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

1.1 Title of the Project:

1.2 Investigators:

1.2.1 Principle Investigator/Supervisor:

Title: Mr. ☐ Ms. ☐ Dr. ☐ Prof. ☐

Name:

Qualifications:

Designation:

Place of Work:

Address:

Contact NOs:

Email Address:

Signature:

1.2.2 Investigator 1:

Title: Mr. ☐ Ms. ☐ Dr. ☐ Prof. ☐

Name:

Qualifications:

Designation:

Place of Work:

Address:

Contact NOs:

Email Address:

Signature:

1.2.3 Investigator 2:

Title: Mr. ☐ Ms. ☐ Dr. ☐ Prof. ☐

Name:

Qualifications:

Designation:

Place of Work:

Address:

Contact NOs:

Email Address:

Signature:

1.2.4 Investigator 3:

Title: Mr. ☐ Ms. ☐ Dr. ☐ Prof. ☐

Name:

Qualifications:

Designation:

Place of Work:

Address:

Contact NOs:

Email Address:

Signature:

1.2.5 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).

Section 02- Nature of Research (Please indicate with a "✓" appropriately)

2.1 Title of the project:

2.2 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.

2.3 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:

- **unlicensed?** **Yes** ☐ **No** ☐
- **a licensed product to be used outside the terms of its product license?** **Yes** ☐ **No** ☐

B.2 Details of medicinal product

Please submit the data sheet for licensed products.

Approved name

Strength

Dosage, form and frequency

Route of administration

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:

* **a prototype / currently unmarketed product?** **Yes** ☐ **No** ☐

* **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