

**Ethics Review Committee**

**The Open University of Sri Lanka, Nugegoda, Sri Lanka**

| ***For office use only*** | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Application No.** |  |  |  |  |  | **Date received** |  |  |  |
| **Decision** |  | | | | | **ERC Meeting** |  |  |  |
| **Date Informed** |  |  |  |
| **Names of the Reviewers** | | | | | | | | | |
| Reviewer 1 |  | | | | | | | | |
| Reviewer 2 |  | | | | | | | | |
| Reviewer 3 |  | | | | | | | | |

**Notes to applicants**

The Open University of Sri Lanka (OUSL) requires all research activity involving human participants and animals to be subjected to ethical scrutiny and this form is designed to enable the Ethics Review Committee (ERC) of the OUSL to assess any research proposed by members of staff or students.

This application consists of mainly four (04) parts: **Part A**, **Part B**, **Part C** and **Part D**.

**Part A -** **All applicants** should complete **Part A**.

**Part B -** If your research study involves **human participants or their data**, you are required to complete **Part B**

**Part C -** If your research study involves **animals**, you should complete **Part C**

**Part D -** If your research study involves **Clinical trial/s**, you should complete **Part D**

**All applicants** should complete **Protocol Checklist**

**All applicants** should complete **Check List for ERC submissions**.

Only duly completed application forms will be reviewed.

**Part A**

To be completed by all applicants

1. **Title of the Research Project**

|  |
| --- |

**Investigators**

1.1 Principal investigator

| Title | Prof./Dr./Mr./Ms. | Name |  |
| --- | --- | --- | --- |
| Qualifications | |  | |
| Designation | |  | |
| Official Address | |  | |
| Telephone | |  | |
| E-mail address | |  | |
| Signature | |  | |

1.2 Co-Investigator 1

| Title | Prof./Dr./Mr./Ms. | Name |  |
| --- | --- | --- | --- |
| Qualifications | |  | |
| Designation | |  | |
| Official Address | |  | |
| Telephone | |  | |
| E-mail address | |  | |
| Signature | |  | |

Co-Investigator 2

| Title | Prof./Dr./Mr./Ms. | Name |  |
| --- | --- | --- | --- |
| Qualifications | |  | |
| Designation | |  | |
| Official Address | |  | |
| Telephone | |  | |
| E-mail address | |  | |
| Signature | |  | |

Co-Investigator 3

| Title | Prof./Dr./Mr./Ms. | Name |  |
| --- | --- | --- | --- |
| Qualifications | |  | |
| Designation | |  | |
| Official Address | |  | |
| Telephone | |  | |
| E-mail address | |  | |
| Signature | |  | |

**(If there are any more investigators, please add their details in an additional sheet)**

**Is this a supervised project? If yes, name of the supervisors and the student.**

|  |
| --- |

| 1.3 | Is the principal investigator affiliated to the OUSL? | Yes |  | No |  |
| --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |
| 1.4 | Are any of the investigators affiliated to the OUSL? | Yes |  | No |  |

If answer to 1.3 and 1.4 are NO, please justify submitting your proposal to the ERC of the OUSL.

|  |
| --- |

**2. Nature of the Research Project**

| 2.1 | Is this for an academic degree? | Yes |  | No |  |
| --- | --- | --- | --- | --- | --- |

2.1.1 If for an academic degree, specify:

|  |
| --- |

Please give the methodology you intend to use in the proposed research (Give details about settings of the research, sample, sampling, sample size, details of participants, Instruments)

|  |
| --- |

**3. Dates of Commencement and Completion**

*[From initial recruitment of participants until completion of all data collection]*

| 3.1 | Proposed date of commencement |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| 3.2 | Expected date of completion |  |  |  |

**4. Has ethical review for this study been requested earlier from ERC of OUSL?**

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

If Yes,

| Reference Number |  |
| --- | --- |
| Decision\* |  |
| Date |  |

\* Attach documentary evidence.

**5. Has ethical review for this study been requested from any other Ethics Review Committee?**

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

If Yes,

| Reference Number |  |
| --- | --- |
| Decision\* |  |
| Date |  |

\* Attach documentary evidence.

**6. Has this study been subjected to scientific review?**

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

If Yes,

| Name and Address of the Committee |  |
| --- | --- |
| Decision\* |  |
| Date of approval |  |

\* Attach documentary evidence.

If the answer is ‘No’, give reason(s).

|  |
| --- |

**7. Funding**

| 7.1 | Is this research funded? | Yes |  | No |  |
| --- | --- | --- | --- | --- | --- |

7.1.1 If Yes,

| Name and Address of funding agency/ies |  |
| --- | --- |
| Amount |  |
| Date of approval |  |

\* Attach documentary evidence.

| 7.1.2 | Have you had a prior relationship with the funding agency? | Yes (Specify) |  | No |  |
| --- | --- | --- | --- | --- | --- |

7.2 **Funding for payment of participants.**

| 7.2.1 | Do the study participants have to incur any expenses by being participants in the study? |
| --- | --- |

| Yes (Specify) |  | No |  |
| --- | --- | --- | --- |

7.2.2 If Yes, will the expenses incurred by participants be remunerated?

| Yes (Specify) |  | No |  |
| --- | --- | --- | --- |

7.2.3 If Yes, Give details

|  |
| --- |

1. **Collaboration**

| 8.1 | Will you collaborate with other Institutions in this research? | Yes |  | No |  |
| --- | --- | --- | --- | --- | --- |

8.1.1 If Yes, nature of collaboration.

|  | **Institutions (Local or Foreign)** | **Recruitment** | **Service Provided** | | | |
| --- | --- | --- | --- | --- | --- | --- |
| **Lab Facility** | **Logistics** | **Intellectual** | **Any Other** |
| 1 |  |  |  |  |  |  |
| 2 |  |  |  |  |  |  |
| 3 |  |  |  |  |  |  |

* Attach documentary evidence

| 8.2 | Are there any collaborators from outside Sri Lanka? | Yes |  | No |  |
| --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |

8.2.1 If Yes, has this study been submitted to an ERC/similar body in the country/countries of foreign collaborator/s?

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

If Yes, give details.

(a)

| Name and Address of ERC |  |
| --- | --- |
| Decision \* |  |
| Date |  |

(b)

| Name and Address of ERC |  |
| --- | --- |
| Decision \* |  |
| Date |  |

(c)

| Name and Address of ERC |  |
| --- | --- |
| Decision \* |  |
| Date |  |

\* Attach documentary evidence

If the answer is No, give reason(s)

|  |
| --- |

8.3Why is the research carried out in Sri Lanka and not in the sponsoring country?

|  |
| --- |

| 8.4 | Is this study relevant to Sri Lanka? | Yes |  | No |  |
| --- | --- | --- | --- | --- | --- |

Explain.

|  |
| --- |

| **9.** | **Does this research involve any intervention?** | **Yes** |  | **No** |  |
| --- | --- | --- | --- | --- | --- |

If Yes, give details.

|  |
| --- |

**PART B**

To be completed by those who carry out research study involving **human participants or their data.**

1. Give details about the proposed participants.

|  |
| --- |

1. Do you already have any relationship with participants (e.g.: Student, Patient)?

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

If yes, Please explain.

|  |
| --- |

3. How will you select the participants?

|  |
| --- |

4. Do the participants include vulnerable groups (e.g.: children, refugees, disabled, victims of sexual violence, indigenous people, prisoners and people with special needs and/or their relatives, guardians or care givers?

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

If yes, give details.

|  |
| --- |

1. Have you obtained the permission to question the participants/to get their personal records from the relevant institutions?

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

If yes, give details

|  |
| --- |

1. Describe any circumstances during the study that might give rise to safety concerns for participants and/ or researcher(s).

|  |
| --- |

1. What measures will you take to safeguard any participants who may reveal sensitive or confidential information?

|  |
| --- |

1. Will the study involve the discussion of sensitive topics? (e.g.: Sexual activity, drug use, illegal activities, suicide attempted, whistle blowing )

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

If yes, give details.

|  |
| --- |

1. Could any aspect of the research result in any form of harm to participants, and/or researcher(s)?

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

If yes, explain how you would avoid such harm.

|  |
| --- |

1. Please indicate how informed consent of all participants will be obtained (Draft consent forms must be attached).

|  |
| --- |

1. Please indicate how the participants’ Right to Privacy including confidentiality, anonymity and the privacy of their data will be protected and specify any potential limitations to do this.

|  |
| --- |

1. Please indicate how the data will be stored and how it will be destroyed.

|  |
| --- |

**Part C**

**To be completed by those who carry out research studies involving animals. Sections 1, 2, 3 are compulsory for all.**

**Section 1**

1. What is your research about?

| Genetics |  | Behavior |  | Other |  | Specify ……….……. |
| --- | --- | --- | --- | --- | --- | --- |

1.1If the study is on behavior of animals, do the investigators have knowledge and competence to conduct this study and to differentiate between normal and abnormal behavior of animals?

| Yes |  | No |  | Not Applicable |  |
| --- | --- | --- | --- | --- | --- |

If yes, evidence of knowledge and competence. Attach relevant certificates/ documentary evidence in support of previous competence and articles.

