ETHICS REVIEW COMMITTEE
Faculty of Science
University of Kelaniya

For office use only

Application No : ___ /__ / _____ **Date received ____/____/_____**
Version :

Name of the Applicant: (Prof/Dr/Mr/Ms) ……

Names of the reviewers:
1.
2.
3.

Decision of the ERC Faculty of Science, Univ. of Kelaniya:

Annex I – STUDIES INVOLVING ANIMAL RESEARCH

The application for ethical clearance should be completed and signed by the principal investigator of the study involving animals. Please read the **instructions carefully before completing the application** and ensure all relevant documents are included in the application to avoid any delays in processing the application.

CHECK LIST (Mark all included documents)

One copy each of the following

1. Cover letter signed by the applicant ☐
2. Proof of processing fee payment ☐

3. A letter of verification/ certificate(s) of training by the investigator(s)
   - Animal research ☐
   - Biosafety & Research ethics ☐

4. 3 **copies** of the following documents

	Date	**Version***
Application form		☐
Annex I (Animal Studies)		☐

*If you are submitting for the first time, version is 1, If you are resubmitting with comments addressed, version 2

6. Please Email documents submitted (copy of signed cover letter, application form, Annex I, letter of verification/ certificate(s) of Animal research, Biosafety and Research ethics training**)** as *pdf* file to erc.fs.@kln.ac.lk at the time of submission ☐

NOTE:
All documents must carry the date, application number and version number as a header.

PART I

1. Title of Research Project:

2. Principal Investigator(s): (A **principal investigator** (PI) is the holder of an independent grant administered by a university and the lead researcher for the grant **project**, usually in the sciences, such as a laboratory study or a clinical trial.)

Name (Prof./Dr./Mr/Ms):	
Designation (Prof., Senior lecturer, Research officer etc.,)	
Name and address of institution where the applicant is attached:	
Highest educational qualification:	
Mailing address if different from above	
Phone	E mail

3. **Location(s) where the animal study will be conducted:**

3.1 All study sites including laboratories, animal houses and other institutions

Location (University, Institute etc.)	Type of site (laboratory/animal house)

3.2 Will samples/tissue/data collected during the study be removed from the above study site/transported to a different site for investigation etc.? Yes ☐ No ☐

If Yes, provide details:

3.3 Will samples/tissues collected during the study be taken out of the country for investigation or storage? Yes ☐ No ☐

If yes provide details:

4. Investigator(s) training to handle animals in research

4.1 Have all the investigator's handling animals in this study undergone the necessary training? Yes ☐ No ☐

Specify all training received:

Name of investigator	Training Program/ Institution	Duration	Type of training received

5. Ethical review

5.1 Has ethical review for this study been requested earlier from this Ethics Review Committee?
* *Attach documentary evidence* Yes ☐ No ☐

If Yes,

Reference number	
Decision	
Date	

5.2 Has ethical review for this study been requested from any other Ethics Review Committee?

Yes ☐ No ☐

If Yes,

Reference number	
Decision	
Date	

5.2 Has this study been submitted to an ERC / similar body in the country/ countries of foreign collaborator/s? Yes ☐ No ☐

If Yes,

Reference number	
Decision	
Date	

6. Has this project been subjected to scientific review?

Yes ☐ No ☐

If Yes,

Name and address of the committee	
Decision	
Date	

7. Funding for the project

Funding Status	Source of funding	Budget (Rs.)
Funded ☐	Agency:	
Applied for funding ☐	Agency:	
Unfunded ☐		

If unfunded, justify why no funding is needed:

PART II (Research Protocol)

8. Project duration

Estimated start date:	
Estimated completion date:	

9. Summary of the research project

Provide brief background, objectives and the rationale of the project (maximum one page).

10. Background/ Introduction of the research project

Provide detailed background, objectives and the rationale of the project. Please include references in this section. (Use additional sheets)

11. Objective of the project and justification

Describe the objectives and rationale for the proposed project in brief. The rationale for doing the study must be clear.

11.1 General objective (Use additional sheets if necessary)

11.2 Specific aim(s):

11.3 Justification (A clear justification should be given for investigating in ANIMALS). Explain why the research cannot be carried out with non-animal alternatives.

12. Methodology

Description of the procedures: Describe in detail all procedures and techniques to be used, **emphasizing those performed on animals**. Use flow charts to illustrate procedures as appropriate. Append additional page(s) if necessary. Include the following: (Attach additional sheets)

1. Study design
2. Study population
3. Sample size and calculation of sample size
4. Study instrument/s
5. Pilot study
6. Sampling procedure
7. Description of procedure(s)
8. Data collection
9. Data analysis
10. Dissemination of results

13. Description of animal(s)

13.1 What is the species of animals used and the reason for selecting the said animal model?

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

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

13.4 How many animals are going to be sacrificed?

13.5 How long will animals be used in the study?

13.6 How often will animals be monitored?

13.7 Who will handle the animals?

Name	Position in study team (PI, research assistant/supervisor, etc.)	Training received to handle animals
		Yes ☐ No ☐
		Yes ☐ No ☐

