**Institutional Animal Care and Use Committee**

**Application to Use Animals in Research, or Teaching**

Protocols are reviewed by the full IACUC at a convened meeting. A majority of a quorum of the committee is required for certain action, including protocol approval. The committee Chair acts as, or selects a committee member to act as, the primary reviewer, who take responsibility for presenting the protocol at the full committee meeting. The Attending Veterinarian and the Chair also perform a "pre-review" prior to distributing the protocols to the IACUC. If a member has a real or perceived conflict of interest, they may not contribute to the quorum, deliberate or vote on that project.

**Instructions:**

* Use the most recent version of this form to apply for IACUC approval of any new use of animals for teaching or research, or for renewal of a previously IACUC-approved animal use. Current versions may be found on the TCU Office of Research’s website at <http://research.tcu.edu/compliance/iacuc/iacuc-policies-procedures-and-forms/>.
* Consult with the Attending Veterinarian during protocol development is recommended for all protocols and required for any protocol that includes USDA Categories D and E.
* Answer each section of this form completely and accurately.
* Submit the completed form (minus this instruction page), to iacuc@tcu.edu.
* Upon return receipt of protocol application approved by IACUC, forward copies of the signed Committee Action Form to the appropriate sponsoring agency.
* The Chairperson of the IACUC will notify the Investigator as to the Committee action. Approved applications will be assigned a protocol number which must be referenced on: (1) All internal correspondence regarding the negotiated animal use, (2) Purchase order requisitions for the animals, and (3) Identification cards required for all of the animals.

***Expiration:*** All protocols expire three years from the date of approval, if not earlier*, and all are* subject to Annual Continuing Review (after the first and second year of research/instructional activity). Within 30 days following the first and second anniversaries of the initial IACUC approval (the date referenced on the Committee Action Form of this application), an Annual Animal Protocol Review application must be submitted to the IACUC. If activity is *desired* to be continued beyond the third anniversary, a new Animal Use Protocol Application (this form) must be submitted for full IACUC review.

***Amendment*:** Following initial approval of a protocol, proposed changes in personnel, funding agency, species, numbers of animals, and/or procedures should be submitted to the IACUC using the Animal Use Protocol Amendment application form.

|  |
| --- |
| **For IACUC Office Use Only** |
| Protocol Number:  |  |
| Original Approval Date:  |  |
| Approval Period |  | Expiration Date: |  |
| Amendment #: |  | Amendment Approval Date: |  |
| Previously Assigned Protocol Number: |  |
| **Veterinarian Consultation** | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_ Veterinarian Date |

1. **General Information**

|  |  |
| --- | --- |
| **Principal Investigator (“PI”)** | Name:       Telephone Number:      Email:       |
| **PI’s Department** |       |
| **Principal Researcher** |       |
| **Protocol Number** (for IACUC use only): |       |
| **Project Title/Course Name/Number:** |  |
| **Type of protocol**: | [ ]  New [ ]  3 year renewal for Protocol#       |
| **Emergency Contact Information:** List daily and weekend contact numbers for animal emergencies. Parties listed in this section must also be listed as project personnel. | Name:       Telephone Number:      Alternate Name:       Telephone Number:       |
| **Assigned Designee for Protocol Oversight** (acts on behalf of PI in his/her absence, e.g. sabbatical)  | Name:       Telephone Number:      Email:       |

 Other Collaborators:

|  |  |  |
| --- | --- | --- |
| **Name and Department** |  |  |
| **Name and Department** |  |   |

1. **Nature and Purpose of Proposed Studies**
2. **Lay Summary**

Describe the specific aims and details of animal use in non-scientific terms. The lay summary is used by community representatives on the IACUC and also may be used in the event of an external inquiry into the project. Define all acronyms. Only describe the use of live animals. Give a short paragraph for each of the following:

1. **Background and Significance**

1. **Summarize Specific Aims or Question being addressed**

1. **How will the results of the study be used? Describe the relevance to human or animal**

**health, the advancement of knowledge, or the good of society**

1. **Technical Abstract**

Use the following outline to create a structured technical abstract that provides a clear and concise overview of the proposed work. It must include enough detail to allow the reviewers to understand the rationale for the project, the specific objectives of the work, and the animal-related experiments that will be performed. It is not necessary to include excessive detail about the ex vivo analysis of tissues.