If No, please indicate how investigators are going to acquire knowledge and skills (e.g. participation in training programmes).

|  |
| --- |

1.1.1How will data/samples be obtained?

|  |
| --- |

1.1.2How long will data/samples be kept?

|  |
| --- |

1.1.3What is the number of samples that you propose to collect?

|  |
| --- |

1.1.4Are you collecting the minimum information/samples required to fulfill the study objectives?

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

1.2 Is the use of animals **absolutely** necessary to obtain the required information?

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

1.3Why cannot the research be carried out with non- animal alternatives? Give justification.

|  |
| --- |

1.4What is the ancillary care (treatment that is not part of the protocol) provided, if relevant?

|  |
| --- |

1.5What are the provisions for continuity of care, if relevant?

|  |
| --- |

**Section 2 (applicable only if the research is externally sponsored)**

2.1.If the research is sponsored by a foreign country, research project been approved by an ERC in the sponsoring country in which the agency is located?

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

If Yes, please attach documentary evidence. If No, give reasons.

|  |
| --- |

2.2What are the post research benefits to Sri Lanka, if any and follow up action(s)?

|  |
| --- |

2.3What are the implications of research? (optional for students)

|  |
| --- |

2.4Are you adhering to any specific laws/ regulations /guidelines of Sri Lanka and the sponsoring country/countries applicable to the study?

| Yes |  | No |  | Not Applicable |  |
| --- | --- | --- | --- | --- | --- |

If Yes, give details

|  |
| --- |

If No, Explain.

|  |
| --- |

2.5Have you taken into consideration cultural and social customs, practices, and taboos in Sri Lanka when designing your study?

| Yes |  | No |  | Not Applicable |  |
| --- | --- | --- | --- | --- | --- |

If Yes/No Explain

|  |
| --- |

2.6Are the animals used in the study receiving the best current treatment as part of the protocol?

| Yes |  | No |  | Not Applicable |  |
| --- | --- | --- | --- | --- | --- |

If No, explain why.

|  |
| --- |

2.7How will the rights to intellectual property be shared?

|  |
| --- |

2.8Will any of the data or biological samples be transferred overseas?

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

If Yes, describe the fate of the data or biological samples of the study.

|  |
| --- |

2.9How will the results of research be conveyed to relevant authorities in Sri Lanka? Section A

|  |
| --- |

**Section 3**

**3. Responsibilities of the researcher**

3.1What are the responsibilities of the researcher for provision of Veterinary services to animals used in the study? (not applicable to wild animals)

|  |
| --- |

3.2What are the provisions for continuation of care after the research is completed?

|  |
| --- |

3.3Have you followed the applicable legal regulations or other guidelines, if any?

| Yes |  | No |  | Not Applicable |  |
| --- | --- | --- | --- | --- | --- |

If YES, provide details

|  |
| --- |

If NO, Explain

|  |
| --- |

3.4Please declare any conflict of interest including payments and/or other benefits, financial or non- financial received by you or co-researchers and other rewards (Please list them and state how you would prevent them from influencing the conduct of the study).

|  |
| --- |

3.5Do you see any other ethical/legal/social/financial issues related to your study? (Please list them and state how you would prevent them from influencing the conduct of the study).

|  |
| --- |

| Issues that may arise | Strategies to prevent/mitigate the issue |
| --- | --- |
|  |  |
|  |  |
|  |  |
|  |  |

**If the work involves laboratory / veterinary/ domestic animals, go to Section 4 and/ or 5: if work involves wild animals, go to Section 6.If the work *involves vulnerable* groups (Stray animals, animals from animal homes/shelter, animals under the threat of extinction, animals having specific diseases etc.) go to Section 7.**

**Section 4: To be filled by those who carry out research study involving Laboratory/veterinary/domestic animals.**

4.1What is the species of animals used and the reasons for selecting the said animal species?

