East Carolina University

**Institution Animal Care and Use Committee**

003 Ed Warren Life Sciences Building | Greenville NC 27834 – 4354

**252-744-2436** office | **252-744-2355** fax

**iacuc@ecu.edu**

**Animal Use Protocol Form – AUP**

Revised in 2022

**READ ALL SECTIONS FOR INSTRUCTIONS. Answer all applicable questions. Answer N/A if the question does not apply. Complete electronically. No hand-written versions accepted. Submit a signed electronic version to the IACUC Director at** **iacuc@ecu.edu****.**

**Instructions**

* All **REQUIRED** sections are marked with an “ **\*** ”
	+ Sections **I.** to **IV.** and Sections **VI** and **VII**. **MUST** be completed.
	+ In Section **V**., you **MUST** complete sub-section **V.A.** For sub-sections **V.B.** to **V.S.**, **only** answer applicable questions, **check** the N/A box if the question does not apply.
* All sections in the “**Table of Contents**” are hyperlinks that are bookmarked in the document. Please place your mouse on the desired section, press the “**Ctrl**” key on your keyboard and **left click** on your mouse simultaneously. This will take you to the corresponding section in the document.
* All sections are presented as collapsed. To expand the sections, please click on the and answer all applicable questions.
* To come back to the first page of the document, please press the “**Ctrl**” key on your keyboard and the “**Home**” key simultaneously.

**! For Mac Users – Instructions!**

* In **OUTLINE** Mode:
	+ To expand text under heading, use “**Control+Shift+ Plus Sign (+)**”
	+ To collapse text under heading, use “**Control+Shift+Minus Sign (-)**”

***For IACUC Use Only***

|  |  |  |  |
| --- | --- | --- | --- |
| **AUP #** |  | **PI** |  |
| **New/Renewal** |  |  |  |
| **Full Review Date** | DR/Date |  |  |
| **Approval Date** |  |  |  |
| **Study Type** |  |  |  |
| **Species** |  |  |  |
| **Number of Animals Approved** |  |  |  |
| **Pain/Distress Category** |  |  |  |
| **Surgery** | SS | MSS |  |
| **Prolonged Restraint** |  |  |  |
| **Food/Fluid Regulation** |  |  |  |
| **Other** |  |  |  |
| **Hazard Approval/Dates** | IBC | EHS | Rad |
| **Non-Centralized Housing** |  |  |  |
| **Exception to the Guide** |  |  |  |
| **Amendments Approved** |  |  |  |

# SS: Survival Surgery, MSS: Multiple Survival Surgery

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|  |  |
| --- | --- |
| **Principal Investigator:****Department:****E-mail:****Phone #:** **(best # to contact in case of emergency)** | **Secondary Contact:** |
| **Department:****E-mail:****Phone #:** **(best # to contact in case of emergency)** |

# **SECTION I. General Protocol Information\***

1. **Protocol Identification**
	1. Project Title:

Click or tap here to enter text.

* 1. Project Type:

[ ]  Research

[ ]  Breeding

[ ]  Teaching

[ ]  Training

[ ]  Other Click or tap here to enter text.

* 1. Project Funding/Sponsor\*:

|  |  |  |
| --- | --- | --- |
|  | **Sponsor** | **Grant/Proposal Number** |
| **Federal (NIH/NSF/other)** |  |  |
| **Federal (DOD)** |  |  |
| **Private**  |  |  |
| **State** |  |  |
| **Institutional** |  |  |
| **Departmental** |  |  |
| **Start-up** |  |  |
| **Other** |  |  |

\*If this application is covered on an awarded grant, please attach the grant proposal to this application.

1. Collaboration:

Will any live animal work for this project be performed at a facility or institution other than ECU?

[ ]  Yes [ ]  No If yes, complete the following

1. Which institution/facility will have ownership of the animals?

Click or tap here to enter text.

1. What is the nature of the collaborative work being performed, including where and with whom work will be performed?

Click or tap here to enter text.

1. If the collaborative work is being performed as part of an approved IACUC protocol at the other institution, please include a copy of the approval letter with this protocol submission and complete the tracking protocol form.
2. **INDICATE the type of submission below by checking the applicable box and *follow the bolded instructions***

[ ]  INITIAL APPLICATION – **Complete this form beginning with Section II**.

[ ]  AMENDMENT - **All changes incorporated into this document must be done using the “Track Changes” feature in Word (under “Review” tab, select “Track Changes”) so the changes are plainly discernible.**

* 1. Amendment # Choose an item.
	2. Type of Modification (check all that apply and describe in question section II.B.3)

[ ]  Personnel Changes

[ ]  Location Changes

[ ]  Species Changes

[ ]  Animal Number Changes

[ ]  Procedure Changes

[ ]  Other

**Please proceed to Section III.A., provide the rationale to the amendment, and review the entire document, making changes as needed using “Track Changes”.**

[ ]  3-YEAR RENEWAL - **All changes incorporated into this document must be done using the “Track Changes” feature in Word (under “Review” tab, select “Track Changes”) so the changes are plainly discernible.**

1. Over the last 12 months, have you encountered any unexpected outcomes or complications? If so, describe below.

Click or tap here to enter text.

