PI: IACUC Number:

**NOTE:** All submissions (including revisions) must include the **LATEST VERSION** of the Word protocol template which can be obtained at [**http://www.ttuhsc.edu/sponsoredPrograms/acuc**](http://www.ttuhsc.edu/sponsoredPrograms/acuc/)**/**.

***Please do not change the questions or the format of this document***.

**I. GENERAL INFORMATION**:

1. Enter the title(s) of your study:

B. Enter an optional study identifier you would like to use to reference the study (i.e., Diabetes Study):

**II. INDICATE** the type of submission below by checking the applicable box *and follow the instructions.*

A. **INITIAL APPLICATION** – Complete this form beginning with Section III.

B. **AMENDMENT**

All changes **incorporated** into this document must be HIGHLIGHTED so that changes are plainly discernible (**remove** all prior highlighting - then incorporate changes for this amendment and highlight them).

1. Type of Modification (check all that apply and describe in question 2.):

(a) Personnel Changes

(b) Title Changes (revise Section I.A. to reflect all applicable titles)

(c) Location Changes

(d) Species Changes (if adding a different species, check (e) as well)

(e) Animal Number Changes

(f) Procedure Changes (update X. - Literature Search section)

(g) Other (Describe in question 2.)

2. Amendment Summary:

Briefly describe the type of modification(s) you indicated in B.1. (i.e., *add a species, change of anesthe*sia).

To incorporate the detailed description of the changes you indicated in B.2., proceed to Section III and review the

entire document, making changes as needed (be sure to highlight **all** new changes). Do not delete information that

is still applicable to your study.

C. **ANNUAL STATUS REPORT**

All changes incorporated into this document must be HIGHLIGHTED so that changes are plainly discernible (remove all prior highlighting - then highlight all changes you make in this submission).

1. Check the applicable statement below

(**prior** to selecting (a) or (b), re*view Sections III through XXI*):

(a) I request continuation of this protocol **without** change (if selected-complete C1-C5)

(b) I request continuation of this protocol **with** changes (complete C1-C5 and Section II.B and incorporate changes in the applicable section(s) [III-XXII]). Sections III-XXI should reflect currently approved study information, as well as, the changes you identified in Section II.B. (be sure to highlight changes)

2. Provide the number of animals used within the last 12 months (indicating animals lost as well). If needed, list each species and/or experiment divided by a comma.

3. Provide a summary of study progress made over the last 12 months.

4. Provide a summary of the goals for the upcoming 12 months.

5 If the agency which funds your project requires a progress report, please attach as a pdf document.

D. **3-YEAR RENEWAL**

All changes incorporated into this document must be HIGHLIGHTED so that changes are plainly discernible (remove all prior highlighting - then highlight new changes you make in this submission).

1. Provide a summary of study progress over the last 12 months. Also, provide the number of animals used within the last 12 months (discuss all animals who unexpectedly died or were humanely euthanized prior to the experimental endpoint. Provide any changes made to assure successful experimental outcomes and whether animals were replaced**)**. If needed, list each species divided by a comma.

2. If the agency which funds your project requires a progress report, please attach as a pdf document.

3. Provide a summary of the goals for the upcoming 12 months and briefly **describe all changes** being made to the protocol:

To incorporate the detailed description of the changes, proceed to Section III, review the entire document and

make changes as necessary.

**III. LAY SUMMARY**:

Provide a **nontechnical** description of the project related to the significance of the animal use to the scientific objective. An effective lay summary includes a **general overview** of the intended use of animals that provides a nonscientist with an understanding of the scientific question being asked, the **species** used and the anticipated benefit. An acceptable Lay Summary should not normally exceed 250 words.

The Flesch-Kincaid Grade Level test within the Microsoft Word spelling and grammar checker will evaluate the grade level readability **(8th-10th grade level recommended**). Although, it is understood that some technical terms cannot be simplified we suggest the following websites if having difficulty simplifying scientific terms: <http://humansubjects.stanford.edu/general/glossary.html>

The lay summary needs to answer four basic questions:

1) What is the problem being studied?

2) What species of animal will be used to study the problem?

3) In very general terms, what will happen to the animals?

4) If successful, how will your study benefit mankind or the animal kingdom (or both)?

**IV. DEPARTMENTS**:

List of Departments associated with this study (if more than one department, indicate primary first:

|  |  |  |
| --- | --- | --- |
| **Department** | **Center**  **(AB, AM, EL or L)** | **School**  **(i.e., SOM, SOP)** |
|  |  |  |
|  |  |  |

**V. KEY STUDY PERSONNEL (KSP)** To add additional rows to a table, tab through the last column of the table:

Principal Investigator for the study:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Name (first, initial, last):** | **Degree** | **Ctr/School/ Dept:** | **Email Address** | **Phone #** | **Affiliation (ie. TTUHSC or Company if outside collaborator)** |
|  |  |  |  |  |  |

Additional Investigators for the study:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Name (first, initial, last):** | **Degree** | **Ctr/School/ Dept:** | **Email Address** | **Phone #** | **Affiliation** |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

Research Support Staff for the study:

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Name (first, initial, last):** | **Degree** | **Indicate Role (ie. Technician)** | **Ctr/School/ Dept:** | **Email Address** | **Phone #** | **Affiliation** |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

Study Contact (typically a Study Coordinator): Input information below for any person *you wish to receive the same system notifications as the PI.*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Name (first, initial, last):** | **Degree** | **Ctr/School/ Dept:** | **Email Address** | **Phone #** | **Affiliation** |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

Designated Department Approval: If applicable, a*dd the name of the individual authorized to approve and sign off on this protocol from your Department (e.g. Department Chair or Dean)*

|  |  |
| --- | --- |
| **Name (first, initial, last):** | **Center/School/Department:** |
|  |  |
|  |  |

**VI. PI and RESEARCH SUPPORT STAFF EDUCATION/EXPERIENCE**:

*Note: All individuals involved in this project must be appropriately qualified and trained in the proposed animal care and use.*

For each person: describe any education, training, and experience each has received in the procedures applicable to this project and animal species (e.g. handling, restraint, daily husbandry, injections, blood collection, anesthesia monitoring, monitoring for pain/distress, surgery, surgery prep, postsurgical care, euthanasia, etc.).

**VII. IACUC PROTOCOL**:

What is the purpose of this protocol? *Select only one: These topics cannot be combined into one IACUC Application/Protocol.*

(1) Experimental.

(2) Breeding Colony.

(3) Training, Instructional, and/or Coursework

1. If any study material (i.e., handouts, slides, Powerpoint presentations, etc.) will be used to conduct this training, please attach to your submission. They will be considered a part of the protocol and therefore protected as a ‘Confidential Medical Committee Document’. Materials can be accepted after protocol is approved.

**VIII. STUDY SPONSOR**:

Indicate the Study Sponsor:

|  |  |  |
| --- | --- | --- |
|  | **Sponsor** | **Grant Number** |
| Federal (NIH/NSF) |  |  |
| *Attach grant document(s) related to animal use as pdf docs.* |  |  |
| Federal (DOD) |  |  |
|  |  |  |
| Pharmaceutical |  |  |
|  |  |  |
|  |  |  |
| Private – Non-Profit |  |  |
|  |  |  |
|  |  |  |
| State |  |  |
|  |  |  |
|  |  |  |
| Internal |  |  |
|  |  |  |
|  |  |  |

**IX.** **ANIMAL SPECIES AND NUMBERS**:

A. Use common name (i.e., mouse, mouse-transgenic, rat, etc.NOT C57). Copy and paste a table as needed.

|  |  |
| --- | --- |
| **Species List:** |  |
| Species Name |  |
| Sex: |  |
| Age: |  |
| Weight: |  |
| Total Number RequestedΔ |  |

|  |  |
| --- | --- |
| **Species List:** |  |
| Species Name |  |
| Sex: |  |
| Age: |  |
| Weight: |  |
| Total Number RequestedΔ |  |

Overall total number of animals requested here must match total in item D below (Animal Numbers Justification). For a breeding protocol, indicate total number of animals as individual breeders not as pairs (i.e., 20 breeders not 10 pairs).

B. TRANSGENIC, KNOCK-OUT/IN, GENETIC MODIFICATION

1. Will transgenic or other genetically modified animals be used on this protocol (ie, Nude mice, SCID mice, etc.)? *Select only one:*

(a) Yes. List the expected phenotype for each transgenic mouse listed in table IX.A above and please

provide a web link to the animal description):\_\_\_\_\_\_\_\_\_\_

(b) No. Proceed to C.

C. ANIMAL USE JUSTIFICATION:

1. Why must living animals be used?

2. Provide justification of every species selected (*Cost is not a justification)*.

D. ANIMAL NUMBERS JUSTIFICATION:

1. How was the number of animals requested in IX.A Table(s) determined?

The following are examples of acceptable ways of determining group sizes.

**Please check all that apply**.

(a) Previous experience with the assay or experiment. Explain how previous experiments have led to current numbers.

(b) Information from literature about variability of results.

(c) Power analysis. Include the magnitude of expected change and explain how this was determined.

(d) Numbers needed to provide sufficient tissue for a single assay.

(e) These are best estimates until pilot studies are complete.

(f) Other: Please explain:

1. Describe the methods used to determine the number of animals that are needed for each group. Group sizes are expected to represent the **minimum** number of animals that are needed to achieve the goals of this study. If the numbers used for different groups were determined in different ways, include an explanation for all the groups. The IACUC prefers a breakdown be provided in a formula or in a table format. An easy power analysis for sample size calculator can be accessed at [**http://www.danielsoper.com/statcalc/calc47.aspx**](http://www.danielsoper.com/statcalc/calc47.aspx). This calculator requires knowledge of effect size, which can be determined with knowledge of a similar studies’ mean and std using the calculator at [**http://www.danielsoper.com/statcalc/calc48.aspx**](http://www.danielsoper.com/statcalc/calc48.aspx).

If this is a breeding protocol, provide justification for the number of breeders (not pairs) needed.

