**MSU Agricultural Animal Care and Use Committee (AACUC)**

**Protocol Submission Form**

**Project Information**

1. Project Title: Click here to enter text.
2. Project Type: Choose an item.
	1. If a renewal please provide previous protocol number. Click here to enter text.
3. Principal Investigator
	1. Name: First - Last: Click here to enter text.
	2. Department: Click here to enter text.
	3. Title: Click here to enter text.
	4. Phone: Click here to enter text.
	5. E-mail: Click here to enter text.
4. Indicate funding information (any that apply):
	1. Extramural grant application (USDA, etc.)
		1. Provide funding agency name. Click here to enter text.
		2. Assigned MSU grant number (if available). Click here to enter text.
		3. Grant submission date. Click here to enter a date.
		4. PI on the grant submission. Click here to enter text.
	2. Intramural funding application (Dept/College). Click here to enter text.
	3. Commercial/Industry/Foundation funding (Private Sector)
		1. Provide complete company name. Click here to enter text.
	4. Other. Click here to enter text.

**Personnel**

Name: Click here to enter text.

Title: Click here to enter text.

E-mail: Click here to enter text.

Training and Experience: Click here to enter text.

Click below to add another ‘building block’ to include additional personnel if needed.

Choose a building block.

Choose a building block.

Choose a building block.

Choose a building block.

Choose a building block.

**General**

1. Please include a separate document (PDF preferred) with your submission that includes the following two items. Please name the file with your last name, followed by a space, then the word Abstract. (ex: Smith Abstract)
	1. Provide a brief abstract that summarizes the overall scientific goals and specific objectives of the proposed work. (Use language that community members or those not in your field of scientific discipline can understand. Define all abbreviations.)
	2. Describe in nonscientific language (high school level of understanding) how the proposed animal project will benefit human or animal health, the advancement of knowledge, or the good of society.
2. As principle investigator, I have determined, by means of the following sources, searches or methods, that alternatives to procedures which may cause pain or distress are not available, and that this protocol does not unnecessarily duplicate previous experiments. Choose an item.
 USDA regulations require documentation (to be maintained by the PI) of the following sources searched. The documentation may be requested by AACUC for review.
	1. Databases searched
	2. Specify all key words that were used in the search (e.g. MESH headings)
	3. What years were covered by the search?
	4. Provide the most recent date on which the search was performed (must be within six months)
	5. Did your search find any alternatives to your proposed animal related procedures that would allow:
		1. Reduction?
		2. Replacement?
		3. Refinement?
3. Why must animals be used in this study? (Check all that apply.)

No in vitro options are available.

Systemic interactions are needed.

Studies cannot or should not be undertaken in humans.

Studies involve analysis of behaviors or biologic processes.

Other. Explain. Click here to enter text.

1. Will any portion of the live work performed under this protocol be conducted at facilities not owned by MSU/MAES or institutions outside of MSU? Choose an item.

If yes:

* 1. What procedures will be done? Click here to enter text.
	2. What species will be involved? Click here to enter text.
	3. Name producers, facility or institution where this activity will take place. Click here to enter text.
	4. Provide the Office of Laboratory Animal Welfare (OLAW) Assurance Number of the institution. Click here to enter text.
	5. Provide the AACUC or IACUC approval number for the project at that institution, if applicable. Click here to enter text.

Agricultural Research

1. Species. Click here to enter text.
2. Breed. Click here to enter text.
3. Who owns the animals? Click here to enter text.
4. Rationale for using this species.

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

The studies are species specific for analysis related to management, behavior, production, etc.

Other. Explain. Click here to enter text.

1. Describe, in chronological order, all procedures that will include the use of animals. (Note: This description should allow AACUC to understand the experimental course of an animal from its entry into the experiment to the endpoint of the study.)
Click here to enter text.
2. Animal Numbers
	1. Total number of animals (Justification in question #7). Click here to enter text.
	2. Number of animals in Category C (minimal, transient, or no pain/distress, i.e., standard agricultural practices. Refer to the FASS Guide). Click here to enter text.
	3. Number of animals in Category D (pain/distress relieved by appropriate measures). Click here to enter text.
	4. Number of animals in Category E (unrelieved pain/distress). Click here to enter text.
	5. Will animals be used concurrently for other research projects? Choose an item. If yes, please give name of P.I. for other research and explain why concurrent use of animals will not negatively influence either project. Click here to enter text.
	6. The Animal Operations Manager or Station Superintendent has approved the use of these animals for this research project. You may be asked to provide an approval form. Choose an item.
3. Justify the number of animals required for the 3 year duration of the AACUC protocol (check and complete all that apply).

Animals will be assigned to experimental groups. Provide statistical or equivalent justification for the number of groups and number of animals per group. Explain.
Click here to enter text.

The procedures are technically difficult and extra animals will be needed to replace failures of the experiment. Explain. Click here to enter text.

