Complete the form and submit to the IACUC Coordinator and IACUC Chairperson via email. All sections in this form must be completed. If a section is not applicable, please indicate not applicable (NA). Do not change the formatting of this document. ***An incomplete or unclear proposal will require revision and resubmission.***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| |  |  | | --- | --- | | **For IACUC OFFICE USE ONLY** | | | **Date Approved: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Protocol Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Species: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Total: No. of Animals Approved: \_\_\_\_\_\_\_\_\_**  **USDA Pain Category: \_\_\_\_\_\_\_\_\_\_**  NO  YES USDA Regulated Protocol  NO  YES IBC Approval Required  NO  YES Grant/IACUC Proposal Cross Review  **DMR/IACUC Chair (for full committee review):**  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  Signature Date  **Veterinarian Reviewer**  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  Signature Date | **Expiration Date:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **1st Annual Renewal Date:** \_\_\_\_\_\_\_\_\_  **2nd Annual Renewal Date:** \_\_\_\_\_\_\_\_\_  **3-rd Annual Renewal Date:** \_\_\_\_\_\_\_\_\_  **4th Annual Renewal Date:** \_\_\_\_\_\_\_\_\_  **Amendment Modification Date(s):**  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |

|  |  |  |
| --- | --- | --- |
| **IACUC Proposal #** (indicate if renewal) |  | New Protocol  Renewal  Pilot |
| **Title** (include Species to be Utilized in Title) |  | |
| **Principal Investigator** |  | |
| **WPI Department / Company** |  | |
| **Phone Number** |  | |
| **Email Address** |  | |
| **Check all applicable Housing/Test Facilities** | Gateway 1  Gateway 2  Goddard Hall  Other. List: Click here to enter text | |

**1 Funding Source(s) – WPI Departmental Funding Only**

Not Applicable

List Department Committee Name, Name of Committee Chairperson or Official Designee

Click here to enter text.

Signature of Department Head Signature Date

**2 Project Personnel (excluding husbandry staff)**

|  |  |
| --- | --- |
| **Name(s)** of all individuals involved in project | **Role in Project/ Relevant Experience** (Indicate who will do clinical observations, any non-surgical procedures, anesthesia, surgery, and euthanasia,). |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |

**Note:** *CVs/Resumes of ~~non-test facility~~ project personnel including external individuals (exception for student attending courses) must be sent to the IACUC Coordinator and kept on file.*

**A. Training of Personnel**

NO  YES Are all personnel trained on the procedures they will be performing?

If no, please indicate who will be training them, and verify the AV will validate proficiency/competency:

Click here to enter text.

**B. Teaching / Training Protocol**

Not Applicable

### Is this protocol for teaching / training / or education? Check all that apply:

#### Undergraduate students

#### Graduate students

#### Course # / Title: Click here to enter text.

#### Only dead animals or tissues obtained through euthanasia by the PI

#### Non‑survival surgery (complete the section titled “Animal Surgery Information”)

#### Demonstration only by PI

#### Student involvement ‑ live animal observation and handling

#### Student involvement ‑ exposure to research

#### Student involvement ‑ gain skills, more than just handling (Explain below)

Other : Click here to enter text.

**Standard Operating Procedures (SOPs) and IACUC Policies are available in the Vivarium, Vivarium Operation Manager’s and the IACUC Coordinator’s offices. They are also available at** <https://www.wpi.edu/research/resources/compliance/institutional-animal-care>.  **(please contact the IACUC coordinator for the login information and password)**

**3 Project Summary Table**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | | |  | **Procedures:** Check ALL that apply  (See below for corresponding *List of Procedures*) | | | | | | | | | | | | | | | |  |
|  | Common Name and Strain | | **Total Animals** | a | b | | c | d | e | f | | g | h | i | j | k | l | m | z | USDA Pain CAT |
| 1 | |  |  |  |  | |  |  |  |  | |  |  |  |  |  |  |  |  |  |
| 2 | |  |  |  |  | |  |  |  |  | |  |  |  |  |  |  |  |  |  |
| 3 | |  |  |  |  | |  |  |  |  | |  |  |  |  |  |  |  |  |  |
| 4 | |  |  |  |  | |  |  |  |  | |  |  |  |  |  |  |  |  |  |
| 5 | |  |  |  |  | |  |  |  |  | |  |  |  |  |  |  |  |  |  |
| **List of Procedures**: | | | | | | h. Food / Water Deprivation | | | | | | | | | | | | | | | |
| a. Survival Surgery  b. Non-survival Surgery | | | | | | i. Biohazard (i.e. Radioisotopes, Infectious Agents, Cell Lines,  Toxin/Mutagen/Carcinogen, Recombinant DNA) | | | | | | | | | | | | | | | |
| c. Multiple Survival Surgery | | | | | | j. Burns or Trauma | | | | | | | | | | | | | | | |
| d. Prolonged Restraint | | | | | | k. Drugs | | | | | | | | | | | | | | | |
| e. Collection of Cells, Tissues, or Organs | | | | | | l. Antibody production | | | | | | | | | | | | | | | |
| f. Aversive Conditioning | | | | | | m Diagnostic X-rays | | | | | | | | | | | | | | | |
| g. Special Diet | | | | | | z. Other (Specify:) | | | | |  | | | | | | | | | | |

**4 Proposal Description**

**A. Briefly describe in layman's terms (<300 words) the purpose of the study and the importance of the study to human or animal health, why the animals approved for research will be an advancement of knowledge or the good of society.**

Click here to enter text.

**B. Briefly provide in layman's terms (<300 words) a clear and concise sequential description of the procedures**

**involving the use of animals that is easily understood by all members of the committee.**

Click here to enter text.

**C. Is this protocol a duplication of past experiments (training protocols not included)?**

NO  YES If yes, provide appropriate justification in detail below:

Click here to enter text.

**5 Justification for the Selection of Species**

**A. Briefly describe justification of test systems below:**

Click here to enter text.

**B. Justification for selection of species (check all that apply):**

There is demonstrated similarity of the process under study in this species to those in humans.

A large amount of relevant data has already been derived from this species.

Manipulations required for this experiment (e.g. surgery) require an animal of this size.

An animal of this size is necessary in order to obtain sufficient biological materials to permit the proposed study.

Other. Please describe below:

Click here to enter text**.**

**6 Rationale for Number of Animals**

**A. Does this protocol involve breeding?**

NO  YES If yes, provide the breeding scheme and estimated number of offspring produced per

year below including the percentage of animals that will be used for study:

Click here to enter table/text.

## B. Grouping of animals to be used: Summarize the experimental study designs that outlines the types of studies being proposed, number of studies anticipate to be performed, how many groups/study, how many animals needed per group (and justify this number of animals), duration of study types, and totals of animal proposed over 3 years.

Click here to enter text.

**C. Complete the table below:**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Species** | **Strain** | **Sex (M/F)** | **Age Range** | **Number of**  **Groups** | **Number of**  **Animals/Group** | **Number of Studies** | **Total # Required**  **(3 years)** |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |

**D. The proposed numbers of animals, and group size should be based on one or more of the following: supporting historical data, regulatory requirements, published literature, *in vitro* requirements, and biometric analysis.**

**Rationale for appropriateness of number of animals obtained for the study, including additional animals bred/procured:**

Click here to enter text.

**E. Is the percentage of additional animals needed as spares > 10% of the proposed number of study animals?**

NO  YES If yes, justify above in Question 3.C.

Will the spare animals (un-manipulated) be utilized on other protocol(s)? (If YES, indicate protocol number and PI)  NO  YES Protocol #: PI Name:

**7 In-Life Observations and Procedures**

**A. List and describe all in-life observations and procedures below** (indicate if procedure(s) are considered USDA Pain Category D or E, as applicable)

**Note:** Surgical procedures are to be list in this section, but details of surgical procedures are described in **Section 14**

**Note:** Blood collections are to be list in this section, but details of blood collections to be described in **Section 7 B**

**Note:** If the proposal includes antibody production, list here and complete the Antibody Production Form using the following link <https://www.wpi.edu/sites/default/files/AntibodyProductionFormapproved9192019.docx>