**X. LITERATURE SEARCH**:

A. An up-to-date literature search is required by Federal and non-Federal oversight organizations in order to satisfy the 3 R’s (**REDUCTION** in number of animals necessary to obtain valid scientific results, **REFINEMENT** of techniques and procedures that reduce pain or distress, and **REPLACEMENT** of animals with non-animal techniques or alternate animal models lower on the phylogenetic scale that would still provide the data needed).

The IACUC recommends you use the literature search worksheet available at: <http://www.ttuhsc.edu/sponsoredprograms/acuc/documents/Worksheet_for_altwksht_revised_by_Dawn.docx>

Databases used should be appropriate for the area of study. Please indicate all databases consulted.

For database descriptions please refer to the following:

[http://www.ttuhsc.edu/research/hrpo/acuc/documents/Worksheet\_for\_altwksht\_revised\_by\_Dawn.docx](http://www.ttuhsc.edu/research/hrpo/acuc/documents/Worksheet_for_altwksht_revised_by_Dawn.docx%20)  or feel

free to contact the TTUHSC librarians for assistance.

Please indicate the databases used below (at least two):

(1) Pubmed/Medline

(2) Embase

(3) Scopus

(4) ISI Web of Knowledge/Biosis

(5) Animal Welfare Information Center (AWIC)

(6) Toxnet/Toxline

(7) NCBI

(8) ALTBIB

(9) Agricola

(10) Other (Specify):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

B.

|  |  |
| --- | --- |
| Provide **Keywords/Concepts** used in literature search |  |
| **Reduction/Refinement Search Phase** (i.e., analgesic or analgesia or painkiller; sedative; tranquilizer; technique or method or procedure; anesthetic or anaesthetic; monitor or evaluate or supervise; restrain or immobilize or restrict; positive reinforcement or animal training; housing or facility or caging; endpoint or biomarker; environment or enrichment; pain, model, well-being) | |
|  | |
| **Replacement Search Phase** (i.e., ‘vitro’ or culture or artificial; tissue or cell or organ; insect or arachnid or invertebrate; fish or mollusk or cephalopod; simulation or digital image or interactive; mannequin or manikin or model; cadaver, alternative\* the species being used, other species | |
|  | |

C. Date Search Conducted:

D. Database year(s) of coverage: to (i.e., 1921 to 2011).

Literature Searches should be updated every three years or when major (ie. procedural) amendments are submitted.

E. Other Methods/Sources Used to determine the availability of alternatives

(useful in supporting/rebuking potential alternatives found in the search):

**Check all that apply**.

(1) Scientific Meetings (Specify):

(2) Consultation with Expert(s) [i.e., lab animal vet, animal welfare specialist, statistician, other investigator]

**Specify:**

(3) Other Information Services

**Specify:**

F. Search Results:

1. Duplication:

(a) No **unnecessary** duplication of previous experiments found.

(b) Necessary duplication exists, but is not appropriate for these studies. Please explain:

(c) Other: Please explain:

2. Alternatives/Narrative of Literature Search:

(a) Did you find any ways to reduce animal numbers? Describe why you can or cannot use them here:

(b) Did you find any methods that minimize pain or distress? Describe why you can or cannot use them here:

(c) Can you replace your animal model with a non-animal model or less sentient species?

Why or why not?

Additional Comments:

**XI.** **GENERAL STUDY INFORMATION**:

1. Does this protocol involve the use of client-owned animals? *Select only one:*

(1) Yes. A pdf of the **consent form** that the owner(s) sign **must** be attached to the submission.

   (2) No.

1. What does this protocol involve? *Check all that apply:*

(1) *In Vitro* studies [no procedures conducted - all animals euthanized and tissue removed].

(2) *In Vivo* studies.[procedures conducted on animal while alive]

1. In which LARC vivarium/facility will the animals be housed?

Abilene.

Amarillo.

El Paso.

Lubbock.

1. Will animal experimentation, surgery, or instruction be conducted somewhere other than LARC rooms? *Select only one:*

(1) Yes. Provide location below.

(2) No.

a. If Yes, provide laboratory location. To avoid contamination it is highly recommended that animals **not** return to the LARC.

|  |  |  |
| --- | --- | --- |
| Campus: | Bldg: | Rm #: |

b. If Yes, and animals will be returned to the LARC, provide LARC location below that will receive these animals:

|  |  |  |
| --- | --- | --- |
| Campus: | Bldg: | Rm #: |

1. Will animals be transported by protocol staff (Principal investigator or any other protocol staff) in a motorized vehicle, cart, etc.? *Select only one:*

(1) Yes. [You **must** agree to adhere to the LARC transportation SOP.]

(2) No.

1. Housing **Outside** LARC Facility:

*Note: If animals will be held outside of the primary housing area, you* ***must*** *provide an appropriate scientific justification. The IACUC* ***must*** *approve the area as a housing facility and is required to conduct periodic inspection of that facility. The facility* ***must*** *meet all Federal guidelines, as appropriate.*

*Note: The provision of adequate veterinary care includes Principle Investigator’s posting LARC contact information, IBC Licenses, and IACUC “whistleblower” information to assure prompt care during illness observations and/or emergencies.*

*Note: It is the Principal Investigator’s responsibility to ensure animals are cared for by appropriately trained personnel approved on this protocol; animals must be observed every day, including weekends and holidays; to monitor and document (e.g. log sheets) daily the high and low temperatures and humidity levels when animals are present. The Principal Investigator is also responsible to ensure a defined light cycle, air exchange rate and room air pressure differential (positive or negative). Contact the LARC for recommendations on monitoring devices and log sheets for recording monitoring data.*

1. Will any live animals (EXCEPT the laboratory mouse, rat or bird) be housed outside the LARC facility for more than **12 hours (USDA-regulated species)**? *Select only one:*

(a) Yes. Provide location below and then proceed to question # 2.

|  |  |  |
| --- | --- | --- |
| Campus: | Bldg: | Rm #: |

(b) No. Proceed to question # 2

2. Will any live animals (any species) be housed outside the LARC facility for more than **24 hours** (OLAW regulated species)? *Select only one:*

(a) Yes. Provide location below and then proceed to question # 3.

|  |  |  |
| --- | --- | --- |
| Campus: | Bldg: | Rm #: |

(b) No. Proceed to G.

If you checked **both** F.1 and F.2 as ‘No’, skip to ‘G’, if you checked ‘yes’ to either, address # 3 - 10 below.

3. Indicate how long the animals will be outside of the LARC facility?

4. Provide a brief scientific justification for animal housing outside the LARC facility. *Convenience is not an appropriate justification*.

5. Describe the caging (include feeders and watering devices).

6. Describe what food and water will be used (include storage details).

7. Describe what bedding will be used (include storage details).

8. Describe the sanitation procedures (include cage-change frequency, washing/disinfection procedures, etc).

9. Describe the procedure for disposal of soiled bedding, refuse, and animal carcasses.

10. Describe procedures for provision of weekend and holiday care.

G. SPECIAL HOUSING OR ABNORMAL ENVIRONMENTAL CONDITIONS (Housing within the LARC):

1. Will special housing or abnormal environmental conditions be required within the LARC?

(a) Yes. Complete # 2 – 4 below. If not applicable indicate N/A.

(b) No. Proceed to H.

2. For each species listed, describe the special or abnormal housing and husbandry requirements.

3. Indicate all abnormal conditions for temperature, humidity, light cycle, cage type or size, use of cage filter-tops, change in frequency of cage/bedding changes, etc*.*

4. Indicate below any special instructions for Animal Care staffand/or Veterinary support care required to maintain these animals.

H. DIETARY MANIPULATIONS:

*Note: Caloric or nutrient restrictions include rodents fasted beyond* ***3 hours****, neonates of any species fasted beyond* ***3 hours****, and/or animals of other species fasted beyond* ***48 hours****. Overnight fasting of animals subject to anesthesia and surgical procedures need not be described in this section (see Surgery below).*

1. Are special diets and/or dietary restrictions (other than fluids) required?

(a) Yes. Complete # 2 - 7. If not applicable indicate N/A.

(b) No. Proceed to I.

2. If rodents will be fasted beyond 3 hours, neonates of any species fasted beyond 3 hours, and/or animals of other species fasted beyond 48 hours, explain and justify why this is needed.

3. For each species listed, describe any dietary manipulation (e.g. caloric or nutrient restrictions or excesses) and/or special feeding requirement.

4. Describe how long the animals will be on the diet manipulation, experimental diet, or special feeding requirement.

5. Describe any pain or distress that animals may experience due to dietary manipulations. Justify the need for induction of pain or distress and explain the nature and level of pain or distress expected.

6. Describe how animal health will be monitored (e.g. body weight, blood urea nitrogen, urine/fecal output, food/fluid consumed, hydration status, etc.)*.*

7. Describe the anticipated impact of the dietary restriction on the weight of the animal. Include the method and frequency of monitoring the animal’s weight loss.

I. FLUID RESTRICTIONS**:**

*Note: This section is to include description of fluid restriction providing less than daily ad lib fluid intake, and that providing equal daily ad lib intake, but scheduled during the day to create periods of thirst.*

1. Are fluid restrictions required?

(a) Yes. Complete # 2 - 4. If not applicable indicate N/A.

(b) No. Proceed to J.

2. Describe the fluid restriction (e.g. describe providing less than and/or equal, but scheduled, daily ad lib intake, or if fluids are withheld for more than 24 hours, 5 hours for rodents), the schedule and delivery route for providing fluids, and how long will the animals be on fluid restriction.

3. Describe how animal health will be monitored (e.g. body weight, blood urea nitrogen, urine/fecal output, food/fluid consumed, hydration status, etc.)*.*

4. Describe the anticipated impact of the fluid restriction on the weight of the animal. Include the method and frequency of monitoring the animal’s weight loss*.*

J. COLLECTION OF BLOOD OR OTHER BODY FLUIDS (other than Ascites):

1. Will blood or other bodily fluids be collected while the animal is alive? *Select only one:*

(a) Yes. Complete # 2 - 3. If not applicable indicate N/A.

(b) No. Proceed to K.