This experiment is for obtaining pilot data that will be used to develop or learn new procedures or provide data for planning future studies. Explain. Click here to enter text.

The experiment requires a specific amount of tissue or number of cells for work in vitro. Explain. Click here to enter text.

This protocol is a teaching or training protocol. (If applicable, provide the MSU course number and title.) Explain. Click here to enter text.

Other experimental design or justification. Explain. Click here to enter text.

1. Describe the most commonly recognized clinical signs or side effects the animals may experience in response to the proposed experimental procedures.
Click here to enter text.
2. Where will the animals be housed?
Click here to enter text.
3. Who is responsible for animal care? Click here to enter text.
	1. What is the source of food and water? Click here to enter text.
	2. How often are the food and water sources checked? Click here to enter text.
	3. Describe other specialized housing or husbandry practices. Click here to enter text.
4. Will a surgical procedure, either survival or terminal, or tissue harvest prior to death be performed on the animals? Choose an item.
	1. Describe the required pre-operative procedures (fasting, etc.).
	Click here to enter text.
	2. Describe the surgical or tissue harvest procedures performed on living animals in detail, including the name of the procedure, anatomic approach, tissue manipulation, and closure techniques. Click here to enter text.
	3. Who will perform the surgical procedure or tissue harvest? Click here to enter text.
	4. Where will the procedure be performed? Click here to enter text.
	5. Will animals be allowed to recover from the anesthetic? Choose an item.
		1. Describe the practices that will be used to ensure asepsis. Click here to enter text.
		2. Describe the post-operative procedures and monitoring of animals.
		Click here to enter text.
		3. Who is responsible for the post-operative care of the animals?
		Click here to enter text.
	6. Will a single animal experience more than one major survival surgical procedure (penetrates and exposes a body cavity or produces substantial impairment of physiologic function and the animal recovers from anesthesia)? Choose an item. If yes, answer all sub-questions.
		1. How many surgeries will the animal experience? Click here to enter text.
		2. What will be the time period between surgeries? Click here to enter text.
		3. Provide a scientific rationale for the necessity of multiple major survival surgical procedures on the same animal. Click here to enter text.
5. Will the animals be anesthetized? Choose an item.
	1. Will the procedure be conducted by a DVM? Choose an item.
		1. If yes, provide name and contact information.
		Click here to enter text.
		2. If no, answer the following questions.
			1. Induction Agent; Dose (mg/kg); Route. Click here to enter text.
			2. Maintenance Agent; Dose (mg/kg); Route; Frequency of administration. Click here to enter text.
			3. Describe the method for monitoring anesthetic depth (parameters, frequency). Click here to enter text.
	2. Who will be responsible monitoring anesthesia? Click here to enter text.
6. Will muscle relaxants, tranquilizers or sedatives be utilized? Choose an item.
	1. Will the procedure be conducted by a DVM? Choose an item.
		1. If yes, provide name and contact information.
		Click here to enter text.
		2. If no, provide Induction Agent; Dose (mg/kg); Route
		Click here to enter text.
	2. Provide the justification for the use of a muscle relaxant or tranquilizer. Click here to enter text.
7. Will analgesic (pain relievers) be used? Choose an item.
	1. List behavioral and/or clinical signs that will be used to evaluate pain.
	Click here to enter text.
	2. Agent; Dose (mg/kg); Route; Frequency of administration. Click here to enter text.
8. Will blood be collected from the animals? Choose an item.
	1. Describe the blood collection method(s). (Note: anesthesia is required for a terminal bleed and/or cardiac puncture.). Click here to enter text.
	2. Maximum volume of blood to be obtained at each collection. Click here to enter text.
	3. Frequency of blood collection. Click here to enter text.
9. Will tumors be implanted or induced in the animals? Choose an item.
	1. Identify the tumor line and/or tumor type. Click here to enter text.
	2. What is the anatomical site of tumor implantation or induction in the animals?
	Click here to enter text.
	3. Will the tumor-bearing animals be observed daily for adverse effects? Choose an item.
10. Will conscious animals be restrained for periods longer than two hours? Choose an item.
	1. Provide the maximum length of time conscious animals will be restrained.
	Click here to enter text.
	2. What type of restraint device will be used? Click here to enter text.
	3. How will the animal be trained or acclimated to the restraint device? (note the approximate number of sessions and duration of each). Click here to enter text.
11. Will conscious animals be subjected to aversive stimuli to elicit a response? Choose an item.
	1. Explain why this is required and why alternative non-aversive stimuli cannot be used. Click here to enter text.
	2. Describe the aversive stimulus, including frequency and duration. Click here to enter text.
	3. Describe the limits of the stimulus if the desired response does not occur.
	Click here to enter text.
12. Is water or food restriction required for this study? Choose an item.
	1. Provide scientific justification for the restriction, including why alternatives cannot be used. Click here to enter text.
	2. Describe the restriction protocol, including frequency, duration and scheduling of “vacation” periods. Click here to enter text.
		1. Provide the maximum restriction levels. Click here to enter text.
		2. What is the minimum duration of time daily that an animal has access to flood or fluids? Click here to enter text.
	3. What baseline data will be collected prior to restriction? Click here to enter text.
	4. Describe the initial acclimation to restriction. Click here to enter text.
	5. Describe the health monitoring program for restricted animals (parameters measured, frequency). Click here to enter text.
	6. Describe criteria used for temporary or permanent removal of animals from the restriction protocol. Click here to enter text.
13. Will radioisotopes be administered to the animals in this study? Choose an item.
	1. List the personnel who will handle the radioisotopes. Click here to enter text.
	2. List all locations where the radioisotopes will be used. Click here to enter text.
	3. Number of animals to which radioisotopes will be administered. Click here to enter text.
	4. List the radioisotope that will be used. Click here to enter text.
14. Will recombinant DNA be administered to the animals? Choose an item.
	1. Name. Click here to enter text.
	2. Biosafety level. Choose an item.
	3. Route of administration. Click here to enter text.
	4. Housed. Click here to enter text.
	5. Special handling. Click here to enter text.
15. Will organisms that are potentially infectious to humans (classified by CDC at a biosafety level) be administered to the animals? Choose an item.
	1. Name of the organism. Click here to enter text.
	2. Biosafety level. Choose an item.
	3. Route of administration. Click here to enter text.
	4. Shed. Click here to enter text.
	5. Length of shed. Click here to enter text.
16. Will organisms that are infectious to other animals be administered to the animals in this protocol? Choose an item.
	1. Name of the organism. Click here to enter text.
	2. Biosafety level. Choose an item.
	3. Route of administration. Click here to enter text.
	4. Shed. Click here to enter text.
	5. Length of shed. Click here to enter text.
17. Will a toxic substance, carcinogen or mutagen be administered to the animals? Choose an item.
	1. Name. Click here to enter text.
	2. Route of exposure. Click here to enter text.
	3. Exposure. Click here to enter text.
	4. Excreted. Click here to enter text.
	5. Length of excretion. Click here to enter text.
18. How will animals be released from the study?

Animals will be returned to the MSU/MAES herd, flock, etc.

Animals will be returned to the cooperators herd, flock, etc.

Animals will be sold or donated to a non-university entity. Describe process and, if applicable, identify account number for proceeds.

Animals will be euthanized by research investigators or technicians on this project. (Answer Question 27)

Death as an endpoint is a necessary part of this study. (Answer Question 26)

1. Is natural (no intervention) death required as an endpoint for this study? Choose an item.
	1. Justify why alternative endpoints (hypothermia, weight loss, lethargy, etc.) are not acceptable for this study. Click here to enter text.
	2. Describe the expected clinical signs and time to death for this study. Click here to enter text.
	3. List personnel responsible for animal observations. Click here to enter text.
	4. How often will animals be monitored? Click here to enter text.
	5. In order to minimize pain or distress, are there any circumstances in which intervention (anesthetics, analgesics, supportive therapy) is permissible? If yes, please describe. Click here to enter text.
2. Will an overdose of a chemical (pentobarbital, etc.) be used as the means of euthanasia for the animals? Choose an item.
	1. Agent; Route; CO2 training. Click here to enter text.
3. Will physical means of euthanasia be used on the animals? Choose an item.
	1. What physical method of euthanasia will be used? Click here to enter text.
	2. Will the animal be under sedation or anesthesia at the time of euthanasia? Choose an item.
		1. Who will perform the physical method of euthanasia? Click here to enter text.
		2. What training has been provided? Click here to enter text.

**Principal Investigator Assurance and Statement of Accuracy**

* I certify that the information provided in this application is complete and accurate and consistent with any proposal(s) submitted to external funding agencies.
* I accept full responsibility for abiding by all applicable federal, state, local and Montana State University animal care and use policies.
* I will provide proper surveillance of this project to ensure that the health and welfare of animal subjects are protected. As such, I will report any problems to the appropriate review committee(s).
* I agree that modifications to the originally approved project will not take place until reviewed and approved by the animal care and use committee.
* I will ensure that all personnel listed on this application have been trained in proper and humane procedures of animal handling and, where applicable, appropriate procedures for the administration of anesthetics, analgesics or euthanatizing agents.
* I certify that I have reviewed the pertinent scientific literature and have found no valid alternative to any procedures described herein, especially those which may cause more than momentary pain or distress, whether it is relieved or not. Animal usage in this protocol does not unnecessarily duplicate previous experiments.

Signature: I am aware that electronic submission of this form constitutes my signature.

I agree (check box if agree): 

**The PI should submit the completed form to Diane Dorgan, AACUC Program Manager at** **dorgan@montana.edu** **The file can be in the original Word 2007 format or in PDF format.**