|  |  |  |
| --- | --- | --- |
|  | **Application Form for Ethical Review**  **Research Ethics Committee**  **Uva Wellassa University** | http://www.uwu.ac.lk/wp-content/uploads/logo_uwu.jpg |

**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 |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

1. **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 |

1. **Nature of the study:**

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

1. **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:

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

Yes :  No:

If Yes, Board of Study:

Details:

1. **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:

1. **Funding (if any)**

Name and Address of the funding source:

Amount:

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

Yes :  No:

If Yes, Details:

1. **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**

1. **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** | | | | | | |

1. **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**

1. **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** | | | | | | |

1. **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:**

1. Acceptable  (135 – 201) (If Animal Based, 163 – 243)
2. Conditionally Acceptable  (68 – 134) (If Animal Based, 82 – 162)
3. 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: