# **Institutional Animal Care and Use Committee (IACUC) Laboratory Research Protocol**

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| **Protocol Number:**  |
| **Project Title:** |
| **Protocol Approval Date:**  | **Protocol Expiration Date:**  |

*This form is designed specifically for research with vertebrate animals in the laboratory. If animals will be remain in the field for the study, please complete the IACUC Protocol Application for Field Research. If animals will be observed only, please complete the IACUC Field Study Exemption Protocol.*

***\*\*Please submit a signed, completed IACUC application electronically to*** [***https://forms.office.com/r/EbkRuiEpDh***](https://forms.office.com/r/EbkRuiEpDh)***\*\*Questions can be directed to*** ***iacuc@uwsp.edu******. (Please note documents for committee review will no longer be accepted via email.)*** All individuals listed on the protocol must complete CITI certification requirements. Training requirements and instructions can be obtained [here](https://www3.uwsp.edu/iacuc/Pages/default.aspx).

**I. Project Identification, Personnel and Signatures**

 **A. Type of Application:**

[ ]  **New Protocol/Triennial Review resubmission** [ ]  **Major Revision to Previously Approved Protocol-Original Approval Date:**

 **B. Project Funding Source:**       **C. Project Dates:**

 **D. Is this project federally funded?** [ ]  **No** [ ]  **Yes : Provide Grant Identification Number:**

***Note:*** *A Financial Conflict of Interest (FCOI) Disclosure and FCOI Training through* [*CITI Program*](http://www.citiprogram.org) *must be current and filed with the Office of Research and Sponsored Programs for all federally funded projects.*

  **E. Principal Investigator (PI)**

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| --- |
| **Name:** |
| **Mailing Address:**  | **City:**  | **Zip:**  |
| **Office Phone: Personal Phone:** |
| **Qualifications; licenses or certifications:** |
| **Email:** |

**Co-Principal Investigator (PI) (If applicable)**

|  |
| --- |
| **Name:** |
| **Mailing Address:**  | **City:**  | **Zip:**  |
| **Office Phone: Personal Phone:** |
| **Qualifications; licenses or certifications:** |
| **Email:** |

**F.** **Personnel Qualifications:**

Describe the training of *any additional* research personnel (list PI & co-PI training above). Please include which protocol procedure(s) each individual has been trained to perform, how training was received (hands-on experience, supervisor training, CITI coursework, etc.) and length of time the individual has been proficient in the procedure/technique. If using UWSP Animal Care Staff, please indicate. Also include the date CITI training was completed and attach the completion certificate/report as an appendix.

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| --- | --- | --- |
| Name and Contact Information | Role in Study and Description of Expertise and Relevant Experience | CITI Certification Date & No. |
| Name:E-Mail:Phone: |  |  |
| Name:E-Mail:Phone: |  |  |
| Name:E-Mail:Phone: |  |  |
| Name:E-Mail:Phone: |  |  |

**PI Certification:**

*Upon approval, I agree to execute this work as described; request approval from UWSP’s Animal Care and Use Committee for changes prior to initiating said changes; comply with the guidelines set forth by the IACUC and be responsible for the training, supervision and work of my staff. I realize that failure to adhere to policies related to animal care and use may result in suspension or revocation of permission to perform animal research in UWSP facilities. The activities described in this study do not unnecessarily duplicate previous experiments.*

*All individuals working under this protocol will comply with the procedures and methods outlined in the Animal Welfare Act, its implementing regulations, the public health service policy, the Guide to the Care and Use of Laboratory Animals, and the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training. All work proposed herein is designed to avoid discomfort, distress, and pain to animals to the extent possible; does not unnecessarily duplicate previous experimentation; and non-animal alternatives have been considered.*

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**Signature of PI Print PI Name Date**

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**Signature of Co-PI Print Co- PI Name Date**

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**Signature of Dept. Chair/Supervisor Print Name Date**

**II. Animal Species, Numbers and USDA Pain Level Category**

**USDA Pain Level Categories Chart - Definition of Painful Procedures defined by the Animal Welfare Act:** “As applied to any animal, pain means any procedure that would be expected to cause more than slight or momentary pain or distress in a human being to which that procedure was applied, pain in excess of that caused by injections or other minor procedures.

