The Institutional Animal Care and Use Committee (IACUC) Cairo University

Application Template for Approval to Use Animals in Research and Teaching

Faculty/Institute:_____

Principal Investigator (PI):

PI Name: _____

Phone: _____

Designated Emergency Contact(s):

Name: _____

Phone: _____

FILLED BY OFFICE ONLY

IACUC Protocol Number

CU				

Date Application Received : _____

Approval Period: _____ _____

From **To**

Protocol Title	
Category	☐ Research ☐ Teaching ☐ Training ☐ Pilot study
Duration of Approval requested?*	☐ 1 Year ☐ 2 Years ☐ 3 Years
Anticipated Start Date	
Type of submission	☐ New prtocol ☐ Re-Submission ☐ Related to another protocol (If Re-Submission or related to another protocol, please provide its number……)
This protocol for:	☐ M.Sc. ☐ Ph.D. ☐ Research ☐ Project
Is the protocol currently funded?	☐ Yes ☐ No ☐ Pending Funding Source: ☐ Cairo University ☐ Others (Please specify ……)

**Protocol duration begins on the date of approval by the CU- IACUC and continues for the period requested in this section.*

SECTION 1: Overview of protocol

1.1. Research team information (Add more lines if necessary)

Study Team Members			
Principal Investigator			
Name		**Position**	
Institution		**Department**	
Phone		**Email**	
Co-Investigator (s)			
Name		**Position**	
Institution		**Department**	
Phone		**Email**	

1.2 Has this protocol been peer reviewed by specialized scientific reviewing committee?

☐ No ☐ Yes

If yes, please provide the full name of the reviewing committee

_____

1.3. Literature Search for Duplication

This search must be performed to prevent unnecessary duplication with previous experiments and and to assess the possibility of the 3Rs (Reduction, replacement and refinement) alternatives.

1. Database search engine(s)	☐ Pubmed ☐ Google Scholar ☐ Science Direct ☐ Others (If others please specify……..)
2. The last date of database search was performed:	
3. Time period covered by the search:	☐ 5 years ☐ 10 years ☐ Others (If others please specify….)
4. Keywords used in the search	

5. Acronyms or abbreviations	

1.4. The objective(s), hypothesis and outcomes of this protocol

Please list the objective(s), hypothesis and anticipated outcomes of the project using lay language

Objective(s)	
Hypothesis	
Outcomes and significance (benefits)	

1.5. Background

Please provide adequate background with references that indicates the importance of the proposed study.

1.6. Summary or Synopsis in simple English (layman) language

Avoid using technical terminology overly. The summary should be simple and concise in a way that makes sense to a person with no discipline-specific training.

*If this is a thesis research proposal or a grant application, please do not write down the full length proposal.

SECTION 2. Project Information

2.1 Primary purpose

☒ Research ☐ Diagnostic ☐ Other (please specify)
☐ Teaching ☐ Product development

2.2 Social relevance or significance

☐ Conservation/Environment ☐ Veterinary Science ☐ Basic Biology
☐ Medical Science ☐ Other (please specify……)

2.3 Subject area

☐ Behavior ☐ Biochemistry ☐ Biomaterials
☐ Cell Biology ☐ Clinical sciences ☐ Drug development
☐ Ecology ☐ Genetics/gene manipulation ☐ Immunology
☐ Molecular biology ☐ Parasitology ☐ Neurobiology
☐ Pharmacology ☐ Physiology ☐ Toxicology
☐ Embryology & comparative anatomy ☐ Other (please specify……)

SECTION 3. Justification of animal use and 3Rs:

The CU-IACUC requires "that animals should be used only if the researcher's best efforts to find an alternative have failed". The three Rs (Replacement, Reduction and Refinement) are the cornerstone of ethical animal research, and CU-IACUC requires investigators to implement the 3Rs whenever possible upon preparing to use animals for scientific or teaching purposes.

3.1 Requested animals

Species / Common Name	Strain/ Breed	Weight range and/or Age	Sex (M, F)	Total Number	Source

In female animals, please check its reproductive status

☐ **Mature female** ☐ **Immature female**

☐ **Pregnant female** ☐ **Lactating female**

3.2. Replacement

Replacement refers to methods that avoid or replace the use of animals.

3.2.1. Justification of Animal Use

3.2.1.a. Explain why animals are required for these studies, and why non-animal model replacements, such as cell culture or computer modeling, cannot fully replace animals:

3.2.1.b. **Species – Specific Consideration**

Provide a clear justification explaining choice of species to be used:

What characteristics of this/these species make them appropriate for the proposed study? These might include structural, behavioural, physiological, biochemical, or other features or considerations (such as availability of species-specific reagents, or the use of well-established model) which make the model compatible with the research objectives. **Cost is not a primary consideration**.

3.3. Reduction

Reduction refers to methods that minimize the number of animals required to achieve the aims of the work. Applicants must demonstrate that the minimum number of animals required to attain scientifically meaningful or statistically significant results will be used. Reducing the number of animals used should not result in greater harm, including pain and distress, to the animals that are used.

