|  |  |  |
| --- | --- | --- |
|  | The Institutional Animal Care and Use Committee (IACUC) Sohag University. |  |
| **Application Template for Approval to Use Animals in**  **Research and Teaching** | | |

**Faculty/Institute: Principal Investigator (PI):**

**FILLED BY OFFICE ONLY**

IACUC Protocol Number

Date Application Received:

Approval Period:

**From**

**To**

PIName:

Phone:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **SU** |  |  |  |  |

**Designated Emergency Contact(s):** Name: Phone:

|  |  |  |
| --- | --- | --- |
| **Protocol Title** |  | |
| **Category** | Research Pilot study | Teaching Training |
| **Duration of Approval requested?\*** | 1 Year | 2Years 3 Years |
| **Anticipated Start Date** |  | |
|  |  | |
| **This protocol for:** | M.Sc. | Ph.D. Research Project |
| **Is the protocol currently funded?** | Yes Funding Source:  Sohag University | No Pending  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

# Literature Search for Duplication

This search must be performed to prevent unnecessary duplication with previous experiments 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:** | 5years 10 years Others  (If others please specify….) |
| **4. Keywords used in the search** |  |

|  |  |
| --- | --- |
| **5. Acronyms or abbreviations** |  |

# 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)** |  |

# Background

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

# 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

* 1. **Primary purpose**

|  |  |  |
| --- | --- | --- |
| Research | Diagnostic | Other (please specify) |
| Teaching | Product development | |

* 1. **Social relevance or significance**

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

* 1. **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 (pleasespecify……)

**SECTION 3. Justification of animal use and 3Rs:**

The SU-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**

**Pregnantfemale Lactatingfemale**

# Replacement

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

* + 1. **Justification of Animal Use**

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

* + - 1. **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**.

# 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.

# 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.

* + 1. **Justification of animal number**

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

* + 1. **Did three Rssearch determine any possible reduction?**Statistical methods should

## be described where possible.

|  |  |
| --- | --- |
| **Reduction Alternative Category** |  |
| **Experimental design** | Randomised Doubleblind Other (if other pleasespecify) |

|  |  |
| --- | --- |
| **Sample size calculation** | Power calculation Reference Pilot Study Other  (if other please specify) |

* + 1. **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**:**

# 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.

# Have you considered pilot studies?

**Yes No**

**If Yes please explain:**

**If No please justify:**

## **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** |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

* + 1. **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 | Frequencyof  Collection(s) |
|  |  |  |  |  |
|  |  |  |  |  |

* + 1. **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.

# Are less painful or stressful alternative available?

**No Yes**

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

* + - 1. **Describe the anticipated pain or distress for animals?**
      2. **Describe how pain or distresses will be monitored?**
      3. **List who will monitor or observe animals?**
      4. **Indicate the schedule of monitoring?**
      5. **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** |  |  |  |  |

* 1. **Does this protocol involve surgery?**

**Yes NO**

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

* + 1. **Surgical procedures**

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

* + 1. **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** |  |  |  |  |

* + 1. **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 manytimes? ( ).**

* **Provide scientific justification for more than one major, survival surgery on eachanimal.**
  1. **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.]

* 1. 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 theresearch.

**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**

# 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.*

# [Confirmation of Death in Animals](http://www.research.uci.edu/compliance/animalcare-use/research-policies-and-guidance/euthanasia.html#euth4)

|  |  |  |
| --- | --- | --- |
|  | 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 Cage type Bedding Feeding Watering** | Group Conventional Normal Normal Normal | Individual IVC  Special Special diet Supplemented | Micro-isolator  Special regime Specialregime |
| **Macro environment** | **Temperature Humidity Containment** | Ambient Ambient Normal | Other(Details )  Other(Details )  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………).**

**- SU. 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 Guidefor

the Care and Use of Laboratory Animals 8th Edition 2011 (theGuide).

I/We understand that I must notify the IACUC of Sohag 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 Sohag 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 SU\_IACUC member's comments, please be sure that the resubmitted protocol is signed from the designated reviewing members.*

*Designated reviewing members.*

|  |  |  |
| --- | --- | --- |
| **Name** | **Date** | **Signature** |
|  |  |  |
|  |  |  |
|  |  |  |