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| --- | --- | --- | --- |
| **USDA Category B** | **USDA Category C** | **USDA Category D** | **USDA Category E** |
| Animals being held, bred, or conditioned for use in Teaching, Testing, Experiments, Research, or Surgery but not yet used for that purpose | No more than momentary or slight pain or distress and no use of pain-relieving drugs, or no pain or distress. | Pain or distress appropriately relieved with anesthetics, analgesics, and/or tranquilizer drugs or other methods for relieving pain or distress | Pain or distress or potential pain or distress that is **NOT** relieved with anesthetics, analgesics, and/or tranquilizer drugs or other methods for relieving pain or distress  |
| **Examples:** | **Examples:** | **Examples:** | **Examples:** |
| * Animal breeding, pregnancy, parturition, and lactation
* Preventative health veterinary procedures
* Routine husbandry procedures
 | * Animals upon which teaching or research will be conducted involving no pain, distress, or use of pain-relieving drugs
* Animals observed under normal conditions
* Live trapping
* Holding or weighing animals in teaching or research activities
* Routine procedures such as injections, blood collection, or catheter implantation via superficial vessels done per standard veterinary practice by trained personnel
* Tattooing or microchipping animals
* Ear punching of rodents
* Routine physical examinations
* Feeding studies that do not result in clinical health problems
* Positive reward projects
* AVMA approved humane euthanasia procedures
* Animals sacrificed for tissues
* Management procedures in agriculture species as listed in the Ag Guide
* Animal transportation
 | * Diagnostic procedures such as laparoscopy or needle biopsies
* Non-survival surgery
* Survival surgical procedures
* Post operative pain or distress
* Periorbital blood collection in rodents
* Terminal cardiac blood collection
* Any post procedural outcome resulting in evident pain, discomfort, or distress such as that associated with decreased appetite or activity level, adverse reactions such as open skin lesions, abscesses, lameness, conjunctivitis, corneal edema, and photophobia.
* Exposure of blood vessels for catheter implantation
* Exsanguinations under anesthesia
* Induced infections or antibody production with appropriate anesthesia and post-op/post-procedure analgesia when necessary
* Administration of drugs, chemicals, toxins or organisms that would be expected to produce pain or distress but which will be alleviated by analgesics.
 | * Toxicological or microbial virulence testing, cancer research or infectious disease research that requires continuation until clinical symptoms are evident or death occurs
* Ocular or skin irritancy testing
* Food or water deprivation beyond that necessary for ordinary per-surgical preparation
* Application of noxious stimuli such as electrical shock if the animal cannot avoid/escape the stimuli and/or it is severe enough to cause injury or more than momentary pain or distress
* Infliction of burns or trauma
* Prolonged restraint
* Any procedures for which needed analgesics, tranquilizers, sedatives, or anesthetics must be withheld for justifiable study purposes.
* Use of paralyzing or immobilizing drugs for restraint
* Exposure to abnormal or extreme environmental conditions
* Euthanasia by procedures not approved by the AVMA
* Induction of self-mutilation
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**This Page Will NOT Print - For Reference Only**

**Indicate the number of animals anticipated to be used under each category over the course of this research period or the next** **3-year period whichever more closely identifies the timeframe of your animal use, work**. A range may be given when exact numbers are unknown. If over the course of the study, the range of animals listed is exceeded or you wish to study additional species, please submit a modification form to the IACUC to justify additions.

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| --- | --- | --- | --- |
| **Species** **(Scientific and Common Names)** | **Number of Animals per USDA Category (Use chart on previous page)** | **Source (where animals came from)** | **Housing Location** |
| **B** | **C** | **D** | **E** |
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**III. Scientific Justification of Species**

1. **Describe the features of the species (e.g., anatomic, physiologic, genetic. etc) that make it desirable for the model. Contrast with other available models, if any. Provide a thorough and appropriate scientific justification.**

1. **Explain how this work will benefit this particular species or community level. If you are studying this species as a surrogate, how this species will serve as a model for the other species of interest.**

1. **How is the number of animal(s) requested scientifically justified? Select and answer all that apply.**

[ ]  **Pilot study or preliminary project, group variances unknown at present**. Minimal number of animals should be requested. Explain justification of numbers for each species:

[ ]  **Group sizes determined statistically.** What statistical analysis was performed including the analysis employed and the power function?

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

**IV. Study Objectives**

**What is the objective of this project? What is the research or development question?** In layman’s terms, describe the relevance of the study to advancing scientific knowledge and/or the benefits of the study to human and/or animal health. Provide sufficient information to indicate that the potential new knowledge from the project justifies the use of animals. Jargon should be avoided or explicitly explained (please define all acronyms).

**V. Study Procedures**

1. **Provide a complete and accurate description of what procedures will be performed on/with the animal. Answer in language understood by a person unfamiliar with your area of research.**
* Describe all procedures, their frequency and time points over the course of the experiments. Include how long the animals will be maintained.
* Include dose, route of administration and frequency of any drugs to be administered.
* Describe methods used in behavior studies (including use of noxious stimuli or other methods of positive or negative reinforcement).
* Described surgery here, only as it relates to the study design. Provided surgical details in Appendix “B”.

1. **Safety procedures for Animal Handlers:** Please describe the personal protective equipment (PPE) to be worn during procedures described in this protocol. Questions regarding PPE requirements for the animal facilities should be directed to the Laboratory Animal Manager.

**VI. Diet, Housing, Enrichment, Transportation and Identification**

1. **Diet-** Provide a description of the type of diet (food type, source, etc) animals will receive while in study. If animals’ diet will be restricted or limited, please complete Appendix F: Dietary Manipulations and Fluid restriction, additionally. Ex: Free-fed Pelleted rodent chow from Envigo

1. **Housing-** Describe where and the way the animals will be housed. If this project requires social animals to be housed singly, please provide justification. **If housed in one of the UWSP Animal Care Facilities, will your project adhere to the Standard Operating Procedure for the proposed species? If not, provide housing information and justify.**

1. **Quarantine -** Describe where and the manner in which the animals will be quarantined.

1. **Alternate Housing-** Is the selected location considered satellite or alternative housing?

[ ]  Satellite [ ]  Off-Campus [ ]  Not applicable, animals are currently housed on campus in the ACF

If housed off campus, provide requested location, length of stay, reasoning and justification for alternative housing. **Alternative housing must be inspected and approved by IACUC prior to introducing animals.**

1. **Enrichment-** Describe the type of enrichment that will be offered to animals. If enrichment is described in your species specific SOP please reference that SOP here.

1. **Transportation-** From where (name of vendor and US State/Country) will animals be transported?

 [ ]  Not applicable, animals are currently housed on campus

 If a commercial vendor will not be used, explain the source and the procedures used to transport animals to campus:

Would you like to request permission to use a personal vehicle to transport animals? [ ]  Yes [ ]  No

**Note: Personal vehicles must be inspected and approved by the IACUC before use. Please schedule an appointment with the Chair to get your personal vehicle inspected by a subcommittee of the IACUC prior to use.**

**Will animals be transported off UW-Stevens Point campus?** [ ]  Yes [ ]  No

If Yes, explain transportation procedures:

 **Will animals return to UW-Stevens Point campus?** [ ]  Yes (If Yes, please explain) [ ]  No [ ]  N/A

1. **Animal Identification-** Describe which animal identification method(s) will be utilized (Examples: cage cards, microchip, ear tag or punch, tattoo, etc).

1. **Animal Records -** Describe where and how animal records will be kept (Examples: paper records in housing room, campus computer, etc) and who is responsible for maintaining them if requested by IACUC.

**VII. Potential Animal Pain and Distress**

1. **What is the potential for study-induced or study-related problems, that animals in this research may experience (i.e. health problems, pain, distress, complications, etc…)?**

1. **How will pain and/or distress be monitored? Provide the specific clinical signs, that will be monitored, monitoring frequency, and provision for off hours.**

1. **Explain what steps will be taken to alleviate any pain, distress, or discomfort the animals may experience. Provide dose, route of administration, frequency, and type of analgesic drugs or tranquilizers to be administered. Or Justify not taking steps to alleviate pain, distress or discomfort.**

1. **All medications, compounds and drugs to be used in vertebrate animals must be of pharmaceutical grade (Human or Veterinary Grade) unless approved by the IACUC. If a non-pharmaceutical grade medication, compound, or drug is requested, please provide scientific justification.**

**E. Will animals be restrained for study procedures?** [ ]  Yes [ ]  No

 **If Yes, will restraint be:** [ ]  Physical [ ]  Chemical

**Please describe any restraint procedures to be utilized and justification for use:**

**VIII. Euthanasia/Disposition/Endpoint of Animals**

1. **Which criteria will be used to determine when the animals’ critical endpoint is reached** Example: tumor size/appearance, percentage body weight gain/loss, behavioral abnormalities or other abnormal clinical signs

- Determination for removal of animal from study?

- Determination for medical or health maintenance care of animal?

- Determination for Euthanasia?

1. **What will happen to the animal at the end of the study?**
2. **Will the animals be euthanized at the end of the study?** [ ]  **No** [ ]  **Yes**

If yes, please specify euthanasia method, agent, dosage, and route of administration to be used for each species, referencing the AVMA Guidelines. Please include how carcasses will be disposed of:

Does this method of euthanasia fall under AVMA guidelines for:

[ ]  **Acceptable Methods** OR [ ]  **Acceptable with Conditions Methods** [ ]  **No**

If No, please provide scientific and/or medical justification for deviation from the AVMA guidelines:

[ ]  **No** If animals will not be euthanized at the end of the study, please describe their final disposition (adoption, release, animal holding protocol, donated to ACF):

**NOTE:** Please review the [AVMA Guidelines for the Euthanasia of Animals: 2020 Edition](https://www.avma.org/KB/Policies/Documents/euthanasia.pdf) for the animals you will be working with. Euthanasia must be in accord with the methods approved in the 2020 Edition, unless scientific justification or medical reasons are provided and approved by the IACUC. You may reference specific animal SOP’s found on the IACUC intranet site, for euthanasia methods on species commonly used at UWSP.

**Appendices Checklist:** Check all that pertain to your project, complete the appropriate appendices, and attach as part of your application. Appendices that do not pertain to your project may be omitted when submitting your application.

[ ]  Animals Classified in USDA Reporting Category D or E – Appendix A

[ ]  Surgery – Appendix B

[ ]  Wild-Caught Animals – Appendix C

[ ]  Antibody Production – Appendix D

[ ]  Toxicology Studies/Microbial Virulence Testing – Appendix E

[ ]  Dietary Manipulations or Fluid Restriction – Appendix F

[ ]  Use of Hazardous Agents – Appendix G Part 1: Hazardous Chemicals, Part 2: Radiation, Part 3: Infectious Agents and work with human blood and fluids, Part 4: Recombinant DNA including transgenic mice Must also complete an IBC application/protocol

**You have reached the end of this form UNLESS you are required to attach one or more of the Appendices (A-G), which appear on the next page. Please make sure that you have responded to every question on this application and that you have filled out ALL of the applicable appendices.**

**IACUC Appendix A: Alternatives to Animals Classified in Reporting Category D or E**

**1. Briefly describe how you have considered each of the following alternatives or how they are not applicable**

 **Replacement of vertebrate animals** (i.e. with in vitro models, computer models or less sentient animals):

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**Refinement of experimental procedures to minimize pain or distress** (i.e. early endpoints; use of analgesics, anesthetics or sedatives; techniques that reduce stress in animals):

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**Reduction in the number of animals** (i.e. using appropriate statistical methods in the design and analysis of the study; sharing tissue among investigators):

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**2. Methods used to search for alternatives (indicate all that apply):**

[ ]  **Literature search conducted**

See <http://www.nal.usda.gov/awic> for resources to assist in the search. The Norwegian 3Rs Center and the Animal Welfare Information Center (AWIC) have launched a new database called 3R Guide (<http://www.3rguide.info/>). The aim is to offer investigators a "one-stop shop" for locating key resources. All entries in the 3R Guide are categorized by Type (e.g. guidelines), Category (e.g. species) and 3R-relevance (Replacement, Reduction, Refinement).

**List names of databases** (more than one required):

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| 1. |  |
| 2. |  |
| 3. |  |

**Keywords used in database search** (specific to animal use):

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**Brief summary of what information was found during the literature search:**

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| **Date search was completed:** |  |
| **Years searched (should go back several years):** |  |

[ ]  **Other information/service utilized** (Elaborate below, providing specific information):

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**IACUC Appendix B: Surgery**

Complete this appendix for each surgical procedure and/or species even if the same information exists elsewhere in the application. USDA Animal Welfare Act regulations require veterinary consultation for any Category D or E animal use.

**Reference any applicable laboratory or Animal Care Facility SOP’s (ex: Anesthesia Monitoring, Equipment Sterilization Procedures and Monitoring Expiration Dates, Surgery Requirements when planning a surgical procedure)**

**Definition:** Major survival surgery is defined as penetrating a body cavity or having the potential for producing a permanent handicap for an animal expected to recover from surgery.

**1. Surgical procedure is:** [ ]  Non-Survival [ ]  Survival

**2. Species:**

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**3. Name of surgeon(s):**

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**4. Relevant experience with the animal model and procedure being used for each individual performing the surgical procedure:**

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**5. Location (room) of surgery:**

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**6. Describe pre-operative procedures (fasting, analgesic loading, etc…) and surgical procedures (include monitoring and supportive care):**

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**7. Anesthetic(s) (include dose, route, frequency and criteria for judging depth of anesthesia):**

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**8. Describe how aseptic methods will be maintained throughout the procedure (include use of gloves, surgical masks, sterile instruments and aseptic technique):**

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**For Survival Surgery:**

**How long will the animals be maintained after surgery?**

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**Describe postoperative care to be given: (Include analgesics, antibiotics and monitoring of fluids and body temperature. Please include time intervals for post-operative monitoring.)**

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**Describe the procedure that will be followed for the detection and management of post-operative complications during normal work hours, weekends, and holidays:**

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**IACUC Appendix C: Wild-Caught Animals**

**1. Does this research require federal or state permits?**

[ ]  No

[ ]  Yes. Attach a copy or indicate the dates of permit application and addresses of the agencies to which applications were made.

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**2. Describe the location of the field site or capture site:**

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**3. If the research will have an effect on the survival or reproduction of the animal, explain the anticipated extent of the impact and the alternative protocols considered:**

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**4. Describe the methods of capture to be used and cite the literature reference if the method is standard procedure or provide a detailed description if it is a non-standard method:**

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**5. Describe what procedure will be used if an unintended/accidental capture of a species not listed on the protocol occurs:**

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**6. Explain the method of animal transportation that will be used if applicable. If a university vehicle is not available or practical to carry out your research, the IACUC must approve the use of personal vehicles. An ad hoc subcommittee of the IACUC may inspect vehicles on demand and during IACUC semi-annual evaluations:**

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**7. Provide an estimate of the expected mortality for each capture method. Describe what procedure will be followed if a sick or injured animal is captured:**

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**8. If blood, teeth, or tissue samples are to be taken, indicate the type of sample, the method used, a literature reference if the method is standard procedure or provide a detailed description if it is a non-standard procedure. Include an estimate of the expected mortality for each sampling method.**

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**9. If the animals are held in captivity for a period longer than necessary to band, mark, measure, or take samples from, indicate the type of enclosure or cage, provide details on the care to be provided:**

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**10. Is Federal or state approval required to return the animals to the wild after being held in captivity?**

[ ]  No

[ ]  Yes (Include copies of the permit or approval documents)

