

PROTOCOL APPLICATION FOR ANIMAL USE INSTRUCTIONS

General Information

The Institutional Animal Care and Use Committee Protocol Application for Animal Use (the Application) must be completed by the Principal Investigator and approved by the Institutional Animal Care and Use Committee (IACUC) prior to beginning a project that involves live vertebrate animal use, as well as for significant revisions to an existing protocol or a three year triennial review of an expiring protocol. Animals may not be ordered or used in experiments, teaching or breeding without an approved protocol.

APPLICATION PREPARATION

- The most recent version of the Application and instructions can be obtained from the Creighton University [IACUC website](#):
- A good overview of the process of writing a grant application that involves the use of animals can be found on [NIH's Office of Laboratory Animal Welfare](#) website. In particular, the section *Write your protocol* succinctly hits the main points of preparing your application for the IACUC. The underlying principles that the IACUC follows in evaluating your application are expressed in the *U.S. Interagency Research Animal Committee's Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training*, on pages 4-5 of the *Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy)*. *The Guide for the Care and Use of Laboratory Animals (The Guide)* provides more detail. Both publications are found on the [IACUC website](#).
- The Health Science Reference Librarian (280-5138 or refdesk@creighton.edu) can help you construct searches to optimize the choice of animal and species (question B2ii), prevent duplication (question B4), and minimize pain and distress (question E10). These searches should be conducted at least 1 to 2 months prior to submission of the application so that alternative approaches (see Animal Welfare Act) can be incorporated into the design.
- Animal Welfare Act regulations require Principal Investigators to consider alternatives to procedures that potentially cause more than momentary or slight pain or distress to the animals. Whenever possible, you should Replace, Reduce, and Refine (the three Rs) potentially painful procedures. This means:
 - Replacing animals in part or full with non-animal systems (for example, *in vitro*, computer or mathematical models) or less sentient animal species (for example, insect or molluscan models instead of mammalian models).
 - Reducing the number of animals to the minimum required to obtain scientifically valid data through a *priori* consideration of appropriate experimental and statistical design (for example, more advanced statistical tests, power analyses).
 - Refining procedures to lessen or eliminate pain or distress, thereby enhancing animal well-

being (for example, more effective analgesia and anesthesia, less-invasive surgical techniques, terminating experiments at earlier stages of morbidity).

- The Attending Veterinarian can provide advice on refining procedures, choosing drugs and dosages, etc. The IACUC Chair, IACUC Office, or other IACUC members may also be consulted for assistance in preparing the Application.
- Applications ideally encompass a single complete set of experiments testing closely related hypotheses examined with similar procedures. You should submit only one application for each funding source. Multiple protocols may be appropriate when a large breeding colony is involved to provide animals for several sets of experiments; in this case, you may find it more convenient to submit one protocol for breeding work and others for the experimental work. If the requirements of a grant include verification that the animal work has been approved by the IACUC, it is advantageous that all the work be covered by a single protocol. The title of the protocol does not have to match that of the grant proposal.
- Answer all questions on the Application; answer N/A where appropriate rather than leaving an answer blank. Please use language suitable for a lay reader throughout the application so that all members of the IACUC can understand your protocol. *Federal regulations require that the IACUC include at least one non-scientist.* If the non-scientist cannot readily understand the Application, it will be returned for clarification and resubmission.
- The Application is designed to be completed in your word processing program. Check boxes can be marked within Microsoft Word by double-clicking on the box and then selecting “checked” under “default value.” The tables included in the Application can be expanded or duplicated as needed by copying and pasting, or deleted when not applicable. Handwritten Applications will not be accepted.
- All personnel working with animals must abide by the [Animal Resource Facility \(ARF\) Standard Operating Procedures](#). Investigators planning to use animals with special needs or obtained from sources other than approved commercial vendors should contact the ARF Manager prior to submitting an Application to ensure that housing and care can be provided. Animals from non-approved facilities must be quarantined; please design your experimental timelines to account for the quarantine period.

APPLICATION SUBMISSION

- All Applications are initially subject to full committee review at a full committee meeting. The IACUC meets on either the last or the next to the last Monday of the month. The IACUC does not conduct less than full committee review of Applications.
- An electronic version must be submitted to the IACUC Office no later than 5:00 p.m. of the first Monday of the month in which IACUC review is requested. If the first Monday falls on a University holiday, the deadline is the first working day that follows. A signed version of the application will be requested upon approval of the protocol.
- Urgent Review – Under *exceptional* circumstances, a Principal Investigator may request an urgent application review (3.0 IACUC Review Process Section 1.5.5 of the IACUC Policies and Procedures). The granting of an urgent review is rare and is subject to a processing fee of \$500.00. Missing a regular monthly submittal deadline is not in itself sufficient reason to request

an urgent review.

Specific Instructions

SECTION A – ADMINISTRATIVE INFORMATION

1. Principal Investigator

The faculty or staff member responsible for the research project. Must have the authority to make decisions in the event of emergency or catastrophe situations. The principal investigator does not have to be the same as the grant funding for the research.

2. Project Title

Provide a descriptive title for the project. The protocol title need not match the title of any grants to which it will apply.

3. Submission Type

Check one box to indicate the type of Application:

New Application – A first-time submission for a protocol. If the study is based on information learned from a pilot project, please provide the protocol number of the pilot study and a brief overview of the study and the outcome.

Triennial review –A new application form is required by PHS every three years. A complete Application is required regardless of whether any procedures have changed. Provide the previous protocol number and give a brief explanation of what has been completed in the previous period and what will continue into the triennial protocol. Indicate any changes in the experimental design that are suggested by your results so far. Provide the number of animals used and animals to be carried over into the triennial protocol. This section is intended to help the IACUC understand the relationship of your expiring protocol to the triennial, and is not a request for a scientific "progress report."

Modification to open protocol –Make requests for modifications to a protocol by checking the Modification to open protocol and provide a brief explanation of the changes requested and the reasons(s). If animals are to be added or reduced, provide the total number. Use the track/change feature in Word to incorporate all necessary changes throughout the document and then send an electronic version to the IACUC office. If animal numbers or strains are being changed, provide the total number of animals. Ensure that numbers are consistent in all sections of the protocol including euthanasia and procedure numbers. Once the changes are approved an electronic version will be sent to you and a signed version will be requested. This provides both the IACUC and your laboratory personnel with an up-to-date version of your protocol. This up-to-date version of your protocol should be available for review by both your laboratory personnel and the IACUC. All older versions should be replaced.

4. Special Categories

Check the appropriate box or multiple boxes if any of the following apply:

Breeding only – Protocols intended solely to generate animals for research or teaching use are classified as breeding protocols. The actual experimental procedures or teaching use of the animals must be covered by other approved protocols – if a protocol includes a research or

teaching component, this box should not be checked.

Teaching only – Protocols covering animal use for teaching purposes only are classified as teaching protocols. If the protocol includes a research component, this box should not be checked.

Pilot study – Protocols intended to allow the investigators to perfect new techniques or to obtain preliminary data to be used in the design of more complete experiments. A pilot study typically involves few procedures and a small number of animals. Some uncertainty in the experimental and statistical designs is allowable. The approval period is generally short (one year); requests for a longer approval period or a renewal must be justified.

Single Survival- Please check if the animals will undergo one survival surgery

Multiple Survival Surgery – Please check if the animals will undergo 2 or more survival surgeries.

Food or Fluid Restrictions – Please check if any of the animals will be restricted from food or fluid for more than 12 hours in one day.

Non-Central Housing- Please check if the animals will be held outside of the Animal Research Facility for more than 12 hours in one day

Prolonged Restraint - Please check if the animals will be restrained and unable to move for more than 15 minutes in one sitting

Hazardous & Infectious Substance Use – Please check if any hazardous or infectious substances will be used in the live animals.

5. **Protocol Duration**

Protocol duration begins on the date of approval by the IACUC and continues for the number of years requested in this section. An approved protocol is valid for a maximum of three years and is reviewed annually or more if warranted for the period requested. Protocols may be closed early by contacting the IACUC office. Projects running longer than three years will require submission of a triennial application 2 months before the end of the initial three-year approval period.

6. **Grant Support**

If known, list the funding agency supporting the research, the title of the grant, the submission date and the effective date; and the grant or contract number. . The grant title must match the protocol title. Please submit one protocol for each funding source.

7. **Record Keeping**

Identify all locations where records will be kept during the protocol period, and how they can be made available for inspection by IACUC, USDA, AAALAC or PHS staff members if necessary.

8. **Principal Investigator Certification**

The signature of the Principal Investigator on the Application indicates that the Principal Investigator has read and understands the information and assurances contained in the Application and that it is an accurate description of the proposed use of animals. The investigator must sign the certification before the protocol is initiated.

SECTION B — RESEARCH OVERVIEW

1. Objectives

This section should include a short description of the research aims, and explain the scientific merit of the proposal. The use of animals should contribute to the enhancement of human or animal health, the advancement of knowledge or the good of society. Language and terminology must be understandable by a member of the general public, for example, the community representative on the IACUC. Technical terms should be avoided when possible, and explained when they are indispensable. *Language copied from a grant application is usually inappropriate.*

2. Justification for Animal Use and Species Choice

Two issues must be addressed in this section:

- i.** Explain why it is necessary to use live vertebrate animals in this project rather than an alternative study system. The Animal Welfare Act requirement to replace animals in part or full with non-animal systems or with less sentient animal species or stages when possible must be addressed. Please refer to the three R's (Replace, Reduce, and Refine). Non-animal systems include cell cultures, microorganisms, plants, *in vitro* systems, and computer and mathematical models. Less sentient alternatives to vertebrate animals include invertebrates and eggs of birds and reptiles. When a research question can be meaningfully pursued using reasonably available alternatives, these alternatives should be chosen.
- ii.** Justify the selection of the particular species and strain/line (if appropriate) requested. The most appropriate species/strain/line for the project based upon anatomical, physiological, or other characteristics in consideration of the scientific objectives and the need to obtain valid results should be chosen. This information is required to assure that the animal model is appropriate. The species selected should be the least sentient one possible.

3. Outline of Experimental Design

This overview of the experiments should provide the context for the animal numbers and the procedures described later. Number of animals used in experimental groups should not be provided in this section. All animal numbers should be provided in Section C Animal Numbers. The use of outline or tabular format is encouraged. Include information on experimental and control groups, a list of procedures to be performed on each (using the procedure names in Section E 7, 8, or 9), variables to be measured, and the endpoint for each group. It is very important to list the time intervals between the beginnings of the animal's role to the end of the experiment. For designs that involve multiple procedures occurring at different times, please provide a clear timeline. A flowchart or similar diagram can also be helpful for more complex experimental designs. The details of the procedures should be provided in your response to Section E 7, 8, or 9, not here.

4. Duplication

Have previous experiments answered the questions or tested the hypotheses on which your research focuses? If the study duplicates previous experiments in whole or part, check other and explain why the duplication is scientifically necessary. If there is no duplication of previous research, this should be stated along with a brief indication of how this conclusion was reached (for example database search, journal review, scientific conferences). An example would be, “Based on a database search of studies in this area, the proposed work does not duplicate previous studies.” Provide a date when the search was performed. You should retain a copy of the search results on which you base your answer, but currently the search need not be detailed in the Application. Applications for teaching or breeding need not explain the need for duplication.

SECTION C — ANIMAL NUMBERS

1. Summary Animal Number Table

State the number of animals of each species/strain requested. Provide separate totals for animals in the categories as applicable. Use the table provided to show the number of animals you are requesting. Complete each column. If no animals are being used in a category, please indicate by using a zero. Pregnant dams are animals that will be euthanized to procure embryos for experimental purposes. If you purchase pregnant dams solely to acquire embryos for experimentation, they would be included in the pregnant dam column. Breeders are animals that are used to maintain an animal colony or generate experimental animals. The number of adult breeders should be based on the number of experimental, embryos or pre-weaned animals needed. Excess are all animals that are not used for experimental procedures. Note for rats and mice embryos and pups, provide the numbers that will be used in experiments. Do not include this number in the TOTAL animal numbers column.

Note: Post-weaning all non-USDA species animals are included in animal usage adult numbers regardless of their ultimate status (experimental or excess). Once you wean them, regardless if you know they are experimental or excess, they will be counted against the total number of weaned adult animals.

For breeding, state the numbers of weaned and adult animals that will be required to 1) maintain the breeding colony and 2) supply experimental animals. If a breeding protocol is used, then you must indicate in the experimental animal columns, the total number of animals that will be transferred and the protocol number they will be transferred to. Additional animals can be added to the breeding protocol in conjunction with new experimental protocols that receive animals from the breeding colony by a modification request stating the increase in breeders and offspring (weaned or pre-weaned). You must modify the experimental protocol at the same time. Justification for the animals is to be included in the experimental protocol.

When computing numbers for a breeding protocol, please consider the experimental animals needed, periodic replacement of breeders and predicted number of offspring per dam.

2. Justification of Animal Numbers

The Animal Welfare Act requires that you use the minimum number of animals necessary to obtain scientifically valid data through appropriate experimental and statistical design. Please justify the number of animals needed to accomplish your goal(s) and explain how you arrived at this number. Explain how the number of animals per group (or per time point) was selected. The justification should include a description of the statistical approach and an associated power test (with expected group

differences and standard deviations) used to determine the minimum number required to obtain adequate statistical power. Estimate the number of animals anticipated as replacements for animals lost or unusable due to failure of procedure or other factors. In the event of unanticipated losses after a protocol has been approved, additional animals may be requested by filing a protocol modification.

Statistical consultation may be obtained through the IACUC. You will find free power analysis programs are available. See the [IACUC webpage](#)

Sample Size Calculations.

If tissues are being collected for *in vitro* studies, justify the animal number based on the amount of material needed and the amount of material obtained from each animal (e.g. number of animals per antigen, or number of cells needed and number of cells obtained per animal) in order to obtain statistically valid results.

