** Ethical Clearance Form for Research Projects**

**Faculty of Allied Health Sciences, University of Peradeniya**

***For official Use***

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

**Section 01- Basic Information**

* 1. **Title of the Project:**
	2. **Investigators:**
		1. **Principle Investigator/Supervisor:**

Title: Mr. Ms. Dr. Prof.

Name:

Qualifications:

Designation:

Place of Work:

Address:

Contact NOs:

Email Address:

Signature:

* + 1. **Investigator 1:**

Title: Mr. Ms. Dr. Prof.

Name:

Qualifications:

Designation:

Place of Work:

Address:

Contact NOs:

Email Address:

Signature:

* + 1. **Investigator 2:**

Title: Mr. Ms. Dr. Prof.

Name:

Qualifications:

Designation:

Place of Work:

Address:

Contact NOs:

Email Address:

Signature:

* + 1. **Investigator 3:**

Title: Mr. Ms. Dr. Prof.

Name:

Qualifications:

Designation:

Place of Work:

Address:

Contact NOs:

Email Address:

Signature:

* + 1. **Investigator 4:**

Title: Mr. Ms. Dr. Prof.

Name:

Qualifications:

Designation:

Place of Work:

Address:

Contact NOs:

Email Address:

Signature:

**1.3 Where will the study take place?**

(If the study will take place in more than one centre please indicate which other research ethics committees have been approached and what is the outcome to date).

**(Start section 02 on a new page)**

**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. (<500 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 < 1000 words)**



**3.5 Is all or part of your application a pilot study?**

 **Yes [ ]** **No [ ]**

A pilot study is an **initial** investigation to give information that will be necessary when designing a future trial or study

**3.6 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** | **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  |  |  |  |  |  |  | *If “yes” please complete APPENDIX -A* |
| Non-radioactive imaging investigations |  |  |  |  |  |  |  |
| Other medicinal products  |  |  |  |  |  |  | *If “yes” please complete APPENDIX -B* |
| Medical Devices/Equipment / Procedures  |  |  |  |  |  |  | *If “yes” please complete APPENDIX -C* |
| Other instrument / Procedures  |  |  |  |  |  |  | *If “yes” please complete APPENDIX -D* |
| Hospitalization of Animal/Human Subjects |  |  |  |  |  |  |  |
| Longer inpatient stays |  |  |  |  |  |  |  |
| Additional outpatient attendance |  |  |  |  |  |  |  |
| Genetic modifications  |  |  |  |  |  |  | *If “yes” please complete APPENDIX -E* |
| Other investigations / Procedures not part of routine care |  |  |  |  |  |  |  |

**\*\*** If “yes” please give details of the estimated degree and frequency of discomfort/distress/ inconvenience entailed.

**Section 04 - Safety of Subjects and Investigator/s, Risks, Ethical problems**

**4.1 Are there any potential hazards/ risks to the Animal/Human Subjects their relatives and Investigator/s.**

 **If “yes” give details including estimation…….**

**4.2 What are the Ethical concerns of your proposed study? (Include any ethical problems or issues that the investigators consider to be important or difficult with proposal study)**

 **(a)**

 **(b)**

 **(c)**

 **(d)**

 **(e)**

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

 **(a)**

 **(b)**

 **(c)**

 **(d)**

 **(e)**

**Section 05 - Finances, Confidentiality and Indemnity**

**5.1 Are there any financial incentives for the subject?**

 **Yes** **[ ]** *If* ***Yes,*** *please give details.*

 **No [ ]**

**5.2 Are there any financial interests for the applicants over and above those detailed on the registration form?**

**Yes** **[ ]**  *If* ***Yes****, please give details.*

 **No [ ]**

5.**3 Will any expenses incurred by the subject be refunded?**

 **Yes [ ]** *If* ***Yes,*** *please give details.*

 **No** **[ ]**

**5.4 Who besides the named investigators will have access to the subjects’ medical records?**

**5.5 Is there any Indemnity, insurance and liability cover for the project?**

 **Yes [ ]  No [ ]**

If **No** who would take responsibilities in the event of a claim?



*ONLY COMPLETE APPENDICES* ***A****,****B*** *AND* ***C*** *IF APPROPRIATE TO YOUR STUDY*

**Appendix A Radioactivity**

**A.1 Radioactive substances**

 **a) Details of substances to be administered.**

 **b) Estimated effective dose (effective dose equivalent) (mSv)**

 *Please supply source of reference or submit calculation****.***

 **c) Absorbed dose to organ or tissues concentrating radioactivity (mGy)**

 *Please supply source of reference or submit calculation.*

**A.2 X-rays**

 **a) Details of radiographic procedures**

 **b) Estimated effective dose (effective dose equivalent) (mSv)**

 *Please supply source of reference or submit calculation*.

**I have delegated authority to administer the radioactive substance(s) in this project to Rev/ Prof/ Dr/Mr/Ms…………………………………………… and I approve the arrangements that have been made.**

Signature of Consultant/Head Radiology or Nuclear Medicine or oncology.

Date

**Appendix B Medicinal Products**

**B.1 Will the medicinal product be:**

1. **unlicensed? Yes [ ]  No [ ]**
2. **a licensed product to be used outside Yes [ ]  No [ ]**

**the terms of its product license?**

**B.2 Details of medicinal product**

*Please submit the data sheet for licensed products.*

 Approved name

 Strength

 Dosage, form and frequency

 Route ofadministration

**B.4 Safety, stability and purity data relevant to the protocol usage.**

 *Please provide information on the following, including references where appropriate.*

 **a) Toxicity**

 **b) Purity**

 **c) Stability**

**B.5 Who will administer the product? ( Name/Designation, Address?)**

**B.6 Manufacturing information.**

 **a) Who is the supplier?**

 **b) What manufacturing license(s) do they hold?**

**B.7 Have arrangements for dispensing been made with the pharmacy?**

 **Yes** **[ ]** *If* ***Yes****, state who your advisor was.*

 **No** **[ ]** *If* ***No****, explain why not.*

**Appendix C Medical Devices/Equipment**

**C.1 Will the medical device / item of medical equipment be:**

1. **a prototype / currently unmarketed product? Yes [ ]  No [ ]**
2. **a new application of an existing product? Yes [ ]  No [ ]**

**C.2 Details of Medical Devices/Equipment**

 *Please attach any details of manufacturer’s recommended usage for existing products.*

 Approved name

 Intended study usage

**C.3 Safety data relevant to the protocol usage.**

 **a) Is there any quality approval mark for this product? Yes** [ ]  **No** [ ]

*If* ***No,*** *please indicate the classification of a company manufactured device under the EC Directive. It relates to the level of risk attached to the product and can be obtained from the manufacturer.*

**b) Please give details of relevant safety data, including references where appropriate.**

**C.5 Who will fit the device / use the equipment?**

**C.6 Who is the supplier and how do they ensure appropriate manufacturing quality?**

 *Please supply certification or registration numbers.*

 **Appendix D Research involving Genetic Modification**

**D.1 Have you considered Genetic Modification Safety to perform this work?**

 **Yes [ ]**  **No [ ]**

*If Yes, please give details*