Common name: ……………………….. Scientific name: …………………………………….

Reason: ………………………….......……………………………………………………………………..

……………………………………………………….……………………………………………………….

4.2What is the source of animals and the arrangements that you have made to ensure a constant supply of animals?

Source:

| MRI |  | Breeding Centre |  | Laboratory |  | Wild |  | Other |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |

4.3 Is it necessary to transport animals from the source to the site where the research is carried out?

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

If yes, what are the arrangements that you have made to transport animals with optimum care?

|  |
| --- |

Will all the animals be supplied by the same supplier?

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

4.4 What is the total number of animals to be used in the study and how did you calculate the sample size?

|  |
| --- |

4.5If the study is conducted in an animal house/facility (if relevant), are the facilities available there adequate to conduct this study, give evidence.

|  |
| --- |

4.6Are the facilities adequate to provide optimum care to animals?

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

Give details.

|  |
| --- |

4.7 How long will the animals be housed?

|  |
| --- |

4.8What are the housing conditions available at the site?

| Single/group housing |  |
| --- | --- |
| Temperature |  |
| Humidity |  |
| Type & size of cages |  |
| No. of animals per cage |  |
| Bedding materials |  |
| Light-dark regime |  |
| Ventilation |  |

4.9Are the facilities adequate to provide good post-experimental care and rehabilitation or euthanasia of animals as appropriate upon completion/ cessation of research?

| Yes |  | No |  | Not Applicable |  |
| --- | --- | --- | --- | --- | --- |

4.10What is the type and source of food given to animals?

|  |
| --- |

4.11What are the arrangements made for feeding and providing water?

|  |
| --- |

4.12 Who is responsible for maintaining the welfare diary of the animals during the study?

|  |
| --- |

**Procedures and drugs used**

4.13Are there any invasive and stressful procedures used during the study?

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

If Yes, give details.

|  |
| --- |

4.14 If you observe an animal suffering severely, will you take necessary steps to euthanize the animal to prevent further suffering?

| Yes |  | No |  | Not Applicable |  |
| --- | --- | --- | --- | --- | --- |

**Experimental end points**

4.15What is the method/mode of disposal of used animals after research?

|  |
| --- |

4.16Are you euthanizing the animals at the end of the study?

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

4.17What is the method used to euthanize the animals? If a drug is used give details.

|  |
| --- |

4.18Who will be responsible for euthanizing the animal?

4.19 How do you plan to prevent/minimize the negative impacts on the animals in the study?

|  |
| --- |

**Assessment of Risks/Benefits**

4.20Will there be any risk (Physical, psychological) to animals during the study?

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

If yes, identify them and state how you would plan to prevent or minimize these risks?

|  |
| --- |

4.21Will there be any risk to the research team by conducting this study?

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

If yes, identify them and state how you would minimize these risks.

|  |
| --- |

4.22Will the standard therapy used for therapeutic studies on sick animals be withheld from the animals used for the study?

| Yes |  | No |  | Not Applicable |  |
| --- | --- | --- | --- | --- | --- |

If yes, justify.

|  |
| --- |

4.23Will Veterinary support for the animals be adequate?

| Yes |  | No |  | Not Applicable |  |
| --- | --- | --- | --- | --- | --- |

Explain.

|  |
| --- |

4.24What is the procedure for dealing with unexpected adverse events?

|  |
| --- |

4.25Is there any procedure for reporting unexpected adverse events?

| Yes |  | No |  | Not Applicable |  |
| --- | --- | --- | --- | --- | --- |

If Yes, give details.

|  |
| --- |

If No Explain.

|  |
| --- |

**Humane care of the animals**

4.26Explain how do you ensure that the animals are handled with care and compassion.

|  |
| --- |

4.27Explain how you ensure that you take adequate measures to reduce suffering of animals during the research? Explain.

|  |
| --- |

***Sections 5 is applicable only to projects that involve veterinary animals***

**Informed consent**

5.1Write briefly your procedure for obtaining informed consent for the use of animals in the research.

|  |
| --- |

5.2Who will obtain consent?

|  |
| --- |

Attach consent forms

5.3 How will you ensure that the owner is adequately informed? Please include information sheets with translations.

|  |
| --- |

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5.4How will you ensure that owner would not feel obliged to give consent in order to receive better veterinary care for their animals?

|  |
| --- |

5.5Are you offering any financial or other incentives/rewards/ compensation to the owners for giving consent for the use of their animals?

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

If yes please list them and state how they would not constitute undue inducement for granting consent?

(All incentives to be provided to owners must be approved by the ERC).

|  |
| --- |

5.6Will you obtain fresh informed consent if the procedures are changed during the research?

| Yes |  | No |  | Not Applicable |  |
| --- | --- | --- | --- | --- | --- |

**Confidentiality**

5.7 Who will have access to the personal data of the owners and animals?

|  |
| --- |

5.8 How will you safe guard the privacy of the owner (if relevant)?

|  |
| --- |

5.9Explain the procedure to collect, store and dispose data/sample in relation to ensuring confidentiality and security of information.

|  |
| --- |

5.10Explain how you will obtain appropriate consent to store data/samples for future study, if necessary.

|  |
| --- |

**Rights of the owners of animals**

5.11How will you ensure the owners unconditional right to withdraw their animals from the research at any time?

|  |
| --- |

5.12Who will be the contact person for the owners?

|  |
| --- |

5.13 Will the results of the clinical research be informed / made available to the owner if they wish?

| Yes |  | No |  | Not Applicable |  |
| --- | --- | --- | --- | --- | --- |

If Yes/No Explain.

|  |
| --- |

**Fair selection of animals**

5.14What is your study population?

|  |
| --- |

5.15Justify your selection of study population.

|  |
| --- |

5.16Is the selection of animals (inclusion and exclusion criteria) appropriate so that risks are minimized and benefits are maximized and the burden of research equitably distributed?

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

If Yes/No Explain.

|  |
| --- |

***Sections 6 is applicable only to projects that require observation, capture and handling of animals in the field/wild***

6.1 Location of the study site

|  |
| --- |

6.2 Does this research involve any protected animal(s) or does the area fall within any Protected Area?

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

If yes, specify.

|  |
| --- |

6.3 What is the current conservation status of the species (e.g. nationally threatened, rare, endemic)

|  |
| --- |

6.4What are the laws applicable to your study?



6.5Have you obtained clearance from relevant authorities (e.g., Wild Life and Forestry) to use the said animal species for your research?

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

If yes, please attach the relevant document.

If No, when and from where will you obtain permission?



**Details of the animal subjects**

6.6 What is the species being studied?

Scientific name: ………………………………… Common name: ………………………………….

**Observation, capture and handling**

6.7 Will you be required to capture and handle the animal?

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

If yes, indicate the purpose of capturing and handling:

To collect morphometric data

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

To collect samples- blood/ hair/ flesh/ any other part ……………….. (specify)

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

To collect parasites

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

| Other (specify) |  |  |
| --- | --- | --- |

6.8 Briefly outline the capture method.

|  |
| --- |

6.9 Will the observation/capturing/handling procedure/s be the standard method/s that is/are used for the study of these animals? Give evidence.

|  |
| --- |

State any previous experience in using the method/s.

|  |
| --- |

Will the captured animals be removed from the environment in which it was captured?

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

6.10 If animals are to be removed, how will they be transported?

|  |
| --- |

6.11 Where will the animals be housed during the project period and for how long?

|  |
| --- |

6.12 Will the animals be released at the sites of capture after the study?

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

If No, explain.

|  |
| --- |

6.13 If animals are injured due to capture or handling, explain the measures you would adopt to treat the animals.

|  |
| --- |

6.14 What measures have you taken to minimize disturbance to the animals in the field?

|  |
| --- |

**Tranquilization**

6.15 Will tranquilization of the animals be necessary?

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

If yes, describe the method used for tranquilization.

|  |
| --- |

6.16 Is the tranquilization procedure a standard method used for the study of these animals?

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

If yes, give evidence.

|  |
| --- |

If No, explain.

|  |
| --- |

***Sections 7 applicable only to projects that involve* vulnerable groups (Stray animals, animals from animal homes/shelter, animals under the threat of extinction, animals having specific diseases etc.)**

7.1What is the justification for using a vulnerable group instead of the general animal population of the same species?

|  |
| --- |

7.2What is the procedure for obtaining consent of the owners/ authorities of the vulnerable group of animals?

|  |
| --- |

7.3What is the procedure for withdrawal from research due to the refusal of owners of the vulnerable group of animals?

|  |
| --- |

7.4Are you providing adequate Veterinary support? Explain.

|  |
| --- |

* 1. Will the benefits of research be made reasonably available to the relevant authorities/ owners of this group of animal population?

|  |
| --- |

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

If Yes, explain.

|  |
| --- |

**Section 8 applicable only if clinical trials are conducted on animals**

8.1What phase of a clinical trial is being conducted?

|  |
| --- |

8.2Is it a multi centre trial?