Click here to enter text**.**

**B. Blood Collection**

Not Applicable

**B.1.** Does the blood collection volume(s) comply with the guidelines described in the Table below (adopted from Diehl, et al., J. Appl Toxicology, 2001; Table 4):

|  |  |  |  |
| --- | --- | --- | --- |
| **Limit Volume and Recovery Periods** | | | |
| **Single Sampling** | | **Multiple Sampling** | |
| **% CBV Removed** | **Approx. Recovery Period** | **% CBV Removed in 24 hours** | **Approx. Recovery Period** |
| 7.5 % | 1 week | 7.5 % | 1 week |
| 10 % | 2 weeks | 15 % | 2 weeks |
| 15 % | 4 weeks | 20 % | 3 weeks |

CBV = circulating blood volume = 7% of lean body weight

Yes  No If no, provide justification and any additional precautionary measures proposed below:

Click here to enter text**.**

**B.2.** List all methods, site/routes of collection and purpose for blood collection that maybe used:

|  |  |  |
| --- | --- | --- |
| **Method of Collection** | **Site/Route of Collection** | **Purpose of Collection (e.g. PK, Serum Chemistry)** |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

|  |  |
| --- | --- |
| Number of scheduled blood collections per animal: |  |
| Maximum volume collected at one time point: |  |
| Maximum frequency and volume collected per 24 hrs per animal: |  |
| Maximum frequency and volume collected per 2 weeks per animal: |  |

**B.3.** Are survival blood collections part of the experimental design?

No  Yes

Will sedation or anesthesia be used?

No  Yes If yes, fill out **Section 15.**

The purpose of the sedation/anesthesia is (check all that apply):

Relief of pain and/or distress  Restraint

No  Yes If blood volumes exceed Test Facility SOPs and Test Facility IACUC approved polices and guidelines, provide justification of amount(s) and calculations of amounts to be collected:

Click here to enter text**.**

Will replacement fluids be used?

No  Yes If yes, check all that apply below:

Injectable 0.9% Sodium Chloride (saline)

Lactated Ringer Solution

Other. Describe:

Click here to enter text**.**

**B.4.** Is there a terminal blood collection?

No  Yes If yes, the terminal blood collection will be performed on:

an anesthetized or sedated animal

an euthanized animal (cervical dislocation)

**8 Proposed Animal Use & Source**

**A Describe the source of animals (check all that apply) –** Note all animals MUST have health status approved by the AV prior to ordering animals**:**

WPI Pre-Approved Commercial Vendor

Commercial Vendor: Commercial Vendor Name: Click here to enter text**.**

Non-Commercial/Alternative Source: Source Name: Click here to enter text**.**

Please describe why this source is needed: Click here to enter text**.**

**9 Provisions for Food and Water**

**A. Feed to be provided:**

Standard, commercially available rodent diet and IACUC approved fed schedule (5001 Lab Diet-Rodent Diet, 5053 Picolab Rodent Diet 20),

Standard, commercially available frog diet and IACUC approved fed schedule (Nasco Frog Brittle for Adult Xenopus)

Standard, commercially available zebrafish diet and IACUC approved fed schedule (Ziegler adult zebrafish irradiated diet, Ziegler Larval AP100 Dry Larval Diet)

Special diet is requested.

Other. Please list below:

Please describe the diet below, including regimen, any special storage conditions or husbandry practices required for administration (Please include diet formulation):

Click here to enter text**.**

**B. Water to be provided (check all that apply):**

Not Applicable (e.g. aquatics)

Filtered tap water  Autoclaved water

Special water is being requested.

Please describe the water below, including regimen, any special considerations or husbandry practices required for administration (Please include water formulation).

Click here to enter text**.**

**C. Food and water restriction:**

Feed and water will be provided according to Test Facility SOPs and Test Facility IACUC approved policies or guidelines.

Please describe the procedure and duration below:

Click here to enter text**.**

Feed or water will be restricted for duration greater than that described in Test Facility SOPs or Test Facility IACUC approved policies or guidelines. Please describe and scientifically justify this restriction below:

Click here to enter text**.**

**10 Animal Housing**

# A. Proposed Facility where Animals will be housed (Must be an IACUC Approved Facility)

## Special Conditions / Situations

NO  YES Animals are to be used/housed outside Gateway 1 / or

Gateway 2 (Swine only)

### If yes, will the duration be for greater than 12 hours (in a study area)? NO YES

### If yes, please describe procedure/purpose, building/room/IACUC approved location, duration, frequency, methods of transportation (include safety precautions for animals and personnel)

Click here to enter text**.**

Transportation outside of the Institution's facilities (complete *Animal Transport Request Form* for AV approval).

Click here to enter text**.**

**B. Primary Caging/Enclosure/Housing will be:**

Polycarbonate flat bottom with contact bedding - Ventilated Racks (rodents)

Metabolic caging, state duration below:

Click here to enter text**.**

Polycarbonate tanks – Aquatic tanks (frogs)

Polycarbonate tanks that include a bacteria bed– Aquatic tanks (zebrafish)

Pens with contact bedding – Housing room (swine)

Other. Please describe below:

Click here to enter text**.**

Housing for this species used is as described in the *Guide*, Test Facility SOPs and Test Facility IACUC approved policies or SOPs.

Housing varies from the *Guide*, Test Facility SOPs or Test Facility IACUC approved policies or SOPs.

Describe variation and include justification below:

Click here to enter text**.**

## C. Animal Housing Provisions

How long is the environmental acclimation period? Click here to enter text**.**

How long will the animals for each study be housed within the facility? Click here to enter text**.**

Will animals require care above the standard care levels (i.e. frequent cage changing or cage cleaning/disinfection, , special bedding, etc.)

NO  YESIf yes, indicate procedures to be followed and if it will be conducted by husbandry staff or laboratory research personnel (Consult with the Vivarium Director to determine if additional costs are associated with this level of care):

Click here to enter text**.**

**D. Bio-safety Housing Conditions will be (check all that apply):**

BSL1/ABSL1  BSL2/ABSL2

**E. Social Housing and Enrichment**

Environmental Enrichment Devices/Food Supplementation will be provided as described in the Test Facility SOPS and Test Facility IACUC approved polices and guidelines.

An exemption from enrichment is requested.

Please justify and detail which enrichment will not be provided below:

Click here to enter text**.**

Social housing (full/periodic commingling) will be provided as described in the Test Facility SOPs and Test Facility IACUC approved polices and guidelines.

Full  Periodic, please describe below:

Click here to enter text**.**

An exemption from social housing is requested.

Please justify and detail the circumstances of this exemption below:

Click here to enter text**.**

**11 Animal Restraint**

Not Applicable

**A. Please indicate methods of restraint to be performed on study** (check all that apply):

Manual  Chemical  Mechanical

**B. Please describe the method(s) of restraint below.** For each method, include purpose, frequency and length of restraint. If applicable, indicate the acclimation required prior to performing the procedure on study and indicate vital sign monitoring for the restraint period, including frequency and method(s) utilized. Indicate if restraint will be less or greater than 20 minutes. If greater than 20 minutes, please justify.

Click here to enter text**.**

Restraint method(s), frequency and length will comply with Test Facility SOPs and Test Facility IACUC approved polices and guidelines

Restraint method(s), frequency and length will not comply with Test Facility SOPs and Test Facility IACUC approved polices and guidelines. Please provide scientific justification below:

Click here to enter text**.**

If **chemical** restraint agent(s) are to be used on study, please complete **Section 15.**

**12 Test Material Administration**

Not Applicable

**A. Provide detailed information on each test material to be administered in this study (including any induction materials, challenges, adjuvants, etc.) in the table below:**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Species** | **Test Material ID** | **Intent of Test Material** | **Dose**  **Enter Units** | **Volume**  **Enter Units** | **Site(s)** | **Route of Admin.** | **Treatment**  **Regimen** |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |

\* If this is for a global protocol application include information on cell lines as an attachment.

**B. Will non-pharmaceutical grade material(s) be used? Do they comply with the Test Facility IACUC approved polices and SOPs?**

No  Yes If yes, list the material(s) and check applicable justification below:

New investigational compound  Scientific necessity

Non-availability of acceptable veterinary or human pharmaceutical-grade compound

Other. Describe and justify below:

Click here to enter text**.**

**C. Rationale for Dose Selection**

Not Applicable

**A. For each test material listed in the table above, include detailed information from previous studies or PI/client-supplied information. Be as specific as possible. If no information is available, state and justify.**

Click here to enter text**.**

1. **Occupational Health and Safety Standard Procedures - Hazardous Agents**
2. **Recombinant DNA Use**

Will this proposal utilize (i) recombinant nucleic acid molecules, (ii) synthetic nucleic acid molecules, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, and (iii) cells, organisms, and viruses containing such molecules in animals?

Not Applicable

Yes. If yes has this nucleic acid use been reviewed/approved by an Institutional Biosafety Committee (IBC) and in compliance with the most recent guidelines *For Research Involving Recombinant or Synthetic Nucleic Acid Molecules (‘NIH Guidelines’)?*

No. If no, submit to to IBC review prior to IACUC approval.

Yes. If yes, please indicate the IBC entity who conducted the review/approval:

WPI IBC  Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**If performed by external IBC, please include a letter from that IBC of review/approval and recommendations for in vitro/in vivo (in animal handling and use).**

Were the nucleic acid constructs considered ‘Exempt’ per *NIH guildelines*?

Yes.  No. If no, please describe what the IBC recommended for handling, and when in used in vivo (in animals) “and must include details of the proposed rDNA experiments, including stating which gene or synthetic nucleic acid construct is to be inserted or knocked out (species and gene function, including whether it is a known oncogene or toxin), the vector to be used (plasmid, virus, CRISPR, Talen, ZFN), and whether the experiment is expected to have a deleterious effect on the animal (such as causing harm to the animal, or increasing its sensitivity to pathogens, etc.)”.

:

Click here to enter text**.**

**B. Other Hazardous Agents include but are not limited to:**

* Biohazardous materials: *injection of cell lines, infectious agents (bacteria, fungi, parasites, prions, rickettsias, viruses, etc), etc.*
* Chemical hazardous materials: *carcinogens, allergens, corrosives, irritants, neurotoxins, teratogens, etc.;*
* Physical hazards: *lasers, X-ray machines, radioisotopes, etc.*

**List hazardous agents being used *in vivo*:**

Click here to enter text**.**

For each agent hazardous to animals or personnel not in compliance with the Institution’s SOPs, the PI ***must complete***Hazardous Agents form <https://www.wpi.edu/sites/default/files/HazardousAgentsFormandStudySafetyPlanIACUCapproved9192019.docx> If needed, assistance is available from the IACUC Biosafety Member.

Not Applicable

**14 Surgical Procedures**

Not Applicable

**A. Indicate the type of aseptic surgical procedure performed (check all that apply):**

Survival  Non-Survival

Minor surgical procedure  Major surgical procedure

**B. Will multiple survival surgeries be performed on any animal?**

No  Yes

**Federal guidelines specify that no animal is to be used in more than one major survival operative procedure except in cases of scientific necessity or to provide adequate veterinary care. If requesting to perform multiple major survival surgeries, provide substantial scientific justification below: (See** [**http://www.aphis.usda.gov/ac/polmanpdf.html**](http://www.aphis.usda.gov/ac/polmanpdf.html)**, Policy 14).**

Will two or more of these survival surgeries involve **major** procedures (defined as a surgical intervention that penetrates and exposes a body cavity or any procedure that produces substantial or permanent impairment of physical or physiological functions)?

No  Yes

If yes, please indicate the rationale for performing multiple procedures below. Also, please indicate if these surgeries must be performed on separate occasions, versus one anesthetic event.

Click here to enter text**.**

**C. Provide details of surgical procedure, including pre-surgical procedures (preparation, pre-emptive analgesia, paralytic agents, etc.), use of anesthesia/analgesia (including re-dosing), anesthesia monitoring, post-operative, and other supportive care below:**

**Pre-operative:** Click here to enter text**.**

**Intra-operative:** Click here to enter text**.**

**Post-operative:** Click here to enter text**.**

D. Describe in detail below the schedule for animal observation for health and well-being and anticipated adverse effects for any potential post-operative complication, acute or chronic pain:

Click here to enter text**.**

**E. Will euthanasia be the chosen action for animals exhibiting unrelieved pain or distress caused by the proposed surgical procedure?**

No  Yes If yes, fill out **Section 18**.

**15 Anesthesia and Analgesia**

Not Applicable

If the use of these agents is for euthanasia purposes only, please skip to **Section 18 for Euthanasia**.

**Note:** **All drugs used on animals before, during, or after an experiment or surgical procedure must be obtained from legal sources**. All controlled substances should be kept in a double-locked compartment. Records should be kept documenting each use of a controlled substance. USE ONLY DRUGS THAT ARE WITHIN THEIR EXPIRATION DATE. All drugs should be disposed of properly when out of date or no longer needed. This applies to IV fluids as well.

**Note: Paralytic agents** (example: pancuronium, succinylecholine etc.) are not analgesics or even sedatives and must be used in combination with anesthetics during painful procedures (9 CFR 2.31:NRC. 1996: PHS. 1996).

**A. Complete the table below for all anesthetic, sedative, tranquilizer, paralytic, analgesic. Antibiotics agents and other drugs to be used for experimental purposes:**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Agent** | **Class\*** | **Purpose** | **Route of Admin.** | **Dose Level** | **Dose Volume** | **Regimen** |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

Class\* abbreviations: A= Anesthetic, Ana= Analgesic, Ant= Antibiotics, S= Sedative, T= Tranquilizer, P= Paralytic, O= Other

No  Yes Will all drugs used be USP Grade? (If not, please justify below)

Click here to enter text**.**

**B. Describe method(s) for monitoring to ensure adequate effect and proper recovery from the agents listed in the table above. Include any potential adverse effects and method of documentation.**

Click here to enter text**.**

**16 Pain and Distress**

**A. Animal Observations, Humane Interventions & Endpoints**

**Provide detailed schedules for observing health and well-being.**

**(1)** Describe any expected significant/adverse effects or potential complications or conditions (e.g. weight loss, fever, neurological deficits, and behavioral abnormalities) on the health or behavior of the animals for the animal model, procedures or stimuli, and include suspected target organ(s).

**(2)** Indicate frequency of observations.

**(3)** Describe any post-procedural monitoring to be performed, including the assistance, supportive or clinical care involvement to be provided to the animal’s during the progress of the study (e.g. analgesic, food on the cage floor, veterinary involvement) and criteria (e.g. 20% weight loss, clinical scoring system, maximum tumor size, clinical chemistry level, vocalizing) to be used as humane intervention/endpoints that would necessitate euthanasia of an animal before the expected completion of the experiment.

Click here to enter text**.**

**B. Animal Disposition to Unanticipated Pain/Distress**

No  Yes If an animal is sick or injured, should the PI be called? **(If YES, complete below)**

Click here to enter text**.**

No  Yes **In case of an emergency, should the Veterinarian or staff treat the animals?** (If YES, explain any restrictions on treatment below.)

Click here to enter text**.**

**17 Disposition of Animals**

**A. Describe the final disposition of animals** (check all that apply):

Euthanized (**complete Section 18**)

Transferred to active IACUC proposal(s) listed below:

Click here to enter text**.**

Transfer of live animals to other Institution not covered under Test Facility's IACUC.

Complete *Animal Transport Request Form.(requires AV approval prior to moving animals)* [*https://www.wpi.edu/sites/default/files/docs/Research/Animal\_Transfer\_Form.pdf*](https://www.wpi.edu/sites/default/files/docs/Research/Animal_Transfer_Form.pdf)

Click here to enter text**.**

**18 Method of Euthanasia**

Not Applicable

**A. Please provide a written description of the method(s) of euthanasia including, but not limited to, the euthanasia material(s), dose, site of injection(s), and a secondary method of euthanasia.**

Click here to enter text**.**

**B. Is the euthanasia method an AVMA-accepted method?**

Yes  No If no, please describe and provide scientific justification below:

Click here to enter text**.**

**C. Does the euthanasia method comply with Test Facility SOPs and Test Facility IACUC approved polices and guidelines?**

Yes  No If no, please describe and provide scientific justification below:

Click here to enter text**.**

**D. Will euthanasia be performed humanely away from live animals?**

Yes  No If no, please describe and provide scientific justification below:

Click here to enter text**.**

## E. Disposition of Animals Post Euthanasia

No  Yes Refrigerate carcass?

No  Yes Freeze carcass?

No  Yes Red biohazard bag disposal? (required for animals injected with any biohazard

agents)

No  Yes Other? (If YES, explain below)

No  Yes Non-USDA regulated species unexpected deaths require necropsy? If Yes,

Necropsy special instructions. *NOTE: all unexpected USDA regulated species deaths require a necropsy*, and needs to be described below.

Click here to enter text

**19 Search of Alternatives**

The IACUC is responsible for ensuring that investigators have appropriately considered alternatives to vertebrate animal use, appropriateness of animal species selected, as well as test materials and procedures that may cause unnecessary pain and distress (USDA Pain Category D or E). Please keep the “Three R’s of Animal Research” in mind when completing this section of the form:

**Replacement** – refers to methods which avoid or replace the use of animals in an area where animals would otherwise be used. This includes both absolute replacements (i.e. replacing animals with inanimate systems, such as inanimate models, computer programs, etc.) and relative replacements (i.e. replacing more sentient animals, such as vertebrates animals that current scientific evidence indicates have a significantly lower potential for pain perception, invertebrates, etc.).

**Refinements** – refers to the modification of husbandry, experimental or surgical procedures to minimize pain and distress, and to enhance the welfare of an animal used in science from the time of receipt through euthanasia.

**Reduction –** refers to any strategy that will result in fewer animals being used to obtain sufficient data to answer the research question or in maximizing the information obtained per animal and thus potentially limiting or avoiding the subsequent use of additional animals, without compromising animal welfare.

Provide documentation of the methods and sources used to determine what alternatives are available and/or if alternatives do not satisfy the experimental objectives.

List animal models to be used, potential painful and/or distressful test material administrations, experimental procedures or surgeries, for which the search for alternatives is to be performed:

Click here to enter text.

**A. Describe how and what search for alternatives was conducted**.

Information by literature search – complete the table below.

When performing your search key words to be considered should include “in vitro”, “in silica”, the animal species used, “in vivo”, “alternative”, “pain”, “distress”, the class of compound, relevant experimental and test procedures, as well as all any subject related key words.

A separate literature search should be conducted for each item listed above. Database(s) searched, INCLUDING the date range of the search and the date search was done (<6 months prior to submission). A minimum, to be done is for USDA Pain Category D & E procedures

AND

For proposals that use ***USDA regulated animal species, a minimum of two databases is required for each procedure*** consideration of alternatives to each procedure which may cause pain or distress must state sources consulted. Please check database(s) searched.

National Library of Medicine (NLM’s Medline/PubMed) – http://www.nlm.nih.gov

Elsevier – <http://www.elsevier.com>

Current Research Information Service (CRIS) – http://cris.csrees.usda.gov

Animal Welfare Information Center (AWIC) – http://awic.nal.usda.gov

European Center for the Validation of Alternative Methods Scientific Informational System (ECVAM SIS databases and ECVAM Thesaurus) – <http://ecvam.jrc.ec.europa.eu>

Biological Abstracts – <http://science.thomsonreuters.com>

Google Scholar - – <http://scholar.google.com>

Other: Click here to enter text.

**IACUC Literature Search Summary**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Performed By: |  | Date of Search: |  | Dates Covered by Search: |  |

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| --- | --- | --- |
| Key Words Searched | Number of Hits | Comments |
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Information other than literature search (e. historical data generated by the laboratory)

Please attach supporting documentation or explain and provide documentation below:

Click here to enter text.

Consultation with colleagues

Please explain and provide documentation below. Provide individual’s names, credentials and experience with/knowledge of the model, procedure or compound class.

Click here to enter text.

Required by regulatory agency. Identify agency(s) below:

Click here to enter text.

Training or pilot study. Alternatives must be considered. Please describe below:

Click here to enter text.

**B. Results of the search for alternatives conducted.**

Please provide a written narrative of your search results for each listed item below. Indicate if no alternatives were identified in the literature searches or other methods selected above, if consideration for the use of alternatives is limited because the specific test procedures or study design used in this study protocol are required in a living biological system (such as breeding study, etc.), or if alternatives were identified; however, they will not satisfy the experimental objectives.

Click here to enter text.

**20 Principal Investigator Assurance – Signed Post-IACUC Approval**

1. I assure compliance and understanding of all federal, state, and local mandates as well as abide to all WPI SOPs and Policies concerning the use of animals.
2. As required by Federal regulations, I assure that the activities described do not unnecessarily duplicate previous experiments and I assure the animal models proposed are the most appropriate for achieving the objectives of this project and have provided justification for each model used in the protocol (Animal Research Plan Rationale).
3. I assure that, to the best of my knowledge, this narrative, in conjunction with the relevant study protocol(s), Test Facility IACUC approved polices, guidelines and SOPs, is a complete and factual description of the animal care and use procedures to be followed in the IACUC proposal.
4. I certify that appropriate measures have been taken to ensure the minimal number of animals required to achieve research objectives are being used and the activities in this IACUC proposal do not unnecessarily duplicate previous experiments.
5. I certify that appropriate pain-relieving drugs will be used throughout the study(ies) to relieve pain or distress, including postoperative or post procedural care, unless specifically stated in this IACUC Proposal.
6. I certify that I will notify the IACUC regarding any unexpected results that impact animals. Any unanticipated pain, distress, morbidity, or mortality will be reported to the Attending Veterinarian.
7. I certify that the use of alternatives to the described animal models and procedures have been considered and employed where compatible with study goals unless found to be unavailable or unacceptable.
8. I certify that all personnel performing any procedures on vertebrate animals will be performed under my supervision or that of other qualified individuals as indicated on this form. The personnel involved have received the proper training prior to any animal work in proper procedures of animal handling, administration of anesthetics and analgesics, and the AVMA recommended methods of euthanasia to be used on this project. The personnel will participate in training programs available. Proof of such training for all personnel will be provided to the IACUC upon request.
   1. If a USDA Pain Category E protocol, I certify that all personnel performing any procedures on animals are listed below.
   2. I certify that all non-Test Facility personnel performing any procedures on animals have proper training and a description of their training and experience is provided in this proposal. A copy of their CV/Resume will be kept on file.
9. I understand that it is my responsibility as the Principal Investigator to ensure that all individuals listed on the protocol have read and understood the procedures described for each species in the IACUC proposal.
10. I certify there will be no use of radioactive materials, infectious agents, or other biologically or chemically hazardous materials other than those specifically stated in this IACUC proposal and approved by the IACUC, Biosafety Officer, as required.
11. I assure all my research personnel will be trained on how to report any concerns for inhumane care and treatment of animals or unlawful acts involving animals should be reported according to the Whistle Blower Policy and that anyone reporting such concerns cannot be discriminated against or be subject to any reprisal for reporting their concerns. Contact information for reporting, including names and telephone numbers, can be found at <http://www.wpi.edu/Admin/Research/IACUC/>.
12. I agree to give consideration and apply 3Rs of animal research (replace, reduce, refine) as best possible.
13. I certify that any animal use proposed in a grant or contract proposal to support this research corresponds to the information provided herein.
14. I agree to abide by, and accept responsibility for compliance with, the provisions of the Federal Animal Welfare Act, Public Health Service Policy on Humane Care and Use of Laboratory Animals, and the NRC *Guide for the Care and Use of Laboratory Animals*.
15. I understand that any failure to comply with the requirements of the IACUC may result in suspension of my study(ies) and notification to the funding agency, the PHS and/or as mandated by law.
16. I understand that all changes to this IACUC proposal involving the care and use of animals must be detailed as an amendment and submitted to the IACUC for review and approval before implementation of the changes. If necessary, I will submit a new proposal. I understand that failure to request an amendment for changes in animal use may place WPI and myself in violation of Federal regulations and the Animal Welfare Act.
17. I understand that no animal procurement or procedures involving animals may be performed prior to approval by the IACUC.

Signature of Principal Investigator Date