKALA, SRI LANKA**

**Letter for clarification / Information**

Date:

……………………………..

……………………………..

……………………………..

Dear ……………………….

**Regarding the ethical clearance application on “………………………….”**

**(Ref. No:ERC/\_\_\_/ )**

Ethics review committee meeting held on\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, decided that clarifications have to be made/ additional information is required prior to the granting approval for your ethical application.

Therefore, please address the queries attached to consider your proposal for approval.

Thanking you.

Yours sincerely,

Chairperson

Ethics Review Committee

Gampaha Wickramarachchi University of Indigenous Medicine,

Sri Lanka

**Chairperson:**

………………………

**Secretary:**

…………………………

**Assistant Secretary:**

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**Committee Members:**

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Address all correspondence to: Secretary, Ethics Review Committee, Gampaha Wickramarachchi University of Indigenous Medicine, Sri Lanka

Tel. +94 (033) 2238206, E-mail: erc@gwu.ac.lk

**Annexure 12**

Annexure 12

REPORT OF ADVERSE REACTIONS TO MEDICINES, VACCINES, DEVICES, TRADITIONAL REMEDIES & COSMETICS

(Identities of Reporter, Patient and Institution will remain confidential)

PATIENT DETAILS:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **BHT/Record no.** | **Name& address(optional)** | **Age** | **Ethnicity** | **Sex** | **M** |
| **F F** |
|  |  |  |  |  |  |

ALL MEDICINES IN USE:

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Suspected Drug-generic & trade name( batch no if available) | Dose &  frequency |  | Route | Date  Begun | Date  Stopped | Reason for Use |
|  |  |  |  |  |  |  |
| Other Drugs in use: | | | | | | |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

DESCRIPTION OF ADVERSE REACTION:

System involved

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| RESP | CVS | GIT | CNS | GUT | SKIN | OTHER |
|  |  |  |  |  |  |  |

|  |  |  |
| --- | --- | --- |
|  |  |  |

Date of Onset:

Description of the event: Lab investigations if any:

Outcome: tick "√"or circle "o"

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Recovered | Continuing | Hospitalized | Severity | | | | Date of Death | Birth defect:  Specify: |
| Mild | Moderate | Severe | Fatal |

Result on discontinuation of suspect drug: √ Result on reintroduction of drug Alternative diagnosis

|  |  |  |  |
| --- | --- | --- | --- |
| Improved | Disappeared | Persisted | Not Known |
|  |

Reappeared: Yes/ No/ Not known

Risk factors present: √

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Renal  Dysfunction | Cardiac  Dysfunction | Hepatic  Dysfunction | Previous Allergies | Smoking | Alcohol | Drug addict | Other (name) |
|  |
| REPORT ON MEDICAL DEVICE/COSMETIC/QUALITY PROBLEM | | | | | | | |
| Name (Brand & Generic): | | | Device | Cosmetic | Drug | Date of expiry: | |
| Manufacturer (Name & Address): | | | | | | Model/Serial/Batch/Other Number: | |
| Description of the problem: | | | | | | | |

REPORTING DOCTOR/ PHARMACIST/ NURSE/ DENTIST/OTHER

Name & Designation:………………………………………………………………………..\

Address: …………………………………………………………………………………

………………………………………………………………...

Telephone Number: ………...………………… Hospital & Ward No: …….....…………….

Signature: ………...………………………… Date of Reporting: …../…../……

Annexure 13

**Annexure 13**

**Ethics review Committee**

**GAMPAHA WICKRAMARACHCHI UNIVERSITY OF INDIGENOUS MEDICINE**

**YAKKALA, SRI LANKA**

**Format for progress report**

1. Title of the project:
2. ERC number:
3. Principle investigator:
4. Duration for which the report is submitted:
5. Date of commencement of the study:
6. Number of previous progress reports submitted for the same study:
7. Research work conducted (briefly explain the following)
   * 1. Objectives
     2. Methodology in brief
     3. Progress to date / outcome:
     4. Maintenance & security of records:
     5. Steps taken to maintain confidentiality:
     6. Informed consent procedure:
     7. Compliance with the approved protocols:
     8. Compliance with conditions of approval:
     9. Any deviations from the approved protocol:
     10. Reasons for deviations:
8. Work planned for next 6 months:

**Annexure 14**

Annexure 14

**ETHICS REVIEW COMMITTEE**

**GAMPAHA WICKRAMARACHCHI UNIVERSITY OF INDIGENOUS MEDICINE**

**YAKKALA, SRI LANKA**

**Format for Final report**

1. Title of the project:
2. ERC number:
3. Principle investigator:
4. Duration of the study:
5. Date of commencement:
6. Number of previous progress reports submitted for the same study:
7. Date of completion:
8. Any extensions done:
9. Reasons for extension:
10. Research work conducted (briefly explain the following)
    * 1. Objectives
      2. Methodology in brief
      3. Progress to date / outcome:
      4. Maintenance & security of records:
      5. Steps taken to maintain confidentiality:
      6. Informed consent procedure:
      7. Compliance with the approved protocols:
      8. Compliance with conditions of approval:
      9. Any deviations from the approved protocol:
      10. Reasons for deviations
11. Details of dissemination of results (Full paper publications, abstracts, etc):

**Annexure 15**

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: ……………………………**

**Annexure 16**

Annexure 16

APPLICATION FOR CONSULTATION ON CLINICAL ETHICS

**PART 1 - BASIC INFORMATION**

|  |  |
| --- | --- |
| Received date |  |

* 1. Title of Research Project: descriptive and short

|  |
| --- |
|  |
|  |

* 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. Brief description of the consultation needed.
  2. 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*) |  |

1.24

a. Where will the study take place?

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

No

Yes

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

c. 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.
     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.

**Please note that the application form should be accompanied with a covering letter and any additional documents which would be helpful for consultation (Eg – Draft of ERC application form, information sheet, consent form etc).**

**Annexure 17**

Annexure 17

**Ethics Review Committee**

**Gampaha Wickramarachchi University of Indigenous Medicine, Sri Lanka**

**Evaluation Form for Ethics Review Process**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| ERC No: | | Reviewer: First/Second/Third | | Date received: | | |
|  | | | **Yes** | **No** | **NA** | **Compatible with reviewers**  **comments** |
| **Background and social value (Refer background and justification sections of the protocol)** | | | | | | |
| 1 | Background and justification – sufficient? | |  |  |  |  |
| 2 | Literature review – adequate? | |  |  |  |  |
| 3 | Need for human participation justified? | |  |  |  |  |
| 4 | Has the protocol been approved by a competent body? | |  |  |  |  |
| 5 | Should the study be referred to a technical or statistical expert? | |  |  |  |  |
| **Scientific value (Refer methodology section of the protocol)** | | | | | | |
| 6 | Objectives – clear? | |  |  |  |  |
| 7 | Methodology – clear? | |  |  |  |  |
| 8 | Study design – appropriate? | |  |  |  |  |
| 9 | Sample size – adequate? | |  |  |  |  |
| 10 | Statistics used – appropriate? | |  |  |  |  |
| **Subject selection (Refer methodology section of the protocol)** | | | | | | |
| 11 | Inclusion criteria – appropriate? | |  |  |  |  |
| 12 | Exclusion criteria – appropriate? | |  |  |  |  |
| 13 | Voluntary, non-coercive recruitment of participants | |  |  |  |  |
| 14 | Inducement for participation | |  |  |  |  |
| 15 | Vulnerable populations involved?  If yes, is it justifiable? | |  |  |  |  |
| **Assessment of risk/benefits** | | | | | | |
| 16 | Researcher qualifications, competence and experience suitable for safe conduct of research? | |  |  |  |  |
| 17 | Risks: benefits assessment acceptable? | |  |  |  |  |
| 18 | Medical and psychological support for participants – adequate? | |  |  |  |  |
| 19 | Provision for treatment in study related injuries? | |  |  |  |  |
| 20 | Provision for compensation (where applicable)? | |  |  |  |  |
| **Informed consent** | | | | | | |
| 21 | Procedures for obtaining informed (written/verbal) consent – appropriate? | |  |  |  |  |
| 22 | Information sheet and consent form contain clear and adequate details? | |  |  |  |  |
| 23 | Translations of all sheets/forms consistent? | |  |  |  |  |
| 24 | Contact details of PI available for participants on the information sheet? | |  |  |  |  |
| 25 | Arrangements for proxy consent –appropriate? (where applicable) | |  |  |  |  |
| 26 | Incentives offered – approved? | |  |  |  |  |
| **Respect for participants and confidentiality** | | | | | | |
| 27 | Privacy and confidentiality of the participants – safeguarded? | |  |  |  |  |
| 28 | Participants’ right to dissent, unconditional withdrawal safeguarded? | |  |  |  |  |
| 29 | Data/ sample storage and disposal procedures appropriate? | |  |  |  |  |
| **Independent review** | | | | | | |
| 30 | Disclosure or declaration of potential conflicts of interest | |  |  |  |  |
| **Is all the documentation provided?** | | |  |  |  |  |
| **Final recommendation** | | | **Approve /Approve with corrections / Re-submit/ Reject** | | |  |

**Additional comments:**

**……………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………….**

**Name of the evaluator :**

**Sub-committee : Internal evaluation / External evaluation**

**Signature :**

**Date :**

**Annexure 18**

Annexure 18

**PAYING-IN-VOUCHER**

**Ethical Review Committee**

Gampaha Wickramarachchi University of Indigenous Medicine,

Yakkala

**PAYING-IN-VOUCHER**

1. Name of payee: ................................................................

2. Address : ................................................................

3. Tele. No. ................................................................

4. Amont: ................................................................

Amount (Rs).

.............................................. ...............................................

