**Ethical Clearance Form for Undergraduate Research Projects**

**Faculty of Allied Health Sciences**

**University of Peradeniya**

**Section 01- Basic Information**

* 1. **Research Project Title:**
	2. **Name of the Student:**
	3. **Registration Number:**
	4. **Contact Number:**
	5. **Email:**
	6. **Nature of Project:** Group Individual
	7. **Investigators:**
		1. **Principle Investigator/Supervisor:**

Title: Mr. Ms. Dr. Prof.

Name:

Qualifications:

Designation:

Place of Work:

Address:

Contact NOs:

Email Address:

Signature:

* + 1. **Co-Supervisor 1:**

Title: Mr. Ms. Dr. Prof.

Name:

Qualifications:

Designation:

Place of Work:

Address:

Contact NOs:

Email Address:

Signature:

**Section 02- Nature of Research (Please indicate with a “🗸” appropriately)**

* 1. **Title of the project:**
	2. **Proposed starting and ending dates:**

Start Date: End Date:

*\* From initial recruitment of animals until completion of data collection.*

*‡ Retrospective approval will not be given for projects already started or completed.*

* 1. **Has ethics review for this study been requested earlier from this committee or another similar committee?**

Yes No

\* Where?

\* When?

\* Result:

|  |  |  |  |
| --- | --- | --- | --- |
| **2.4 Nature** | **Yes** | **No** | **Specification** |
| Questionnaire only |  |  |  |
| Questionnaire + Sampling |  |  |  |
| Observational Only |  |  |  |
| Interventional Study |  |  |  |
| Involving Animal Subjects (If “Yes”, specify) |  |  |  |
| Involving Human Subjects (If “Yes”, specify the age group) |  |  |  |
| Others (Please specify) |  |  |  |

**2.5 Will Consent be sought? Yes No Not Required**

(If “Yes”, attach a copy of the consent form)

**2.6 Nature of the consent: Oral Written**

**Section 03- Methodology**

**3.1 What is your research question? (Give a brief description of the Hypothesis / Objectives in < 100 words)**

**3.2 Scientific background study :**

**3.2.1. Has similar type of studies been done before? Yes No**

**3.2.2 If “Yes”, give the results of the previous study briefly.**

**3.2.3 If “Yes”, please give reasons why you wish to repeat it.**

**3.2.4 Brief literature review of your study. (< 250 words)**

**3.3 Sample Size (justify whenever necessary):**

**3.4 Brief research design of the study (Describe the method in *lay person’s terms* including the measurements to be made and all data to be collected in < 500 words)**

**3.5 What investigations and/or interventions will the subjects have?**

* **Absolutely necessary to use animal/Human subjects Yes No**
* **Minimum required number of Animal/Human subjects are used Yes No**
* **Animals are housed/looked after properly Yes No**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Investigation/Intervention** | **Routine Procedure** | **Additional Procedure** | **Will cause additional discomfort / distress / inconvenience to subjects** | **Please specify when required** |
|  | **Yes** | **No** | **Yes** | **No** | **Yes** | **No** |  |
| **Local/General anesthesia**  |  |  |  |  |  |  |  |
| **Venepuncture** |  |  |  |  |  |  |  |
| **Arterial puncture** |  |  |  |  |  |  |  |
| **Biopsy** |  |  |  |  |  |  |  |
| **Other tissue/Body Sample** |  |  |  |  |  |  |  |
| **Ionizing Radioactive Substances/X-rays \*\*** |  |  |  |  |  |  |  |
| **Non-radioactive imaging investigations** |  |  |  |  |  |  |  |
| **Other medicinal products \*\*** |  |  |  |  |  |  |  |
| **Medical Devices/Equipment / Procedures \*\*** |  |  |  |  |  |  |  |
| **Other instrument / Procedures \*\*** |  |  |  |  |  |  |  |
| **Hospitalization of Animal/Human Subjects** |  |  |  |  |  |  |  |
| **Longer inpatient stays** |  |  |  |  |  |  |  |
| **Additional outpatient attendance** |  |  |  |  |  |  |  |
| **Other investigations / Procedures not part of routine care** |  |  |  |  |  |  |  |

**\*\* If additional procedures are done, please give details of the product / procedure / device / equipment and the quality and safety of the procedure / product with the estimated effective dosage / recommended usage.**

**Section 04- Safety of Subjects and Investigator/s**

**4.1 Briefly explain the precautions taken for the safety of the Animal/Human Subjects and Investigator/s.**

**4.2 What are the Ethical concerns of your study?**

 **(a)**

 **(b)**

 **(c)**

 **(d)**

 **(e)**

**4.3 How do you address the above ethical issues in your study?**

 **(a)**

 **(b)**

 **(c)**

 **(d)**

 **(e)**

**\*\* Please note that Clinical Trials need Trial Registration in an acceptable database before commencing the project.**

**Section 05- Comments and Observations of the Supervisor**

1.
2.
3.
4.

**Section 06- Comments and Observations of the Reviewer**

1.
2.
3.

**Name of Reviewer :…………………………………………………………………………………………………….**

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

**Date : ………………………………………………………………………………………………….**

***For official Use***

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Application No: |  |  |  |  |  |  |  |  | Date Received: |  |  | **⁄** |  |  | **⁄** |  |  |
| Reviewed By: |  |  |  |  |  |  |  |  | Meeting Date: |  |  | **⁄** |  |  | **⁄** |  |  |
| Decision: |  |  |  |  |  |  |  |  | Date Informed: |  |  | **⁄** |  |  | **⁄** |  |  |