2.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Species:** | **Fluid:** | **Frequency:** | **Volume:** | **Method of Collection:** |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

1. Will the animals be anesthetized or restrained or sedated during the collection of blood or other body fluids? *Select only one:*

(1) Yes. If Yes, all anesthetics and analgesics must be disclosed in the Anesthetics/Analgesics section **XVIII.**

(2) No. If No, provide a BRIEF justification here:

K. ANIMAL RESTRAINT:

*Note: This section is to include only those procedures that require prolonged restraint (e.g. longer than* ***15 minutes****). Brief restraint for the purpose of performing routine clinical or experimental procedures need not be described.*

1. Are conscious animals going to be physically restrained for longer than fifteen (15) minutes? *Select only one:*

(a) Yes. Complete # 2 - 7. If not applicable indicate N/A.

(b) No. Proceed to L.

2. For each species listed, describe what type of restraint will be used (e.g. hand, restraint device, tether, other).

3. Describe how long and at what frequency the animals will be restrained.

4. Describe how animals will be acclimated to the restraint device.

5. Describe how the animals will be monitored during the restraint experience.

6. Describe steps taken to minimize any distress from the restraint experience.

7. Describe the criteria that will be used to determine when the animals should be released from the restraint device.

L. TOXICOLOGICAL STUDY:

Note:The IACUC defines a toxicological study as one in which the primary aim is to assess the ability of an agent to cause adverse biochemical or physiologic effects. This applies to both range-finding studies as well as studies designed to determine product safety.

1. Is this a toxicological study? *Select only one*

(a) Yes.

(b) No.

**XII. STUDY PROCEDURES**:

If a breeding colony protocol **only**, state so here and skip to the next section.

A. What are the objectives/specific aims of this study?

B. Describe what will be done to the animals while they are alive in the sequence it will be done. Include all steps involving the animals in the project and the drugs or other treatments that will be imposed on the animals. (Include a step-by-step description of all procedures, treatments, etc, as well as dose, route, and frequency of administration of experimental drugs or other treatments.) List all expected effects on animals of any experimental drug or other treatments and describe animal care given during and after procedures

C. Describe the established criteria and process for timely intervention, removal of animals from a study, and/or euthanasia if painful or stressful outcomes should occur.

D. If you are using animals only as a source of tissue, state which tissues will be harvested and the purpose for the tissue.

**XIII. BREEDING COLONY INFORMATION**:  **Not Applicable (skip to next section)**

A. Provide any species/strain information for the animals to be used.

B. Explain and justify the need for this breeding colony (e.g. animals are not commercially available; there may be specific requirements that cannot be met by a commercial breeder; physiological status is too fragile to withstand shipment.) *Cost is not a justification.*

C. Provide a complete description of what will be done. **Include the following**: average daily census of breeders; where breeders will come from; what ages will the breeders be; what will be done with retired breeders; how many breeders and how many young will be housed in one cage; what breeding system will be used (# of females per male, continuous versus interrupted mating); weaning age; separation of animals at weaning; method for collection of tissue sample for genotype analysis; and methods for identification of individual animals (e.g. earnotching).

D. What is the estimated number of progeny that will be used for experiments under Animal Use protocols?

E. What will be the estimated number of progeny that cannot be used in experiments because they are the wrong genotype or sex? These animals must be removed from this protocol in accordance with the IACUC Breeding Colony Policy # 3 at <http://www.ttuhsc.edu/sponsoredprograms/acuc/policyindex.aspx>.

F. Will genotyping be done?

(1) Yes.

(2) No.

If yes, describe the method of tissue collection which will be used for genotype analysis (i.e. refer to IACUC Policy #16 “Tail Snipping and Tail Biopsy for Rodents” at <http://www.ttuhsc.edu/sponsoredprograms/acuc/policyindex.aspx>.).

**XIV. IMMUNIZATION AND ANTIBODY PRODUCTION:    Not Applicable (skip to next section)**

**(including Ascites)**

A. Indicate what antigen(s) will be used.

B. Indicate what vehicle/adjuvant(s) will be used for the initial immunization and for subsequent immunizations (booster injections).

C. Indicate the route and sites(s) of immunization (include total and per site injection volumes and frequency of immunization).

D. If animals will be anesthetized, restrained, or sedated during the procedure, supply drug, dosage, and route in Section XVIII.

**Not Applicable**

**E. Ascites/Hybridoma Production**:

1. Are ascites/hybridomas going to be produced? Select only one:

   (a) Yes.

   (b) No.

2. Will hybridomas be produced at TTUHSC? Select only one:

   (a) Yes.

   (b) No.

If Yes, list IACUC protocol number here:

3. Will hybridomas be produced by another institution, individual, or commercial vendor?

Select only one:

   (a) Yes.

   (b) No

If Yes, provide the name of the institution, individual or commercial vendor and the protocol number under which the hybridomas will be/are being produced. The appropriate approval documentation must be attached in pdf format.

4. Justify the use of ascites rather than an alternative (e.g. tissue culture). Fluid accumulation associated with ascites should not become greater than 10% of bodyweight. Animals should be euthanized if they become moribund. Written justification must be presented in this section for larger fluid burdens where increased monitoring is required. Indicate the number of fluid collections and provide a timeline/schedule including the point of euthanasia.

5. Describe the specific procedure for ascites production (e.g. volume of ascites fluid collected per sampling, number of fluid collections per animal, any special procedures for caring for animals with ascites, how long animals with ascites are to be maintained, and a timeline or schedule for sampling including the point of euthanasia).

**XV.** **SURVIVAL SURGERY**: **Not Applicable (skip to next section)**

*Note: Survival surgery in* ***ALL*** *species* ***must*** *be conducted utilizing aseptic techniques, in areas dedicated for surgical activity, and by personnel trained in the procedure. Aseptic techniques require, but should not be limited to, use of sterile instruments, surgical gloves, and surgeon mask. Please see IACUC Policy #15 for the definition of Survival Surgery.*

*Note: Professional and technical personnel and students who perform anesthesia, analgesia, surgery, and euthanasia* ***must*** *be trained to accomplish these tasks in a humane and scientifically acceptable manner. The LARC veterinary staff is available to provide assistance with, or training in, aseptic and surgical techniques, and the proper administration of anesthesia, analgesia, and euthanasia.*

A. Will survival surgery be performed? *Select only one:*

(1) Yes.

(2) No.

B. Will the surgical procedures be performed in the LARC? *Surgery on non-rodent mammals* ***must*** *be conducted in the LARC surgery suite. PI’s are* highly encouraged to conduct surgery on rodents in the LARC surgery suite as well.

(1) Yes.

(2) No. If no, be sure to include the location in Section XI.D - E.

C. Survival Surgery procedure(s) is/are:

Major (procedures penetrating and exposing a body cavity or producing substantial impairment of physical or physiological functions)

Minor (procedures not exposing a body cavity and causing little or no physical impairment)

1. Will any animal undergo **more than one** major survival surgery procedure (see definition above)?

*Note: Multiple survival surgical procedures on a single animal* ***are discouraged*** *but may be permitted if* ***scientifically justified*** *and approved by the IACUC. Select only one:*

(1) Yes.

(2) No.

E. If animals undergo more than one major survival surgery procedure, provide an appropriate scientific justification describing any pain, distress or functional deficit that may result and how such distress will be minimized.

**Not Applicable**

F. Will analgesia be used? *Select only one:*

(1) Yes. Please list analgesic drugs in section XVIII.A.

(2) No.

If No, provide a BRIEF scientific justification here:

G. Describe the surgical procedure.

H. Describe the approximate length of time required for the surgical procedure and anesthesia.

I. Describe how long the animals will be maintained after surgery.

J. Describe the pre-operative preparation of the animal (e.g. include fasting procedure, pre-operative procedures, pre-emptive analgesia, and pre-operative medications).

K. Describe the animal monitoring procedures during the surgery (e.g. include intra-operative monitoring devices, provision or maintenance of body temperature, use of aseptic technique, anesthesia maintenance, fluid therapy, and emergency procedures).

L. Describe both short-term and long-term post-operative care procedures (e.g. animal monitoring, fluid therapy, oxygen, maintenance of body temperature, antibiotics, and analgesics).

M. Describe who will provide and coordinate post-operative care with the LARC veterinary staff:

N. Describe any adverse effects that are expected or might result from this procedure. Provide monitoring instructions, treatment methods, and endpoint criteria for humane intervention.

**XVI.** **NON-SURVIVAL SURGERY**: **Not Applicable (skip to next section)**

*Note: Non-survival surgery is defined as a surgical procedure that requires complete anesthesia (Stage IV) where the animal does not regain any level of consciousness, leading to perception of pain, prior to euthanasia. Aseptic techniques using sterile instruments are highly recommended for non-survival surgical procedures.*

*Note: Professional and technical personnel and students who perform anesthesia, analgesia, surgery, and euthanasia* ***must*** *be trained to accomplish these tasks in a humane and scientifically acceptable manner. The LARC veterinary staff is available to provide assistance with, or training in, aseptic and surgical techniques, and the proper administration of anesthesia, analgesia, and euthanasia.*

A. Describe the surgical procedure.

B. Describe the approximate length of time required for the surgical procedure and anesthesia.

C. Describe the pre-operative preparation of the animal (e.g. include fasting procedure, pre-operative procedures, and pre-operative medications).

D. Describe the animal monitoring procedures during the surgery (e.g. include intra-operative monitoring devices, provision or maintenance of body temperature, anesthesia maintenance, and fluid therapy).

**XVII.** **NON-SURGICAL PAIN AND DISTRESS DETAILS**:

A. Procedures used in this study that could potentially cause pain or distress include

Check all that apply:

Tumor or malignant cell growth

Exposure to toxic, irritating or infectious substances/agents

Addictive substances

Aversive stimuli use

Mother/infant separation

Abnormal environmental conditions

Other, describe here:

B. Will animals experience pain or distress (non-surgical) for which analgesics/anesthetics **WILL** be administered? *Select only one:*

(1) Yes.

(2) No.

C. Will animals experience pain or distress (non-surgical) for which analgesics/anesthetics **WILL NOT** be administered? *Select only one:*

(1) Yes.

(2) No.

D. If any procedure(s) will cause pain or distress and analgesia/anesthesia CANNOT be administered, list each procedure with a justification for the exclusion of analgesia/anesthesia.

E. Describe the methods for ensuring that discomfort, distress, pain and injury will be limited to that which is unavoidable in the conduct of this project (e.g. placing food and water within reach, providing additional soft bedding materials, providing supplemental warmth).

**XVIII. ANALGESICS, ANESTHETICS, TRANQUILIZERS, AND PARALYTICS**: **Not Applicable**

**(skip to next section)**

1. List all Analgesics used in the course of the study, including agents used pre-emptively and post-operatively. Also include a “Yes” or “No” indicating whether a drug is DEA controlled.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Species:** | **Analgesic Drug:** | **DEA:** | **Route:** | **Dose:** | **Frequency:** | **Monitoring:** |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

1. List all Anesthetics used during the course of the study.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Species:** | **Anesthetic Drug:** | **DEA:** | **Route:** | **Dose:** | **Frequency:** | **Monitoring:** |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

1. List all Tranquilizing Agents used during the course of the study.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Species:** | **Tranquilizing Drug:** | **DEA:** | **Route:** | **Dose:** | **Frequency:** | **Monitoring:** |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

1. List all Paralytics used during the course of the study.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Species:** | **Paralytic Drugs:** | **DEA:** | **Route:** | **Dose:** | **Frequency:** | **Monitoring:** |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

**XIX.** **ENVIRONMENTAL HEALTH AND SAFETY**:

1. Will animals be exposed to biohazardous agents (carcinogens, toxins, noxious chemicals, or other biohazardous chemicals), radioactive materials, infectious agents (malignant cells or hybridoma cells), and/or recombinate DNA? *Select only one:*

(1) Yes.

(2) No.

1. Will humans, while working with animals, be exposed to biohazardous agents (carcinogens, toxins, noxious chemicals, or other biohazardous chemicals), radioactive materials, infectious agents (malignant cells or hybridoma cells), and/or recombinate DNA? *Select only one:*

(1) Yes.

(2) No.

1. For each agent(s), indicate what major class of materials you will be using? *Check all that apply:*

The appropriate entities approval documentation **must be attached** as a pdf document.

(1) Hazardous Chemicals and Carcinogens.

(2) Radioactive Materials.

(3) Living Cells (including infectious agents, malignant cells, hybridoma cells & viruses).

(4) Recombinant DNA.

1.HAZARDOUS CHEMICALS AND CARCINOGENS:**Not Applicable (skip to next section)**

a. List substance(s), concentration, route of delivery to the animal (e.g. injection, aerosol inhalation, dermal application, other) and total amount that will be used on animals.

b. For each substance listed above, indicate route and duration of excretion from the animal. Include whether cages, bedding, carcasses, etc. are hazardous to personnel and for how long.

c. Indicate the containment equipment to be used (e.g. fume hood, Class II Type B, ducted, biological safety cabinet).

d. Indicate personal protective equipment to be used (e.g. nitrile gloves, face mask, gown, tyvek sleeves, hood, etc.).

e. Describe the decontamination and monitoring procedures necessary for the area and personnel.

f. Describe disposal requirements for the animal carcasses (e.g. place into biohazard bags, autoclave, and incinerate; hazardous chemical waste disposal).

g. Describe disposal requirements for bedding (e.g. separate bedding into biohazard bags, autoclave, and incinerate; hazardous chemical waste disposal).

*Remember to* ***attach*** *the appropriate entities approval documentation**as a pdf document.*

2. RADIOACTIVE MATERIALS: **Not Applicable (skip to next section)**

a. List radioisotope agents(s), concentration, route of delivery to the animal (e.g. injection, aerosol inhalation, dermal application, other) and total amount that will be used on animals.

b. For each agent listed above, indicate route and duration of excretion from the animal. Include whether cages, bedding, carcasses, etc. are hazardous to personnel and for how long.

c. Indicate the containment equipment to be used (e.g. fume hood, shields, etc).

d. Indicate personal protective equipment to be used (e.g. gloves, face mask, gown, tyvek sleeves, hood, etc.).

e. Describe decontamination (e.g. count-off spray) and monitoring procedures (e.g. swipe tests, Geiger counts, etc.) necessary for the area and personnel.

f. Describe disposal requirements for the animal carcasses (e.g. frozen for immediate disposal as cold/regular waste, placed in radioactive waste bags and frozen for immediate disposal as radioactive waste or storage for decay then disposal as cold/regular waste).

g. Describe disposal requirements for bedding (e.g. placed in radioactive waste bags and frozen for immediate disposal as radioactive waste or storage for decay to background).

*Remember to* ***attach*** *the appropriate entities approval documentation**as a pdf document.*

3. LIVING CELLS AND INFECTIOUS AGENTS: **Not Applicable (skip to next section)**

a. List cells/infectious agents(s), concentration, route of delivery to the animal (e.g. injection, aerosol inhalation, dermal application, other) and total amount that will be used on animals.

b. Indicate the animal biosafety level that is appropriate for the agent(s).

   ABSL-1

   ABSL-2

   ABSL-2 plus

   ABSL-3

c. For each agent listed above, indicate route and duration of excretion from the animal. Include whether cages, bedding, carcasses, etc. are hazardous to personnel and for how long.

d. Indicate the containment equipment to be used (e.g. HEPA-filtered ventilated caging, biosafety cabinet, air-flow hood, etc).

e. Indicate personal protective equipment to be used (e.g. gloves, face mask, gown, tyvek sleeves, hood, etc.).

f. Describe any special immunizations personnel need to have prior to work with these animals.

g. Describe the decontamination and monitoring procedures necessary for the area and personnel.

h. Describe disposal requirements for the animal carcasses (e.g. place into biohazard bags, autoclave, and incinerate).

i. Describe disposal requirements for bedding (e.g. separate bedding into biohazard bags, autoclave, and incinerate).

*Remember to* ***attach*** *the appropriate entities approval documentation**as a pdf document.*

4. RECOMBINANT DNA: **Not Applicable (skip to next section)**

a. List the gene and vector to be introduced into animals (e.g. creation of transgenic animals, knockout/ins, DNA vaccinations, etc).

b. List the species of animal and the expected phenotype (e.g. immunodeficient, disease resistant, toothless, etc.).

c. Based on the expected phenotype, list signs of clinical disease, if any, and treatments to be given.

d. Indicate delivery route and duration of vector excretion. Include whether cages, bedding, carcasses, etc. are hazardous to personnel and for how long.

e. Describe disposal requirements for the animal carcasses (e.g. place into biohazard bags, autoclave, and incinerate).

f. Describe disposal requirements for bedding (e.g. separate bedding into biohazard bags, autoclave, and incinerate).

*Remember to* ***attach*** *the appropriate entities approval documentation**as a pdf document.*

**XX. EUTHANASIA METHODS**:

1. Anesthetic drug must be used in conjunction with a physical method. Also include a Yes or No indicating whether a drug is DEA controlled.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Species:** | **Anesthetic Drug:** | **DEA:** | **Route:** | **Dose:** | **Monitoring:** |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

1. Is this method consistent with the recommendation of the AVMA Panel on Euthanasia and IACUC policy? *Select only one:*

(1) Yes.

(2) No.

If No, provide a BRIEF scientific justification here: (Convenience is not an appropriate justification)

1. Besides absence of heartbeat and respiratory effort, indicate the physical method that will be used to confirm death? *Check all that apply but* ***check at least one****:*

(1) Bilateral Thoracotomy.

(2) Decapitation.

(3) Cervical Dislocation (appropriate for Rats <200g body weight & Mice only).

(4) Removal of major organ (i.e. brain, heart, liver, etc.).

(5) Intravascular perfusion with tissue fixative.

**XXI.** **RECORDS**:

It is the responsibility of the investigator to maintain current and complete animal treatment (including research manipulations) and surgical records. Group records may be kept for hamsters, guinea pigs, and other rodents. Individual records must be maintained on all USDA regulated animals (non-rodent species). All treatment, surgical, and protocol records must be available for review by the IACUC and other inspecting agencies. **Provide the following specific location of such records:**

**1.**

|  |  |  |
| --- | --- | --- |
| **Campus** | **Bldg** | **Room #’s** |
|  |  |  |

2. Do you store DEA controlled substances in your lab? Select only one:

(a) Yes You must have a secure, double-locked place to store the drugs and you must maintain complete use and disposition records.

(b) No.

**Reminder!** Complete the next section, then **save to your PC** and attach it and other applicable documents (i.e., IBC approval, Radiation Sublicense, Training Materials, NIH Grant Documents related to use of vertebrate animals, Consent Form, etc.).

**XXII.** **PRINCIPAL INVESTIGATOR AGREEMENT**

**(Read carefully before signing):**

**I,**  *(****you must******insert PI’s name****)* ***,* certify that**

-> I will comply with the regulations of the TTUHSC1, USDA2 and OLAW3 for the protection of animals with respect to the conduct of this study;

-> the experiments do not, to the best of my knowledge, unnecessarily duplicate any previous experiments as required by the Code of Federal Regulations, Chapter. 9, Part 24;

-> the proposed research project will be conducted by me or under my supervision at the location(s) designated in this protocol;

-> the proposed research project will be conducted in accordance with the protocol submitted to and approved by the IACUC;

-> changes or modifications in the research project during the period for which IACUC approval has been granted shall not be initiated without prior IACUC review and approval;

-> I agree to accept responsibility for providing all laboratory personnel (including students and volunteers) who will work with the live animals on this study with appropriate training in proper laboratory practices and techniques; I also assure that personnel who will work with live animals on this study will complete the TTUHSC IACUC training requirements prior to working with any animal;

-> personnel who will work with live animals on this study will be enrolled in the Occupational Health and Safety Program prior to working with any animal;

-> a copy of the approved protocol application will be provided for all research personnel involved in the study.

**By checking this box, I am affirming that I agree to the statements above.**

**IACUC Protocol Compliance**

The signatures below indicate that the individual has completely read the most current version of protocol ##### .

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

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

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

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

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

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

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

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

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

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