1. Please provide the number of animals used within the last 12 months.

Click or tap here to enter text.

1. Please provide a brief update on the progress of this project over the last 3 years.

Click or tap here to enter text.

1. Please provide a brief rationale for the renewal of the AUP.

Click or tap here to enter text.

**To incorporate the detailed description of the changes, proceed to Section III., review the entire document and make changes as necessary**.

# **SECTION II. Personnel\***

List all personnel (PIs, co-investigators, researchers, students, technicians) that will be working with live animals and describe their qualifications and experience with these specific procedures. If people are to be trained, indicate by whom:

|  |  |  |  |
| --- | --- | --- | --- |
| **Name/Degree/Certification** | **Position/Role(s)/Responsibilities** | **Required Training\*****(Yes/No)** | **Relevant Animal Experience/Training****(include species, procedures, number of years, etc…)** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

\*Required Training: IACUC online training, enrollment in the Occupational Health program (basic health history form), animal handling training (if applicable), experimental surgery training (if applicable). Find all information on Required Training on the [IACUC Website](https://iacuc.ecu.edu/).

# **SECTION III. Regulatory Compliance\***

1. **Non-Technical Summary**

Provide a non-technical description of the project relating the significance of the animal use to the scientific objective. An effective lay (non-scientific) summary includes a **general overview** of the intended use of animals that provides the **general public** with an understanding of the scientific question being asked, the **species** used and the anticipated benefit.

The lay summary needs to answer the following basic questions below.

1. What is the research or teaching objective of the protocol?

Click or tap here to enter text.

1. What species of animal will be used?

Click or tap here to enter text.

1. Please provide a clear, concise, and sequential overview of animal use (do NOT provide a detailed description of the procedures here and do not copy and paste grant abstract).

Click or tap here to enter text.

1. If successful, how will the study benefit advancement of knowledge, human or animal health, or good of society (or all)?

Click or tap here to enter text.

1. Amendment

Provide the rationale for the amendment here

Click or tap here to enter text.

1. **Ethics and Animal Use**
2. Duplication

Does this study duplicate or contain elements that duplicate existing research?

[ ]  YES [ ]  NO

If YES, why is it necessary (note: teaching by definition is duplicative)

Click or tap here to enter text.

1. 3R’s – Refinement, Reduction, and Replacement

Address the 3 Rs of refinement, reduction, and replacement. **Refinement** refers to modification of husbandry or experimental procedures to enhance animal well-being and minimize or eliminate pain and distress. **Replacement** refers to absolute (i.e. replacing animals with an inanimate system) or relative (i.e. using less sentient species) replacement. **Reduction** involves strategies such as experimental design analysis, application of newer technologies, use of appropriate statistical methods, etc., to use the fewest animals or maximize information without increasing animal pain or distress.

Click or tap here to enter text.

1. Alternatives to the Use of Live Animals

Are there less invasive procedures, other less sentient species, isolated organ preparation, cell or tissue culture, or computer simulation that can be used in place of the live vertebrate species proposed here?

[ ]  YES [ ]  NO

If YES, please explain why you cannot use these alternatives.

Click or tap here to enter text.

1. Consideration of Alternatives to Painful/Distressful Procedures

Include a literature search to ensure that alternatives to all procedures that may cause more than momentary or slight pain or distress to the animals have been considered.

1. Please list **all** the potential painful or distressful procedures in the protocol

Click or tap here to enter text.

1. For the procedures listed above, provide the following information (do not submit search results but keep them for your records)

|  |  |
| --- | --- |
| **Date search was performed:** |  |
| **Database(s) searched (i.e. PubMed, Google Scholar, etc):** |  |
| **Time period covered by the search****(i.e. 2000 - present)** |  |
| **Search strategy (including scientifically relevant terminology)** |  |
| **Other sources consulted** |  |

1. In a few sentences, please provide a brief narrative indicating the results of the search(es) to determine the availability of alternatives and explain why these alternatives were not chosen.

Click or tap here to enter text.

1. **Hazardous Agents**
	1. Protocol Related Hazards (chemical, biological or radiological)

Please indicate if any of the following are used in animals and the status of review/approval by the referenced committees:

|  |  |  |  |
| --- | --- | --- | --- |
| **Hazards** | **Oversight Committee** | **Status (Approved, Pending, Submitted)/Date** | **AUP Appendix I Completed?** |
| **Radioisotopes** | Radiation |  | Choose an item. |
| **Ionizing radiation** | Radiation |  | Choose an item. |
| **Infectious agents (bacteria, viruses, rickettsia, prions, etc.)** | IBC |  | Choose an item. |
| **Toxins of biological origins (venoms, plant toxins, etc.)** | IBC |  | Choose an item. |
| **Transgenic, Knock In, Knock Out Animals---breeding, cross breeding or any use of live animals or tissues** | IBC |  | Choose an item. |
| **Human tissues, cells, body fluids, cell lines** | IBC |  | Choose an item. |
| **Viral/Plasmid Vectors/Recombinant DNA or recombinant techniques** | IBC |  | Choose an item. |
| **Oncogenic/toxic/mutagenic chemical agents** | EH&S |  | Choose an item. |
| **Nanoparticles** | EH&S |  | Choose an item. |
| **Cell lines, tissues or other biological products injected or implanted in animals** | IBC |  | Choose an item. |
| **Other** |  |  | Choose an item. |

* 1. Incidental Hazards

Will personnel be exposed to any incidental zoonotic diseases or hazards during the study (field studies, primate work, etc)? If so, please identify each and explain steps taken to mitigate risk.