* Background: Present the ideas and reasoning behind the proposed work.
* Objective/Hypothesis/Specific Aims: State the objective/hypothesis to be tested. Provide evidence or rationale that supports the objective/hypothesis.
* Study Design: Briefly describe the study design including appropriate controls.
* Justification of the animal model, including explanation why lower species or computer models are not available
* Justification of the number of animals used

**2. Description of Procedures Performed on Live Animals**

**a. Summary of procedures to be performed**

Provide a clear and concise sequential list of **all** procedures involving the use of live animals that will be easily understood by all IACUC members. Please use non-scientific terminology. **Detailed descriptions of surgical and non-surgical but potentially painful or distressful procedures are to be included.** **Complete descriptions of procedures should be described in detail below**, including the use of any sedatives or anesthetics.

*Examples of procedures include: tail snips, surgery, tumor induction, blood collection, metabolism procedures, behavioral studies, injections of chemical/biological agents, etc. If additional procedures will be performed as part of the present protocol, please add additional items as needed.*

1.

|  |  |  |
| --- | --- | --- |
| Procedure name: | Pain Category: | Scientific purpose of the procedure |
|       | [ ]  B [ ]  C [ ]  D [ ]  E |       |
| Brief description:       |

|  |  |  |
| --- | --- | --- |
| Procedure name: | Pain Category: | Scientific purpose of the procedure: |
|       | [ ]  B [ ]  C [ ]  D [ ]  E |       |
| Brief description:       |

|  |  |  |
| --- | --- | --- |
| Procedure name: | Pain Category: | Scientific purpose of the procedure: |
|       | [ ]  B [ ]  C [ ]  D [ ]  E |       |
| Brief description:       |

**3. Substances Administered to Animals**

 **a. Experimental/study agents, therapeutic drugs, chemicals**

Identify all therapeutic drugs, experimental/study agents, chemicals, or other materials administered to live animals by injection, intubation, implantation, or surface application in the appropriate tables below.

**Species #1:**       (*Please duplicate table if agents will be administered to multiple species.)*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Name and Purpose** | **Source (specify)** | **Pharmaceutical Grade? (*If no, justify below)*** | **1. Dose (mg/kg)****2. Volume****3. Route (e.g. ip, im, po)****4. Frequency (e.g. sid, bid)** | **5. Timing of administration (e.g. pre-op, intra-op, post-op)****6. Expected duration of effect** |
| Agent:        |         | [ ]  Yes [ ]  No | 1. Dose      2. Volume      3. Route      4. Frequency       | 5. Timing      6. Duration       |
| Agent:       |         | [ ]  Yes [ ]  No | 1. Dose      2. Volume      3. Route      4. Frequency       | 5. Timing      6. Duration       |

To add additional agents, you can copy and paste the table above.

**b. Justification for the use of non-pharmacological grade agents**

Federal regulations require the use of pharmaceutical-grade medications wherever possible, even for acute and non-survival procedures. All materials administered by parenteral routes, (e.g., intravenous, intramuscular, intraperitoneal and intracranial) must be sterile unless otherwise approved by the IACUC. See the [OLAW FAQ’s](http://grants.nih.gov/grants/olaw/faqs.htm#useandmgmt_4) (F4) for rationale and elaboration.

|  |  |  |
| --- | --- | --- |
| **Drug/Agent name (from table above)** | **Justification** | **Preparation(*e.g. diluents, sterilization, pH balancing, storage and labeling*)** |
|       | [ ]  Pharmaceutical grade not available[ ]  Scientific necessity (specify)      [ ]  Other (specify)       |       |
|       | [ ]  Pharmaceutical grade not available[ ]  Scientific necessity (specify)      [ ]  Other (specify)       |       |
|       | [ ]  Pharmaceutical grade not available[ ]  Scientific necessity (specify)      [ ]  Other (specify)       |       |

 To add additional agents, you can copy and paste the table above.

