COLORADO MESA UNIVERSITY
Sponsored Programs
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INSTITUTIONAL ANIMAL CARE AND USE PROTOCAL APPLICATION

Introduction

All vertebrate animals used for research or teaching must be assigned to a USDA pain and distress category on the protocol under which they are used. Procedures that could cause pain or distress in humans should be assumed to cause pain or distress in other animals. Below are definitions and examples of the USDA pain and distress levels to ensure that animals are listed on their protocol under the correct USDA pain and distress category.

It is important to understand that if multiple procedures will be performed on an animal, the animal is placed in the category appropriate for the most painful/distressful procedure. One animal cannot be placed in multiple categories.

Category B animals are those that are being "bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes." These animals have not been used for any research procedure, however minor. Category B is the place to put breeders and other animals that are not undergoing any experimental procedures.

Category C animals are not subjected to more than momentary or slight pain or distress and no use of pain-relieving drugs, or no pain or distress. Routine procedures such as injections and blood sampling from veins that produce only mild, transient pain or discomfort are reported in this category.

Other examples of category C procedures are:

- Holding or weighing animals in teaching or research activities.
- Injections, blood collection or catheter implantation via superficial vessels.
- Tattooing animals.
- Ear punching of rodents.
- Routine physical examinations.
- Observation of animal behavior.
- Feeding studies, which do not result in clinical health problems.
- AVMA approved humane euthanasia procedures.
- Routine agricultural husbandry procedures.
- Live trapping.
- Positive reward projects.

Category D animals are those subjected to potentially painful procedures for which anesthetics, analgesics, or tranquilizers will be used. The important concept is that animals are given appropriate anesthesia and/or pain relief to limit their pain and distress as much as possible.

Examples of category D procedures are:

- Diagnostic procedures such as laparoscopy or needle biopsies.
- Non-survival surgical procedures.
- Survival surgical procedures.
- Post-operative pain or distress.
- Ocular blood collection in mice.

- Terminal cardiac blood collection.
- Any post procedural outcome resulting in evident pain, discomfort or distress such as that associated with decreased appetite/ activity level, adverse reactions, to touch, open skin lesions, abscesses, lameness, conjunctivitis, corneal edema and photophobia.
- Exposure of blood vessels for catheter implantation.
- Exsanguination under anesthesia.
- Induced infections or antibody production with appropriate anesthesia and post-op/post-procedure
- Analgesia when necessary.

Category E animals are those that are subjected to painful or stressful procedures without the use of anesthetics, analgesics, or tranquilizers. Withholding of anesthetics, analgesics, or tranquilizers can only be allowed if it is scientifically justified in writing and approved by the IACUC. Examples of category E procedures are lethal dose studies (e.g. LD50 studies) that allow animals to die without intervention, pain studies that would not be possible if pain-relieving agents were administered, and psychological conditioning experiments that involve painful stimuli such as a noxious electrical shock that cannot immediately be avoided by an animal.

Category E studies are given increased scrutiny by IACUCs because they must be satisfied that less painful or stressful alternatives are not available, or that less painful/stressful endpoints cannot reasonably be used. By law, the institution must annually report all category E procedures to the USDA (on the new draft ACORP) and include a scientific justification supporting the IACUC's decision to approve them. Often, the justification given by the researcher on the animal forms submitted to the IACUC is used for the annual report.

Guidelines for determining USDA classification in protocols involving tissue collection before/after euthanasia and/or animal perfusion:

If an animal will be euthanatized by an approved physical or chemical method of euthanasia solely for the collection of tissues (after the animal's death), the procedure should be classified as USDA C.

If an animal will be anesthetized so that non-vital tissues can be collected (liver or skin biopsy), and the animal will then be allowed to recover, the procedure should be classified as USDA D (survival surgery).

If an animal will be anesthetized so that non-vital tissues can be collected (liver or skin biopsy, etc.); and the animal will then be euthanatized, the procedure should be classified as USDA D (non-survival surgery). In this scenario, it is necessary to justify why the animal couldn't be euthanatized (USDA category C) rather than anesthetized.

If an animal will be anesthetized so that vital tissues can be collected (heart, both kidneys or lungs, whole liver, etc.), the animal will obviously succumb to the procedure. To determine whether this will be euthanasia or non-survival surgery, we must consider the definition of euthanasia. A critical component of this definition is "rapid unconsciousness followed by loss of cardiac, respiratory and brain function". Based on this definition, procedures which require tissue manipulation or other prolonged techniques prior to the animals death (more than a few minutes) should be classified as non-survival surgery (USDA D). Similarly, if an animal will be anesthetized so that the tissue can be collected in the "freshest" possible state (i.e. heart) and the tissues will be rapidly excised, the procedure should be classified as euthanasia (USDA C). (Note: In this scenario, it is difficult to justify why the animal couldn't be euthanatized rather than anesthetized.)

If an animal will be anesthetized so that it can be chemically perfused, the same "test of time" applies (i.e.: long, technical manipulations should be classified as USDA D; while rapid intravascular injection of the perfusate without other manipulations should be classified as USDA C).

SECTION A: General Information

OVERVIEW

1. Title of Protocol:
2. Anticipated Start Date: Anticipated End Date:

INVESTIGATORS

3. Principal Investigator (PI) (Please refer to the Human Subjects policy on PI Roles & Responsibilities. Graduate Students PI's must have a Faculty member/Administrator as a Co-PI. Undergraduate Students cannot be PI's)

   Name:
   Status:
   Telephone:
   CMU Email
   Department:
   CITI Training Number: *CITI Training required prior to application submission.*
   CITI Training Completed: ☐ Working with the IACUC Course
   ☐ Working With Animals in Biomedical Research
   Species Specific:
   Roles and responsibilities in this study:

4. Co-Investigator(s)

   Name:
   Status:
   Telephone:
   CMU Email
   Department:
   CITI Training Number: *CITI Training required prior to application submission.*
   CITI Training Completed: ☐ Working with the IACUC Course
   ☐ Working With Animals in Biomedical Research
   Species Specific:
   Roles and responsibilities in this study:

Name:
Status:
Telephone:
CMU Email
Department:
CITI Training Number: *CITI Training required prior to application submission.*
CITI Training Completed: ☐ Working with the IACUC Course
☐ Working With Animals in Biomedical Research
Species Specific:
Roles and responsibilities in this study:

Name:
Status:
Telephone:
CMU Email
Department:
CITI Training Number: *CITI Training required prior to application submission.*
CITI Training Completed: ☐ Working with the IACUC Course
☐ Working With Animals in Biomedical Research
Species Specific:
Roles and responsibilities in this study:

VETERINARIAN

Name:
Status:
Telephone:
Email
Affiliation:
CITI Training Number: *CITI Training required prior to application submission.*
CITI Training Completed: ☐ Working with the IACUC Course
☐ Working With Animals in Biomedical Research
Species Specific:
Roles and responsibilities in this study:

5. Is this research supported in whole or in part by a grant or contract?
   - ◯ No
   - ◯ Yes

   Sponsors Name:
   PI on Grant:
   Grant Title/Contract:
   Project Period: From to
   OSP Proposal Number (if known):
   ☐ Grant Project Summary Attached **Attach Document**

6. Has this protocol previously been considered by Colorado Mesa University IACUC?
   - ◯ No
   - ◯ Yes

   IACUC Number:
   Date Approved:

SECTION B: Research Details

OVERVIEW

7. Describe the specific aims and details of animal use in non-scientific terms. The lay summary is used by community representatives on the IACUC and also may be used by Public Relations in the event of an external inquiry into the project. Define all acronyms. Only describe the use of live animals.
   a. Background and significance. (1-4 sentences)

   b. Question being addressed. (1-4 sentences)

   c. How will the results of the study be used? Describe the relevance to human or animal health, the advancement of knowledge, or the good of society. (1-4 sentences)

d. Summarize the specific aims (derived from the grant proposal/research plan).

8. Use the following outline to create a structured technical abstract that provides a clear and concise overview of the proposed work. It must include enough detail to allow the reviewers to understand the rational for the project, the specific objectives of the work, and the animal-related experiments that will be performed. It is not necessary to include excessive detail about the ex vivo analysis of tissues.
    a. Background: Present the ideas and reasoning behind the proposed work.

    b. Objective/Hypothesis: State the objective/hypothesis to be tested. Provide evidence or rational that supports the objective/hypothesis.

    c. Specific aims: State the specific aims of the study.

d. Study Design: Briefly describe the study design including appropriate controls.

9. Please state/describe your Experimental Design. Include a flowchart(s) or diagram(s) to explain the proposed animal experiments, including the study groups, treatment time points, and euthanasia time points. Begin with the arrival of animals in the facility and/or the first procedure and end with euthanasia. Note when individual animals will be used for more than one procedure.

10. What will you do with the results of your study (e.g. contributing to generalizable knowledge, publishing, sharing at conference, etc.)? Please contact the Office of Sponsored Programs and Academic Research for additional information.

ANIMAL NUMBERS

11. Complete a separate column for each species or rodent strain to be used. If more than 3 species or strains are to be used, copy this table and insert appropriately. Please include all information that applies to the animals you propose to use in this proposal.

	Species or Rodent Strain		
Demographics	**1**	**2**	**3**
Species (Common Name)			
Vendor/Source			
Breed/Strain			
Sex			
Age/Type			
USDA Pain Category			
Number of animals to be purchased			
Number of animals to be born on-site (or fetuses for in utero studies)			
Number of animals to be used (# purchased + # born on site)			
Average days each animal is to be kept			

DESCRIPTION OF PROCEDURES PERFORMED IN LIVE ANIMALS

12. Does your research involve surgical and non-surgical but potentially painful or distressful procedures?

- ◯ No: If no, in the space provided below, provide a clear and concise sequential list of all procedures which do not involve surgery or do not present pain or distress, including the use of any sedatives or anesthetics (e.g. use of sedation for restraint prior to imaging or EKG). Please use non-scientific terminology that will be easily understood by all members of the committee.
- ◯ Yes: If yes, identify, complete and attach the appropriate Appendices for the following procedures:
  - ☐ Surgical Procedures
  - ☐ Non-Surgical Procedures
  - ☐ Hazardous Agent Use
  - ☐ Breeding
  - ☐ Antibody Production

Attach Document

13. Will tissue or body fluids be collected from live animals (excluding tail snips)?

- ◯ No
- ◯ Yes: If yes, complete the table below:

Species (Common Name)	Tissue or Body Fluid	Method of Collection	Amount and Frequency of Collection	Agents* Administered prior to Specimen Collection

*Anesthetic, analgesic, sedative or tranquilizer.

SUBSTANCES ADMINISTERED TO ANIMALS

14. Will you be administering any experimental/study agents, therapeutic drugs, chemicals or other materials to live animals by injection, intubation, implantation, or surface application (excluding anesthetics and/or analgesics).

    No

    Yes, If YES, Identify all therapeutic drugs, experimental/study agents, chemicals, or other materials administered to live animals by injection, intubation, implantation, or surface application in the appropriate tables below.

Agent Name	Dose (mg/kg)	Volume	Route (e.g., ip, im, po)	Frequency (e.g., sid, bid)	Timing (e.g., pre-op, intra-op, post-op)	Duration of effect
Species 1 (Common Name):						
Species 2 (Common Name):						
Species 3 (Common Name):						

Note: Federal regulations require the use of pharmaceutical-grade medications wherever possible, even for acute and non-survival procedures. All materials administered by parenteral routes, (e.g., intravenous, intramuscular, intraperitoneal and intracranial) must be sterile unless otherwise approved by the IACUC.

15. Will you be using non-pharmacological grade agents for acute and non-survival procedures?

- ◯ No
- ◯ Yes: If yes, please complete the justification below for the use of the non-pharmacological grade agents.

Agent Name (from question 14)	Justification: Pharmaceutical grade not available	Justification: Scientific necessity (explain)	Justification: Other (explain)	Preparation(e.g. diluents, sterilization, pH balancing, storage and labeling)
Species 1 (Common Name):				
	☐	☐	☐	
	☐	☐	☐	
	☐	☐	☐	
Explain:				
Species 2 (Common Name):				
	☐	☐	☐	
	☐	☐	☐	
	☐	☐	☐	
Explain:				
Species 3 (Common Name):				
	☐	☐	☐	
	☐	☐	☐	
	☐	☐	☐	
Explain				

16. Will you inject transplantable tumors, cell lines, blood products, or other biological materials into animals?

- ◯ No
- ◯ Yes: If YES,

Source	Viral testing date	Dose (mg/kg)	Route (e.g., ip, im, po)	Volume	Diluent/ Media	Frequency (e.g., sid, bid)
Agent 1 Name:						
Agent 2 Name:						
Agent 3 Name:						
Agent 4 Name:						

At what Animal Biosafety Level will the study to be conducted?

- ◯ Level 1
- ◯ Level 2

JUSTIFICATION FOR ANIMAL USE

17. Describe the potential scientific benefit of the proposed study. Be convincing as to why this work is important for advancement of knowledge, improving human or animal health, or for the good of society.