Click or tap here to enter text.

# **SECTION IV. Animals and Housing\***

1. **Species and Strains** Click or tap here to enter text.
2. **Age, Sex, and/or Weight**

Please check ALL that apply.

[ ]  Young (rodent fetuses, pre-weaned pups; fish embryos/larvae; tadpoles; hatchling/fledgling)

[ ]  Adult

[ ]  Female

[ ]  Male

If you are using a species other than rodents, fish, amphibians, reptiles, or birds, please indicate weight range and/or age range

Click or tap here to enter text.

1. **Animal Numbers**
2. Please complete the following table:

|  |  |  |
| --- | --- | --- |
| **Number of Animals in Treatment and Control Groups**  | **Additional animals (Breeders, substitute animals, training)** | **Total Number of Animals Used for this Project** |
|  |  |  |
|  |  |  |
|  |  |  |

1. Justify the above species and animal numbers (use statistical justification when possible):

Please also include all animals born even if their genotype is non-desirable or numbers not needed for experimental purposes, also include fetuses if used for experiments.

Click or tap here to enter text.

1. For breeding situations, will you be following the DCM breeding guidelines as shown on the DCM website?

[ ]  Yes [ ]  No [ ]  N/A

If NO, describe and justify.

Click or tap here to enter text.

1. If genotyping, will you be following IACUC genotyping guidelines as shown on [IACUC Website](https://iacuc.ecu.edu/)?

[ ]  Yes [ ]  No [ ]  N/A

If NO, describe and justify.

Click or tap here to enter text.

1. Will the phenotype of mutant, transgenic or knockout animals predispose them to any health, behavioral, physical abnormalities, or cause debilitating effects in experimental manipulations?

[ ]  Yes [x]  No

If YES, describe.

Click or tap here to enter text.

1. Are there any deviations from standard husbandry practices as shown on the DCM website?

[ ]  Yes [ ]  No

If YES, describe conditions and justify the exceptions to standard housing (temperature, light cycles, sterile cages, special feed, prolonged weaning times, wire-bottom cages, etc.).

Click or tap here to enter text.

1. The default housing method for social species is pair or group housing (including mice, rats, guinea pigs, rabbits, dogs, pigs, monkeys). Is it necessary for animals to be singly housed at any time during the study?

[ ]  Yes [ ]  No

If YES, describe housing and justify the need to singly house social species.

Click or tap here to enter text.

1. Are there experimental or scientific reasons why routine environmental enrichment should not be provided?

[ ]  Yes [ ]  No

If YES, describe and justify the need to withhold enrichment.

Click or tap here to enter text.

1. If wild animals will be captured or used, provide permissions (collection permit # or other required information)

Click or tap here to enter text.

1. List all laboratories or locations outside the animal facility where animals will be used. Note that animals may not stay in areas outside the animal facilities for more than 12 hours without prior IACUC approval. For field studies, list location of work/study site.

Click or tap here to enter text.

# **SECTION V. Animal Procedures**

## **Experimental Design\***

Outline the experimental design including all treatment and control groups and the number of animals in each. Tables or flow charts are particularly useful to communicate your design. Briefly state surgical plans in this section. Surgical procedures can be described in detail in V.S. If applicable, you can reference Standard Operating Procedures (SOPs) listed on the [IACUC Website](https://iacuc.ecu.edu/). If deviation from approved SOP – please describe.

Click or tap here to enter text.

***In sections V.B-V.S below, please respond to all items relating to your proposed animal procedures. If a section does not apply to your experimental plans, please check N/A.***

Please refer to [DCM Website](https://comparativemedicine.ecu.edu/) and [IACUC Website](https://iacuc.ecu.edu/) for relevant guidelines and SOPs.

## **Anesthesia/Analgesia/Tranquilization/Pain/Distress Management for Procedures other than Surgery** [ ]  **N/A**

For all procedures, provision of **pre-emptive** (pre-procedural) **analgesia** is **required**, unless specifically exempted by DCM veterinarians. For major survival surgical procedures and extensive non-surgical procedures requiring anesthesia, **post-procedural analgesia** must be provided for a minimum of **3 full days following** anesthetic recovery, unless specifically exempted by DCM veterinarians. **Analgesic** administration should be continued for at least **1 full day following** recovery from minor surgical and non-surgical procedures. Please contact DCM veterinary staff for recommendations and guidance when formulating anesthetic and analgesic regimens.

Adequate **records** describing anesthetic monitoring and recovery must be maintained for all species. Please see Guidelines for Intra-operative and Intra-procedural Monitoring on the IACUC website.

If anesthesia/analgesia must be **withheld for scientific reasons**, please provide compelling scientific justification as to why this is necessary:

Click or tap here to enter text.

1. Describethe pre-procedural preparation of the animals.
2. Food restricted for Click or tap here to enter text. hours
3. Food restriction is not recommended for rodents and rabbits and must be justified

Click or tap here to enter text.

1. Water restricted for Click or tap here to enter text.hours
2. Water restriction is not recommended in any species for routine pre-op prep and must be justified

Click or tap here to enter text.

1. Anesthesia/Analgesia **for Procedures Other than Surgery**

If anesthetics/analgesics will be administered for procedure other than surgery, please fill out the appropriate section in the table below.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Agent** | **Concentration** | **Dose (mg/kg)** | **Max Volume** | **Route** | **Frequency** | **# of Days Administered** |
| **Pre-procedure analgesic** |  |  |  |  |  |  |  |
| **Pre-anesthetic** |  |  |  |  |  |  |  |
| **Anesthetic** |  |  |  |  |  |  |  |
| **Post procedure analgesic** |  |  |  |  |  |  |  |
| **Other** |  |  |  |  |  |  |  |

1. Reasons for administering agent(s)

Click or tap here to enter text.

1. For which procedures

Click or tap here to enter text.

1. Methods for monitoring anesthetic depth

Click or tap here to enter text.

1. Methods of physiologic support during anesthesia and recovery

Click or tap here to enter text.

1. Duration of recovery

Click or tap here to enter text.

1. Frequency of recovering monitoring

Click or tap here to enter text.

1. Specifically, what will be monitored

Click or tap here to enter text.

1. When will animals be returned to their home environment?

Click or tap here to enter text.

1. Describe any behavioral or husbandry manipulations that will be used to alleviate pain, distress, and/or discomfort

Click or tap here to enter text.

## **Use of Paralytics** [ ]  **N/A**

1. Will paralyzing drugs be used?

[ ]  Yes [ ]  No

If YES, answer questions 2 to 6 below.

1. For what purpose?

Click or tap here to enter text.

1. Please provide scientific justification for paralytic use.

Click or tap here to enter text.

1. Paralytic drug

Click or tap here to enter text.

1. Dose

Click or tap here to enter text.

1. Methods of ensuring appropriate analgesia during paralysis.

Click or tap here to enter text.

## **Blood or Body Fluid Collection** [ ]  **N/A**

If blood and/or body fluid will be collected, please fill out the appropriate sections in the table below.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Location on animal** | **Needle/catheter size** | **Volume Collected** | **Frequency of Procedure** | **Time interval between collections** |
| **Blood Collection** |  |  |  |  |  |
| **Body Fluid Collection** |  |  |  |  |  |
| **Other**  |  |  |  |  |  |

## **Injections, Gavage, and Other Substance Administration** [ ]  **N/A**

If any substances will be injected, gavage or administered in any other way, please fill out the appropriate sections in the table below.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Compound** | **Location & Route of admin** | **Needle/catheter/gavage size** | **Max volume admin** | **Frequency (ie two times per day)** | **# of days admin (ie for 5 days)** | **Max dosages (mg/kg)** |
| **Injection** |  |  |  |  |  |  |  |
| **Gavage** |  |  |  |  |  |  |  |
| **Other**  |  |  |  |  |  |  |  |

1. Non-Pharmaceutical Grade Compounds

Pharmaceutical grade drugs, biologics, reagents, and compounds are defined as agents approved by the Food and Drug Administration (FDA) or for which a chemical purity standard has been written/established by any recognized pharmacopeia such as USP, NF, BP, etc. These standards are used by manufacturers to help ensure that the products are of the appropriate chemical purity and quality, in the appropriate solution or compound, to ensure stability, safety, and efficacy. For all injections and infusions for CLINICAL USE, PHARMACEUTICAL GRADE compounds must be used whenever possible. Pharmaceutical grade injections and infusions for research test articles are preferred when available. If pharmaceutical grade compounds are not available and non-pharmaceutical grade agents must be used, then the following information is necessary:

Does this study involve the administration of non-pharmaceutical grade compounds?

[ ]  Yes [ ]  No If YES, fill out sections V.E.1.a. and b. below.

* 1. Please provide a scientific justification for the use of ALL non-pharmaceutical grade compounds. This may include pharmaceutical-grade compound(s) that are not available in the appropriate concentration or formulation, or the appropriate vehicle control is unavailable.

Click or tap here to enter text.

* 1. Indicate the method of preparation, addressing items such as purity, sterility, pH, osmolality, pyrogenicity, adverse reactions, etc. (please refer to ECU IACUC guidelines for non-pharmaceutical grade compound use), labeling (i.e. preparation and use-by dates), administration and storage of each formulation that maintains stability and quality/sterility of the compound(s).

Click or tap here to enter text.

## **Prolonged Restraint with Mechanical Devices** [ ]  **N/A**

Prolonged restraint in this context means **beyond routine care and use procedures** for rodent and rabbit restrainers, and large animal stocks. Prolonged restraint also includes **any**use of slings, tethers, metabolic crates, inhalation chambers, primate chairs and radiation exposure restraint devices.

* + - 1. For what procedure(s)

Click or tap here to enter text.

* + - 1. Explain why non-restraint alternatives cannot be utilized

Click or tap here to enter text.

* + - 1. Restraint device(s)

Click or tap here to enter text.

* + - 1. Duration of restraint

Click or tap here to enter text.

* + - 1. Frequency of observations during restraint/person responsible

Click or tap here to enter text.

* + - 1. Frequency and total number of restraint(s)

Click or tap here to enter text.

* + - 1. Conditioning procedure

Click or tap here to enter text.

* + - 1. Steps to assure comfort and well-being

Click or tap here to enter text.

* + - 1. Describe potential adverse effects of prolonged restraint and provide humane endpoints (criteria for either humanely euthanizing or otherwise removing from study)

Click or tap here to enter text.

## **Tumor Studies, Disease Models, Toxicity Testing, Vaccine Studies, Trauma Studies, Pain Studies, Organ or System Failure Studies, Shock Models, etc.** [ ]  **N/A**

1. Describe methodology

Click or tap here to enter text.

1. Expected model and/or clinical/pathological manifestations

Click or tap here to enter text.

1. Signs of pain/discomfort

Click or tap here to enter text.

1. Frequency of observations

Click or tap here to enter text.

1. Describe potential adverse side effects of procedures and provide humane endpoints (criteria for either humanely euthanizing or otherwise removing from study)

Click or tap here to enter text.

## **Treadmills/Swimming/Forced Exercise** [ ]  **N/A**

1. Describe aversive stimulus (if used)

Click or tap here to enter text.

1. Conditioning

Click or tap here to enter text.

1. Safeguards to protect animal

Click or tap here to enter text.

1. Duration

Click or tap here to enter text.

1. Frequency

Click or tap here to enter text.

1. Total number of sessions

Click or tap here to enter text.

1. Describe potential adverse effects of procedures and provide humane endpoints (criteria for either humanely euthanizing or otherwise removing from study)

Click or tap here to enter text.

## **Projects Involving Food and Water Regulation or Dietary Manipulation** [ ]  **N/A**

Note: Routine pre-surgical fasting not relevant for this section

1. Food Regulation
	1. Amount regulated and rationale

Click or tap here to enter text.

* 1. Frequency and duration of regulation (hours for short term/weeks or months for long term)

Click or tap here to enter text.

* 1. Frequency of observations/parameters documented (i.e. recording body weight, body condition, etc.)

Click or tap here to enter text.

* 1. Describe potential adverse effects of procedures and provide humane endpoints (criteria for either humanely euthanizing or otherwise removing from study)

Click or tap here to enter text.

1. Fluid Regulation
	1. Amount regulated and rationale

Click or tap here to enter text.

* 1. Frequency and duration of regulation (hours for short term/weeks or months for long term)

Click or tap here to enter text.

* 1. Frequency of observations/parameters documented (i.e. recording body weight, hydration status, etc.)

Click or tap here to enter text.

* 1. Describe potential adverse effects of procedures and provide humane endpoints (criteria for either humanely euthanizing or otherwise removing from study)

Click or tap here to enter text.

1. Dietary Manipulations
	1. Compound supplemented/deleted and amount

Click or tap here to enter text.

* 1. Frequency and duration of manipulation (hours for short term/weeks or months for long term)

Click or tap here to enter text.

* 1. Frequency of observations/parameters documented (i.e. recording body weight, body condition, etc.)

Click or tap here to enter text.

* 1. Describe potential adverse effects of procedures and provide humane endpoints (criteria for either humanely euthanizing or otherwise removing from study)

Click or tap here to enter text.

## **Endoscopy, Fluoroscopy, X-Ray, Ultrasound, MRI, CT, PET, Other Imaging** [ ]  **N/A**

1. Describe animal methodology

Click or tap here to enter text.

1. Duration of procedure

Click or tap here to enter text.

1. Frequency of observations during procedure

Click or tap here to enter text.

1. Frequency/total number of procedures

Click or tap here to enter text.

1. Method of transport to/from procedure area

Click or tap here to enter text.

1. Describe potential adverse side effects of procedures and provide humane endpoints (criteria for either humanely euthanizing or otherwise removing from study)

Click or tap here to enter text.

1. Please provide or attach appropriate permissions/procedures for animal use on human equipment

Click or tap here to enter text.

## **Polyclonal Antibody Production** [ ]  **N/A**

1. Antigen/adjuvant used and justification for adjuvant choice

Click or tap here to enter text.

1. Needle size

Click or tap here to enter text.

1. Route of injection

Click or tap here to enter text.

1. Site of injection

Click or tap here to enter text.

1. Volume of injection

Click or tap here to enter text.

1. Total number of injection sites

Click or tap here to enter text.

1. Frequency and total number of boosts

Click or tap here to enter text.

1. What will be done to minimize pain/distress

Click or tap here to enter text.

1. Describe potential adverse effects of procedure and provide humane endpoints (criteria for either humanely euthanizing or otherwise removing from study)

Click or tap here to enter text.

## **Monoclonal Antibody Production** [ ]  **N/A**

1. Describe methodology

Click or tap here to enter text.

1. Is pristane used?

[ ]  Yes [ ]  No

If YES, what volume?

Click or tap here to enter text.

1. Will ascites be generated?

[ ]  Yes [ ]  No

If YES, answer the following sections.

1. Criteria/Signs that will dictate ascites harvest

Click or tap here to enter text.

1. Size of needle for taps

Click or tap here to enter text.

1. Total number of taps

Click or tap here to enter text.

1. How will animal be monitored/cared for following taps

Click or tap here to enter text.

1. What will be done to minimize pain/distress

Click or tap here to enter text.

1. Describe potential adverse effects of procedure and provide humane endpoints (criteria for either humanely euthanizing or otherwise removing from study)

Click or tap here to enter text.

## **Temperature/Light/Environmental Manipulations** [ ]  **N/A**

1. Describe manipulation(s)

Click or tap here to enter text.

1. Duration

Click or tap here to enter text.

1. Intensity

Click or tap here to enter text.

1. Frequency

Click or tap here to enter text.

1. Frequency of observations/parameters documented

Click or tap here to enter text.

1. Describe potential adverse effects of procedures and provide humane endpoints (criteria for either humanely euthanizing or otherwise removing from study)

Click or tap here to enter text.

## **Behavioral Studies** [ ]  **N/A**

1. Describe aversive stimulus (if used)

Click or tap here to enter text.

1. Conditioning

Click or tap here to enter text.

1. Safeguards to protect animal

Click or tap here to enter text.

1. Duration

Click or tap here to enter text.

1. Frequency

Click or tap here to enter text.

1. Total number of sessions

Click or tap here to enter text.

1. Describe potential adverse effects of procedures and provide humane endpoints (criteria for either humanely euthanizing or otherwise removing from study)

Click or tap here to enter text.

## **Capture with Mechanical Devices/Traps/Nets** [ ]  **N/A**

1. Describe the capture device/method

Click or tap here to enter text.

1. Maximum time animal will be in capture device

Click or tap here to enter text.

1. Frequency of checking capture device

Click or tap here to enter text.

1. Methods to ensure well-being of animal in capture device

Click or tap here to enter text.

1. Methods to avoid non-target species capture

Click or tap here to enter text.

1. Method of transport to laboratory/field station/processing site and duration of transport

Click or tap here to enter text.

1. Method to ensure animal well-being during transport

Click or tap here to enter text.

1. Expected mortality rates

Click or tap here to enter text.

1. Describe potential adverse effects of procedures and provide humane endpoints (criteria for either humanely euthanizing or otherwise removing from study)

Click or tap here to enter text.

## **Manipulations of Wild-Caught Animals in the Field or Laboratory** [ ]  **N/A**

1. Parameters to be measured/collected

Click or tap here to enter text.

1. Approximate time required for data collection per animal

Click or tap here to enter text.

1. Method of restraint for data collection

Click or tap here to enter text.

1. Methods to ensure well-being of animal during processing

Click or tap here to enter text.

1. Disposition of animal post-processing

Click or tap here to enter text.

1. Describe potential adverse effects of procedures and provide humane endpoints (criteria for either humanely euthanizing or otherwise removing from study)

Click or tap here to enter text.

## **Wildlife Telemetry/Other Marking Methods** [ ]  **N/A**

1. Describe methodology (including description of device)

Click or tap here to enter text.

1. Will telemetry device/tags/etc be removed?

[ ]  Yes [ ]  No

If YES, describe.

Click or tap here to enter text.

1. Describe potential adverse effects of procedures and provide humane endpoints (criteria for either humanely euthanizing or otherwise removing from study)

Click or tap here to enter text.

## **Other Animal Manipulations** [ ]  **N/A**

1. Describe methodology

Click or tap here to enter text.

1. Describe methods to ensure animal comfort and well-being

Click or tap here to enter text.

1. Describe potential adverse effects of procedures and provide humane endpoints (criteria for either humanely euthanizing or otherwise removing from study)

Click or tap here to enter text.

## **Surgical Procedures** [ ]  **N/A**

All **survival** surgical procedures must be done **aseptically**, regardless of species or location of surgery. Adequate **records** describing surgical procedures, anesthetic monitoring and postoperative care must be maintained for all species. Please see Guidelines for Intra-Operative and Intra-Procedural Monitoring on the [IACUC Website](https://iacuc.ecu.edu/) .

1. Location of surgery (building and room#)

Click or tap here to enter text.

1. Type of surgery

Describe the type of surgery and check all that apply

Click or tap here to enter text.

[ ]  Non-survival surgery (procedure is performed under anesthesia, followed by euthanasia, and animal does not regain consciousness). Please note if the animal is first euthanized prior to any manipulations or tissue harvest, this does not constitute non-survival surgery.

[ ]  Major survival surgery (major surgery penetrates and exposes a body cavity or produces substantial impairment of physical or physiologic function)

[ ]  Minor survival surgery

[ ]  Multiple survival surgeries – if YES, please provide scientific justification for multiple survival surgical procedures

Click or tap here to enter text.

1. Describe the pre-op preparation of the animals
2. Food restricted for Click or tap here to enter text. hours
3. Food restriction is not recommended for rodents and rabbits and must be justified

Click or tap here to enter text.

1. Water restricted for Click or tap here to enter text.hours
2. Water restriction is not recommended in any species for routine pre-op prep and must be justified

Click or tap here to enter text.

1. Minimal sterile techniques will include – check all that apply

Please refer to DCM Guidelines for Aseptic Surgery for specific information on what is required for each species and type of surgery (survival vs. non-survival).

[ ]  Sterile instruments

How will instruments be sterilized?

Click or tap here to enter text.

If serial surgeries are done, how will instruments be sterilized between surgeries:

Click or tap here to enter text.

[ ]  Sterile gloves

[ ]  Mask

[ ]  Cap

[ ]  Sterile gown

[ ]  Sanitized operating area

[ ]  Clipping of plucking of hair or feathers

[ ]  Skin preparation with a sterilant such as betadine

[ ]  Practices to maintain sterility of instruments during surgery

[ ]  Non- survival (clean gloves, clean instruments, etc.)

1. Describe all surgical procedures
	1. Skin incision size and site on the animal

Click or tap here to enter text.

* 1. Describe surgery in detail (include size of implant if applicable)

Click or tap here to enter text.

* 1. Method of wound closure

Click or tap here to enter text.

* + 1. Number of layers

Click or tap here to enter text.

* + 1. Type of wound closure and suture pattern

Click or tap here to enter text.

* + 1. Suture type/size/wound clips/tissue glue

Click or tap here to enter text.

* + 1. Plan for removing skin suture/wound clips/etc

Click or tap here to enter text.

1. Anesthetic protocol

For **all procedures**, provision of **pre-emptive (pre-procedural)** **analgesia** is **required**, unless specifically exempted by DCM veterinarians. For **major survival surgical** procedures and **extensive non-surgical** procedures requiring anesthesia, **post-procedural analgesia** must be provided for a minimum of **3 full days** following anesthetic recovery, unless specifically exempted by DCM veterinarians. **Analgesic** administration should be continued for at least **1 full day** following recovery from **minor surgical** and **non-surgical** procedures. Please contact DCM veterinary staff for recommendations and guidance when formulating anesthetic regimens.

* 1. If anesthesia/analgesia must be withheld for scientific reasons, please provide compelling scientific justification as to why this is necessary

Click or tap here to enter text.

* 1. Anesthesia/Analgesia for surgical procedures

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Agent** | **Dose (mg/kg or %)** | **Max Volume** | **Route** | **Frequency** | **# of Days Administered** |
| **Pre-procedure analgesic** |  |  |  |  |  |  |
| **Pre-anesthetic** |  |  |  |  |  |  |
| **Anesthetic** |  |  |  |  |  |  |
| **Post procedure analgesic** |  |  |  |  |  |  |
| **Other**  |  |  |  |  |  |  |

* 1. Methods that will be used to monitor anesthetic depth (include extra measures employed when paralyzing agents are used)

Click or tap here to enter text.

* 1. Methods of physiologic support during anesthesia and immediate post-op period (fluids, warming, etc.)

Click or tap here to enter text.

* 1. List what parameters are monitored during immediate post-op period. Provide the frequency and duration.

Click or tap here to enter text.

* 1. Describe any other manipulations that will be used to alleviate pain, distress, and/or discomfort during the immediate post-op period (soft bedding, long sipper tubes, food on floor, dough diet, etc.)

Click or tap here to enter text.

* 1. List criteria used to determine when animals are adequately recovered from anesthesia and when the animals can be returned to their home environment

Click or tap here to enter text.

1. Recovery from surgical manipulations (after animal regains consciousness and is returned to its home environment)

Click or tap here to enter text.

* 1. What parameters (behavior, appetite, mobility, wound healing, etc.) will be monitored

Click or tap here to enter text.

* 1. How frequently (times per day) will animals be monitored

Click or tap here to enter text.

* 1. How long post-operatively (days) will animals be monitored

Click or tap here to enter text.

1. Surgical manipulations affecting animals
	1. Describe any signs of pain/discomfort/functional deficits resulting from the surgical procedure

Click or tap here to enter text.

* 1. What will be done to manage any signs of pain or discomfort (include pharmacologic and non-pharmacologic interventions)

Click or tap here to enter text.

* 1. Describe potential adverse effects of procedures and provide humane endpoints (criteria for either humanely euthanizing or otherwise removing from study)

Click or tap here to enter text.

# **SECTION VI. Euthanasia\***

Please refer to the AVMA Guidelines for the Euthanasia of Animals: 2020 Edition and DCM Guidelines on the [IACUC Website](https://iacuc.ecu.edu/) to determine appropriate euthanasia methods.

## **Euthanasia Procedure**

All investigators, even those conducting non-terminal studies, must complete this section in case euthanasia is required for humane reasons.

* + - 1. Physical method

If a physical method is used, the animal should be first sedated/anesthetized with CO₂ or other anesthetic agent. If prior sedation is not possible, a scientific justification must be provided.

Click or tap here to enter text.

* + - 1. Inhalant method

[ ]  Carbon Dioxide [ ]  Other

If OTHER, describe the agent and delivery method

Click or tap here to enter text.

* + - 1. Non-inhalant pharmaceutical method (injectables, MS-222, etc.)

Please provide the following

1. Agent

Click or tap here to enter text.

1. Dose or concentration

Click or tap here to enter text.

1. Route

Click or tap here to enter text.

## **Method of Ensuring Death**

The method can be physical method, such as pneumothorax or decapitation for small species and assessment method such as auscultation for large animals)

Click or tap here to enter text.

## **Describe disposition of carcass following euthanasia**

Click or tap here to enter text.

# **SECTION VII. Assurance and Signatures\***

Iacknowledge that humane care and use of animals in research, teaching and testing is of paramount importance, and agree to conduct animal studies with professionalism, using ethical principles of sound animal stewardship. I further acknowledge that I will perform only those procedures that are described in this AUP and that my use of animals must conform to the standards described in the Animal Welfare Act, the Public Health Service Policy, The Guide for the Care and Use of Laboratory Animals, the Association for the Assessment and Accreditation of Laboratory Animal Care, and East Carolina University.

Please submit the completed animal use protocol form via e-mail attachment to iacuc@ecu.edu. You must also carbon copy your Department Chair.

**PI Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

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

**IACUC Chair: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Animal Use Protocol Form – Appendix 1**

Revised in 2022

East Carolina University

**Institution Animal Care and Use Committee**

003 Ed Warren Life Sciences Building | Greenville NC 27834 – 4354

**252-744-2436** office | **252-744-2355** fax

**iacuc@ecu.edu**

READ ALL INSTRUCTIONS. Answer all questions and fill out applicable page(s). Complete electronically and submit a copy to the IACUC Director at iacuc@ecu.edu. You will date and sign after review and approval by subject matter experts.

|  |  |
| --- | --- |
| **Principal Investigator:****AUP#:****Department:****E-mail:****Phone #:** **(best # to contact in case of emergency)** | **Secondary Contact:** |
| **Department:****E-mail:****Phone #:** **(best # to contact in case of emergency)** |

**THE FOLLOWING HAZARDOUS AGENT(S) WILL BE USED – check all that apply**

[ ]  CHEMICAL AGENTS –fill out the top portion of the **blue page**

[ ]  BIOLOGICAL AGENTS – fill out the top portion of the **orange page**

[ ]  RADIATION – fill out the top portion of the **yellow page**

1. **Verify** that all planned hazardous agents use matches what is in the approved AUP (and Lab Safety Plan).
2. **Notify** the Facility Manager Aaron Hinkle by phone (744- 2997) or email (hinklea@ecu.edu) at least one week before planned hazard use (two weeks if this is the first time you are using the agent).
3. On the day of hazard use, **flip** this door sign over and display all applicable Appendix 1 hazard signs that describe the hazard(s) and associated handling procedures so they are visible to all personnel.
4. **Place** the appropriate hazard stickers on each animal cage after the hazard has been administered.
5. **Record** the hazard administration and related information on the yellow procedure card for each cage and continue per Yellow Procedure Card PowerPoint (on IACUC website).
6. If there are any questions, **contact** the Facility Manager (744-2997).

**PI Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**When HAZARD in USE**

**Display ALL that apply**

|  |
| --- |
| **CHEMICAL HAZARD** |
| **Principal Investigator:****AUP#:****Department:****Email:****Phone#:****(best # to contact in case of emergency)** | **Secondary Contact:****Department:****Email:****Phone#:****(best # to contact in case of emergency)**  |
| **Chemical Agents used:** |
| **Below this line – FOR IACUC USE ONLY** |
| **PERSONAL PROTECTIVE EQUIPMENT REQUIRED:** |
| Route of Excretion: |
| Precautions for Handling Live or Dead Animals: |
| Animal Disposal: |
| Bedding/Waste Disposal: |
| Cage Decontamination: |
| Additional Precautions to Protect Personnel, Adjacent Research Projects including Animals and the Environment: |
| **Safety/Subject Matter Expert Signature & Date**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |

|  |
| --- |
| Logo, company name  Description automatically generated |
| **Principal Investigator:****AUP#:****Department:****Email:****Phone#:****(best # to contact in case of emergency)** | **Secondary Contact:****Department:****Email:****Phone#:****(best # to contact in case of emergency)** |
| **Biological Agents used**: |
| **Below this line – FOR IACUC USE ONLY** |
| **PERSONAL PROTECTIVE EQUIPMENT REQUIRED:** |
| Route of Excretion: |
| Precautions for Handling Live or Dead Animals: |
| Animal Disposal: |
| Bedding/Waste Disposal: |
| Cage Decontamination: |
| Additional Precautions to Protect Personnel, Adjacent Research Projects including Animals and the Environment: |
| **Safety/Subject Matter Expert Signature & Date**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |

|  |
| --- |
|  **A picture containing text, sign, yellow  Description automatically generated**  |
| **Principal Investigator:****AUP#:****Department:****Email:****Phone#:****(best # to contact in case of emergency)** | **Secondary Contact:****Department:****Email:****Phone#:****(best # to contact in case of emergency)** |
| **Radiation**: |
| **Below this line – FOR IACUC USE ONLY** |
| **PERSONAL PROTECTIVE EQUIPMENT REQUIRED:** |
| Route of Excretion: |
| Precautions for Handling Live or Dead Animals: |
| Animal Disposal: |
| Bedding/Waste Disposal: |
| Cage Decontamination: |
| Additional Precautions to Protect Personnel, Adjacent Research Projects including Animals and the Environment: |
| **Safety/Subject Matter Expert Signature & Date**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |