The University *of* North Texas Health Science Center
Institutional Animal Care and Use Committee

Animal Use Protocol Amendment

Protocol Number:	**Application Date (as MM-DD-YYYY):**
Protocol Title:	
Principal Investigator:	**Department:**
Species:	**Funding:**

Changes that qualify for Administrative Review (AR):

☐ Addition of Trained Personnel
☐ Removal of Personnel
☐ Addition of Funding Source
☐ Removal of Funding Source
☐ Change in Protocol Title
☐ Close Protocol
☐ Change PI Department/Contact Information
☐ Change Secondary Contact
☐ Add Animal Use Location (already approved for animal use)

Changes that qualify for Veterinary Review (VVC):

☐ Addition of Animal Strain (within species)
☐ Change in animal age, weight, or sex
☐ Increase in animal numbers <10%.
☐ Change in method for individually identifying animals
☐ Addition of Nontraditional vendor source
☐ Change in special housing/husbandry requirements
☐ Addition of nonhazardous Substance
☐ Changes in anesthetic or analgesic agent
☐ Changes in restraint procedure (<10 min)
☐ Change in breeding (<10% increase in animal #s)
☐ Addition of AVMA approved euthanasia method
☐ Change in IACUC approved method of blood/fluid/tissue collection.
☐ Addition of non-survival surgery procedure or procedures during terminal surgery/post euthanasia
☐ Addition of behavioral procedures (not cat E)
☐ Changes in duration or frequency of a procedure that will not increase pain, distress, or discomfort
☐ Change in Imaging Procedure (not radioactive)

Changes that qualify for Designated Member Review (DMR):

☐ Addition of prolonged restraint (>10 min)
☐ Change in Principal Investigator
☐ Increase in animal numbers >10%
☐ Addition of non-USDA covered species
☐ Addition of hazardous substance
☐ Changes in Imaging Procedure (radioactive)
☐ Addition of Food/Water Restriction
☐ Addition of tumor/biological material procedure
☐ Addition of Breeding (> 10% increase in animal #s)
☐ Addition of a procedure that requires the use of analgesics
☐ Addition of a procedure that results in increase pain, distress, or discomfort.
☐ Addition of Animal Use location (not already approved for animal use)

Changes that qualify for Full Committee Review (FCR):

☐ Addition of USDA Covered Species
☐ Changes in study objectives
☐ Addition of Category E procedures
☐ Addition of invasive procedures
☐ Addition of Survival Surgery (not already approved for surgery)
☐ Addition of Multiple Survival Surgeries
☐ Addition of Cat E Behavior procedure

1. **Describe the changes you would like to make (Use the guide for information that will need to be provided).**
   [Type text in the text box --- Spacing will adjust to accommodate the length of the narrative]

2. **Provide Justification for the change.**
   [Type text in the text box --- Spacing will adjust to accommodate the length of the narrative]

Guidance for the information to include:

- **Addition of Trained Personnel:** Ensure all personnel have completed all training requirements before adding. For all personnel being added to a protocol, include the following: Name, Title, Email Address, Years of experience with the animal model and procedures.
- **Removal of Personnel:** Simply list the names of all personnel being removed from the protocol.
- **Addition of Funding Source:** Include the Funding Agency, the Grant Title, the Grant or Project Duration dates, and the Grant/Contract Number. If this is publicly funded, be sure to include a copy of the Vertebrate Animal Section and the Research Strategy Section of the grant.
- **Removal of Funding Source:** Simply list the names of the funding sources that will be removed. If it was the only funding source, be sure to indicate the funding source used to replace the funds used for the study.
- **Change in Protocol Title**: Clarify if this will be an addition or a change to the existing title. Provide the new title in its entirety.
- **Close Protocol:** Indicate that you would like to close out the protocol. Include what will happen to any animals housed on this protocol, and if there is a grant attached to the protocol, what will happen to the funds of the award.
- **Change PI Department/Contact Information:** Identify the name of the new department and/or new contact information.
- **Change in Secondary Contact:** Identify the name of the Secondary Contact or Co-PI, include an emergency contact phone number for the person.
- **Add Animal Use Location (already approved for animal use):** Identify the Building, Room Number, and the Reason for taking the animals to this location (Non-surgical Procedure, Housed, Survival Surgery, Non-survival Surgery, Euthanasia, Behavioral Studies, other (with explanation)). Indicate if the location is within or outside of the animal facility. If outside of the animal facility, provide a justification for removing animals from the facility, and how animals will be transported (in accordance with IACUC SOP 022: Animal Transport). Will animals be held at this location outside of the facility for greater than 12 hours or overnight? If so, then provide a justification.
- **Addition of Animal Strain (within species)**: Provide the full nomenclature of the strain (Jax Stock Numbers are okay to use). Be sure to include the sex, age and/or weight of the animal.
- **Change in animal age, weight, or sex:** Include the name of the species and strain of the animal model in which the changes are made, and include the change in the age, weight, or sex.
- **Increase in animal numbers <10%:** Provide the number of animals that will be added to the protocol. Include the pain category for the added numbers. Provide a justification as to how this number was determined to be statistically significant.
- **Change in method for individually identifying animals:** Describe any changes to the method for individually identifying animals, or if a new method is applied, indicate the new method.
- **Addition of Nontraditional vendor source**: This is reserved for if animals will need to be purchased from a vendor that is not on the Approved Vendor List. Identify the name of the vendor that will be used to purchase animals.
- **Change in special housing/husbandry requirements:** Indicate any new Special Housing/Husbandry Requirements (Individual Housing, Metabolic Cages, Special Diet, Treated Water, Alternative Lighting, Static Caging, Sterilized Cages, Radiated Feed/Bedding, Other (with explanation). If individually housing, select the reason (Experimental Reasons, Incompatibility Reasons). If adding a special diet, be sure to indicate the source of the diet, and if it is nutritionally balanced. For all special requirements, indicate who will be responsible for introducing the special requirement to the animals (PI staff or DLAM staff).

- **Addition of nonhazardous Substance:** Identify the name of the substance, the dose, the route of administration, the frequency, Expected Results/Complications, if it is pharmaceutical grade, and which species will receive it (if multiple species are listed on the protocol). If non-pharmaceutical grade, be sure to provide a justification for the use of a non-pharmaceutical grade substance and address the consideration of adverse events related to the following points: Grade, Purity, Sterility, pH Balance, Pyrogenicity, Osmolality, Stability, Formulation, Compatibly of Components, Pharmacokinetics.
- **Changes in anesthetic or analgesic agent:** Identify the name of the anesthetic/analgesic, the dose, the route of administration, the frequency, Expected Results/Complications, if it is pharmaceutical grade, and which species will receive it (if multiple species are listed on the protocol).
- **Changes in restraint procedure (<10 min):** Identify the Method (Manual, Device Type), Duration of restraint, Frequency, and the reason for restraint, also identify the species that will be restrained (if more than one species is on the protocol). Explain the procedure, and consideration of alternatives and the frequency of observation.
- **Change in breeding (<10% increase in animal #s):** Any changes to the breeding or Timed Pregnant animals that results in not increasing animal numbers >10%. Provide any changes made to the already approved breeding procedure in the protocol. This could include the breeding scheme (Trio, Timed/Hand Mating, Post-partum Breeding, or Pair Breeding); When the animals will be weaned (justification for weaning outside of 21-28 days); if Genetically Modified Animals are produced, and any health concerns associated with the phenotypes; and any genotyping procedures.
- **Addition of AVMA approved euthanasia method:** Describe the euthanasia method, if using any anesthetic agents, provide the substance, dose range and route of administration. If using Carbon Dioxide, be sure to provide the displacement rate. Be sure to include a secondary method to ensure death.
- **Change in IACUC approved method of blood/fluid/tissue collection:** Describe the blood or fluid collected, the amount collected, the method of collection, if the animal will be anesthetized or restrained, and if there will be any supplemental fluids administered.
- **Addition of non-survival surgery procedure or procedures during terminal surgery/post euthanasia:** Describe the terminal surgery prep, how the animal and surgeon are prepared for surgery, how the instruments are cleaned, the procedure from start to finish, and how the animal is euthanized. Include the tissue collected, and any substances used to fixate the tissue.
- **Addition of behavioral procedures (not cat E):** Identify the Behavior test, the species used, the maximum times the animal will perform the test, the amount of time the animal is allowed to rest between tests, and what happens to the animal if it fails the test. Include a description of how the new behavior test(s) fit in with the rest of the protocol.
- **Changes in duration or frequency of a procedure that will not increase pain, distress, or discomfort:** Describe the procedure, and the changes made within the frequency and or timing of the test.
- **Change in Imaging Procedure (not radioactive):** To add an imaging procedure, describe the Imaging procedure, the species used, the maximum times the animal will be imaged, if the animal will be anesthetized or restrained, and the duration of the imaging procedure. Describe any changes made to an existing procedure.
- **Addition of prolonged restraint (>10 min):** Identify the Method (Manual, Device Type), Duration of restraint, Frequency, and the reason for restraint, also identify the species that will be restrained (if more than one species is on the protocol). Explain the procedure, and

consideration of alternatives and the frequency of observation. Provide a justification for prolonged restraint.

- **Change in Principal Investigator:** Identify the name, the department, the email address, emergency phone number, and the experience of the new PI.
- **Increase in animal numbers >10%:** Provide the number of animals that will be added to the protocol. Include the pain category for the added numbers. Provide a justification as to how this number was determined to be statistically significant.
- **Addition of non-USDA covered species:** Identify the species, the strain/stock/breed, the Sex, the Age and/or Weight of the animal. Provide a rationale for the use of the species, and how it will relate to the protocol. Describe the procedures this species will undergo.
- **Addition of hazardous substance:** Provide the substance, the dose, and the route of administration, the agent type (Carcinogen, Radioisotope, Biohazard, Chemical, other), IBC approval numbers and approval date (for bio-hazards), if the animal is expected to survive the exposure, length of time that animals/environment considered hazardous, Maximum number of animals exposed, decontamination procedures for equipment, personnel, housing areas, and how contaminated animals, feed, bedding and disposable supplies be handled. Be sure to attach the Hazardous Agent attachment and any safety approvals and attachments.
- **Changes in Imaging Procedure (radioactive):** To add an imaging procedure, describe the Imaging procedure, the species used, the maximum times the animal will be imaged, if the animal will be anesthetized or restrained, and the duration of the imaging procedure. Describe any changes made to an existing procedure. Be sure to include the details of the radioisotopes administered, and include the hazardous agent attachment, and radiation safety approvals.
- **Addition of Food/Water Restriction:** Identify what will be restricted (Food, Water, or both), indicate how long the restriction will last in hours, provide a description and justification of the restriction.
- **Addition of tumor/biological material procedure:** Describe the procedure, will the animal be anesthetized or restrained, the injection/inoculation site, the tumor/cell concentration used, how will it be administered, how will the animal be monitored afterwards. Total number of inoculations/injections per animal. If tumors are expected, will they be external or internal. If metastasis or potential side effects expected.
- **Addition of Breeding (> 10% increase in animal #s):** Addition of breeding or timed pregnant animals, or any changes to the breeding that results in increasing animal numbers >10%. Provide the following details: the breeding scheme (Trio, Timed/Hand mating, Post-partum Breeding, or pair breeding); When the animals will be weaned (justification for weaning outside of 21-28 days); if Genetically Modified Animals are produced, and any health concerns associated with the phenotypes; and any genotyping procedures.
- **Addition of a procedure that requires the use of analgesics:** Description of the procedure. Include the analgesic used, the dose, the route of administration, the dose frequency, and frequency of observation.
- **Addition of a procedure that results in increased pain, distress, or discomfort:** Description of the procedure, and details of how pain, distress, and discomfort will be minimized. If not, then what are the humane endpoints, what interventions will be used (anesthesia, analgesia, euthanasia or other (with explanation), Circumstances under which interventions are to be used (as stated in protocol, as recommended by vet, other (with explanation)), and what interventions are withheld (anesthesia, analgesia, euthanasia, other (with explanation)) with justification for not providing an intervention.
- **Addition of Animal Use location (not already approved for animal use):** Identify the location (building and room number), the Reason for bringing animals to the location (nonsurgical

procedure, housed, survival surgery, non-survival surgery, euthanasia, behavioral studies, or other (with explanation). Indicate if animals will be held outside of the facility at this location for greater than 12 hours, if so, then provide justification. Provide justification for the need to take animals outside of the facility to this location. Describe how the animals will be transported (according to IACUC SOP 022: Animal Transport). This will require an inspection from the IACUC. Refer to the IACUC Webpage for Laboratory Approval for details on arranging this inspection.

- **Addition of USDA Covered Species:** Identify the species, the strain/stock/breed, the Sex, the Age and/or Weight of the animal. Provide a rationale for the use of the species, and how it will relate to the protocol. Describe the procedures this species will undergo.
- **Changes in study objectives:** Describe the changes in the study objective, and the reason for making this change. Describe any procedures that is affected by this change of objective. Please note that changes of objectives may lead to the need for a new protocol.
- **Addition of Category E procedures:** Describe the category E procedures, include a justification for category E. Include the number of animals that will be placed in category E.
- **Addition of invasive procedures:** Description of the procedure, include how the animal will be prepared, the procedure, and how the animal will be monitored after the procedure. Include any anesthetics or post-procedural analgesics.
- **Addition of Survival Surgery (not already approved for surgery):** Describe the type of survival surgery (Major, Minor). Describe the preoperative care (how the animal will be prepped, the surgeon will be prepped, and how the instruments will be sterilized). Describe the surgical procedure from incision to closure. Describe post-operative care. Describe anesthetic maintenance, and what will happen if animals require additional doses. Will neuromuscular blocking agents be used? If so, how will animals be monitored, a justification will need to be provided if used without general anesthesia.
- **Addition of Multiple Survival Surgeries:** Provide a justification for the need of multiple survival surgeries, in addition, include the name of the surgeries that will be performed in conjunction with each other on a single animal, the maximum number of surgeries a single animals will receive, and the time frame between surgeries, the animals will be allowed to recover.
- **Addition of Cat E Behavior procedure:** Identify the Behavior test, the species used, the maximum times the animal will perform the test, the amount of time the animal has to rest between tests, and what happens to the animal if it fails the test. Provide a description of how the added behavior test(s) will fit in with the rest of the protocol. Provide a justification for category E. Include the number of animals placed in category E.

*****Any changes that affect the flow chart of the study, an updated flow chart will need to be attached.