The Animal Welfare Act and USDA Animal Care Policy #12 require PI's to assure the IACUC that you have considered whether or not your proposed work unnecessarily duplicates existing knowledge. Does the proposed activity unnecessarily duplicate any previous work? **Note:** Teaching activities are duplicative but instruction of new students warrants repeat of these activities. It is necessary that a robust alternatives search be performed for ethical category "D" teaching protocols [ethical categories examples are found at the IACUC website] and very briefly include the pertinent alternatives information being done prior to live animal use. It should state, for example, that videos were watched, simulation labs were done, "dummie" models were worked on and that the students are prepared to progress to live animals.

- ◯ No
- ◯ Yes: If YES, please justify.

18. If mathematical or computer models, in-vitro systems, or human studies cannot serve as alternatives to the use of animals in this project, provide the following information on the methods and sources used to determine that alternatives are not available.
    a. List a minimum of 2 databases consulted (e.g., PubMed, Agricola, Toxline, etc.).

    b. Date(s) of your search(s): From to
    c. Years covered by search: From to
    d. Key words or search strategies used (e.g., animals models, in-vitro, tissues, etc.).

    e. Provide a brief summary of your search results.

19. If procedures that may cause more than momentary or slight pain or distress to the animals are used, provide the following information on the methods and sources used to determine that alternatives are not available.

    f. List a minimum of 2 databases consulted (e.g., PubMed, Agricola, Toxline, etc.).

    g. Date(s) of your search(s): From to

    h. Years covered by search: From to

    i. Key words or search strategies used (e.g., animals models, in-vitro, tissues, etc.).

    j. Provide a brief summary of your search results.

20. Justify the species of animals to be used in this experiment.

21. Justify the number of animals to be used in this experiment.

22. Provide the statistical method used to determine the animal numbers requested.

ANIMAL HOUSING AND USE AREAS

23. Please indicate the housing and experiment location of each species or rodent strain to be used in this study.

	Species or Rodent Strain		
Locations	**1**	**2**	**3**
Building & room number where the animals will be housed			
Building & room number where the animal experiment(s) will be conducted			

24. Will live animals be transported outside of the animal care facility?
    - ◯ No
    - ◯ Yes: If YES, please explain.

25. Will animals be transported outside of the animal care facility and then returned to their housing room?
    - ◯ No
    - ◯ Yes: If YES, please explain.

26. Will animals be transported outside of the animal care facility for use of equipment also used for human patients (e.g. MRI, CT scan, etc.)?
    - ◯ No
    - ◯ Yes: If YES, please explain how the equipment will be used and sterilized.

27. Identify the requirement(s) for housing/husbandry.

Topics	Species or Rodent Strain 1	2	3
Social Housing			
Group housing	☐	☐	☐
Single housing (Explain and justify)	☐	☐	☐
Explanation:			
Food and Water			
Standard diet	☐	☐	☐
Non-standard diet (Explain and justify)	☐	☐	☐
Food/water restrictions (Explain and justify)	☐	☐	☐
Explanation:			

Enrichment

○ No (Explain and justify)

○ Yes

Explanation:

28. How will individual animals be identified? (Check all that apply.)

- ☐ No individual identification will be used
- ☐ Ear tags
- ☐ Tattoos
- ☐ Ear punch
- ☐ Temporary marker (e.g. Sharpie)
- ☐ Toe clipping (mice < 10d only; requires IACUC approval) See the IACUC Toe Clipping Policy
- ☐ Subcutaneous RFID microchip (please describe)

- ☐ Other method (please describe)

ANESTHETIC SUMMARY

29. Does the proposed activity use any anesthetic agent(s) (anesthetics, analgesics and tranquilizers) to alleviate pain and distress in the animals during and after the procedures(s)?

- ◯ No: If NO, please explain why.

- ◯ Yes: If YES, specify does routes and frequency of administrations.

	Anesthetic Specifics			
Species (Common Name)	**Agent/Drug**	**Dose (mg/kg)**	**Route**	**Frequency**

EUTHANASIA AND FINAL DISPOSAL OF ANIMALS SUMMARY

30. Does the proposed activity use any methods of euthanasia of the animals after the conclusion of the procedures(s)?

◯ No: If NO, please identify what will happen to the animals.

◯ Yes: If YES, identify the method of the euthanasia:

☐ Carbon dioxide (CO_2)-induced hypoxia followed by a secondary mechanical means of euthanasia.

☐ Exsanguination under anesthesia. Specify drug, dose and route.

Drug Dose Route

☐ Perfusion under anesthesia. Specify drug, dose and route.

Drug Dose Route

☐ Injectable agent overdose. Specify drug, dose and route.

Drug Dose Route

☐ Decapitation (if used without prior anesthesia, you must provide scientific justification).

☐ Cervical dislocation (if used without prior anesthesia, you must provide scientific justification).

☐ Other method of euthanasia. Please specify and justify.

31. How will the animals be monitored to assure that death has occurred?

32. How will the animal's carcasses be disposed of?

METHODS OF DATA COLLECTION

33. Describe how you will maintain the data once it has been collected.

34. Where will you store the data?

35. Who will have access to the data?

SECTION C: Conflict of Interest Disclosure

Colorado Mesa University Human Subjects Policy requires that personnel conducting research involving human participants at Colorado Mesa University must disclose known significant financial interests that would reasonably appear to be affected by the research project and that if the interest is deemed to constitute a conflict of interest with the proposed research, the conflict be managed prior to their engagement in the research with human participants. Significant financial interests include:

- An equity interest in an external entity that, when aggregated for the investigator and the investigator's spouse/ same sex partner and dependent children over the past 12 months and expected over the next 12 months exceeds $5,000 in value, or represents more than 5% ownership interest.
- Salary, royalties, or other payments from an external entity that, when aggregated for the investigator, the investigator's spouse/same sex partner and dependent children over the past 12 months and expected over the next 12 months are expected to exceed $5,000.

Conflict of Interest 1: Have all Colorado Mesa University faculty listed on this protocol (including faculty supervisor) completed the Annual Disclosure for your external commitments and financial interests as required?

◯ Yes ◯ No

Conflict of Interest 2: Have all Colorado Mesa University faculty listed on this protocol (including faculty supervisor) disclosed all significantfinancial interests (as described above) that are reasonably related to this researchproject?

◯ Yes ◯ No

Conflict of Interest 3: Do any of the personnel listed on this protocol, their spouses/same sex partners, or dependent children have any significant financial interests that are reasonably related to this research?

◯ Yes ◯ No

Conflict of Interest 4: Do any of the personnel listed on this protocol, their spouses/same sex partners, or dependent children have any personal financial interest or commitment with any company or entity that sponsors or supports this research?

◯ Yes ◯ No

If you answered "Yes" to either Conflict of Interest 3 or Conflict of Interest 4, please contact the Office of Sponsored Programs and Academic Research at irb@coloradomesa.edu for guidance on next steps regarding disclosure, review of the financial interest and resolution of any real or apparent conflict of interest. The IACUC is not able to review this project until it has been determined by the OSP that no investigator involved in this research activity has a conflict of interest related to this research.

SECTION D: Reminder Check List

1. Have you completed the correct form for your research project (Exempt, Expedited or Full Review)?

   ◯ Yes ◯ No

2. Have you reviewed the form to ensure that it is filled out completely and accurately?

   ◯ Yes ◯ No

3. Have you attached all of the required documents in WORD format (consent, script, survey, etc.)?

   ◯ Yes ◯ No

4. Have all Investigators completed the required CITI training?

   ◯ Yes ◯ No

5. Have the application form and supporting documents been proofed for typos or grammatical errors?

   ◯ Yes ◯ No

6. I understand the study cannot begin until the IACUC has provided a letter of approval.

   ◯ Yes ◯ No

7. I understand the Faculty Advisor must approve the application and attached documents and sign the Signature Page.

   ◯ Yes ◯ No

. SECTION E: Investigator Assurance and Acknowledgement

PRINCIPAL INVESTIGATOR

I certify that the information I provided in the Request for IACUC Review is correct and complete. I also pledge that I will not change any of the procedures, forms, or protocols used in this study without first seeking review and approval from the Institutional Review Board. Please e-sign this document.

_____ _____

Name / Signature of Principal Investigator Date

C0-INVESTIGATOR(S)

I certify that the information I provided in the Request for IACUC Review is correct and complete. I also pledge that I will not change any of the procedures, forms, or protocols used in this study without first seeking review and approval from the Institutional Review Board.

_____ _____

Name / Signature of Co-Investigator Date

_____ _____

Name / Signature of Co-Investigator Date

_____ _____

Name / Signature of Co-Investigator Date

Attach Other Documents Submit **Note: Required fields are highlighted in red.**

OFFICIAL OFFICE USE ONLY

Date Received: Notes:

Protocol Number:

Reviewer:

Date Reviewed:

Revised: April 2017