Breeding Protocols must be justified according to the maintenance of the colony as well as indicating animals that will be transferred to an experimental protocol. The transferring of excess animals should be indicated in Section D4 Disposition of Surviving Animals. Breeding protocols are for colony maintenance only. However, the breeding protocol must justify the number of breeders based on the estimated yield of offspring of the desired genotype. The experimental protocol and breeding protocol must work together for proper justification.

If the proposed work is a pilot study, indicate how the number of animals was estimated.

3. Acquisition and Primary Housing

All Investigators are encouraged to consult with the ARF Manager to discuss animal housing before submitting an Application. Without having prior approval from the IACUC, all animals taken from the animal facility must be returned to the facility the same day. Keeping the animals outside of the facility for more than 12 hours is considered housing and must be inspected as such. All animal orders, regardless of animal origin and destination, must be made through the ARF. For Animals that do NOT come from approved commercial vendor, several items must be in place before animals will be accepted into the Animal Facility. These items are:

Prior arrangement with the ARF Manager is required to obtain animals from other than commercial vendors.

These animals must have a certification of health that is acceptable to the Attending Veterinarian and will normally be quarantined on arrival for a period determined by the Manager (see section 3.1.2 of the ARF Standard Operating Procedures). The source is listed and approved in the IACUC protocol.

If animals can be received from an approved commercial vendor, other sources will not be considered.

Complete the table in the Application for each species or strain of animal to be used under the protocol. Do not include rat or mouse pups (pre-weanlings) in this table.

- **Species/Strain** – Identify the species and strain (if known) as specifically as possible. For projects involving generation of specific genotypes (heterozygotes, recessive homozygotes, etc.), identification of the primary strain or mutation is sufficient.
- **Source** – If the animals are not available through a commercial vendor, please supply the name of an institution if the animals are being obtained from another facility. For animals obtained from a commercial vendor use CV. For animals obtained from an in house breeding program,

use the number of the appropriate breeding protocol “IACUC 0000.” For animals to be bred as part of the submitted protocol, use “bred.” Animals captured in the field should be labeled “wild-caught.” (Note: all wild-caught animals must be discussed with the ARF Director.)

- **Total Number from this source** – Indicate the anticipated number of animals (other than mouse and rat pups) needed for each year of the protocol. The total number for each species or strain should match that indicated in Section C1.
- **Approximate Daily Inventory** – To facilitate planning by the ARF, indicate the expected number of animals needing to be housed at one time.
- **Primary Housing location** – “ARF” may be used, unless animals are to be housed in an auxiliary animal room or laboratory. Housing in laboratory space is by special approval of the IACUC only and requires a disaster plan to be incorporated into the Creighton University policies. It also requires mechanisms to be installed to alert key personnel if there is a sudden change in temperature. Housing is 12 hours or more.

SECTION D – ANIMAL HUSBANDRY

1. Animal Care

Check the appropriate box to indicate who will provide care for the animals. If non-standard care is to be provided by ARF personnel, indicate the type of care to be provided such as special diets or special care for animals with disease or functional deficits, prior arrangements must be made. Any special care needs and all care by non-ARF personnel must be described. Please complete the Special Precautions after consulting with the ARF Director to determine if a Special Animal Safety Protocol (SASP) is required in handling animals, cages, or waste because of hazardous agents (see question F1).

Housing: Social animals will be grouped housed unless scientific justification is provided. Mice, rats, gerbils, hamsters, guinea pigs, rabbits, dogs and pigs are social animals. Animals may be temporarily separated per veterinarian directives.

2. Animal Health

State how animal health, including pain and distress, will be assessed and specify the plan of action in case of animal illness or injury. Please review the SOP for Pain Assessment. Indicate any specific situations in which you wish to be notified prior to initiating treatment by the ARF staff. This is the criteria the Animal Facility will use to determine if they should euthanize an animal in the event they are unable to contact you. **You should describe a method of euthanasia, even if euthanasia is not part of the experimental design, in case it is necessary to terminate due to unexpected pain or morbidity. If it is not part of the experimental design, please indicate in Section E2 the method you will use and place an asterisk for the number of animals that will be euthanized using this method. Below the method used, indicate this method will be used only for unexpected pain or morbidity.** Information regarding the pain assessment as a result of experimental manipulation, should be included in Section E 7, 8, 9.

3. Deficits in Genetically Engineered and Mutant Animals

If no known deficits or pain and distress are expected in any of these animals, please check the appropriate box. However, if phenotypic changes do occur such as abnormal activity, pain or distress, these need to be reported using the [Animal Incident Report](#) form along with any appropriate special care to the IACUC and Attending Veterinarian.

For strains of animals with known deficits are not expected to experience pain or distress (Category B or C) as a consequence of their genome check the appropriate box. However, if phenotypic changes do occur such as abnormal activity, pain or distress, these need to be reported using

the [Animal Incident Report](#) form along with any appropriate special care to the IACUC and Attending Veterinarian.

For strains of animals with known deficits that are expected to experience more than slight pain or distress (Category D or E) as a consequence of their genome, describe nature of the pain or distress, and the methods to be used to alleviate pain or discomfort associated with the deficit (Category D). Copy and paste to create multiple entries as needed. (Functional deficits due to procedures performed on animals should be discussed in Section E instead.) If phenotypic changes occur such as abnormal activity, pain or distress, these need to be reported along with any appropriate special care to the IACUC and Attending Veterinarian

For all animals with known deficits, regardless of the pain category, the following information must be provided:

- **Genotype:**
- **Nature of deficit/plan of care:** Describe any post-natal functional deficit that is known or is likely in genetically engineered and mutant animals. Describe any special care or monitoring that will be required to detect and alleviate pain or discomfort associated with the deficit. If there is no information available as to the phenotype of a novel transgenic strain, indicate how you will assess the health of the animals and the plan of action should deficits arise.
- **Category of pain and distress (see section E1):** Indicate the category of pain and distress if the category is expected to be D or E.

4. Disposition of Surviving Animals

Indicate the disposition of any animals for which the endpoints have not been specified as part of the experimental procedures (for example, if breeding produces excess offspring or unneeded genotypes or if the breeders become too old). If animals are to be transferred to another protocol, specify the protocol. If transferring to another institution, please confirm that a Memorandum of Understanding is in place. If the institution is not AAALAC accredited, please provide a copy of the institution's protocol and a copy of their IACUC policies. Also, please indicate that animals will not be returned to Creighton University.

SECTION E—PROCEDURES

1. Category of Pain and Distress

Use this chart to determine the expected pain or distress for all procedures listed in E7, E8, and E9, or for genotype defects. The examples provided for each category below can assist you in classifying your procedure(s). The Creighton University categories correspond to USDA categories, with the following exception: breeding experiments that have the potential to cause more than momentary pain or distress, or that produce strains with functional deficits, do not fall under Category B. Additional guidance on classification of different procedures is provided by [USDA Policy #11](#), Painful and Distressful Procedures.

Category B – Breeding that involves no procedures or functional deficits that may cause more than momentary slight pain, discomfort, or distress. Includes breeding colonies of any animal species in which there is no potential for the animals to experience more than momentary pain, discomfort or distress as a result of either procedures associated with the breeding program or functional deficits inherent in the strain(s). The definition of “momentary slight pain” in this context is pain no greater

than the level and duration of pain attending a routine injection. Since this category excludes work that could cause pain, anesthesia should not be needed unless to immobilize animals for a non-painful procedure. Animals must be housed and handled in accordance with *The Guide* and other applicable regulations. Note that this category is for breeding only; any research or teaching to be done with the animals must be covered under a separate protocol or Category C, D, or E should be used.

Procedures acceptable in projects in this category include:

- Routine physical examinations and standard radiography
- Brief physical restraint (one minute or less) of awake animals
- Administration of oral medication
- Injections (subcutaneous, intramuscular, intravenous, parenteral) of non-irritating substances; administration of electrolytes/fluids
- Blood collection from a common peripheral vein per standard veterinary practice
- Ear punching or tagging or injection of microchips for purposes of identification
- Tattooing of animals larger than rodents for purposes of identification
- Use of special diets as required for successful breeding or animal health
- Euthanasia performed in accordance with the recommendations of the most recent *American Veterinarian Medical Association Guidelines on Euthanasia*, utilizing procedures that produce rapid unconsciousness and subsequent humane death

Category C – Research or teaching that involves no procedures or functional deficits that may cause more than momentary slight pain, discomfort, or distress. Includes research or teaching use in which there is no potential for the animals to experience more than momentary slight pain, discomfort or distress as a result of either procedures associated with the work or functional deficits inherent in the genotype or strains used. The definition of “momentary slight pain” in this context is pain no greater than the level and duration of pain attending a routine injection. Since this category excludes work that could cause pain, anesthesia, analgesia or sedation should not be needed unless to immobilize animals for a non-painful procedure.

Procedures in this category include:

- Observation or testing of animal behavior without stress; positive reward projects
- Routine physical examinations and standard radiography
- Brief physical restraint (one minute or less) of awake animals
- Administration of an anesthetic or sedation to facilitate a procedure that does not cause pain or distress (for example physical exam, radiography)
- Live trapping, banding or tagging of wild animals
- Feeding studies that do not result in clinical health problems
- Administration of oral medication
- Injections (subcutaneous, intramuscular, intravenous, parenteral) of non-irritating substances; administration of electrolytes/fluids
- Blood collection from a common peripheral vein per standard veterinary practice or short-term catheterization of same
- Gastric gavage by properly trained personnel
- Tail snips (up to 0.5 cm from 21 day or younger mice or other unweaned rodents for purposes of genotyping) for purposes of genotyping
- Ear punching or tagging or injection of microchips for purposes of identification
- Tattooing of rodents for purposes of identification
- Euthanasia performed in accordance with the recommendations of the most recent *American Veterinarian Medical Association Guidelines on Euthanasia*, utilizing procedures that produce rapid unconsciousness and subsequent humane death

Category D- Research, teaching or breeding that has the potential to cause more than momentary pain, discomfort or distress that will be alleviated by anesthetics, analgesics, or tranquilizers. Category D also includes research that involves chronic maintenance of animals with a moderate functional deficit that does not result in *unalleviated* chronic pain or distress. The important concept that distinguishes Category D from Category E is that under Category D animals are given appropriate anesthesia and/or pain relief to limit their pain and distress.

Examples of category D procedures are

- Surgery conducted with appropriate anesthesia and postoperative analgesia
- Tail snips up to 0.5 cm from mice or rodents older than 21 days for purposes of genotyping
These older rodents are anesthetized/sedated before tail biopsies are performed
- Rodent retro-orbital eye bleeding performed under anesthesia
- Removal of a small tumor under local or general anesthesia
- Use of analgesia after an animal's skin is exposed to ultraviolet light to cause a "sunburn"
- Terminal exsanguination (euthanasia by removal of blood) under anesthesia
- Terminal anesthetic surgery
- Induction of mild or moderate behavioral stress
- Physical restraint (less than 15 minutes) of awake animals
- Moderate restriction of food or water intake, including pre-surgical fasting
- Exposure to environmental conditions causing minor to moderate physiological stress
- Diagnostic procedures such as laparoscopy or needle biopsies
- Simple survival surgery with anesthesia and without significant postoperative pain (for example, biopsy, implantation of femoral arterial and venous catheters or flow probes, implantation of electrodes)
- Major survival surgery with anesthesia (for example, orthopedic surgery on major skeletal components, bowel resection, cardiac surgery, adrenalectomy, gonadectomy) with post-op/post-procedure analgesia to minimize pain
- Induced infections or antibody production with appropriate anesthesia and post-op/post-procedure analgesia when necessary
- Any post-procedural outcome that would result in sustained pain, discomfort or distress (such as that associated with decreased appetite or activity level, adverse reactions to touch, open skin lesions, abscesses, conjunctivitis, corneal edema and photophobia) but that is treated with appropriate anesthesia, analgesia or sedation
- Functional deficits in this category include:
 - Inducement of superficial, non-painful tumor
 - Lameness; loss of a functional digit
 - Deafness, congenital blindness

Category E – Research, teaching or breeding involving more than momentary pain, discomfort, or distress that cannot or will not be alleviated through the administration of appropriate anesthetics, analgesics or sedation; and/or that involves chronic maintenance of animals with a severe functional deficit. Includes research, teaching or breeding work in which the animals are likely to experience more than momentary pain, discomfort or distress as a result of procedures associated with the work, or will likely exhibit severe inherent or induced functional deficits. Pain, discomfort or distress either cannot be eliminated because no known drug or treatment is effective, or will not be treated because the treatment would interfere unacceptably with the goals of the study. Any procedures in this category will require a thorough explanation as to why relief cannot be provided and alternative procedures cannot be used.

Procedures in this category include:

- Induction of extreme behavioral stress (for example, application of noxious stimuli such as electrical shock that the animal cannot avoid or escape)

- Prolonged physical restraint (15 minutes or longer) of awake animals, or use of paralyzing or immobilizing drugs (without anesthesia) for restraint
- Prolonged or stressful restriction of food or water intake
- Exposure to environmental conditions causing extreme physiological stress
- Drug or radiation toxicity testing producing unrelieved pain or distress
- Testing of disease states that requires continuation until the animals become moribund or die; or that produces unrelieved pain or distress (for example, lethal dose determination, virulence challenge, painful tumors)
- Ocular or skin irritancy testing without anesthesia or analgesia
- Surgical or other hard or soft tissue damage, including burns or trauma that produces unrelieved pain or distress
- Any procedure causing injury or more than momentary pain or distress to a conscious animal
- Euthanasia by procedures not approved by the American Veterinarian Medical Association
- Functional deficits in this category include:
 - Induced blindness
 - Paraplegia, quadriplegia

2. Euthanasia Methods

Euthanasia is the act of inducing humane death. You should describe a method of euthanasia even if euthanasia is part of the experimental design, in case it is necessary to terminate unexpected pain or morbidity. Place two asterisks for the animal number if euthanasia method will only be used in the event the animals experience unexpected pain or morbidity. The method of euthanasia must be consistent with the recommendations of the most recent [American Veterinarian Medical Association Guidelines on Euthanasia](#) and are provided in the Creighton University [IACUC website](#).