14. Procedures and Drugs

Is there any administration of drugs/herbs/chemicals to the animals: Yes ☐ No☐
If yes, specify for each agent (append additional pages if necessary):

Amount of agent and dosage	
Route of administration	
Potential health risks to humans or animals	
Special animal care requirement(s)	
Precautions to be taken by personnel (including animal care staff)	

PART III (Biological Samples)

15. Biological Samples

Complete this section regarding handling and disposal of biological samples if applicable

15.1 Justify the use of biological sample(s) (Attach additional sheets if necessary)

15.2 Provide procedure(s) for collection, storage and disposal of biological sample(s) (Attach additional sheets if necessary)

15.3 Will samples/tissue/data collected during the study be removed from the above study site/transported to a different site for investigation etc.? Yes ☐ No ☐

If Yes, what is the fate of transferred data and biological/ genetic material?

15.4 Will samples/tissues collected during the study be taken out of the country for investigation or storage? Yes ☐ No ☐

If Yes, provide details:

15.5 Justify transfer of data and /or biological/ genetic materials to the country of foreign collaborator

15.6 Give details of final disposal of animals:

PART V (Ethical Considerations)

16. Assessment of Risks/Benefits

16.1. Are there any risks (physical, psychological) to animals in the study? Yes ☐ No☐

If Yes, identify them and state how you plan to prevent or minimize these risks.

16.2. Are there any benefits to the animals used in the study? Yes ☐ No☐

If Yes, what are the benefits?

16.3. Are there any risks to research team by conducting this study? Yes ☐ No☐

If Yes, identify the risks to the investigators and state the measures to be taken to prevent or minimize these risks.

17. Animal welfare

Are the facilities available at the animal house/facility adequate to conduct this study?
Yes ☐ No ☐

17.1 Are the facilities adequate to provide optimum welfare to animals? Yes ☐No☐

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

18. Endpoints

Please specify ENDPOINTS: Endpoints are clear criteria to define the point at which humane intervention must be implemented to prevent or relieve unnecessary pain and/or distress, should the experimental animal acquire experimentally-induced disease, illness or life threatening condition.

18.1 Are any drugs used for anesthesia /analgesia of animals: Yes ☐ No ☐
If yes, specify the drug, dosage and route of administration

18.2 Please specify the method of euthanasia:

18.3. Briefly describe how you deal with unintended consequences during you research (i.e. Sudden death or reactions of animals etc.)

19. Conflicts of Interest

19.1 Will the researcher(s), members of the research team, and/or their partners or immediate family members receive any personal benefits (e.g., financial benefit such as remuneration, intellectual property rights, rights of employment, consultancies, board membership, share ownership, stock options, etc.) as a result of or in connection with this study? Yes ☐ No ☐

19.2 If Yes, please describe the benefits below. (Do not include conference and travel expense coverage, or other benefits which are considered standard for the conduct of research)

PART VI (Feasibility)

20. Experience/Training of Investigators with this type of research

20.1 Please provide a brief description of previous experience with this type of research by (i) the principal investigator, (ii) the research team and (iii) the people who will have direct contact with the animals. Include the CV of the investigators involved in the study with recent publications.

If there has not been previous experience, please describe how the principal investigator/research team will be trained.

21. Declaration of applicant

As the Principal Investigator on this project, my signature confirms that I will ensure that all procedures performed under the project will be conducted in accordance with all relevant national and international policies and regulations that govern research involving animal participants. I understand that if there is any significant deviation from the project as originally approved I must submit an amendment to the ERC for approval prior to its implementation. I have submitted all significant previous decisions by this or any other ERC and/or regulatory authorities relevant for the proposed study. I declare that I am not seeking approval for a study that has already commenced or has already been completed. I understand that at least two months are required for ethics review and granting of ethics clearance. I will submit progress reports/reports of adverse events and side effects as requested by the ERC FS/UoK.

…….. _ /____/_____
Signature of Principal Investigator Date

Full name of Principal Investigator:

…….. _ /____/_____

Name and Signature of Coinvestigator/collaborator Date

…….. _ /____/_____

Name and Signature of Coinvestigator/collaborator Date

…….. _ /____/_____

Name and Signature of Coinvestigator/collaborator Date

…….. _ /____/_____

Name and Signature of Coinvestigator/collaborator Date

…….. _ /____/_____

22. Acknowledgment

Name of Applicant: (Prof/Dr/Mr/Ms**)**
Title of study:

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Thank you for submitting the above research proposal. The proposal has been assigned the protocol number stated above. It will be considered by the Ethics Review Committee at its meeting on _____and will be assigned to three principal reviewers. The ERC may contact you in due course if any clarifications; additional documentation; or revisions are required.

Secretary
Ethics Review Committee University of Kelaniya

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RISK MATRIX: VULNERABILITY AND RESEARCH RISK

(a) Indicate the Risk Level for this project by checking the intersecting box

	Research Risk		
Group Vulnerability	**Low**	**Medium**	**High**
Low	1☐	1☐	2☐
Medium	1☐	2☐	3☐
High	2☐	3☐	3☐

Overall Risk Level :☐

Risk level= 1: Expedited Review; Risk level = 2 or 3: Full Board Review