IACUC PROTOCOL REVIEW CHECKLIST

Protocol Number	
Principal Investigator	
Reviewer	

Based on your review of the above referenced protocol, complete the following sections as they relate to the corresponding sections of the protocol:

1. Information Section

Has the Principal Investigator (PI)/author provided all of the following?

Yes	No	N/A	
			1. Project Title The title should be clear and concise and should include the species
			2. Project Type
			3. Principal Investigator a. selected by PI/author - no comment necessary b. Department c. Title d. Phone # e. Email address f. Has PI attended ARC training/orientation
			4. Indicate funding Information- check all that apply ai, b c or d must be answered a) Extramural grant application (NIH,USDA, etc.) i. **Provide funding agency name** ii. Assigned grant number (if available) iii. MSU fund number (OSP or designated) and/or sponsor (Federal/state/private) iv. Submission date:[yyyy/mm/dd] v. In whose name is the grant submitted **b) Intramural funding application (Dept/College): Dept. and College** **c) Commercial/Industry funding (Private Sector):** if Yes, i must be answered **d) Other :**

Comments or Concerns

2. General Section

Yes	No	N/A	
			1. Provide an abstract that summarizes the overall scientific goals and specific objectives of the proposed animal work. Lay language should be used, abbreviations should be defined
			2. Describe in non-scientific language (high-school level of understanding) how the proposed project will benefit human or animal health, the advancement of knowledge, or the good of society. Lay language should be used, abbreviations should be defined. Is the benefit of the project clear?
			3. As primary 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. **a) Databas es searched (Minimum of two):** Are two sources listed? **b) Specify all key words that were used in the search (e.g. MESH headings):** Are the key words listed? Are they applicable to the proposed work? **c) What years were covered by the search?** Are the years listed? **d) Provide the most recent date on which the search was performed. (must be within six months):[yyyy/mm/dd]** Is the date listed? Is the date within six months of this submission? **i. Reduction** Has question been answered Yes or No? **Explain:** Is narrative answer provided? Does it align with answer above? **ii. Replacement** Has question been answered Yes or No? **Explain:** Is narrative answer provided? Does it align with answer above? **ii. Refinement** Has question been answered Yes or No? **Explain:** Is narrative answer provided? Does it align with answer above?
			4. **Why must animals be used in this study? (Check the appropriate boxes)** Is Yes or No selected a-d? a) No in vitro options are available. b) Systemic interactions are needed. c) Studies cannot or should not be undertaken in humans d) Studies involve analysis of behaviors or biologic processes e) Other: If Yes – is narrative explanation provided?
			5. Will any portion of the live work performed under this protocol be conducted at facilities or institutions outside Montana State University? Has question been answered Yes or No? If **Yes,** has an answer been provided for each item i.-v.?
			6. Will any live animals be housed outside the Animal Resources Center for continuous periods of longer than 12 hours? Has question been answered Yes or No? If Yes, has an answer been provided for each item i.-iii?
			Personnel: Are the first 4 columns complete? **Type** can be left blank

Name	**Title**	**email**	**ARC/Training**	**Type**
First and last name	Job title	Email address	Answer provided	Can be blank

Comments or Concerns

2. Species Mouse

Yes	No	N/A	
			1. Strain(s) Is a strain listed? Are all strains mentioned in protocol listed?
			2. Age/weight: Is/are ages and/or weights provided? Do they align with procedures described in Q4, experimental start and endpoints?
			3. Rationale for using this species: Is Yes or No selected a-d? a) There is demonstrated similarity of the process under study to that of humans b) A large amount of relevant data has already been derived from this species. c) The manipulations (e.g. surgery) require an animal of at least this size. d) The studies are species specific for analysis related to management, behavior, production, etc. e) Other If Yes – is narrative explanation provided?
			4. Describe, in chronological order, all procedures that will include the use of animals: *Note: This description should allow the IACUC to understand the experimental course of an animal from its entry into the experiment to the endpoint of the study. • Is the experimental design clear and does it make it possible to track animals throughout the course of the study? • Are routes of administration, dose volumes, and frequencies listed? • Are blood collection methods listed, volumes and frequencies? Is the experimental start and experimental endpoint clear? Can you determine when the experiment ends and animals will be euthanized if applicable?
			5. Justify the number of animals required for the 3 year duration of the IACUC protocol (Check and complete all that apply): Is Yes or No selected a-f? Do narrative explanations make sense? a) Animals will be assigned to experimental groups Is the addition correct? b) The procedures are technically difficult c) The experiment is for obtaining pilot data d) The experiment required antibody production e) This protocol requires breeding f) This protocol is a teaching or training protocol g) Other If Yes – is narrative explanation provided?
			6. Animal Numbers: *Note: Should be listed for the 3 year duration of the protocol. Is the addition correct? Does the selected category align with the proposed experimental model and/or procedures? a) Total number of animals justified in question #5 b) Category C: minimal, transient, or no pain/distress c) Category D: pain/distress relieved by appropriate measures d) Category E: unrelieved pain/distress

Yes	No	N/A	
			7. Describe the most commonly recognized signs or side effects the animals may experience in response to the proposed experiment. Include frequency of monitoring). Anticipated adverse clinical signs due to disease progression should be described here. Expected or reasonably expected responses due to administration of a potentially toxic or infectious material must be explained. Is the monitoring and frequency described?
			8. Where will the animals be housed? Is the question answered? Areas outside of ARC should be questioned.
			9. Will any specialized housing and/or husbandry be required (special diets, single housing, metabolic cages, etc.)? Is the question answered? If Yes, does the narrative explain all special requirements?
			10. Will a surgical procedure, either survival or terminal, or tissue harvest prior to death be performed on the animals? Is the question answered? If Yes, are answers provided for a-f below a) Describe the required pre-operative procedures (fasting, etc.): b) Describe the surgical or tissue harvest procedures performed on living animals in detail, including name of procedure, anatomic approach, tissue manipulation, and closure techniques c) Who will perform the surgical procedure or tissue harvest? d) Building and room # where the procedure will be performed: e) Will animals be allowed to recover from the anesthetic**?** If Yes, are answers provided to i. ii, and iii? f) Will a single animal experience more than one survival surgical procedure? If Yes, are answers provided to i. ii, and iii?
			11. Will the animals be anesthetized? Is the question answered? If Yes, are answers provided for a-d below. a) Induction**:** Agent, Dose mg/kg, Route b) Maintenance: Agent, Dose mg/kg, Route, Frequency of administration c) Describe the method for monitoring anesthetic depth. d) Who will be responsible for monitoring anesthesia?
			12. Will muscle relaxants (paralytics, neuromuscular blocking agents) be utilized? Is the question answered? If Yes, are answers provided for a-c below. a) Induction**:** Agent, Dose mg/kg, Route, Frequency of administration b) How will it be determined that the paralyzed animal is adequately anesthetized? c) Provide the justification for the use of a muscle relaxant.
			13. Will analgesics (pain relievers) be used? Is the question answered? If Yes, are answers provided for a) below? a) List behavioral and/or clinical signs that will be utilized to evaluate pain. Agent, Dose mg/kg, Route, Frequency of administration
			14. Will animals be immunized? Is the question answered? If Yes, are answers provided for a-b below? a) Initial Immunization: Are answers provided to i ,ii, iii, iv,v,vi? b) Re-immunization (booster) Are answers provided to i,ii, iii, iv,v?

Yes	No	N/A	
			15. Will monoclonal antibodies be generated utilizing the ascites production method? Is the question answered? If Yes, are answers provided for a-b below? a) Justify why this method is required and why alternatives are not available: b) Describe methods that will be used to decrease pain and distress:
			16. Will blood be collected from the animals? Is the question answered? If Yes, are answers provided for a-c below? a) Describe the blood collection method(s). b) Maximum volume of blood to be obtained at each collection: c) Frequency of blood collection:
			17. Will tumors be implanted or induced in the animals? Is the question answered? If Yes, are answers provided for a-e below? a) Identify the tumor line and/or tumor type: b) What is the anatomical site of tumor implantation or induction in the animals? c) Will the tumor be permitted to grow to greater than 10% of the animal's body weight or become ulcerated? If yes, justify the reason: d) Will the tumor-bearing animals be observed daily for adverse effects? e) Is the tumor of rodent origin or has the tumor been passaged in rodents? (If yes, MAP or PCR testing must be performed.)
			18. Will conscious animals be restrained for periods longer than two hours? Is the question answered? If Yes, are answers provided for a-c below? a) Provide the maximum length of time conscious animals will be restrained? b) What type of restraint device will be used? c) How will the animal be trained or acclimated to the restraint device (note the approximate number of sessions and duration of each)?
			19. Will conscious animals be subjected to aversive stimuli to elicit a response? Is the question answered? If Yes, are answers provided for a-b below? a) Explain why this is required and why alternative non-aversive stimuli cannot be used. b) Describe the adverse stimulus, including frequency and duration**.**
			20. Is water or food restriction required for this study? Is the question answered? If Yes, are answers provided for a-f below? a) Provide scientific justification for the restriction, including why alternatives cannot be used: b) Describe the restriction protocol, including frequency, duration, and scheduling of "vacation" periods: c) What baseline data will be collected prior to restriction? d) Describe the initial acclimation to restriction: e) Describe the health monitoring program for restricted animals (parameters measured, frequency): f) Describe criteria used for temporary or permanent removal of animals from the restriction protocol:

Yes	No	N/A	
			21. Will animals be irradiated? Is the question answered? If Yes, are answers provided for a-c below? a) Number of animals to be irradiated and dose per mouse: b) Who will operate the gamma irradiator? c) List relevant radiation safety protocol number(s):
			22. Will radioisotopes be administered to the animals in this study? Is the question answered? If Yes, are answers provided for a-e below? a) List the personnel who will handle the radioisotopes: b) List all rooms where radioisotopes will be used: c) Number of animals to which radioisotopes will be administered: d) Radioisotope that will be used and dose per mouse: e) List relevant radiation safety protocol number(s):
			23. Will organisms that are potentially infectious to humans (classified by CDC at some biosafety level) be administered to the animals? Is the question answered? If Yes, are answers provided for a-f below? a) Name of organism: b) Biosafety level: c) Route of administration: d) Shed: e) Length of shed: f) List relevant biosafety protocol number(s):
			24. Will recombinant DNA be administered and/or a new transgenic mouse be produced? Is the question answered? If Yes, are answers provided for a-f below? a) Name: b) Biosafety level: c) Route: d) Housed: e) Special handling: f) List relevant biosafety protocol number(s):
			25. Will organisms that are infectious to other animals be administered to the animals in this protocol? Is the question answered? If Yes, are answers provided for a-e below? a) Name of organism: b) Biosafety level: c) Route of administration: d) Shed: e) Length of shed:
			26. Will a toxic substance, carcinogen, or mutagen be administered to the animals? Is the question answered? If Yes, are answers provided for a-e below? a) Name: b) Route of exposure: c) Exposure: d) Excreted: e) Length of excretion:

Yes	No	N/A	
			27. Will a piece of tail be amputated for DNA analysis or any other testing? Is the question answered? If Yes, is an answer provided for a.? a) Will the tail amputation be performed on animals after 21 days of age? If Yes ensure Q.11 is answered.
			28. Will any non-pharmaceutical grade compounds be used for this study (yes/no)? (A pharmaceutical grade compound is defined as any active or inactive drug, biologic or chemical reagent, for which a chemical purity standard has been established by a recognized national or regional pharmacopeia.) Is the question answered? If Yes, are answers provided for a.-b.? a. Justify the use of each non-pharmaceutical grade compound(s). b. Compound(s) will be: i. purchased (grade and Certificate of Analysis available from vendor) ii. laboratory-produced
			29. The experimental endpoint occurs when scientific objectives have been reached. A humane endpoint is a point at which an animal is removed to prevent, terminate, or relieve pain or distress in advance of the experimental endpoint. Please answer part a-d: a) Define the criteria for humane endpoints at which an animal will be removed from the study: Are the criteria listed relevant to the experimental model? Are there expected adverse clinical signs associated with the experiment? The PI should state if there are no anticipated signs of disease or toxicity. b) How often will animals be observed and what recordkeeping will be performed to establish if an endpoint has been reached? Is this question answered? Does the answer include how often the animals are observed and where it is documented? c) What intervention will be performed when a defined endpoint is reached? Is this question answered? – If supportive care or treatment of animals is described in Q4 it should be described here as well. d) List personnel who will determine if an endpoint has been reached. How have they been trained to recognize the endpoint? Is this question answered?
			30. Euthanasia: Will an overdose of a chemical (CO_2, pentobarbital, etc.) be used as the means of euthanasia for the animals? Is the question answered? **If Yes, THIS SHOULD BE A PRIMARY METHOD OF EUTHANASIA,** does this align with method of euthanasia described/mentioned elsewhere in the protocol (Q4)? Agent: Is the agent(s) listed? Route: Does the route align with the agent?

Yes	No	N/A	
			31. Will a physical means of euthanasia be used on the animals? Is the question answered? **If Yes, THIS SHOULD BE A PRIMARY METHOD OF EUTHANASIA,** does this align with method of euthanasia described/mentioned elsewhere in the protocol (Q4)? If Yes, are answers provided for a), b) i., ii, 1. a) What physical method of euthanasia will be used? Is this question answered? b) Will the animal be under sedation or anesthesia at the time of euthanasia? i. Provide rationale for the use of physical methods of euthanasia w/out anesthesia. ii. Who will perform the physical method of euthanasia? 1. What training has been provided?

Comments or Concerns

END OF PROTOCOL REVIEW FORM