The use of physical methods of euthanasia without anesthesia or other methods classified as “conditionally acceptable” by the American Veterinary Medical Association must be justified. The use of methods classified as “unacceptable” by the American Veterinary Medical Association is not considered humane and must be fully justified on grounds of scientific necessity.

- **If using Carbon Dioxide Euthanasia** following the IACUC SOP, check the box using this method. Indicate the required physical method that will be used to verify death.
- **If using drug or inhalant** based methods check this box and indicate the required physical method that will be used to verify death. Check this box only if the animal will be killed using the method. If the animal is anesthetized and then non-survival (i.e., thoracotomy or perfusion) is conducted to kill the animal, do not check this box.
- **If using a physical method** check this box.

Please indicate if the drug is Pharmaceutical grade. *Pharmaceutical-grade* means that the preparation has received FDA approval for use in humans and/or animals. Non-pharmaceutical-grade chemical compounds may be used only after specific approval by the IACUC for reasons such as scientific necessity or non-availability of an acceptable pharmaceutical-grade product. Cost savings alone are not an adequate justification for using a non-pharmaceutical-grade compound. For any non-pharmaceutical-grade drug, explain why a pharmaceutical-grade compound cannot be used and describe any relevant details of preparation. Use generic names for drugs. Indicate the dose and route of administration for any inhalant or injectable agent. Drug choice and dosages must be appropriate for the species. Express the dose as quantity of active drug per g or kg of animal (for example, mg/kg or ml/kg) rather than as volume of solution.

For any methods of euthanasia that is not definitive, indicate the criterion or method used to verify that death has occurred. Definitive methods are those in which death is certain – for example, decapitation. .

Number of Animals—indicate the number of euthanasia procedures that will be performed. These numbers should be consistent with Section C1.

Location of Procedure– indicate the room number(s) and building where the euthanasia procedure will be performed. If in the Animal Facility indicate (ARF).

Controlled substances (such as pentobarbital and other barbiturates, morphine, ketamine and other narcotics) can be ordered only by individuals licensed from the Drug Enforcement Administration (DEA). A list of controlled substance can be found on the [DEA website](#). If you plan to use any controlled substance, provide the registration number and the name of the licensee.

3. Anesthesia and Sedatives (Including Pre-anesthesia)

Please indicate if the drug is Pharmaceutical grade. *Pharmaceutical-grade* means that the preparation has received FDA approval for use in humans and/or animals. Non-pharmaceutical-grade chemical compounds may be used only after specific approval by the IACUC for reasons such as scientific necessity or non-availability of an acceptable pharmaceutical-grade product. Cost savings alone are not an adequate justification for using a non-pharmaceutical-grade compound. For any non-pharmaceutical-grade drug, explain why a pharmaceutical-grade compound cannot be used and describe any relevant details of preparation. Use generic names for drugs. Indicate the dose and route of administration for any inhalant or injectable agent and the criteria used to ensure that the animal is in the appropriate anesthetic plane or properly sedated. Drug choice and dose must be appropriate for the species - consult the Attending Veterinarian for advice when planning your experiments. Express the dose as quantity of active drug per g or kg (for example, mg/kg or ml/kg) of animal rather than as volume of solution. Use only unexpired, pharmaceutical-grade drugs even in acute procedures. Anesthetic waste gases are classified as environmental hazards and must be used in a fume hood or have a gas scavenging system in place.

Controlled substances (such as pentobarbital and other barbiturates, morphine, ketamine and other narcotics) can be ordered only by individuals licensed from the Drug Enforcement Administration (DEA). A list of controlled substance can be found on the [DEA website](#). If you plan to use any controlled substance, provide the registration number and the name of the licensee.

4. Analgesics

Animal welfare requires that appropriate analgesia be used to prevent pain or other discomfort in animals. If the amount or duration of pain that may be experienced by animals is not known, follow the standard of care for humans. All procedures classified in category D (Section D3 and E 7, 8, or 9) should include appropriate analgesics unless the pain is completely relieved by anesthesia.

Please indicate if the drug is Pharmaceutical grade. *Pharmaceutical-grade* means that the preparation has received FDA approval for use in humans and/or animals. Non-pharmaceutical-grade chemical compounds may be used only after specific approval by the IACUC for reasons such as scientific necessity or non-availability of an acceptable pharmaceutical-grade product. Cost savings alone are not an adequate justification for using a non-pharmaceutical-grade compound. For any non-pharmaceutical-grade drug, explain why a pharmaceutical-grade compound cannot be used and describe any relevant details of preparation. Use generic names for drugs. For each analgesic, indicate the dose and route of administration and the frequency and duration of treatment. Drug choice and dose must be appropriate

for the species - consult the Attending Veterinarian for advice when planning your experiments. Express the dose as quantity of active drug per g or kg (for example, mg/kg or ml/kg) of animal rather than as volume of solution. Use only unexpired, pharmaceutical-grade drugs even in acute procedures.

List the criteria used to assess analgesia requirements if dosing is based on need. Pain assessment criteria vary among species and the type of pain the animal will potentially experience. Review the [Pain Assessment SOP](#). Relevant criteria may include:

- Decreased activity
- Abnormal postures, hunched back, muscle flaccidity or rigidity
- Poor grooming
- Decreased food or water consumption
- Decreased fecal or urine output
- Weight loss (generally 20-25% of baseline), failure to grow, or loss of body condition (cachexia)
- Dehydration
- Decrease or increase in body temperature
- Decrease or increase in pulse or respiratory rate
- Abnormal physical response to touch (withdrawal, lameness, abnormal aggression, vocalizing)
- Teeth grinding (seen in rabbits and farm animals)
- Self-aggression
- Inflammation
- Photophobia
- Vomiting or diarrhea

Controlled substances (such as pentobarbital and other barbiturates, morphine, ketamine and other narcotics) can be ordered only by individuals licensed from the Drug Enforcement Administration (DEA). A list of controlled substance can be found on the [DEA website](#). If you plan to use any controlled substance, provide the registration number and the name of the licensee.

5. Drugs and Biological and Chemical Agents

Please list the pharmacological grade reagents first, followed by the non-pharmacological grade/reagents. List any drugs or other agents not already listed in Section E 2, 3, or 4, using generic names. Please indicate if the drug is Pharmaceutical grade. *Pharmaceutical-grade* means that the preparation has received FDA approval for use in humans and/or animals. Non-pharmaceutical-grade chemical compounds may be used only after specific approval by the IACUC for reasons such as scientific necessity or non-availability of an acceptable pharmaceutical-grade product. Cost savings alone are not an adequate justification for using a non-pharmaceutical-grade compound. For any non-pharmaceutical-grade drug, explain why a pharmaceutical-grade compound cannot be used and describe any relevant details of preparation. Include the dose and route of administration, as well as any other relevant information, such as the purpose of the drug and the frequency of administration. Express the dose as quantity of active drug per g or kg (for example, mg/kg or ml/kg) of animal rather than as volume of solution.

Use unexpired, pharmaceutical-grade medications whenever they are available, even in acute procedures.

Controlled substances (such as pentobarbital and other barbiturates, morphine, ketamine and other narcotics) can be ordered only by individuals licensed from the Drug Enforcement Administration (DEA). A list of controlled substance can be found on the [DEA website](#). If you plan to use any controlled substance, provide the registration number and the name of the licensee.

Please check with the Animal Facility Director to ensure a Special Animal Safety protocol **is not** required for the care and housing of the animals in the facility.

6. Non-Pharmaceutical Compounds Used in Live Animals

Non-Pharmaceutical compounds used in live animals: List all compounds from E2-E5 that are non-pharmaceutical grade, this includes dilution of pharmaceutical grade drugs. Provide a) scientific rationale for use of each compound in animals, b) source of compound, grade/purity, c) formulation, and d) quality control to include sterility, pyrogenicity, stability, PH, osmolality, pharmacokinetics, physiological compatibility, and quality control.

7. Non-surgical Procedures

Every procedure to be carried out on live animals should be described in this section or in Section E 7, 8 or 9 (Surgical Procedures), as appropriate. If the sequence of procedures is complex, provide a clear timeline in your response in Section B3.

Duplicate this section as necessary to provide the information for each non-surgical procedure:

Procedure name – Provide a suitable name for reference purposes.

Description of procedure –For any procedure that might cause more than momentary slight pain, discomfort or distress, identify that you will use the analgesic(s) or anesthetic(s) to be used as identified in Sections E 3 or 4. (Do not provide the name of the agents used). For category E explain the scientific necessity, and why relief cannot or will not be provided. Justify the reason for withholding them. Indicate the duration of the procedure when not obvious. In addition, describe:

- any methods of restraint (for example, collars, vests, harnesses, slings, tubes) and the duration of restraint
- any potential stressors (for example, food or water deprivation, noxious stimuli, environmental stress) and procedures to monitor and minimize distress
- any special diets or feeding or exercise regimens
- the nature and duration of any behavioral conditioning

Category of pain and distress (See Section E1)

Location(s) at which procedure will be performed – Indicate ARF if done in the Animal Facility. Indicate the room number and building where the procedure will be performed if done outside of the Animal Facility. Check the box if the animals will be kept in this location for more than 12 hours. Any locations outside the ARF in which an individual animal will be kept for more than twelve continuous hours must be noted. Prior approval by the IACUC is required for any locations that fall in this category. A Disaster Plan must be on file with the IACUC office and incorporated into the Creighton University policies before housing of animals outside the animal facility will be considered.

Number of procedures to be performed – Indicate the number of times the procedure will be performed, (i.e. the product of the number of times each animal will have the procedure and the number of animals receiving the procedure). If different animals will be subject to the procedure different numbers of times, alter the text as needed, but please provide a final, all-inclusive total for the number of times the procedure will be carried out.

8. Rodent and Non-mammal Surgical Procedures

Describe every surgical procedure to be carried out on live rodents (rats, mice, gerbils, hamsters, guinea pigs) or on non-mammals. A surgical procedure is any procedure that involves incisions or other penetration of the body beyond what is described as Category C in Section E1. If the sequence of procedures is complex, provide a clear timeline in your response in section B3. Please reference the

Survival Surgery in Rodents SOP.

- **Surgical category** – Characterize the surgical procedures to be performed on a single animal as:
 - “Single non-survival” indicates only one surgical procedure will be performed, and the animals will be euthanized without recovery from anesthesia.
 - “Single survival” indicates only one surgical procedure will be performed, after which the animals will recover from anesthesia.
 - “Single survival followed by non-survival” indicates that two surgical procedures will be performed. The animals will recover from the first but be euthanized without recovery from anesthesia during the second.
 - “Multiple minor” indicates that two or more surgical procedures will be performed from which the animal will recover, but the surgery does not qualify as “major” (see next category).
 - “Multiple major” indicates that two or more major surgical procedures will be performed from which the animal will recover. Major surgery penetrates and exposes a body cavity, penetrates or alters a major bone, or produces substantial impairment of physical or physiologic function. Federal regulations require that no animal be subjected to more than one major survival operative procedure except in cases of scientific necessity or veterinary care. (See [USDA Policy #14](#), Major Survival Surgery, Single vs. Multiple Procedures,). Therefore full justification must be provided for multiple major survival surgeries.
- **For multiple major surgeries only** – This section must be filled in only if “Multiple Major Surgeries” are planned.

Duplicate this section as necessary to provide the information for each surgical procedure:

- **Procedure name** – Provide a suitable name for reference purposes.
- **Pre-operative procedures** – Describe preparation of animals prior to operative procedures (e.g. fasting) as well as the anesthetic procedure. Describe steps taken to assure asepsis during surgical procedures, including animal prep, instrument prep, and surgeon prep.
- **Description of surgery** – The description should be in layperson's terms and should include any animal restraint methods, incision site(s), the exact nature of the procedure, and the duration of the procedure if not obvious. Describe the steps taken to monitor the intra-operative health and anesthetic depth. If paralytic agents are used, describe how ventilation will be maintained and how pain will be assessed.
- **Post-operative procedures and care** – Postoperative care must be provided in accordance with established veterinary medicine. Describe the monitoring plan for discomfort and pain, including after hours, weekends and holidays, and procedures used to minimize discomfort and pain. Identify analgesics or other drugs. Indicate the frequency of observation to detect and manage post-operative complications.
- **Category of pain and distress (see Section E1).**
- **Location(s) at which procedure will be performed** – Indicate if the procedure will be performed in the ARF. If not, indicate the room number(s) and building where the surgical procedure as well as pre- and post-operative procedures will be performed. Any locations in which an individual animal will be kept for more than twelve continuous hours must be noted. Prior approval by the IACUC is required for any locations that fall in this category. A disaster plan is required to be on file with the IACUC office before any consideration will be granted to house animals outside the facility.
- **Number of procedures to be performed** – Indicate the number of times the procedure will be performed, (i.e. the product of the number of times each animal will have the procedure and the number of animals receiving the procedure). If different animals will be subject to the procedure different numbers of times, alter the text as needed, but please provide a final, all-inclusive total for the number of times the procedure will be carried out.

9 Non-rodent Mammal Surgical Procedures

Every surgical procedure to be carried out on non-rodent mammals (including rabbits, sheep, dogs and pigs) should be described in this section. A surgical procedure is any procedure that involves incisions or other penetration of the body beyond what is described as Category C in section E1. If the sequence of procedures is complex, provide a clear timeline in your response in section B3.

- **Surgical category** – Characterize the surgical procedures to be performed on a single animal as:
 - “Single non-survival” indicates only one surgical procedure will be performed, and the animals will be euthanized without recovery from anesthesia.
 - “Single survival” indicates only one surgical procedure will be performed, after which the animals will recover from anesthesia.
 - “Single survival followed by non-survival” indicates that two surgical procedures will be performed. The animals will recover from the first but be euthanized without recovery from anesthesia during the second.
 - “Multiple minor” indicates that two or more surgical procedures will be performed from which the animal will recover, but the surgery does not qualify as “major” (see next category).
 - “Multiple major” indicates that two or more major surgical procedures will be performed from which the animal will recover. Major surgery penetrates and exposes a body cavity, penetrates or alters a major bone, or produces substantial impairment of physical or physiologic function. Federal regulations require that no animal be subjected to more than one major survival operative procedure except in cases of scientific necessity or veterinary care. (See [USDA Policy #14, Major Survival Surgery, Single vs. Multiple Procedures](#), Attachment B). Therefore full justification must be provided for multiple major survival surgeries.
- **Justification (for multiple major surgeries only)** – This section must be filled in only if “Multiple Major Surgeries” are planned.

Surgeries on non-rodent mammals must follow procedures detailed in a set of species-specific [Standard Operating Procedures](#). These include pre-operative, operative and post-operative activities. Minor modifications to these Standard Operating Procedures (for example a change in a drug or dose) may be requested in this section. More substantial modifications require approval by the IACUC of alternative Standard Operating Procedures.

Duplicate this section as necessary to provide the information for each surgical procedure:

- **Procedure name** – Provide a suitable name for reference purposes.
- **Standard Operating Procedures** – Indicate whether the ARF Standard Operating Procedures will be used. Consult with the Attending Veterinarian if you intend to modify the Standard Operating Procedures or propose to use alternative Standard Operating Procedure.
 - “Non-rodent mammal Surgery Standard Operating Procedures will be followed as written” indicates that there will be no deviations or omissions from the Standard Operating Procedures.
 - “Non-rodent mammal Surgery Standard Operating Procedures will be followed with minor modifications” requires that all additions, changes or omissions from the Standard Operating Procedures be described under **Description of Modifications**.
 - “Alternative Standard Operating Procedures will be followed.” The investigator must provide a set of Standard Operating Procedures of comparable detail to those provided by the ARF and submit these with the Application.
- **Specific procedure description** – Most surgical procedures involve more than the basic steps

covered in the Standard Operating Procedures, such as the manipulation or removal of tissues or organs, implantation of devices, etc. Describe these specific procedures in this section. If paralytic agents are used, describe how ventilation will be maintained and how pain will be assessed.

- **Category of pain and distress**--(See Section E1).
- **Location(s) at which surgery, pre- and post-operative procedure will be performed**—indicate the room number(s) and building where the post-surgical procedure will be performed. Correct room numbers are essential to ensure proper guidelines are followed for semi-annual inspections. Major operative procedures must be conducted in facilities intended for that purpose.
- **Location(s) where animals will be housed outside of the ARF**.—indicate the room number(s) and building where the animals will be housed. Any locations in which an individual animal will be kept for more than twelve continuous hours must be noted. Prior approval by the IACUC is required for any locations that fall in this category. A Disaster Plan must be on file and incorporated into the Creighton University policies before consideration will be granted to house animals outside the Animal Facility.
- **Number of procedures to be performed**—indicate the number of times the procedure will be performed, (i.e. the product of the number of times each animal will have the procedure and the number of animals receiving the procedure). If different animals will be subject to the procedure different numbers of times, alter the text as needed, but please provide a final, all-inclusive total for the number of times the procedure will be carried out.

10 Documentation of Lack of Alternative to Category D or E Procedures

Before choosing any procedures that have the potential to cause pain or distress, you must verify that alternative procedures are not available or are scientifically unacceptable. This verification must be made for each procedure identified in E10. Alternative procedures include methods that (1) refine existing procedures by minimizing animal distress, (2) reduce the number of animals necessary for an experiment, or (3) replace whole animal use with in vitro or other tests. Examples of refinements include less-invasive surgical techniques or terminating experiments during earlier stages of morbidity. Examples of reduction are use of shared control groups, preliminary screening in non-animal systems, or more powerful statistical techniques. If a bona fide alternative method could accomplish one or more goals of the project, justify your decision to reject this alternative. Potential alternatives that do not allow the attainment of the goals of the research are not, by definition, alternatives.

Animal Welfare Act regulations require a written narrative of the methods used and sources consulted to determine the availability of alternatives to painful or distressful procedures. When a search of databases is the primary means of meeting this requirement, the narrative must, at a minimum, include:

- The names of the databases searched.
- The date(s) the searches were performed.
- The period covered by the searches.
- The key words and/or the search strategy used.

To be beneficial, the search for alternatives should be completed while you are in the process of designing your experiment. The Health Sciences Reference Librarian at 402-280-5138 or refdesk@creighton.edu can arrange a search, at no charge, of veterinary and other databases, including databases not available to the general public, for refinements that reduce pain and distress. The Animal Welfare Information Center is an information service of the National Agricultural Library specifically established to provide information about alternatives. Animal Welfare Information Center offers expertise in formulating a search strategy, selecting key words and databases, and accessing unique databases. The Animal Welfare Information Center also is able to perform no-cost or low-cost electronic

database searches. Animal Welfare Information Center can be contacted at 301-504-6212, via e-mail at awic@nal.usda.gov, or via its website at <http://www.nal.usda.gov/awic/>. Additional information on search strategies and links to accessible databases is available from the [IACUC website](#).

Experience and familiarity with the literature in the field, conferences, colloquia, subject expert consultants or other sources may provide relevant and up-to-date information regarding alternatives, in lieu of or in addition to, a database search. When a consultant's opinion is the primary means of considering alternatives, the Principal Investigator must provide the consultant's name and qualifications and the date and content of the consultation to demonstrate the expert's knowledge of the availability of alternatives in the specific field of study (see [USDA Policy #12](#)).

SECTION F – HAZARDOUS AND INFECTIOUS SUBSTANCES

List any substance that presents a potential hazard to human or animal health in this section, either to indicate their hazard or to document their safety. Indicate “None” for each category if no such substances will be used. If multiple substances in a single category will be used, provide the information requested for each substance. When applicable, you must have prior authorization from the appropriate committees (Radiation Safety Committee and/or Institutional Biosafety Committee) before animals can be ordered. In addition, if hazardous substances will be present in the ARF, the Facility Director must approve the safety precautions and a Special Animal Safety Protocol form must be completed. Any special safety precautions or handling requirements for animals, cages or waste of relevance to ARF personnel should be indicated in section D1. Add any additional information in the space provided for each substance.

1. Biohazardous Materials

Biohazardous materials include, but are not limited to, biological agents infectious to humans and recombinant DNA. Use of such materials in animals must comply with all federal, state and university regulations. Primary authority for regulation of biohazardous material use at Creighton University is held by the university's Institutional Biosafety Committee. The Institutional Biosafety Committee must approve use of any such material. The IACUC and IBC communicate with each other during the approval process for each committee's application. Refer to the [Institutional Biosafety Committee policies](#) for detailed information.

- **Substance or organism** – Name the potentially biohazardous substance, organism or agent, including any recombinant DNA.
- **Risk group** – Indicate the risk group, as defined by Institutional Biosafety Committee Policies and Procedures. *Exempt agents must still be registered with the Institutional Biosafety Committee.*
- **Required animal biosafety level** – Indicate the required animal biosafety level, as defined by the Center for Disease Control's Biosafety in Microbiological and Biomedical Laboratories manual, [Section IV: Vertebrate Animal Biosafety Level Criteria](#).
- **Institutional Biosafety Committee approval number** –For non-exempt substances, indicate the Institutional Biosafety Committee approval number and attach a copy of the approved Institutional Biosafety Committee Registration Document. For exempt substances, provide the Institutional Biosafety Committee registration number.
- **Location(s) materials will be stored and used**
- **Special Animal Safety Protocol:** Please confirm with the ARF Director if a Special Animal Safety Protocol is required.
- **Additional information** – Provide any further information about the material or its use of which the IACUC or ARF should be aware. If there are no special precautions or health concerns

associated with the substance, so state.

2. Cell Cultures

Live cell cultures or lines used in animal work must be free of viral pathogens that might be transmitted to other animals or humans. For murine cells, this includes hepatitis, parvo, EDIM, MEV, MHV, MPUL, MPV, PVM, REO, SEND and TMEV. The ARF Director or Attending Veterinarian can provide a list of the pathogens of concern for other species. Documentation that cultures are free of pathogens must be provided before use is approved.

- **Cell line or culture** – Name the cell culture or line.
- **Source species**
- **Testing laboratory** – Provide the name of the laboratory or other facility that tested for viral pathogens, and attach certification that the cells were found to be free of such pathogens.
- **Location(s) cultures will be used**
- **Special Animal Safety Protocol:** Please confirm with the ARF Director if a Special Animal Safety Protocol is required.
- **Additional information** – Provide any further information about the cells or their use of which the IACUC or ARF should be aware.

3. Carcinogens

The International Agency for Research on Cancer classifies materials based on their known or potential carcinogenic risk to humans. Substances in International Agency for Research on Cancer Groups 1, 2A and 2B (known, probable and possible carcinogens) must be listed in this section. Currently listed agents and mixtures can be found at [the International Agency for Research on Cancer](#).

- **Substance** – Name the chemical or substance.
- **International Agency for Research on Cancer Classification** – Indicate the appropriate category for the listed substance.
- **Location(s) agents will be stored and used**
- **Special Animal Safety Protocol:** Please confirm with the ARF Director if a Special Animal Safety Protocol is required.
- **Additional information** – Provide any further information about the substance or its use of which the IACUC or ARF should be aware.

4. Radioisotopes or Radiation Emitting Equipment

Use of radioisotopes or radiation emitting equipment with animals must comply with all federal, state and university regulations. The [Creighton University Radiation Safety Committee](#) has primary authority for regulation of radioactive material use. A Radiation Safety Committee permit or State Registration Number is required before permission can be requested from the IACUC for use of radiation with animals.

- **Substance** – Name the radioisotope or device.
- **Radiation Safety Committee permit number or State Registration Number** – Indicate the Radiation Safety Committee permit number and attach a copy of the permit.
- **Location(s) materials will be stored and used**
- **Special Animal Safety Protocol:** Please confirm with the ARF Director if a Special Animal Safety Protocol is required.

- **Additional information** – Provide any further information about the material or device or its use of which the IACUC or ARF should be aware. If there are no special precautions or health concerns associated with the substance, so state.

5. Other Hazardous Substances

Any materials associated with known or suspected risks to human or animal health not listed above should be described in this section.

- **Substance** – Name the substance.
- **Nature of hazard** – Describe the potential or known risk associated with the substance.
- **Location(s) substances will be stored and used:**
- **Special Animal Safety Protocol:** Please confirm with the Radiation Committee and the ARF Director if a Special Animal Safety Protocol is required.
- **Additional information** – Provide any further information about the material or its use of which the IACUC or ARF should be aware.

SECTION G – PERSONNEL

List every individual who will work on live animals (the only exception is students in a training course, as described in the instruction for A4). Personnel who do not handle live animals (for example, those only receiving tissue samples or providing hands-off technical advice should not be included. The personnel listed in this section must, as a group, be qualified to perform all of the project procedures on the species to be used. A project cannot be approved if it includes any procedure for which there is no qualified individual identified as responsible for the procedure.

1. Principal Investigator

The Principal Investigator is the individual responsible for the implementation of the project, monitoring treatment of the animals by other project staff, and providing accurate information to the IACUC. The Principal Investigator is normally a Creighton University faculty member. If the protocol work is supported by a grant, the Principal Investigator for the protocol is usually the same as for the grant. This is not mandatory. A Postdoctoral Researcher may act as Principal Investigator on a protocol if he/she is the Principal Investigator of the supporting grant. The Principal Investigator must provide full contact information, including a campus phone number and an emergency phone number for after-hours and weekends.

2. Other Project Staff

For each of the personnel, provide name, department (or institution, for non-Creighton University personnel), phone numbers, Creighton e-mail address and status. Copy and paste this section as many times as needed to list all personnel.

Emergency phone numbers should be provided for Co-Investigators and other personnel with sufficient knowledge and authority to respond to an emergency involving either animal health or housing.

For each person, provide status: co-investigator, post-doc/fellow, technician, graduate student, undergraduate student, or visiting scientist. A Visiting Scientist is generally someone with an advanced degree (M.D., Ph.D., D.V.M.) who will spend a short period of time on the project. Visiting Scientists must be experienced with any procedures and species with which they will work. Exempt Personnel include laboratory or training course participants, and observers of animal use activity. Laboratory or training course participants are students or other personnel working under the Personal Supervision of

IACUC-approved personnel in a formal laboratory course or training seminar. Observers are individuals who do not participate in animal care or use but may be present during a procedure. Exempt personnel are typically not listed on an IACUC protocol. When exempt personnel use live animals, they must do so under the Personal Supervision of personnel authorized under the protocol to provide such supervision. The Principal Investigator bears ultimate responsibilities for the treatment of animals by personnel working under his or her supervision. Supervisors are also responsible for providing appropriate instruction to exempt personnel on any health and safety issues and on any care and handling techniques related to animal use.

Duties in project, including specific procedures listed in Section E 2, 7, 8, and 9: Indicate each person's role in the project (the procedure names in Section E). Each procedure on the protocol should have at least one person listed that will be responsible for that procedure.

Experience or training specific to duties above: Provide a brief synopsis of relevant training and experience, especially experience with the procedures and species to be used in Section E 2, 7, 8, and 9. Personnel must be properly trained in the animal procedures you have listed for them. This includes animal handling, restraint and the euthanasia methods listed. Indicate their training and experience and where they were trained. Also list how long they have been doing the procedures. Each person who will work with live animals must have completed IACUC Certification.

Specify any additional training required and plan for completion: for any personnel, who currently lack appropriate experience, indicate planned training, including the techniques to be taught, the trainer, and expected completion date. All training must be done by a qualified individual whose duties on the protocol include training. Unqualified personnel may NOT work with animals unsupervised and are not granted card access to the ARF. If the research involves hazardous materials, describe the qualifications of personnel regarding knowledge of potential dangers and selection and implementation of appropriate safeguards.

For Modification Only-Principal Investigator Certification

When submitting a personnel modification only. Make the necessary changes using track changes, include the protocol number and send an entire electronic copy of the protocol to the IACUC office. Once the modification is approved, please send a signed copy of section G only via intercampus mail. You can print only this section by indicating the page number and the number of the section (i.e., p1s7-p5s7). An email will be sent to you indicating when the modification is approved. When the signed copy is received by the IACUC office, an approval letter will be issued and returned to you along with a copy of the signed modification form.