 **c***.* **Biological Agents**

If you will inject transplantable tumors, cell lines, blood products, or other biological materials into animals you must attach documentation of testing for murine pathogen viruses. The attending or consulting veterinarian will provide further information regarding testing requirements.

 Study Conducted at Animal Biosafety Level: [ ]  1 [ ]  2

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Agent****Name** | **Source** | **Viral****testing date** | **Dose** | **Route** | **Volume** | **Diluent/****Media** | **Frequency****of injection** |
|       |       |       |       |       |       |       |       |
|       |       |       |       |       |       |       |       |
|       |       |       |       |       |       |       |       |
|       |       |       |       |       |       |       |       |

*NOTE:* Any protocol involving the introduction of pathogens into animal subjects should be first approved by the Institutional Biosafety Committee (“IBC”). IACUC approval will not be granted until IBC approval is in place. Any missing sections above need to be justified in the space below:

**4. Animal Numbers**

**List all animals including strain, sex, etc.**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Species** | **Strain** | **Sex** | **Age/****Type** | **Total # to be used1** | **USDA pain category1** |
|       |       |       |       |       |       |
|       |       |       |       |       |       |
|       |       |       |       |       |       |
| **Total # of animals**  |       |       |

1 Indicate the appropriate pain category based on the USDA Pain Category Classifications and Examples and the approximate number of animals in each category. If multiple procedures will be performed on an animal, the animal is placed in the category appropriate for the most painful/distressful procedure. Create separate groups for each different species and pain category.

**5. Animal Use Justification**

**a. Justification for the number of animals requested for each species listed above.**

 Describe the strategy used to determine the number of animals required for the experiments described in this protocol. Statistical power analyses should be used to justify animal numbers whenever possible.

**Provide an explanation of the justification of the animal numbers**:

**Pilot study or preliminary project – Group variances unknown**

*Describe the information used to estimate how many animals are needed.*

**Group Sizes determined statistically- power analysis**

*Describe the statistical analysis used to estimate the number of animals needed (n). This is usually based on the expected size of the treatment effect, the variance associated with the measurement, and the desired statistical power.*

**Group sizes based on quantity of harvested cells or amount of tissue required**

*Describe how the amount of tissue or cells required was determined and explain how much tissue is needed based on the number of experiments you will conduct and how much tissue you expect to obtain from each animal.*

*Example: Need 10 g tissue. Can get 2 g tissue per animal = 5 animals required*

[ ]  **Other**

*Please describe alternate method for sample size determination.*

 **b. Justification of the Proposed Animal Model(s).**

 **Are there lower species or non-animal alternatives available to accomplish your goals?**

 [ ]  yes [ ]  no

If yes, provide a brief narrative as to why those alternatives are not being used.

**6. Animal Procurement**

**a. Source(s) of animals**:

[ ]  Commercial Vendor (specify):

 USDA approved vendor? [ ]  yes [ ]  no

[ ]  Non-Commercial (e.g. academic) Source (specify):

*Note: All mice and rats entering TCU’s Animal Care Facilities from a noncommercial source (such as an academic institution) should be quarantined and tested before being released for project use. Please contact the Facilities Manager if you have questions.*

**7. Animal Husbandry**

* 1. **Housing Location/Facility** (Check all that apply)

[ ]  TCU Vivarium

[ ]  TCU Bat Facility

[ ]  TCU Indoor Aquatic Facility

[ ]  TCU Outdoor Aquatic Facility

[ ]  Other *(specify)*:

**b. Social Housing** (*Check all that apply*)

*Social animals must be housed in stable pairs or groups of compatible individuals unless they must be housed alone for experimental reasons or because of social incompatibility. If both group and single caging will be used, provide specifics in 7.f.*

[ ]  Group housing [ ]  Single housing

Justify the need for single housing.