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

If Yes, give details.

|  |
| --- |

8.3Is the clinical trial registered with a clinical trial registry?

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

If Yes, name it

|  |
| --- |

8.4Have adequate animal toxicity and teratogenicity trials been carried out?

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

8.5If a control group is used what is the justification?

|  |
| --- |

8.7What is the procedure for dealing with adverse events?

|  |
| --- |

8.8What is the procedure for reporting adverse events?

|  |
| --- |

8.9 Will the sponsoring agency provide the test drug/device to the animals until it is marketed in the country?

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

8.10What are the criteria for termination of the trial?

|  |
| --- |

8.11Is there provision for insurance of the animals used in the trial?

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

Explain

|  |
| --- |

**Part D**

To be completed by those who carry out research studies involving **Clinical trials on human participants**.

| Does this research involve any intervention study? | Yes |  | No |  |
| --- | --- | --- | --- | --- |

If yes, give details.

|  |
| --- |

1. What phase (refer to WHO Guidelines) of intervention study (clinical trial included) will be conducted?

| Phase I |  |
| --- | --- |
|  |  |
| Phase II |  |
|  |  |
| Phase III |  |
|  |  |
| Phase IV |  |
|  |  |
| Others (Specify) |  |

2. If the research involves a clinical trial, is it registered with a Clinical Trial Registry (CTR)?

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

2.1 If Yes, give the name of the CTR registered.

| Name of the CR |  |
| --- | --- |

**Submit documentary evidence of approval from the clinical trial registry when you receive registration.**

| 3. | Is it a multicenter trial? | Yes |  | No |  |
| --- | --- | --- | --- | --- | --- |

If Yes, give details of other centers.

| Country | Center |
| --- | --- |
|  |  |
|  |  |
|  |  |

| 4. | Has ethical approval been obtained from relevant bodies? | Yes |  | No |  |
| --- | --- | --- | --- | --- | --- |

If Yes, attach documentary evidence.

If No, Explain.

|  |
| --- |

| 5. | Will there be any possible adverse effects? | Yes |  | No |  |
| --- | --- | --- | --- | --- | --- |

If Yes.

1. Give details of the possible adverse effects.

|  |
| --- |

1. What is the procedure for reporting adverse events/effects and dealing with it including compensation?

|  |
| --- |

\* Attach documentary evidence

5.1. What is/are the criterion/criteria for aborting the trial, if required?

|  |
| --- |

1. If the study involves transfer of biological samples abroad,
2. Attach the material transfer agreement.
3. Describe the fate of the biological sample at the conclusion of the study.

|  |
| --- |

| 7. | Are the investigators remunerated? | Yes |  | No |  |
| --- | --- | --- | --- | --- | --- |

If Yes, give details. (Name of the investigator, Amount, and by whom)

