**To be filled in by IACUC Office – IACUC Form 2016**

**IACUC Number: \_\_\_\_\_\_\_\_\_\_\_\_\_ Use Level: \_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date Received: \_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date Reviewed: \_\_\_\_\_\_\_\_\_\_\_\_\_ Date Approved: \_\_\_\_\_\_\_\_\_\_\_\_\_**

All protocols must be typed. Submit **(1)** an original, clipped, single-sided signed copy of the protocol to the Senior Coordinator, IRB/IACUC, 2059 Church Rd; and **(2)** electronic copy (PDF) to russok@arcadia.edu. Written approval from the IACUC must be obtained before initiating any research, teaching, or testing involving vertebrate animals or animal by-products.

1. **Protocol Title:**
2. **Estimated dates of protocol: From:**  **To:**

*(Not to exceed 3 years)*

1. **Type of Protocol:** [ ]  New Protocol [ ]  Amendment/Modification [ ]  3-year Resubmission
2. **If a Revision or Resubmission, please provide the IACUC protocol # and approval date:** Protocol Number Approval Date
3. **Funding Sponsor/ Agency** *(if applicable)***:**
4. **Principal Investigator** *(Arcadia faculty only)***:**

**Department:** **Extension:**

**Email address:** **Emergency contact #:**

1. **Co-Investigator:**

**Status:** **Extension:**

**Email address:**  **Emergency Contact #:**

1. **Has the Principal Investigator and all co-investigators completed the animal CITI training modules?** [ ] Yes, please attach [ ]  No
2. **Has the Principal Investigator and all co-investigators completed the Instructor Training form** *(if applicable)***?** [ ] Yes, please attach [ ]  No
3. **Are all permits, licenses, or letters of approval required for this research attached?**

[ ]  Yes [ ]  No, please explain

1. **ANIMAL SUBJECTS DESCRIPTION**

**Species:** **Strain/ Breed:**

**Sex:**  **Age:**  **Size:**

**Source:**

1. **Number of animals to be used per year:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Year 1:** | **Year 2:**  | **Year 3:**  | **Total:**  |

1. **Describe how the number of animals needed for this study was determined.**

**II. HUMANE USE CATEGORIES**

1. **Estimate the total number of animals that will be used in each Humane Use Category in the proposed study.**

|  |  |  |
| --- | --- | --- |
|  | Description: | *Number of Animals* |
| C | *No or minimal pain and/or stress (with or without the use of pain-relieving agents and techniques).* No pain or distress beyond that involved in the restraint, injections, or collection of samples. For comparison, no pain relieving drugs would be given under normal circumstances for a human patient going through the same procedure. |       |
| D | *Pain and/or stress that does not become intolerable and thereby distressful.* Potential for pain or distress but relief is provided by analgesics and/or sedatives as appropriate. The USDA regards survival and non-survival surgery to fall in this category. This category includes all procedures in which the animal may experience pain, discomfort, or distress which would be treated with the use of anesthetics, analgesics, or tranquilizers. Therefore, this category includes euthanasia via anesthetic overdose. |       |
| E | *Pain and/or stress that reaches the level of distress.* Pain or distress not relieved by sedatives or analgesics. This category includes procedures expected to cause pain, discomfort, or distress but the administration of normal anesthetics, analgesics, or tranquilizers cannot be used without adversely affecting the experimental results. |       |
|  | *Total Animals:* |       |

1. **Please justify the categorization you have chosen.**

**III. HOUSING**

1. **Are you housing animals?** [ ]  Yes [ ]  No (Skip to section VII)
	1. **Select which building and room or outside location where the animals will be housed.** [ ]  Boyer 102

[ ]  Boyer 3E

[ ] Outside location *(If outside location, please provide details of where.)*

* 1. **Maximum number of animals at any one time:**
	2. **Maximum number of animals per cage (or tank):**
	3. **Number of cages (or tanks) needed:**
	4. **Monitoring plan: How often are animals being monitored (Institutional policy is seven days a week)? What is being monitored and recorded (health and environment)?**

**IV. NUTRITION**

1. **What diet and feeding schedule will be used?**

1. **Will access to food(s) be restricted?**

[ ]  Yes (If yes, enter times or amounts)

[ ]  No

1. **Will access to liquid(s) be restricted?**

[ ]  Yes (If yes, enter times or amounts)

[ ]  No

1. **Will the diet above deprive or enhance the animal(s) of any specific nutrient(s)? (i.e. experimental procedures)**

[ ]  Yes (If yes, enter times or amounts)

[ ]  No

1. **If you responded yes to any of the above three questions, please describe and justify the need for this.**

**V. DRUGS/AGENTS USED AS PART OF EXPERIMENTAL MANIPULATION/VARIABLE**

 **21. Will the animals in the proposed study be administered drugs/agents? Please consider drugs/agents for experimental purposes only.**

[ ] Yes [ ]  No (if no, please proceed to section VI)

1. **List drugs/agents the animals will receive. If it is a controlled drug, put an “x” in the controlled column. For all drugs/agents, include dose (mg/kg), concentration (mg/ml), mode of administration (i.e., oral, subcutaneous injection, intraperitoneal injection, intramuscular injection, etc.), and who will administer the drug/agent.**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Controlled | Drug | Dose | Concentration | Route | Administered by |
|       |       |       |       |       |       |
|       |       |       |       |       |       |
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1. **How did you decide on each drug/dosage for this use? (Examples: a published reference; advice of a colleague with experience in this area. Please be specific.)**

**VI. SURGERY**

1. **Will animals in the proposed study have surgery performed on them?**

[ ]  Yes\* [ ]  No (if no, please proceed to section VII)

\*If yes, you will need to keep a surgical log of these activities. Log should contain a record of kinds and amounts of drugs administered, surgical procedures performed, and complications encountered. Date and name(s) of surgeon(s) should accompany each entry.

1. **Describe the surgical procedure including pre-op prep and wound closure.**

1. **Who will perform the surgery and how has he/she been trained?**

1. **Where will surgeries be performed, where will the animals recover, and what post-op care will be provided?**

1. **Will analgesics be used pre- or post-operatively?**

[ ]  Yes [ ]  No

If yes, provide name, route, timing, dose, and frequency of delivery. If no, provide justification.

**VII. LOCATION(S) OF EXPERIMENT**

1. **List all locations where animals will be handled. (i.e. building and room number, off-site locations, etc.)**

**VIII. DISPOSITION**

1. **What will be the final disposition of the animals?**

[ ] Transfer to a different protocol: Provide the IACUC protocol number

[ ] Euthanasia\*\* (List agent and method)

[ ] Adoption

[ ] Other (please explain)

\*\* **All euthanized animals must be placed in a bag and grouped by treatment (for drug studies). The bag must be labeled with PI name, Study ID, Date of Death, and any corresponding drugs used during the course of the study. Bags must be placed in the freezer in the Animal Facility unless a necropsy (autopsy) has been ordered by either the PI, Animal Care Representative, or Veterinarian. If a necropsy has been ordered, animals should be placed in individual, labeled bags in the necropsy refrigerator.**

**IX. ALTERNATIVES**

1. **Literature Search: The investigator should complete a literature search to determine that the proposed experiments do not unnecessarily duplicate previous experiments, minimize pain and distress, and alternative models are not available for the study. Specify database(s), date searched, years covered, and keywords utilized.**

1. **Are alternative models or methods available that would minimize the use of living animals?**

[ ]  Yes [ ]  No

If yes, describe why these methods are not being used in the proposed study.

**X. DETAILED PROTOCOL**

1. **How would you explain to a lay person the goals and objectives of the proposed work?**

1. **Project Summary: Provide enough information so that the IACUC members can review the rationale and purpose of the proposed study. Detail of experimental procedures, justification of animal numbers, and training and experience of personnel completing the procedures should also be provided. Please use a flow chart, if helpful, to illustrate how the research will be conducted.**

1. **Are any adverse events (such as death, excessive weight loss, body temperature fluctuation, heart rate/respiration changes, etc.) expected or documented in the literature relevant to this particular study? If yes, please describe and provide a detailed course of action to minimize adverse events. You may need to adjust your sample size accordingly.**

**PRINCIPAL INVESTIGATOR (FACULTY) ASSURANCE**

By my signature as Principle Investigator on this research application, I certify that the student investigators are knowledgeable about the regulations and policies governing use of animals and have sufficient training and experience to conduct this particular study in accord with the approved project/protocol. In addition,

* I agree to meet with the student investigators on a regular basis to review study progress.
* Should problems arise during the course of the study, I agree to be available to supervise the student investigators in solving them.
* I assure that the student investigators have completed all required educational IACUC and Occupational Health and Safety programs as required (CITI Training).
* I agree to abide by regulations that govern use of controlled substances (if applicable).
* I agree to assume responsibility for the final disposition of the animals.
* If I will be unavailable (such as on sabbatical, leave or vacation), I will arrange for an alternate faculty member to assume responsibility during my absence, and I will advise the IACUC by letter of this arrangement. The alternate faculty member will need to have passed all appropriate IACUC and Occupational Health and Safety programs (CITI Training).
* I am responsible for documentation of any adverse events or protocol deviations related to the research project and notification of the Animal Care Representative, and the IACUC by e-mail IRB\_IACUC@arcadia.edu **within 24 hours of incidence**.
* **I further certify that these studies do not unnecessarily duplicate previous experiments.**
* **Any failure to provide proper animal care or follow the approved protocol or AU IACUC guidelines may result in the suspension of the project or loss of Arcadia University animal use certification.**

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Principal Investigator Signature Date

**The Principal Investigator must be a member of the Arcadia University faculty. The Principal Investigator is considered the responsible party for legal and ethical performance of the project.**

**STUDENT INVESTIGATOR’S ASSURANCE**

I certify that the information provided is complete and correct.

**I understand that as Student Investigator I have responsibility for**:

* reading and understanding the protocol;
* the care and use of the animals in these proposed research/teaching activities;
* complying with all Arcadia University IACUC policies and procedures, as well as with all applicable federal, state, and local laws regarding the protection of animals in research, teaching, and testing;
* assuring the project will be performed by qualified personnel according to the research project/protocol;
* meeting with my faculty advisor (PI of the study) on a regular basis to review study progress;
* reporting adverse events to the PI and Animal Care Representative immediately;
* reporting protocol deviations to the PI and the IACUC (IRB\_IACUC@arcadia.edu) immediately.

I acknowledge that the completion of this work occurs within the oversight of the Arcadia University Institutional Animal Care and Use Committee. This oversight includes, but is not limited to, the following:

* approving written IACUC protocol prior to any animal use or initiation of the project,
* approving **ANY** revisions to the protocol **PRIOR** to implementing changes,
* reviewing progress report of the protocol on an annual basis,
* reviewing on-going protocols de novo every three years,
* receiving the termination report at the completion of the project, and

**Failure to provide proper animal care or follow the approved protocol or AU IACUC guidelines may result in the suspension of the project or loss of Arcadia University animal use certification.**

I have read and understand the above.

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Student Investigator Signature Student Investigator Signature

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Student Investigator Signature Student Investigator Signature

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Student Investigator Signature Student Investigator Signature

**Animal Health Emergency Protocol**

If an animal is found dead:

1. Immediately remove animal from cage and:
	1. Place it in a bag labeled with Animal ID, Date/Time found, Name of individual who found animal
	2. Place bag in small necropsy refrigerator
2. Visually inspect all of the other animals in the facility/room
3. Immediately contact the Faculty Animal Care Representative (must speak with person):
	1. Professor Wolf (Cell: 715-432-2391; Email: wolfj@arcadia.edu)
4. Must also immediately notify the IACUC Veterinarian and IACUC Senior Coordinator
	1. Dr. Denish ([doggydoc2@comcast.net](file:///C%3A%5CUsers%5Crussok%5CDownloads%5Cdoggydoc2%40comcast.net))
	2. Karen Russo (russok@arcadia.edu)

If an animal appears to be in distress (e.g., bloody nose, wheezing/panting/labored breathing, lying on side/lethargy, rapid weight loss >20%, self-mutilation, abnormal vocalization, diarrhea):

1. Check food and water access.
2. Visually inspect all of the other animals in the facility/room.
3. Immediately contact the Faculty Animal Care Representative (must speak with person)
	1. Professor Wolf, (Cell: 715-432-2391; Email: wolfj@arcadia.edu)
4. Must also immediately notify the IACUC Veterinarian and IACUC Senior Coordinator
	1. Dr. Denish ([doggydoc2@comcast.net](file:///C%3A%5CUsers%5Crussok%5CDownloads%5Cdoggydoc2%40comcast.net))
	2. Karen Russo (russok@arcadia.edu)

My signature below indicates that I have read and agree to abide by the above Animal Health Emergency Protocol:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Principal Investigator Signature

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Student Investigator Signature Student Investigator Signature

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Student Investigator Signature Student Investigator Signature

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Student Investigator Signature Student Investigator Signature

**Instructor Training Request (Please fill out a separate sheet for each student investigator.)**

Name (printed):       Date:

Department:       phone:

Title of Protocol

**This form must be completed for individuals involved in simple animal procedures such as behavioral testing, injections, specimen collection, or euthanasia.**

**Before completing this form you must have passed CITI Laboratory Animal welfare modules Working with the IACUC, Reducing Pain and Distress in Laboratory Mice and Rats, and Working with Rats in Research Settings.**

1. Indicate which procedures you will be conducting: (Note if additional procedures are added at a future date you will need to obtain approval from the IACUC prior to beginning work with the new procedures.
[ ]  Behavioral testing (list specific tests)

[ ]  Injections (identify subcutaneous, intraperitoneal, etc.)

[ ]  Specimen collections (indicate type of specimens to be collected)

[ ]  Euthanasia (indicate technique used)

[ ]  Other (provide specific information)

1. Indicate what special training (reading articles, hands-on training, and previous experience) that prepares you to conduct these procedures?

Supervisor assurance that training has occurred and proficiency has been demonstrated in the above listed techniques:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Principal Investigator Signature