Date Signature

*For Office Use Only*

Shroff,

Please credit above mentioned sum of Rs. ................................ to the ledger account of the Ethical Review Committee.

Receipt no............................... ………………………………...

Officer in Charge

Date: .............................

**RECEIPT**

**RECEIPT**

**Ethical Review Committee**

Gampaha Wickramarachchi University of Indigenous Medicine, Yakkala

1. Reference No. EC/\_\_/\_\_\_

2. Project Title:

.............................................................................................................................................................................................................................................................................................................................................

3.Principle Investigator:….……………………………………………

………………………………………………...

4. Payment Receipt No.

Your research proposal will be discussed on. .....................................\*

*(\* This date could be changed without prior notice)*

……..……............................. ……………………………… Date: Authorized Signature

**Annexure 19**

Annexure 19

**Ethics Review Committee  
Gampaha Wickramarachchi University of Indigenous Medicine, Sri Lanka  
Translation Evaluation Form**

Please consider that you are the person being invited to participate in this research.

|  |  |  |  |
| --- | --- | --- | --- |
| Are explanations given on following information clear to you | | Yes | No |
| 1. | What kind of study is this |  |  |
| 2. | Why you have been invited |  |  |
| 3. | Why should you consider to participate in this research study |  |  |
| 4. | Data collection procedure involving you |  |  |
| 5. | Risks you are exposed |  |  |
| 6. | Benefits you will receive from the study |  |  |
| 7. | Confidentiality of the information you provide |  |  |
| 8. | Whom to contact if there are any concerns |  |  |
| 9. | Participant information leaflet |  |  |
| 10. | The advertisement (if available) |  |  |
| 11. | Are the questions in the study tool clear to you |  |  |

**Additional comments:  
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………………………………………………………………………………………………………………………………………………**

**Name of the reviewer :  
Signature :  
Date :**

**Flowchart 01 : Submission of new application and determination of fees**

Is ethical

Clearance

Needed

Is application

In appropriate

format ?

Assign to next meeting

based on closing dates

Collect fees

No

Yes

No

Yes

**Flowchart 02 : Determination of fees**

Is it

Sponsored?

Pharmaceutical

Industry sponsored

Is at least one

Investigator from

GWUIM staff/

Undergraduate?

Is it for a

degree?

Yes Yes

No No

Yes

No

Yes

No

**Flowchart 03 : Processing of applications of review**

Assign a unique

Identification No

Issue a receipt

Project added to the

database

Is exempted/

expedited

review

requested ?

Secretary decides exempted/

expedited review

appropriate

Yes

No

No

Yes

**Flowchart 04 : Exemptions and expedited review**

4a. Exemptions

Formal application for Exemption

From review

Initial screening by the secretary

Does it involve

Collection/use of

Community level

Data on sensitive

topics

Formal approval by the ERC after next

meeting

Reviewed by

Subcommittee

* Chairperson
* Secretary
* Two other members

Full review

By the

ERC

Does it involve

Collection/use

Of individual

Level data

Is all data

Used in public

domain?

Yes

No

Yes

Yes No

Not Exempted

-------

**Flowchart 05 : Expedited Review**

4b.Expedited review

Formal application for Expedited

review

Initial screening by the secretary

Are participants

considered a vulnerable

group ?

Is there a risk

to

participants?

Is research

considered a sensitive topic ?

Review by subcommittee

* Chairperson
* Secretary
* Two other members

Full review by the

ERC

Formal approved by the ERC

after next meeting

Yes

No

More than minimal

risk

No/ minimal risk

Yes

No

**Flowchart 06 : Preparation of agenda**

Secretary prepare the agenda to the next

meeting

Secretary circulate the agenda to all the ERC members

**Flowchart 07 : Conduct of meetings**

ERC meets monthly

Are

members

able to

participate ?

Attend via teleconference/video

link

Submit written submission to

secretary

IS a quorum

present ?

* 1/ 2of the members
* At least one

non affiliated

Chairperson may reschedule the

meeting within ten working days

**Exceptional circumstances**

chairperson shall decide to proceed

with the meeting

Meeting will be conducted until all

the agenda items are considered in

private ensuring confidentiality

No

Yes

No

Yes

**Flowchart 08 :** **Consideration and approval of applications submitted for ethnical review**

Allocated to 3

reviewers

I hard copy sent

to chairperson

Summery sent to all ERC members

Assessed according

to FERCSL & other national &

international guidelines

Reviewed by all ERC members

the meeting

Simple

majority

Decision made

Decision deferred

Next ERC

ERC members help to improve quality of application

Unanimous

decision

reached ?

Soft copy uploaded to view

by all ERC members

**Flowchart 09 : Preparation of minutes**

Secretary prepares minutes as soon as

practicable

Chairperson checks for accuracy

Circulated to all members of ERC as an

agenda item for the next meeting

All members given opportunity to seek amendments to minutes

Minutes formally ratified in next meeting

Confirmed and amended minutes

Annexure 01