

Institutional Animal Care & Use Committee
LABORATORY RESEARCH
ANIMAL USE PROTOCOL IACUC Admin Use Only



I. GENERAL PROJECT INFORMATION:

A. Project Title: _____

B. Project Type: New Protocol Amendment to protocol number: _____

3rd Year Resubmission – Provide previous protocol number: _____

Complete an [Attachment M](#) – Three-Year Progress Report and include it with your protocol

C. Proposed Project Start Date: _____ Proposed Project End Date: _____ (amendments use original protocol dates)

D. Contact Information: (each protocol must include two emergency contacts)

	Principal Investigator	Emergency Contact 1	Emergency Contact 2
Name			
Campus Phone			
Emergency Phone(s)			
Email Address			
Campus Box No.			
Are emergency contacts to be copied on correspondence?	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	

E. Project Personnel: Complete an [Attachment L – Personnel](#), and include it with your protocol.

F. Project Funding Source: Check all sources of funding that will support activities described in this protocol.

Not funded

Internal funding - Type: [\(e.g., Provost's Fund, REAP Award, School support, etc.\)](#)

State/Federal funding – Grant Number & award start and end dates: _____

Other external grant – Sponsor Name & award start and end dates: _____

II. ANIMAL SUMMARY: In the table below, indicate the animal numbers you anticipate keeping on this protocol. Include all animals.

Genus/Species/Strain, subspecies, breed (Animal)	Common Name	Source/Vendor

To add rows, place the cursor at the end of the text in the last cell of the table and hitting the TAB key.

III. ANIMAL HOUSING:

A. Location(s): Indicate locations where animals will be housed. If animals will require non-standard housing and/or special care, describe in detail below in III-B. If needs differ for different species/strains/etc. complete a separate table for each, otherwise use one table for all.

Animal:	Responsible Parties:	ARF	PI Lab	Special Requirements
	Feeding & watering animals	<input type="checkbox"/>	<input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>
	Changing/cleaning cages	<input type="checkbox"/>	<input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>

Monitoring animal health		<input type="checkbox"/>	<input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>
Animal:				
Bldg & Room #	Responsible Parties:	ARF	PI Lab	Special Requirements
	Feeding & watering animals	<input type="checkbox"/>	<input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>
	Changing/cleaning cages	<input type="checkbox"/>	<input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>
	Monitoring animal health	<input type="checkbox"/>	<input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>
Animal:				
Bldg & Room #	Responsible Parties:	ARF	PI Lab	Special Requirements
	Feeding & watering animals	<input type="checkbox"/>	<input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>
	Changing/cleaning cages	<input type="checkbox"/>	<input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>
	Monitoring animal health	<input type="checkbox"/>	<input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>
Animal:				
Bldg & Room #	Responsible Parties:	ARF	PI Lab	Special Requirements
	Feeding & watering animals	<input type="checkbox"/>	<input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>
	Changing/cleaning cages	<input type="checkbox"/>	<input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>
	Monitoring animal health	<input type="checkbox"/>	<input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>
Animal:				
Bldg & Room #	Responsible Parties:	ARF	PI Lab	Special Requirements
	Feeding & watering animals	<input type="checkbox"/>	<input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>
	Changing/cleaning cages	<input type="checkbox"/>	<input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>
	Monitoring animal health	<input type="checkbox"/>	<input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>

B. Special Housing/Routine Care Needs:

If you indicated a need for special requirements, describe in detail what will be required, including issues such as food/water treatments and/or restrictions and the need for non-standard housing.

To add rows, place the cursor at the end of the text in the last cell of the table and hit the TAB key.

C. If the PI Lab will be responsible for any aspects of animal care, specify what individuals will provide the care and what training has been provided for them. N/A

D. Describe any special requirements regarding purchase, delivery, housing, and/or maintenance of animals and specify who will be responsible for each. N/A

IV. PROCEDURAL LOCATIONS: List all locations in which animals will be used for research procedures, teaching, testing or display. Under Procedure, state specifically how the animals will be used (surgery, orbital bleed, teaching Bio101 lab, etc.). Check to indicate whether animals are expected to survive or if their use at the location will be terminal.

If live animals will be held at any of the locations for 12 hours or more, indicate the number of hours in the table. N/A

Animal	Bldg & Room #	Procedure	Survival	Terminal	>12 hrs

To add rows, place the cursor at the end of the text in the last cell of the table and hitting the TAB key.

A. If procedures will be conducted in satellite facilities (locations not under the control of the Animal Care and Use Program), describe the method(s) that will be employed to transport animals to and/or from those locations. N/A

B. If terminal procedures will be conducted in satellite facilities, describe the procedures for disposing of animal carcasses. N/A

V. PROJECT SUMMARY:

A. Project Rationale:

Describe in layman's terms the hypothesis, objectives, and significance of this study. Justify the use of animals by explaining why non-animal models cannot be used and why this study is likely to 1) improve medical care of humans or animals or 2) contribute important new scientific information. Provide a description of the problem, disease, or challenge that is addressed in this protocol. Do not use acronyms or scientific jargon. It is important to use language that will allow the non-scientist members of the IACUC to understand the nature of the project. This section of the protocol should let the reader know what will be gained by doing the proposed research, why the research is necessary. If the project rationale is incomplete, the protocol will be returned without further review.

B. Summary of Study Design: The IACUC needs to understand everything that will happen to the animals in this project from the time the protocol starts until the time it ends. This section of the protocol should provide adequate information for the committee members to visualize all activities from start to finish, the time-line for experiments, duration of procedures, intervals between successive procedures (recovery time), how animals are monitored, supported, etc.

The study design will be used by the IACUC to assess the number of animals requested and must, at a minimum include:

1. The purpose of each experiment or set of related experiments,
2. The number of experimental groups/subgroups,
3. The number of animals by species/strain per group/subgroup

For each planned experiment, describe the procedures that will be performed using animals in each study group, subset, etc. **Before completing this section, review the Section X Checklist** (see page 5) that refers to attachments addressing specific, common procedures such as surgery, euthanasia, restraint, etc. If this protocol includes any of the specific procedural attachments, describe those procedures only in general terms here and provide a detailed description in the appropriate attachments.

Ensure that adequate information is provided to give naïve reviewers a clear understanding of all procedures employed. Use charts and tables for clarification. **WRITE THIS SECTION FOR THE UNDERSTANDING OF INDIVIDUALS OUTSIDE YOUR FIELD OF EXPERTISE.** Use as much space as needed to write a complete narrative description:

VI. JUSTIFICATION OF SPECIES/STRAIN(S):

What are the scientific reasons for selecting the species/strain(s) for this study? The chosen species should be the lowest possible on the phylogenetic scale. Justification might include the following: compatibility with previous studies; known susceptibility, existing knowledge or database, established animal model. In general, "less sentient" species is preferable to "higher species." However, the justification should be based upon sound scientific principles.

VII. NON-DUPLICATION:

Use the table below to document your search of the literature to determine that the work being proposed in this protocol does not *unnecessarily* duplicate previous work. [ASSISTANCE](#) for conducting searches.

UNC IACUC

Protocol #:

Form 0708

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Database Searched	Key Words & Search Strategy ¹	Date Search Conducted	Years Covered by Search	Number of Relevant References
Identify below any other relevant sources you used to make your determination (scientific meetings/conferences, additional journals, consultation with experts in the procedure and species, etc.)				

¹ The search strategy for non-duplication should not be the same as the search for alternatives to painful procedures. The keywords used here should relate to the scientific model under study, as procedural keywords are not likely to yield information regarding whether the scientific question has already been researched.

Example: Your research proposes to study the role of specific joint changes following injury that lead to the development of osteoarthritis. The studies will include rodent survival surgery to initiate the injury. Your search should include keywords related to the specific changes that are to be observed, osteoarthritis, and perhaps injury, or trauma, but not keywords relating to the specific surgical procedure used to induce the injury.

VIII. **JUSTIFICATION OF NUMBERS: ASSISTANCE** for determining and justifying animal numbers

For many studies, this information can be effectively presented using a table or grid design.

The total number of animals requested should be drawn from the study design described in Section V.C. above. Describe in detail the method(s) used to determine the number of animals needed for each experiment/procedure described in Section V.C.

Experimental design goals commonly reflect one of the categories described below. The respective information for justification of the number of animals should be supplied accordingly. Anticipated animal losses due to morbidity, mortality or other expected difficulties with the experimental procedures must be carefully described in order to justify the need of additional animals. Animal numbers cannot be justified on the basis of how many experiments the lab personnel can perform in a week, month, etc.

A. Data for statistical analysis: If numbers are chosen with the intent of obtaining statistically analyzable data, the most objective tool for justification is usually a power analysis to determine sample size. The *Guide* states, "...whenever possible, the number of animals requested should be justified statistically." When groups are compared, the goal of conducting a power analysis is to determine the appropriate number of animals per group to ensure a specific chance of detecting a specific difference. The chance, or probability, is the statistical power. *At a minimum* the following information will be expected:

- Statistical test/design used and, if applicable, whether the test is one- or two-sided. Note that one-sided tests are usually not justified
- Effect size, or equivalent information (e.g., the size of the difference of interest between population means relative to the population standard deviations)
- Alpha level (significance, or "p" value; typically 0.05)
- Power level used in the analysis (typically 60-80%)
- Sample size determined from the power analysis (per group and total per experiment)
- Complete reference to the method used for power analysis (e.g., book, software, etc.)

B. Statistical analysis alternative: If existing literature exists, minimum numbers may be determined based on the pertinent literature for comparable studies in which desired effect sizes were shown to be statistically significant. The comparable studies must be sufficiently documented and references provided.

B. Exploratory studies requiring no statistical analysis: (e.g., use of live animals to demonstrate success or failure of a desired goal, such as the production of transgenic animals or to determine whether a poisonous plant induces cleft palate in grazer species). Animal numbers determined based on the probability of success of the experimental procedure. Provide a detailed explanation of how that probability was determined.

C. Production of tissues, antibodies, etc.: Animal numbers should be determined by the amount of sample required and the number of individual animals needed to provide the appropriate amount. The narrative justification must describe a calculation based on the amount of sample (e.g., # cells) obtained per animal, the amount of sample needed for X experiment, and the number X experiments to be performed.

D. Pilot studies: When existing data, if any, are insufficient to allow estimation of variances for main study variables, numbers are determined based on the experience and judgment of the PI. If statistical analysis is done, it is primarily descriptive or exploratory. Typically, a pilot study should request no more than 12 animals. At a minimum, the following information will be expected:

- a) Main outcome measure being evaluated (e.g., reduction in tumor size)
- b) The definition of success (e.g., a 50% reduction in tumor size in 3 animals) that would indicate that the study should be followed up by a full study.

NOTE: *The pilot study category should not be used to circumvent performing a power analysis where appropriate. If the IACUC believes that the number of animals requested for a pilot study may reasonably be sufficient for statistical analysis, a request to supply a power analysis may delay approval of the protocol.*

E. Contract or directed work: If the number of animals is set by government regulations or a funding agency, a statement to that effect and a copy of documentation is an adequate justification.

F. Other methods: If you are not using one of the methods listed above, provide a detailed description of the method(s) used.

IX. PAIN & DISTRESS CATEGORIES: [ASSISTANCE](#) for determining and categorizing pain and distress classifications

Use the table below to provide a summary by Pain and Distress Category of the total number of animals that will be a part of this protocol, including those used experimentally and any animals acquired but not used experimentally. If you will be breeding animals for use on this protocol, you must submit a separate breeding protocol. Total the columns in the last row of your table. If you will have animals in category D and/or E, you must consult with the Attending Veterinarian and include an [Attachment A](#) with this protocol.

A painful or stressful procedure is defined one that would reasonably be expected to cause more than slight or momentary pain or distress in a human to which that procedure is applied.

Animal	Year One				Year Two				Year Three			
	B	C	D	E	B	C	D	E	B	C	D	E
TOTAL NUMBERS												

To add rows, place the cursor at the end of the text in the last cell of the table and hit the TAB key.

X. CHECKLIST OF PROCEDURES USED IN THIS PROJECT: This table contains commonly employed procedures that must include additional considerations and provisions for ensuring that animal welfare has been adequately addressed. Check each that applies to this protocol, and complete the relevant attachment. Note that each attachment has additional instructions and clarifications that may help to determine if it should be used.

