# Application Form for Ethical Review
# Research Ethics Committee
# Uva Wellassa University

For Office Use Only:

Application Number: UWU/REC/20___/_____ Date Received: ___/___/20___

Name of the Applicant:
Rev/Prof./Dr./Mr./Ms._____

This application should be forwarded by the Principal Investigator who requests ethical approval for a research project. All the co-investigators should provide signed consent to submit the application to UWU-REC. Application guidelines are available at UWU website.

PART A – ADMINISTRATIVE DETAILS

1. Title of the Research Project: Enter title of the research project here

2. Details of the Investigators: (including supervisors)

| Title, Name, Designation and Affiliation | Role | Signature |
|---|---|---|
| | Principal Investigator | |
| | | |
| | | |
| | | |
| | | |

3. Contact Details of the Principal Investigator:

| | |
|---|---|
| 3.1 Postal Address | Enter the name of Principal Investigator |
| 3.2 Email Address | Enter the name of Principal Investigator |
| 3.3 Telephone | Enter the name of Principal Investigator |

4. Nature of the study:

Observational/non-interventional ☐ Clinical trial (investigator initiated) ☐
Research database/information system ☐ Sponsored clinical trial ☐
Other ☐

5. **Proposed starting (initial date of enrolment of participants) and ending (completion of data collection) dates** (retrospective approval will not be given to the projects already started)
   Start Date: End Date:

6. **Has the Research Proposal been forwarded through a relevant Committee/Board?**

   Yes : ☐ No: ☐
   If Yes, Board of Study:
   Details:

7. **Has ethics approval for this study been requested earlier from UWU-REC, or another Ethical Review Committee?** (if you have received ethics approval already, please attach a copy of the approval)
   Yes : ☐ No: ☐
   Details:

8. **Funding (if any)**
   Name and Address of the funding source:
   Amount:

9. **Do you believe the proposed project has conflicts of interest?**

   Yes : ☐ No: ☐
   If Yes, Details:

10. **List the ethical concerns in your study.**

| No. | Ethical Concerns |
|---|---|
| 1. | |
| 2. | |
| 3. | |
| 4. | |
| 5. | |

## PART B – PROTOCOL CHECK LIST

Under each category, indicate the level of acceptance of the protocol section of the research proposal: **1 – Inappropriate, 2 – Marginally Appropriate, 3 – Appropriate**

### (a) Scientific Validity

| No. | Component | Protocol page/s | Reviewer Evaluation | | | |
|---|---|---|---|---|---|---|
| | | | Acceptance | | | Comments |
| | | | 1 | 2 | 3 | |
| 1 | Title | | | | | |
| 2 | Research problem | | | | | |
| 3 | Research questions/hypothesis | | | | | |
| 4 | Objectives | | | | | |
| 5 | Study setting | | | | | |
| 6 | Study design | | | | | |
| 7 | Study population (giving inclusion exclusion criteria) | | | | | |
| 8 | Sample size | | | | | |
| 9 | Sampling method | | | | | |
| 10 | Measurements/variables | | | | | |
| 11 | Study instruments | | | | | |
| 12 | Procedures to ensure quality of data | | | | | |
| 13 | Plan for analysis | | | | | |
| 14 | Ethical considerations | | | | | |
| 15 | Budget (if relevant) | | | | | |
| 16 | Work plan and time frame | | | | | |
| 17 | Justification for a replication study, if your study is a replication. | | | | | |
| | | | | | | **Maximum 3 x 17 = 51** |

### (b) Social Value

| No. | Criteria | Protocol page/s | Reviewer Evaluation | | | |
|---|---|---|---|---|---|---|
| | | | Acceptance | | | Comments |
| | | | 1 | 2 | 3 | |
| 1 | Benefits of the study to the community/society | | | | | |
| 2 | Plan for dissemination of study findings | | | | | |
| 3 | Scientific importance of the study | | | | | |
| | | | | | | **Maximum 3 x 3 = 9** |

### (c) Risk/Benefit Assessment

| No. | Criteria | Protocol page/s | Reviewer Evaluation | | | |
|---|---|---|---|---|---|---|
| | | | Acceptance | | | Comments |
| | | | 1 | 2 | 3 | |
| 1 | Potential risks to the participants | | | | | |
| 2 | Potential benefits to the participants | | | | | |
| 3 | Justification for risks against benefits | | | | | |
| 4 | Steps taken to minimize risks | | | | | |
| 5 | Support provided to participants (medical, educational, other) | | | | | |
| | | | | | | **Maximum 3 x 5 = 15** |

(d) Participants Rights and Consent

| No. | Criteria | Protocol page/s | Reviewer Evaluation | | | |
|---|---|---|---|---|---|---|
| | | | Acceptance | | | Comments |
| | | | 1 | 2 | 3 | |
| 1 | Procedure for recruiting the participants | | | | | |
| 2 | Information provided to the participants | | | | | |
| 3 | Procedure for obtaining informed consent | | | | | |
| 4 | Procedure for obtaining proxy consent | | | | | |
| 5 | Procedure for obtaining assent | | | | | |
| 6 | Procedure for withdrawing consent | | | | | |
| 7 | Incentives provided to participants | | | | | |
| 8 | Procedure for participants to ask questions/register complaints | | | | | |
| 9 | Participants right to decline consent without losing entitled benefits | | | | | |
| | | | | | | Maximum 3 x 9 = 27 |

(e) Confidentiality and Privacy

| No. | Criteria | Protocol page/s | Reviewer Evaluation | | | |
|---|---|---|---|---|---|---|
| | | | Acceptance | | | Comments |
| | | | 1 | 2 | 3 | |
| 1 | Steps to ensure confidentiality of data | | | | | |
| 2 | Justification for collecting personal identification data | | | | | |
| 3 | Steps taken to ensure privacy during data collection | | | | | |
| 4 | How long data and samples will be kept | | | | | |
| 5 | Who will have access to the data | | | | | |
| 6 | Procedure for storage of data and samples | | | | | |
| 7 | Procedure for disposal of data | | | | | |
| | | | | | | Maximum 3 x 7 = 21 |

(f) Fair participant Selection and Vulnerability

| No. | Criteria | Protocol page/s | Reviewer Evaluation | | | |
|---|---|---|---|---|---|---|
| | | | Acceptance | | | Comments |
| | | | 1 | 2 | 3 | |
| 1 | Justification for selection of study population (Animals concerned: stray animals, animals from animal homes, animals under the threat of extinction, wild animals, animals having specific diseases etc.) | | | | | |
| 2 | Justification for conducting the study in a vulnerable population | | | | | |
| | | | | | | Maximum 3 x 2 = 6 |

Note: Following (g) and (h) are specifically applied for the Animal Based Research.

(g) Community Based Research

| No. | Criteria | Protocol page/s | Reviewer Evaluation | | | |
|---|---|---|---|---|---|---|
| | | | Acceptance | | | Comments |
| | | | 1 | 2 | 3 | |
| 1 | Is the impact and relevance of the research on the community animals in which it is to be carried out acceptable? | | | | | |
| 2 | Will the intervention or product developed or knowledge generated be made reasonably available and affordable for the benefit of the animals of the same species? | | | | | |
| 3 | Will there be any contribution of the research towards improvement of health/welfare of concerned community group of animals? | | | | | |
| 4 | Are the results of the research being made available to the relevant authorities to do necessary improvements of health/welfare of concerned community group of animals? | | | | | |
| | | | | | | Maximum 3 x 4 = 12 |

## (h) Animal Clinical Trials

| No. | Criteria | Protocol page/s | Reviewer Evaluation | | | |
|---|---|---|---|---|---|---|
| | | | Acceptance | | | Comments |
| | | | 1 | 2 | 3 | |
| 1 | If it is a multi-centre trial, are all centres following the same protocol? | | | | | |
| 2 | Is the clinical trial registered with a clinical trials registry? | | | | | |
| 3 | Have adequate animal toxicity and teratogenicity trials been carried out? | | | | | |
| 4 | Is their sufficient justification for using a control arm? | | | | | |
| 5 | Does the control group receive the standard therapy? | | | | | |
| 6 | Are all subject animals treated equally? | | | | | |
| 7 | Is the procedure for dealing with adverse events adequate? | | | | | |
| 8 | Is the procedure for reporting adverse events adequate? | | | | | |
| 9 | Are the criteria for termination of the trial detailed? | | | | | |
| 10 | Is there provision for insurance of the animals used in the trial? | | | | | |
| | | | | | | Maximum 3 x 10 = 30 |

General Aspects for All Researchers

(i) Responsibilities of the Researcher

| No. | Criteria | Protocol page/s | Reviewer Evaluation | | | |
|---|---|---|---|---|---|---|
| | | | Acceptance | | | Comments |
| | | | 1 | 2 | 3 | |
| 1 | Ethical, legal, financial issues related to the study | | | | | |
| 2 | Any conflicts of interest and how the researcher plans to manage them | | | | | |
| 3 | Permissions from relevant institutions/authorities | | | | | |
| 4 | Collaborations with the relevant stakeholder | | | | | |
| 5 | Provision of medical/psychological care to the participants | | | | | |
| 6 | Qualifications of the research team to handle the research study | | | | | |
| | | | | | | Maximum 3 x 6 = 18 |

(j) Foreign Funded Studies

| No. | Criteria | Protocol page/s | Reviewer Evaluation | | | |
|---|---|---|---|---|---|---|
| | | | Acceptance | | | Comments |
| | | | 1 | 2 | 3 | |
| 1 | Justification for conducting the study in Sri Lanka | | | | | |
| 2 | Relevance of the study to Sri Lanka | | | | | |
| 3 | Post research benefits to Sri Lanka | | | | | |
| 4 | The sharing of intellectual property rights | | | | | |
| 5 | How the results will be conveyed to authorities in Sri Lanka | | | | | |
| | | | | | | Maximum 3 x 5 = 15 |

(k) Information Sheet/Consent Form

| No. | Criteria | Section in Info. sheet consent form | Reviewer Evaluation | | | |
|---|---|---|---|---|---|---|
| | | | Acceptance | | | Comments |
| | | | 1 | 2 | 3 | |
| 1 | Purpose of the study | | | | | |
| 2 | Voluntary participation | | | | | |
| 3 | Duration of the study and responsibilities of the participants | | | | | |
| 4 | Potential benefits | | | | | |
| 5 | Risks, Hazards, Discomforts | | | | | |
| 6 | Incentives/Reimbursements | | | | | |
| 7 | Confidentiality | | | | | |
| 8 | Contact person for the participants | | | | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| 9 | Understanding of information provided by the researcher | | | | | |
| 10 | Agreement of the participant to provide information/samples | | | | | |
| 11 | Consent for dissemination of research findings | | | | | |
| 12 | Appropriate translation of the information sheet | | | | | |
| 13 | Appropriate translation of the consent form | | | | | |
| | | | | | | Maximum 3 x 13 = 39 |

Decision of the reviewer:

(i) Acceptable ☐ (135 – 201) (If Animal Based, 163 – 243)

(ii) Conditionally Acceptable ☐ (68 – 134) (If Animal Based, 82 – 162)

(iii) Not Acceptable ☐ (≤67) (If Animal Based, ≤81)

Comments of the Reviewer (specifically expected for (ii) and (iii) above):

| |
|---|
| |

Name of the Reviewer:

Signature of the Reviewer: _____ Date: