**Application to Perform Clinical Research**

**Institutional Animal Care and Use Committee**

GOSHEN COLLEGE

**All research involving vertebrate animals, whether conducted by faculty, staff, or students, must be approved by the Goshen College Institutional Animal Care and Use Committee. Principal investigator must be faculty or staff member.**

**I. PROJECT INFORMATION**

**Project title: \_\_\_­­­­­­­­­­­­­­­­­­­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Principal investigator(s): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Department: \_\_\_\_\_\_\_\_**

**Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Name(s) of investigator(s): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Funding source (if applicable): \_\_\_\_\_\_\_\_\_\_\_\_**

\*Note that the Goshen College IACUC is not registered with the USDA and cannot approve projects with federal funding.

Please ***sign and send this page with all relevant original signatures*** to IACUC Chair Justin Heinzekehr via campus mail or bring the page to AD10B. Send your application and all attachments ***via email*** to the IACUC Chair at justinbh@goshen.edu.

**Certifications:**

My signature below, I certify that

1. The information provided in the protocol is complete and accurate.
2. I have determined that this study is not unnecessarily duplicative of previous work and consideration to alternatives has been given to eliminate or lessen the pain or distress to study animals.
3. The individuals listed in this protocol to perform and participate in research activity under this protocol have received the appropriate training and have completed AALAS certified training. A screenshot of the final exam results is attached.
4. Approval from the IACUC will be obtained prior to initiating any changes to this protocol, including but not limited to, altering procedures, adding additional animal species or increasing the number of animals used, allowing other investigators to use the animals for research on another protocol, etc.
5. This project will be conducted in accordance with the Animal Welfare Act, NIH Guide for the Care and Use of Laboratory Animals, federal and state regulations and institutional policies.

Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**II. ANIMAL REQUIREMENTS**

**Genus/Species: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Common name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Subspecies/Breed: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Age, weight, size: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Sex:** 🞎Male 🞎 Female

**Housing location: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Location where manipulations will occur: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Number of animals used:**

Year 1 \_\_\_\_\_ Year 2 \_\_\_\_\_\_ Year 3 \_\_\_\_\_\_ Total \_\_\_\_\_\_

**Rationale for animal use:**

**III. DESCRIPTION OF RESEARCH PLAN AND OBJECTIVES**

**Study objectives:**

In layman’s terms, describe: the aim of the study, the importance to animal and human health, and the potential contributions to the advancement of knowledge or the good of society.

**Description of research plan and animal procedure:**

Explain the experimental design and specify all animal procedures. The information in this section should allow the IACUC to understand the experimental course of an animal from its entry into the study to the end point of its participation. Provide a clear and sequential description that is easy for all members of the IACUC (including the non-scientific member and the community member) to understand.

**Pain or distress classification and consideration of alternatives:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Species**  (common name) | **USDA Classification**\*  **B, C, D or E** | **Number of animals used each year** | | | **3 year total number of animals** |
|  |  | **Year 1** | **Year 2** | **Year 3** |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
| **Total number of animals:** | | | | |  |

**USDA Classifications:**

Classification B: Animals being bred, conditioned, or held for use in teaching, testing, experiments, or surgery, but not yet used for such purposes. *Examples: breeding animals held in legal sized caging, observation of wild animals*

Classification C: Animals upon which teaching, research, experiments, or tests will be conducted involving no or very minimal pain, distress, or use of pain-relieving drugs. *Examples: intravenous blood collection, oral medication, euthanasia in accordance with AVMA recommendations*

Classification D: Animals upon which teaching, testing, experiments, or surgery will be conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs will be administered. *Examples: surgical procedures, intracardiac blood collection, administration of pain-inducing drugs or chemicals*

Classification E: Animals upon which teaching, testing, research, experiments, or surgery will be conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs will adversely affect the procedures, results or interpretation of the teaching, research, experiments, surgery, or tests. *Examples: stress, shock or pain research; negative conditioning*

**Consideration of Alternatives:**

For any procedures that fall into USDA Classification D or E, causing more than momentary pain or distress, detail the alternatives that were considered and justify the decision that alternatives were not available. Alternative methods include (1) refining existing tests by minimizing animal distress, (2) reducing the number of animals necessary for the study, or (3) replacing whole-animal use with in vitro or other tests. When ascites production is used to produce antibodies, justification needs to be given as to why in vitro systems cannot be used.

**Surgery:**

If surgery is proposed, please address the following:

1. Identify and describe the surgical procedures, preoperative activity, monitoring and supportive care during surgery, and the aseptic methods that will be used.
2. Who will perform the procedure? Include qualification and/or expertise.
3. Where will the surgery and postoperative care take place?
4. Describe the postoperative care plan, including the frequency of observation and the individuals who will perform observation, detection and management of complications during the work week, after hours, and on weekends and holidays.
5. If non-survival surgery, describe humane euthanasia procedures and how death will be determined.
6. Describe any paralytic agents used. Detail how ventilation will be used and pain assessed.
7. Has major survival surgery been performed on any animal prior to participation in this study?
8. Will more than one major survival surgery be performed on an animal while in this study? Justify, if yes.

**Anesthesia, tranquilization, and other agents:**

Specify anesthetics, analgesics, sedatives, and tranquilizers that are to be used. Include:

1. Name of the agent(s)
2. Dosage
3. Route
4. Schedule of administration

**Hazardous agents:**

If hazardous agents will be used, approval from the Biosafety Program is required. Include documentation of approval for the use of recombinant DNA or blood borne pathogens.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Hazardous Agent** | **Yes** | **No** | **Agent** | **Date of Biosafety Approval** | **Tracking #** |
| Radionuclides |  |  |  |  |  |
| Biological Agents |  |  |  |  |  |
| Hazardous Chemicals or Drugs |  |  |  |  |  |
| Recombinant DNA |  |  |  |  |  |

Study Conducted at Animal Biosafety Level: 1 2 3 4

Describe practices and procedures required for the safe handling and disposal of contaminated animals and materials associated with this study. If applicable, provide plans for monitoring radioactivity and removal of radioactive waste.

**Method of euthanasia or disposition of animals:**

Describe the proposed method of euthanasia (even if euthanasia is not the intended outcome at the end of the experimental procedures); specify the dosage or route if chemical agent(s) will be used. If method (s) include those not recommended by the AVMA Panel Report on Euthanasia, provide scientific justification as to why such methods must be used. Indicate method of carcass disposal. Describe the intended method of disposition of the animals if different from euthanasia.

**Field Studies:**

If animals in the wild will be used, describe the following:

1. How they will be observed
2. Any interactions with the animals
3. Whether animals will be disturbed or affected
4. Any special procedures anticipated

If Federal permits are required, provide appropriate documentation proving they have been obtained.

**Special concerns or requirements:**

List any additional requirements, special housing, equipment or animal care.

**IV. PERSONNEL**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Name | Relevant Degree  or  Certification | Species personnel will be working with | Procedures to be performed | | | | | | |
| Non-Invasive Activity | Sample Collection | Euthanasia | Anesthesia | Surgery | Assess Humane Endpoints | Other |
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**How have you determined that all personnel listed above are competent in performing these procedures?**