PROCEDURES / ACTIVITIES

ATTACHMENT

- Pain or Distress Category D or E _____ [Attachment A](#)
- Euthanasia _____ [Attachment B](#)
- Fluid Collection _____ [Attachment C](#)
- Substance Administration (Antigens, Antibodies, Vaccines, Toxins, Microorganisms, etc.) _____ [Attachment D](#)
- Conditioning/training or use of restraint devices for durations longer than one hour _____ [Attachment A](#) & [Attachment E](#)
- Use of anesthetics, analgesics, sedatives, paralytics (Don't complete if use is for euthanasia only) _____ [Attachment F](#)
- Aversive conditioning _____ [Attachment A](#) & [Attachment F](#)

- Tissue transplantation _____ [Attachment G](#)
- Tumor / cancer cell inoculation or transplantation _____ [Attachment G](#)
- Death as an endpoint when animals are expected to die as part of an experimental design (e.g., LD₅₀ studies) but not planned euthanasia _____ [Attachment A & Attachment H](#)
- Surgery (survival or non-survival) _____ [Attachment I](#)
- Antibody production _____ [Attachment J](#)
- Hazardous & controlled substances _____ [Attachment K](#)
- Personnel _____ [Attachment L](#)
- Three-year progress report _____ [Attachment M](#)

XI. ACUP MANAGER ASSURANCE:

I have reviewed this protocol as it relates to needs for Animal Research Facility space, equipment, supplies and ACUP staff effort, and I assure that the needs as described in the protocol can be met by the Animal Care and Use Program.

Animal Care & Use Program Manager Signature

Date

XII. INVESTIGATOR ASSURANCES:

As Principal Investigator on this protocol, I certify that I have read and certify my agreement with all of the following statements:

1. This project does not unnecessarily duplicate previous work.
2. Animals on this protocol may receive medical care by or as directed by the attending veterinarian.
3. All personnel involved on this protocol are or will be adequately trained in the procedures in which they are involved, are aware of responsibilities and ethical conduct in animal research activities, have received adequate training in the biology, handling and care of this species; aseptic surgical methods and techniques (if necessary); the concept, availability, and use of research or testing methods that limit the use of animals or minimize pain and/or distress; the proper use, as applicable, of anesthetics, analgesics, and tranquilizers; and the UNC IACUC procedures for reporting animal welfare concerns.
4. All activities and procedures will be conducted in a manner to minimize pain and/or distress to the animals on the protocol; and I will report any unanticipated pain and/or distress, morbidity or mortality to the attending veterinarian and the IACUC.
5. I understand that the UNC IACUC has the authority to suspend an approved protocol by a majority vote of a convened quorum if there is evidence of lack of adherence to any aspect of this protocol or to federal and/or state laws and regulations governing laboratory animal welfare. Any suspended protocol or other disciplinary action taken by the IACUC will be reported to federal agencies as required by law and to the UNC Institutional Official.
6. All personnel on this project, including myself, are familiar with and will comply with all pertinent institutional, federal, state, and local laws and regulations regarding the use of animals in research, testing or teaching.
7. Prior to their starting work, I will inform all project personnel of all potential hazards and health risks associated with the work they will be performing on the project.
8. Prior to implementing any significant change, as defined by the UNC IACUC, to this application, I will obtain IACUC approval of an amended protocol.

Principal Investigator Signature

Date

XIII. ATTENDING VETERINARIAN APPROVAL (Required prior to protocol submission if animals are classified in pain/distress category D or E)

The PI has consulted with me regarding the need/justification for and the procedures resulting in classification of animals in USDA pain and distress category D and/or E.

Attending Veterinarian Signature

Date

IX. INSTITUTIONAL CARE & USE COMMITTEE APPROVAL

The University of Northern Colorado Institutional Care & Use Committee has approved the use of animals as described in this protocol. The Committee will continue to do post-approval monitoring to ensure that work on the project is in compliance with the protocol, and will perform a formal review of the protocol and related activities at one year intervals during the three-year protocol period.

Approval of this protocol is effective from _____ through _____. If work on the project will continue beyond the approved period a new protocol must be approved before this ending date. If a new protocol is not approved, all work other than animal care will be stopped until such time as a new protocol is approved.

IACUC Chair Signature

Date

NOTE: The protocol is not approved and work cannot be started until all signatures are in place.