**c. Food and Water:**

*If a non-standard diet will be used, provide specifics.*

[ ]  Standard diet [ ]  Non-standard diet

[ ]  Food/Water Restrictions

Justify need for food/water restrictions

**d. Enrichment:**

Is it acceptable for staff to provide standard enrichment as appropriate for the species (e.g. chews, toys, and nesting materials)?

[ ] Yes [ ] No

Justify if standard enrichment is not allowed.

**e. Identification**

How will individual animals be identified? (*Check all that apply*.)

[ ]  No individual identification will be used

[ ]  Ear tags

[ ]  Bird leg bands

[ ]  Ear punch

[ ]  Temporary marker (e.g. Sharpie)

[ ]  Subcutaneous RFID microchip *(please describe in Procedures – question 3)*

[ ]  Other method *(please describe in Procedures – question 3)*

**8. Animal Transport**

**a. Will live animals be transported outside of the animal care facility?** [ ]  Yes  [ ]  No

If *“yes,” provide the procedure used to transport animals including the route and elevator(s) to be used and complete b below)*

**b. Will animals be transported outside of the animal care facility and then returned to their housing room?**[ ]  Yes [ ]  No

*If “yes,” please justify why the procedures could not be performed within the animal facility and describe the containment measures that will be used to minimize the risk of introducing pathogenic agents from the lab back into the animal facility.*

**9. Emergency Treatment**

*In an emergency, animals will be treated to relieve suffering and preserve life, or if necessary, euthanized. In the event that contact with the PI is not possible, staff will do their best to follow the parameters listed below.*

[ ]  No therapeutic restrictions exist.

[ ]  Do not use the following medications (e.g., corticosteroids, antihistamines, antibiotics):

**10. Humane Endpoint Criteria for Euthanasia**

**a. Monitoring of animals**

*Individuals who will be responsible for monitoring animals must be trained to assess and recognize animal pain or distress.*

i. Lab personnel who will be responsible for monitoring animals.

ii. How often will this be done?

Even though euthanasia may not be planned for a particular project, the IACUC requires establishing both humane endpoints for a project and criteria to euthanize animal(s) prior to the end of the experiment in the event that the animal’s condition falls outside the anticipated experimental parameters. Please define both the humane endpoints and criteria to euthanize animal(s) on this protocol for all animals from time of receipt to their final disposition.

 The following signs of ill health will be used as euthanasia criteria:

|  |  |
| --- | --- |
| **Clinical Observation** | **Applicable to this project** |
| Clinical condition that does not respond to treatment (e.g. infected surgical site) | [ ]  |
| Delayed wound healing, dehiscence of surgical site | [ ]  |
| Difficulty in ambulation which render animal unable to access food/water | [ ]  |
| Persistent and progressive dermatitis or self-trauma | [ ]  |
| CNS signs such as tremors, seizures, circles that were not anticipated by the study plan | [ ]  |
| Anorexia >48 hours, other lesions interfering with eating or drinking | [ ]  |
| Sudden behavioral change (e.g. aggression, guarding, hiding) | [ ]  |
| Weight loss of 20% or more from baseline at the start of the experiment or as compared to age/gender/strain-matched controls | [ ]  |
| Markedly discolored urine, excessive urine, or no urine | [ ]  |
| Severe or refractory diarrhea or decreased fecal output > 48 hours | [ ]  |
| Dehydration unresponsive to oral or parental therapy | [ ]  |
| Rough hair coat, hunched posture, distended abdomen, reluctance to move, or lethargy | [ ]  |
| Respiratory signs such as labored breathing, wheezing, or copious nasal discharge | [ ]  |
| Hemorrhage (blood loss) from any site that is estimated to be >10% total circulating blood volume | [ ]  |
| Any condition that a veterinarian (or their designee) deems serve enough to warrant euthanizing the animal and/or animals found in a moribund state | [ ]  |
| Additional humane endpoints: | [ ]  |
| Additional criteria for euthanasia: | [ ]  |

11. Disposition of Animals (*Check all that apply)*

 **Euthanasia**

*Briefly describe the primary and, where applicable, secondary methods of euthanasia for each species. A secondary method is a second procedure that is used to confirm euthanasia. (Example: administration of an anesthetic as primary method followed by thoracotomy as a secondary method)*

**Primary method:**

|  |  |
| --- | --- |
| **Chemical Method** | **Physical Method** |
| [ ]  CO2 inhalation 1 | [ ]  Cervical Dislocation |
| [ ]  Inhaled Anesthetics 1 | [ ]  Decapitation |
| [ ]  Injectable Pharmaceutical Agents 2 | [ ]  Exsanguination Under Anesthesia |
|  Name of Pharmaceutical Agent:       |  |
|  [ ]  Immersion in MS-222 | [ ]  Hypothermia (neonates only) |
| [ ]  Other | [ ]  Pithing |
| Describe:       |

 1 Secondary method of euthanasia is required

 2 If a Pharmaceutical Agent it to be used, please list in Section 4 (Substances Administered to Animals)

**Secondary Method:**

|  |  |
| --- | --- |
| [ ]  Bilateral Thoracotomy  | [ ]  Cervical Dislocation |
| [ ]  Exsanguination | [ ]  Decapitation |
| [ ]  Other |  |
| Describe:       |

[ ]  **Methods are consistent with the current** [***AVMA Guidelines on Euthanasia***](https://www.avma.org/KB/Policies/Pages/Euthanasia-Guidelines.aspx)*.* *Any deviation must be*

 *justified for scientific or medical reasons.*

 Justify any method that is not consistent with current AVMA guidelines

[ ]  **Animals will/may become moribund and die before they can be humanely euthanized**.

 *Death of animals is a planned experimental endpoint (e.g. toxicity testing), or there is a likelihood that animals may/will become moribund and die (e.g. sepsis studies, organ failure studies).*

1. Provide a scientific justification,
2. Estimate how many (i.e. rate or percentage) will die at the end of the experiment, and
3. Indicate the procedures that will be used to minimize non-euthanasia deaths.

[ ]  **Animals will be transferred to another protocol.**

Provide details*:*

[ ]  **Other**

 Provide details*:*

**12. Assurance that the Proposed Work Does not Unnecessarily Duplicate Previously Published Work on the Same Topic**

In accordance with USDA regulations, PHS [9 CFR Part 2.31 (8)] and the Animal Welfare Act, I have conducted a literature search covering the period **from       to** using the following databases and keywords.

**Keywords** *(Scientific search terms related to the proposed model)*

**Databases** *(Minimum of two required)*

      and

**[ ]  I have concluded that the activities described in this protocol are not unnecessarily duplicative of previous experiments, including my own.**

*Please note: OVID, Medline and PubMed search engines use the same database. You may use one of these databases plus one other database, such as Agricola.* Consider contacting a TCU librarian to assist in the search. Other useful tools include the Animal Welfare Information Center (AWIC), the UC-Davis Center for Animal Alternatives, Altweb at Johns Hopkins, and Altbib.

**13. Search for Alternatives to Painful/Distressful Procedures**

 **[ ]  This study does not involve potentially painful or distressful procedures.**

 **[ ]  No alternatives exist. This must be documented by completing the following:**

 I certify that I have reviewed the pertinent sources and have found no valid alternatives to any of the proposed procedures which may cause more than momentary pain or distress. The methods and sources used in my searches included the following databases and keywords.

Please document your searches for alternatives below. Please document separate searches for each painful or distressful procedure. A minimum of two different databases are required.

