IACUC PROTOCOL REVIEW CHECKLIST

Protocol Number	
Principal Investigator	
Reviewer	
Date	

Recommendation to the Committee

	Approve
	Require minor modification to secure approval
	Require major modification to secure approval
	Table
	Withhold approval

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

1. ADMINISTRATIVE DATA

Has the Principal Investigator (PI) provided <u>all</u> of the following?:

	Yes	No	N/A
1.1 Name			
1.2 Degree(s)			
1.3 Workplace Information			
1.4 Type of Submission			
1.5 Title of Project			
1.6 Funding Source			
1.7 Funding Effective Period			
1.8 Co-Investigator (s) and/or Graduate student (s) (if applicable)			

<u>Comments or Concerns</u>

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2. STUDY OBJECTIVES

	Yes	No	N/A
2.1 Are the Study Objectives written in language understandable to a lay person?			
2.2 Are the rationale and purpose of the study clear?			
2.3 Is it clear why the study is important to human or animal health, the advancement of knowledge, or the good of society?			

Comments or Concerns

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3. ANTIBODY PRODUCTION

If the study involves antibody production, complete the following:

	Yes	No	N/A
3.1 Is assurance provided that the proposed use of monoclonal antibodies is scientifically justified?			
3.2 Has the use of *in vitro* methods of monoclonal antibody production been considered?			
3.3 Is there and adequate explanation why the in vitro method of monoclonal antibody production has been found to be unsuitable?			
3.4 Has consideration been given to the use of methods to avoid or minimize animal discomfort, pain, and distress?			
3.5 Has the number of taps to be performed clearly indicated and is this number appropriate?			
3.6 Has the amount of ascites fluid that will be allowed to accumulate been provided and is it appropriate?			
3.7 Has the individual(s) who will monitor the animals after the tap has been performed identified and is the length of the observation period appropriate?			

3. ANTIBODY PRODUCTION (Cont.)

	Yes	No	N/A
3.8 Have the criteria to be used to determine when an animal is in distress and needs to be euthanized been clearly described and are they adequate?			

Comments or Concerns

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4. CONSIDERATION OF ALTERNATIVES AND JUSTIFICATION FOR ANIMAL USE

	Yes	No	N/A
4.1 Is the description of the non-animal alternatives that were considered to replace whole animal use with *in vitro* experiments adequate?			
4.2 Is the description of the methods that were employed to refine existing tests or experiments in order to minimize animal distress adequate?			
4.3 Is the description of the methods that were employed to reduce the number of animals necessary for these experiments adequate?			
4.4 Is the justification for the choice of animal species adequate?			
4.5 Is the justification for the number of animals to be used adequate?			

Comments or Concerns

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5. GENERATION OF TRANSGENIC AND/OR KNOCKOUT ANIMALS

If the study involves the generation of transgenic and/or knockout animals, complete the following:

	Yes	No	N/A
5.1 Has Institutional Biosafety Committee approval been obtained?			
5.2 Has the location where the transgenic and/or knockout animals be generated been provided?			
5.3 Has the location where the resulting breeders will be housed been provided?			
5.4 If there are any predicted phenotypic consequences of the genetic manipulations, have they been adequately described?			
5.5 Has the plan for breeding and the number of animals maintaining in the animal facilities provided and adequately described?			

Comments or Concerns

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6. USE OF TRANSGENIC AND/OR KNOCKOUT ANIMALS

If the study involves the use of transgenic and/or knockout animals, complete the following:

	Yes	No	N/A
6.1 Has the source of the breeders been identified?			
6.2 Has the location where the animals be housed been provided?			
6.3 Have any necessary special care or monitoring procedures been described?			

Comments or Concerns

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7. ANIMAL REQUIREMENTS

	Yes	No	N/A
7.1 Is the number of animals requested reasonable for the goals of the proposed studies?			
7.2 Are the types of animals (breeders, experimentals, culls) appropriately classified for each species listed?			
7.3 Do the number, age and sex of animals described in the text of the protocol match those requested in the summary table?			

Comments or Concerns

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8. TRANSPORTATION

	Yes	No	N/A
8.1 Does the transportation of animals conform to all institutional and national guidelines/policies?			

Comments or Concerns

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9. ANIMAL HOUSING AND LABORATORY LOCATION

	Yes	No	N/A
9.1 Has the building location(s) where the animals will be housed been provided?			
9.2 If the animals will be removed from the animal facility for more than 12 hours, is the justification adequate?			
9.3 Has the building and room number(s) where the research will be conducted been provided?			

9. ANIMAL HOUSING AND LABORATORY LOCATION (Cont.)

Comments or Concerns

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10. ENVIRONMENTAL ENRICHMENT AND EXEMPTIONS

	Yes	No	N/A
10.1 Have methods been described to provide environmental enrichment to the animals used in these studies?			
10.2 Has an exemption been requested for not providing environmental enrichment and is the basis for this request sufficient justification?			

Comments or Concerns

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11. SPECIAL CONCERNS OR REQUIREMENTS OF THE STUDY

	Yes	No	N/A
11.1 Have any special housing, equipment, or animal care requirements (e.g., special caging, water, feed, waste disposal, or environmental enrichment) been described and justified?			

Comments or Concerns

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12. FIELD STUDIES

If the study involves field studies, complete the following:

	Yes	No	N/A
12.1 Does the description of the field studies include the type(s) of observation, interactions with the animals, disturbances to the animals, and/or any anticipated special procedures?			
12.2 Have any required government permits been obtained?			

Comments or Concerns

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13. DATABASE SEARCHES

	Yes	No	N/A
13.1 Have at least two independent databases been searched?			
13.2 Have the beginning and ending dates of the search been provided and are they reasonable?			
13.3 Has the date the search was conducted been provided?			
13.4 Are the keywords used for the database search adequate?			
13.5 Will this study unnecessarily duplicate any previous work?			
13.6 If yes, is the justification for proceeding with the proposed studies adequate?			

Comments or Concerns

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14. DRUG USAGE

	Yes	No	N/A
14.1 For USDA Classification D studies, have all anesthetics, analgesics, sedatives, and tranquilizers been listed along with their dosages and routes of administration?			
14.2 Are the dosages consistent with accepted veterinary practice?			
14.3 If inhalation anesthetics are to be used, are proper scavenging procedures and safety precautions described?			
14.4 Has an attending veterinarian consultation been obtained within the last six months?			
14.5 If any of the listed drugs are scheduled/controlled, has the location, security, and logging of use been adequately described?			

Comments or Concerns

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15. SURGERY

	Yes	No	N/A
15.1 Is the type of surgical procedure (survival/non-survival) correctly identified?			
15.2 Has the location where the surgery is to be performed specified and is this an approved site?			
15.3 Are the pre-operative procedures (fasting, analgesic loading, etc.) clearly described and appropriate?			
15.4 Is the descriptions of the surgical procedure(s) completes and are appropriate aseptic procedures included for survival surgeries?			
15.5 Are the monitoring and supportive care procedures to be used during surgery clearly described and appropriate?			
15.6 Are the individuals who will perform the surgery identified and are they qualified to perform the procedure(s)?			

15. SURGERY (Cont.)

	Yes	No	N/A
15.7 For survival surgery, is the post-operative care and the frequency of observation clearly described and appropriate?			
15.8 For survival surgery, is a procedure described for the detection and management of post-operative complications during normal work hours, weekends, and holidays described and appropriate?			
15.9 If this is non-survival surgery, is the method of euthanasia and the determination of death clearly described and adequate?			
15.10 If paralytic agents are to the used, is the description of how ventilation will be maintained and how pain will be assessed clearly described and adequate?			
15.11 If major survival surgery has been performed on the animals prior to being placed on this study, is the prior surgical procedure described?			
15.12 If more than one survival surgery will be performed, is the justification for the second survival surgery acceptable?			

Comments or Concerns

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16. DESCRIPTION OF EXPERIMENTAL DESIGN AND ANIMAL PROCEDURES

	Yes	No	N/A
16.1 Is the experimental design clear and does it make it possible to track animals throughout the course of the study?			
16.2 Are the procedures to be performed on the animals adequately described?			

16. DESCRIPTION OF EXPERIMENTAL DESIGN AND ANIMAL PROCEDURES (Cont.)

	Yes	No	N/A
16.3 Are the procedures to monitor pain and distress clearly indicated and adequate?			
16.4 Do these procedures include monitoring after normal work hours, weekends, and holidays?			
16.5 Are the experimental endpoint criteria (tumor size, percentage body weight gain/loss, inability to eat or drink, behavior abnormalities, clinical symptomatology, or signs of toxicity) clearly stated and appropriate?			
16.6 Are the substances to be injected clearly identified and, if not in common use, described adequately?			
16.7 Are the doses, injection sites, injection volume, route of administration, and dosing schedule(s) clearly described and appropriate?			
16.8 For blood withdrawal, is the volume, frequency, withdrawal site(s) and methodology clearly described and appropriate?			
16.9 For the use of radioactive materials, is the dosage and schedule clearly described and appropriate?			
16.10 If the study involves the restraint of animals, is it justified appropriately and are any sedation, acclimation, and/or training procedures adequately justified?			
16.11 If animal identification methods are employed are they clearly described and appropriate?			
16.12 Are other procedures such as tail biopsies or tail bleeding clearly described and appropriate?			
16.13 Are the resultant effects that the animals may be expected to experience (e.g., pain or distress, ascites production, etc.) clearly described and justified?			
16.14 Are other potential stressors (e.g., food or water deprivation, noxious stimuli, environmental stress) clearly described and justified?			
16.15 Are the criteria to be used to determine when euthanasia is to be performed clear and appropriate?			
16.16 If death is an endpoint, is it scientifically justified?			

16. DESCRIPTION OF EXPERIMENTAL DESIGN AND ANIMAL PROCEDURES (Cont.)

	Yes	No	N/A
16.17 Is a plan of action described that will be followed in case of animal illness (i.e., initiate treatment, call investigator prior to initiating treatment, euthanasia) clearly described?			
16.18 Is there any other aspect of the proposed study that should be of concern to the IACUC?			

Comments or Concerns

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17. BIOLOGICAL MATERIAL/ANIMAL PRODUCTS FOR USE IN ANIMALS

If the study involves the use of biological material(s) or animal products, complete the following:

	Yes	No	N/A
17.1 Has the animal species from which these materials will be obtained been provided?			
17.2 Has the source of these products been provided?			
17.3 Has the information about the sterility of the materials been provided?			
17.4 Has the information about the attenuation status of the materials been provided?			

Comments or Concerns

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18. METHOD OF EUTHANASIA

	Yes	No	N/A
18.1 Is the method of euthanasia for the animal species/age clearly described and appropriate?			
18.2 Is this method approved by the AVMA Panel Report on Euthanasia?			
18.3 Has a method been included to ensure the death of the animals?			
18.4 If a chemical agent is to be used, is the dosage and route of administration provided?			
18.5 Is the method of carcass disposal indicated and appropriate?			

Comments or Concerns

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19. HAZARDOUS AGENTS

If the study involves hazardous agents, complete the following:

	Yes	No	N/A
19.1 Have the practices and procedures required for safe handling of animals and materials by laboratory personnel and animal facility personnel been adequately described?			
19.2 Have the practices and procedures required for safe disposal of contaminated animals and material by laboratory personnel and animal facility personnel been adequately described?			
19.3 Have these practices and procedures been reviewed and approved by the Institutional Biosafety Committee?			
19.4 Are any required Standard Operating Procedures included with the protocol?			

Comments or Concerns

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20. INFECTIOUS AGENTS OR BIOLOGICAL TOXINS

If the study involves infectious agents, complete the following:

	Yes	No	N/A
20.1 Has Institutional Biosafety Committee approval been obtained for these studies?			
20.2 Is the Animal Biosafety Level indicated and is it appropriate?			
20.3 Are the safety precautions that must be taken to limit the exposure of laboratory personnel and animal facility personnel clearly described and appropriate?			
20.4 Are any required Standard Operating Procedures included with the protocol?			

Comments or Concerns

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21. RADIOACTIVE MATERIALS

If the study involves the use of radioactive materials, complete the following:

	Yes	No	N/A
21.1 Has Radiation Safety Office approval been obtained?			
21.2 Are the specific isotopes to be used indicated?			
21.3 Have the safety precautions that will be employed to limit radiation exposure been clearly described and are they appropriate?			
21.4 Have the methods for removal of radioactive waste been clearly describe and are they appropriate?			
21.5 Have the methods for monitoring radioactivity levels been described and are they appropriate?			
21.6 Are any required Standard Operating Procedures included with the protocol?			

21. RADIOACTIVE MATERIALS (Cont.)

Comments or Concerns

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22. X-RAYS

If the study involves the use of x-rays, complete the following:

	Yes	No	N/A
22.1 Has the specific equipment that will be used and its location been provided?			
22.2 Has the radiation safety status and training status of all individuals who will be exposed to the x-rays during the experimental procedures been provided?			

Comments or Concerns

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23. EXPERIENCE AND TRAINING OF STUDY PARTICIPANTS

	Yes	No	N/A
23.1 Are all individuals who will participate in this study listed?			
23.2 Have all listed individuals taken the appropriate training course(s) consistent with the animal species used in these studies and is this training current?			
23.3 Are necessary documents supporting individual training provided and valid?			

Comments or Concerns

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24. PRINCIPAL INVESTIGATOR CERTIFICATIONS

	Yes	No	N/A
24.1 Has the Principal Investigator checked "Yes" for all applicable certification statements?			

Comments or Concerns

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END OF PROTOCOL REVIEW FORM