1. **Potential Risks-This information should be provided to individuals working in the field.**
	1. **Exposure to infectious disease transmitting vectors (ticks, mosquitos):**
		1. **Attach PDF, “**[**NIOSH Fast Facts: Protecting yourself from Ticks and Mosquitoes**](https://www.cdc.gov/niosh/docs/2010-119/pdfs/2010-119.pdf)**”**
		2. **Attach table, “**[**Characteristics of Tickborne Diseases in Wisconsin**](https://www.dhs.wisconsin.gov/tickborne/tickborne-diseases-chart.pdf)**”, provided by WI Division of Public Health**
		3. **Mosquitoes can transmit several viruses that can cause human disease. In Wisconsin, these include West Nile virus, La Crosse virus, and Jamestown Canyon virus. Symptoms of illness are usually mild and nonspecific, and can include headache, fever, fatigue, muscle aches, and swollen lymph nodes. Some people may experience severe neuro-invasive illness, including flaccid paralysis, encephalitis (brain swelling) and meningitis (**[**WI Division of Public Health**](https://www.dhs.wisconsin.gov/arboviral/index.htm)**).**
2. **Other potential hazards:**

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1. **Likelihood of encountering hazards:**

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1. **Protective measures (may include awareness of potential risks, immunizations, personal protective equipment):**

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**Personnel should inform health care provider of contact with wild animals and field conditions should they become injured or ill.**

**IACUC Appendix D: Toxicology Studies/Microbial Virulence Testing**

**1. Describe materials to be evaluated: If hazardous materials are used, complete Appendix G.**

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**2. Describe the route and duration of administration:**

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**3. Describe the testing method employed (LD50, etc.)**

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**4. Describe criteria that will be used to ensure that the animal does not experience pain or distress and methods to monitor animals:**

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**5. If pain or distress is anticipated, how will they be minimized? Describe methods, including dose and route of administration, if appropriate:**

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**6. What is the endpoint of these studies (i.e. time points)?**

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**IACUC Appendix E: Dietary Manipulations or Fluid Restriction**

**1. Describe any dietary manipulations or special feeding requirements:**

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**2. Describe length of time animals will be on experimental diet:**

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**3. Describe what criteria will be used to determine continued health of animals while on food regulation. Example: regular monitoring for body weight loss and body condition, etc. Please refer to policy: Guidelines for Rodent Food and Fluid Regulation**

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**4. Will animals be provided less than ad lib fluids or drinking water for experimental reasons?**

[ ]  **No**

[ ]  **Yes (provide details including amount/day, monitoring of animals, criteria used to determine well-being of animals and scientific justification)**

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**IACUC Appendix F: Hazardous Agents**

**Note:** Any work with hazardous materials,biological materials, infectious agents, toxins of biological origin, human or nonhuman primate products, and recombinant or synthetic nucleic acid molecules requires IBC approval in congruence with IACUC. Visit our [website](https://www3.uwsp.edu/acadaff/orsp/Pages/What-is-IBC.aspx) for more information on biosafety requirements.

**1. Hazardous Chemicals:**

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| --- | --- | --- | --- | --- | --- | --- |
| **Chemical Name** | **Nature of chemical (carcinogen, toxin, teratogen…)** | **Route of Administration** | **Dosage** | **Route of Excretion** | **Is the carcass hazardous?** | **Is the bedding or caging hazardous?** |
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**2. Radiation:**

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| **Where will the radiation be used (building and room)?** |  |
| **Name of approved radioisotope permit holder:** |  |
| **Duration of permit:** |  |

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| **Radioisotope or radiation source** | **Route of Administration** | **Dosage (activity)** | **Route of Excretion** | **Is the carcass radioactive?** | **Is the bedding or caging radioactive?** |
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**3. Infectious Agents:**

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| --- | --- | --- | --- | --- | --- | --- | --- |
| **Name of Agent** | **Biosafety Level** | **Route of Administration** | **Dosage** | **Is the agent infectious to humans or animals?** | **Route of Excretion** | **Is the carcass hazardous?** | **Is the bedding or caging hazardous?** |
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**4. Recombinant DNA (including transgenic animals):**

Describe the host/vector system:

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| --- | --- | --- | --- | --- | --- | --- |
| **What is the gene that will be modified? Is this a gain or loss of functions?** | **Route of Administration** | **Dosage** | **Is the agent infectious to humans or animals?** | **Route of Excretion** | **Is the carcass hazardous?** | **Is the bedding or caging hazardous?** |
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