*Skin and body cavity penetrations (laparotomy, thoracotomy, craniotomy, and entry into a joint space) are examples of procedures considered to be potentially painful. Prolonged restraint and procedures that result in limited mobility, malaise, etc. are examples of procedures considered to be potentially distressful. Refer to the procedure list (item 3b, above) for a list of potentially painful/distressful procedures.*

|  |  |
| --- | --- |
| Procedure 1: |        |
| Databases searched: | Keywords used: | Years searched: | Date search was performed: |
|       and       |       |       through      |       |
| Narrative:       |

|  |  |
| --- | --- |
| Procedure 2: |        |
| Databases searched: | Keywords used: | Years searched: | Date search was performed: |
|       and       |       |       through      |       |
| Narrative:       |

|  |  |
| --- | --- |
| Procedure 3: |        |
| Databases searched: | Keywords used: | Years searched: | Date search was performed: |
|       and       |       |       through      |       |
| Narrative:       |

 To add additional searches, you can copy and paste the table above.

[ ]  **Consultation with colleagues**

*Provide names, affiliations, credentials, and dates of contact. Describe the colleague’s area of expertise and why this colleague is qualified to provide an opinion on alternatives to the proposed painful/distressful procedures.*

[ ]  **Other information services utilized.**

*Elaborate, providing specific information.*

[ ]  **Alternatives exist, but are not appropriate for these studies.**

*Elaborate, providing specific information.*

**Principal Investigator Assurance**

**By signing below, I certify to the following:**

* The project described herein will be conducted in accordance with applicable TCU policies and procedures, the USDA Animal Welfare Act and implementing regulations (as amended from time to time), the *Guide for the Care and Use of Laboratory Animals, 8th edition*, and all other applicable federal and state laws and regulations (collectively “Applicable Law”)
* I have a working knowledge of Applicable Law
* I will ensure that proper procedures for animal handling, administration of anesthetics and analgesics, and American Veterinary Medical Association (AVMA) recommended methods of euthanasia are used in this project.
* All personnel who work with animals under this protocol have received, or will receive, appropriate training in protocol procedures and animal handling methods prior to working with animals.
* All experiments involving live animals will be performed only by the qualified individuals listed in this protocol and individuals not listed in this protocol will not participate in the protocol experiments.
* Procedures on experimental animals described in this IACUC protocol accurately reflect those described in the funding applications and awards, if externally supported.
* I and all personnel have read and will comply with any pertinent safety information, IACUC requirements, and security procedures.
* I will maintain records of all animals and the procedures carried out throughout the entire term of my project.
* As Principal Investigator, I am aware that I have the ultimate responsibility, on a day-to-day basis, for the proper care and treatment of the laboratory animals.

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

Signature of Principal Investigator Date

**Study Personnel Qualifications**

To add additional personnel, add a new row by clicking the outside of the bracket [at the top right of the table and hit enter. Then copy the information from the table and paste into the new row below.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|

|  |
| --- |
| **Personnel Information** |
| Name |       |  [ ]  PI | Degree |       [ ]  PhD [ ]  MD  |
|  [ ]  TCU Faculty |  [ ]  TCU Staff/Employee | Title |        |
|  [ ]  TCU Student |  [ ]  Undergraduate |  [ ]  Graduate Student | [ ]  Post Doc |
|  [ ]  Non-TCU personnel | If non-TCU, name of institution |       |
| **Qualifications/Relevant Experience** |
| Describe relevant qualifications and experience including number of years’ experience working with each species below. |
|      [ ] Individual has limited or no experience working with animals and will complete all required training prior to working with animals including: Animal Research Orientation (i.e. Vivarium and Lab Safety Training), all relevant CITI modules, Occupational Health and Safety requirements, and any training required by PI or IACUC. |
| **Procedures to be performed** |
| [ ]  Breeding | [ ]  Euthanasia | [ ]  Surgery | [ ]  Restraint | [ ]  Injections |
| [ ]  Drug/agent administration | [ ]  Hazardous Agents | [ ]  Specimen Collection | [ ]  Other (list)        |
| **Check each species this person will be working with on this protocol** |  |  |  |  |  |
| [ ]  Mice | [ ]  Rats | [ ]  Reptiles | [ ]  Fish | [ ]  Birds | [ ]  Bats |
| [ ]  Other (list)       |

 |
|       🡸**Copy the entire table above and paste here.**  **Click here and hit enter to add a new row.** 🡺 |
|        |