3.3.1. Is this a repetition of a previous study?

☐ **No** ☐ **Yes** If Yes please describe the previous work and justify why this needs to be repeated.

3.3.2. Justification of animal number

Provide a clear justification explaining the number of animals to be used.

3.3.3. Did three Rs search determine any possible reduction? Statistical methods should be described where possible.

Reduction Alternative Category	
Experimental design	☐ Randomised ☐ Double blind ☐ Other (if other please specify)

Sample size calculation	☐ Power calculation ☐ Reference ☐ Pilot Study ☐ Other (if other please specify)

3.3.4. Animal Re-use Strategy

Does this protocol involve the re-use of any animals (more than one procedure applied for unrelated experiments on the same animals and in the same project)?

☐ Yes ☐ No

If yes, please explain**:**

3.4. Refinement

This refers to practices that reduce or eliminate the animals' pain, stress and discomfort - not only during experimental procedures, but in relation to the animals' daily social and physical environments, as well.

3.4.1. Have you considered pilot studies?

☐ **Yes** ☐ **No**

If Yes please explain: **If No please justify:**

3.4.2. **Flowchart** of experimental procedures and timelines.

Describe all procedures on the animals and how often they will be done. Surgery should be described here if applicable as it relates to the study design. Specific details on surgery, anesthesia for surgery, and postoperative care are requested in **section 3.5**.

3.4.2. 1. Experimental Agents

Experimental agents include investigational new drugs, placebos, tumor cells, stem cells, gene markers, tracers, radioisotopes, imaging contrast agents, viruses and other biological agents, etc.						
Species	**Drug/Agent**	**Dose (mg/kg body weight)**	**Vehicle**	**Route**	**Frequency**	**Duration**

3.4.2. 2. Collection of biological samples (blood*, body fluid, tissue, hair, swap, tail clip, etc).

Collected sample	Site of collection	Method of collection	Amount (size/ volume) Collected	Frequency of Collection(s)

3.4.3. Degree of pain severity

Based on the experimental design and manipulated procedures in this study. Please check ONLY one box.

The most invasive or potentially painful procedure determines the pain severity level.	
☐ **No pain**	- Animals being bred, acclimatized, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.
☐ **Minimum**	-Animals that are subject to procedures that cause no pain or distress, or only momentary or slight pain or distress and do not require the use of pain-relieving drugs
	-Animals subjected to potentially painful or stressful procedures for which they

☐ **Moderate**	receive appropriate anesthetics, analgesics and/or tranquilizer drugs.
☐ **Severe**	-Animals subjected to potentially painful or stressful procedures that are not relieved with anesthetics, analgesics and/or tranquilizer drugs.

The principle investigator required to document that alternative to procedures that may cause pain or distress to animals have been considered.

3.4.3.1. Are less painful or stressful alternative available?

☐ **No** ☐ **Yes**

If yes, justify why they are not going to be used?

3.4.3.2. Describe the anticipated pain or distress for animals?

3.4.3.3. Describe how pain or distress will be monitored?

3.4.3.4. List who will monitor or observe animals?

3.4.3.5. Indicate the schedule of monitoring?

3.4.3.6. Animals in pain or stress

Describe the interventions and / or dose, frequency and type of anesthetic or analgesic drugs or tranquilizers if pain or distress occurs.

Agent/Substance	Drug	Dosage	Frequency	Route of Administration
Anesthetic Agent				
Analgesic Agent				
Tranquilizers				
Others				

3.5. Does this protocol involve surgery?

☐ **Yes** ☐ **NO**

If answer with Yes, complete the following section and if No, proceed to the following section.

3.5.1. Surgical procedures

Give details and description of the **surgical procedures Guidelines** and pain management during, and/or after surgical intervention.

3.5.2. Anaesthetic, analgesic, antibiotic and other drugs used in pain management.

Agent/Substance	Drug	Dosage	Frequency	Route of Administration
Anesthetic Agent				
Post operative Analgesic				
Antibiotic				
Others				

3.5.3. Important Surgical Consideration.

1. **Location (Room, Building) of surgery:**_____
2. **Pre-operative Care**

- **Describe any care given to the animals prior to the surgery***: [e.g., fasting, sedation, pre-operative physical exam or blood work, etc.]*.

- **Describe how the level of anesthesia is assessed to be adequate to begin the procedure?**

_____

- **Will animals be allowed to recover from anesthesia?**

☐ **Yes** ☐ **NO**

- **If the answer with Yes, will more than one major survival surgery be conducted on each animals?**

☐ **Yes** ☐ **NO** **If the answer with Yes, How many times? (_____).**

- **Provide scientific justification for more than one major, survival surgery on each animal.**

_____

_____

3. Aseptic Techniques

Preparation of the surgical space: _____

Preparation of the surgeon: [e.g., surgical scrub of hands, donning surgical attire, sterile gloves, etc.] _____

Preparation of the animal: [e.g., clip fur, clean surgical site with antiseptics, use of sterile drapes, application of eye ointment, etc.]_____

4. Sterilization of instruments

Describe how instruments will be sterilized: [e.g., autoclave, glass bead sterilizer, chemical sterilant, etc.]_____

Will instruments be used in multiple animals? If so, describe how sterility will be maintained.

_____

SECTION 4: Humane Endpoints

Some experimental manipulations or phenotype abnormalities can be expected to produce a degree of unavoidable pain, distress or illness in experimental animals. These adverse effects will be minimized or alleviated by choosing the earliest endpoints consistent with the scientific objectives of the research.

What is the expected time course of the study? (i.e. how long are animals maintained from the first experimental manipulation until the end of the experiment or planned euthanasia).

What criteria, appropriate to the species, will trigger the decision to end the study, stop the procedure, or humanely euthanize an animal before the experimental objective is achieved? Examples could include the following: a weight loss limit (not more than 20%) as a percentage of body weight, allowable durations of anorexia, ulcerative skin lesions.

_____

SECTION 5: Experimental Procedures

Provide all proposed experiments and different measurements that will be applied on the collected samples.
Experiment I:
Experiment II:
Experiment III:

SECTION 6: Euthanasia

This must be answered even in a non-terminal study, where an animal may experience a Humane Endpoint not related to the research i.e. in case of planned or unplanned (emergency) euthanasia. Methods of euthanasia must be listed as acceptable by the most recent Report of the AVMA (American Veterinary Medical Association) Guidelines on Euthanasia (https://www.avma.org/KB/Policies/Documents/euthanasia.pdf).

☐ **Euthanasia is part of the study design**

☐ **Euthanasia is NOT part of the study design**

6.1 Methods of euthanasia*

Species	Method	Drug	Dose (mg/kg)/ For gas use%	Route
	Anesthetic overdose			
	Decapitation under anesthesia or tranquilization			
	Cervical dislocation (CD) under anesthesia or tranquilization			
	Exsanguination/cardiac perfusion under anesthesia			
	Other method (Please specify)			

**If more than one method is used per species please list all methods.*

6.2 Confirmation of Death in Animals

	Open chest inspection of the heart	
	Exsanguination (cutting a major blood vessel)	
	Physical method *(specify)*:	
	Other *(describe below)*:	

6.3. If you are using any one of the previous methods of euthanasia without using anesthesia, please provide

scientific justification (with references if available) for why anesthesia cannot be used.

SECTION 7: Animal Housing

Animal Housing Requirements. (Select and check)

Specify intended Animal Housing Facility				
Animal Facility Supervisor				
Micro environment	**Housing**	☐ Group	☐ Individual	
	Cage type	☐ Conventional	☐ IVC	☐ Micro-isolator
	Bedding	☐ Normal	☐ Special	
	Feeding	☐ Normal	☐ Special diet	☐ Special regime
	Watering	☐ Normal	☐ Supplemented	☐ Special regime
Macro environment	**Temperature**	☐ Ambient	☐ Other (Details.....)	
	Humidity	☐ Ambient	☐ Other (Details.....)	
	Containment	☐ Normal	☐ Other (Details.....)	

SECTION 8: Animal disposition

If animals are not to be euthanized at the completion of the protocol, please describe their ultimate use.

_____

_____

Identify and explain if any individual animal in this project will be used in any other project.

Please state IACUC protocol number (if known) and justify its use.

What will be the method of disposal of dead animals?

SECTION 9: Safety

Does this protocol involve the use of substances that may pose any health risk (infectious, carcinogenic or toxic) to humans and/ or animals (e.g. bacteria, viruses, fungi, parasites, cell lines, primary cells, tissue, fluids, blood, recombinant DNA, chemicals, laser or radiation)?

☐ YES ☐ NO

If yes, please indicate the hazards that the agent(s) may pose to humans and/or animals and mention the precautions that will be followed to minimize health risk.

Agent	Method of Administration	Method used to capture wastes

SECTION 10: Technical /Training requests

Will researchers perform technical procedures on animals in addition to routine husbandry?

☐ Yes ☐ No

If yes, please fill the following table:

Procedure	Name of the researcher	Training*

***Please explain how the researcher was trained to perform this procedure (Certificate, personnel training, video……).**

- CU. IACUC request for additional training.

☐ Yes ☐ No

- Details

SECTION 11: List of References

INVESTIGATORS DECLARATION

Project title

☐ I/we the undersigned have read the Animal care Guidelines and accept responsibility for the conduct of the experimental procedures detailed in this proposal in accordance with the guidelines contained in the Guide for the Care and Use of Laboratory Animals 8th Edition 2011 (the Guide).

☐ I/We understand that I must notify the IACUC of Cairo University through the amendment process of any changes in the research use of the animals, including the changes of personnel, the number of animals, species used, or procedures performed, and understand that no additional procedures can be started without express prior approval from the IACUC.

☐ At the end of each year, an annual protocol report should be submitted to the IACUC.

I/We (all investigators) confirm that the research team will comply with any other condition laid down by the Cairo University Institutional animal and care and use committee.

Name	Date	Signature

Faculty Recommendation

Head of Department	Signature	Date

N.B. If the protocol is resubmitted after response to CU_IACUC member's comments, please be sure that the resubmitted protocol is signed from the designated reviewing members.

Designated reviewing members.

Name	Date	Signature