|  |
| --- |

8. Details of insurance coverage for participants, if applicable.

|  |
| --- |

9. If recruitment of participants is not taking place in the foreign collaborating institution, if any, explain why.

|  |
| --- |

10. Potential conflict of interest, if any.

|  |
| --- |

**Protocol Checklist**

**Title of the Research Project**

|  |
| --- |

| **No** | **Item** | **Page** |
| --- | --- | --- |
| 1 | Summary of the proposed research project |  |
| 2 | Introduction |  |
| 3 | Background |  |
| 4 | Justification/Rationale |  |
| 5 | Objectives of the study |  |
| **6** | Review of literature |  |
|  | **Methodology** |  |
| 7 | Study design |  |
| 8 | Place of study / Study setting |  |
| 9 | Duration of the study |  |
| 10 | Inclusion criteria |  |
| 11 | Exclusion criteria |  |
| 12 | Study population |  |
| 13 | Sample size and calculation of sample size |  |
| 14 | Sampling/ recruitment procedure |  |
| 15 | Research instrument/s |  |
| 16 | Pilot study |  |
| 17 | Data collection |  |
| 18 | Data analysis |  |
| 19 | Dissemination of results |  |
|  | **Ethical Issues** |  |
| 20 | Assessment of risks/ benefits |  |
| 21 | Procedure for obtaining consent |  |
| 22 | Informed consent form |  |
| 23 | Participants Information sheet |  |
| 24 | Justification for including vulnerable population |  |
| 25 | Fair participant selection |  |
| 26 | Procedures to protect the rights of participants |  |
| 27 | Confidentiality/Privacy |  |
| 28 | Voluntary participation right to refuse or withdraw without penalty |  |
| 29 | Safety monitoring |  |
| 30 | Responsibilities of the investigators |  |
| 31 | Provision of medical and psychological support to participants |  |
| 32 | Maintenance and fate of data |  |
|  | **Biological Samples** |  |
| 33 | Justification for using biological sample/s |  |
| 34 | Procedures for collection, storage and disposal of biological sample/s |  |
| 35 | Consent for collecting biological sample/s |  |
| 36 | Protection of the rights of collaborators |  |
| 37 | Justification for transfer of data and /or biological/ genetic materials to the country of foreign collaborator |  |
| 38 | Fate of transferred data and biological/ genetic material |  |

|  | **Clinical trial** |  |
| --- | --- | --- |
| 39 | Criteria for termination of participants from the trial |  |
| 40 | Criteria for termination of the trial |  |
|  |  |  |
| 41 | Adverse event monitoring, management and reporting |  |
| 42 | Justification for withholding/ withdrawing standard therapy |  |
| 43 | Provision for making the trial drug available after completion of the trial |  |
| 44 | **Budget** |  |
|  |  |  |

Indicate as **NA** any item that is inapplicable to your study.

I have read the completed form and I agree with the content.

I understand that the application for ethics clearance will not be accepted unless all necessary documents are submitted.

I undertake to ensure you that this research project will be conducted in accordance with relevant national and international guidelines that govern research involving human/ animal participants.

I declare that I am not seeking approval for a study that has already commenced or has already been completed.

If there is any deviation from the study as originally approved, I will submit an amendment to the ERC OUSL for approval prior to its implementation.

I will submit progress reports/reports of adverse events and side effects as requested by the ERC OUSL.

I undertake to submit to the ERC OUSL the final reports at the completion of the study.

|  |  |  |
| --- | --- | --- |
| Signature & full name of the Principal Investigator |  | Date: |

**Consent from the Co- Investigator(s)**

| Name | Signature |
| --- | --- |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |

**Check List for ERC submissions**

| **For Office Use Only** | | | |
| --- | --- | --- | --- |
| **Ref. No.** | **New Proposal** |  |  |
| **Re-submission** | **Major Modification** |  |
| **Minor Modification** |  |

**Please make sure to complete this checklist and submit all the hard copies along with your application.**

| 1 | Application form | | | Yes |  |
| --- | --- | --- | --- | --- | --- |
| 2 | Single paged summary/abstract –  (If the summary/abstract is not in the correct format, the application will not be accepted) | | | Yes |  |
| 3 | Please make sure you include the following: | | | | |
| Research Proposal | | | Yes |  |
| Participant Information Sheet | English | | Yes | NA |
| Sinhala | | Yes | NA |
| Tamil | | Yes | NA |
| Consent Form | English | | Yes | NA |
| Sinhala | | Yes | NA |
| Tamil | | Yes | NA |
| Research instrument, if any. | English | | Yes | NA |
| Sinhala | | Yes | NA |
| Tamil | | Yes | NA |
| 4 | Soft Copy (CD) or email to ….. | (attach print out of email) | | Yes | NA |
| 5 | Title in the application and protocol should be the same | | | Yes | NA |
| 6 | Payment receipt | Amount: | Rs. | Yes | NA |
| 7 | Proposals for Postgraduate Degrees only: | | | | |
| Proof of registration | | | Yes | NA |
| Supervisor’s letter | | | Yes | NA |

Name of the person who submitted the proposal : ……………………………………………………………..….

Designation : …………………………………………………………………

Institution/Department : …………………………………………………………………

Signature : ……………………….……………………………………….

Date submitted : …………………………………………………………………

Name and Signature of the Recipient : …………………………………………………………………

Date received : ………………………………………………………………….