St. George's University
Institutional Animal Care and Use Committee

Instruction sheet for IACUC Research applications

Please read the instructions for each section carefully and fill in the form. Incomplete forms will be returned to the PI without the committee evaluating the application. Use the provided textboxes and do not write outside of them. Double clicking on the grey boxes can activate them.

Section 1: Proposed end date may be maximally 3 years after proposed start date.

Section 2: Project category: more than option may be ticked

Section 4:
*Participating Personnel***:** Name all personnel performing the experimental manipulations or working with animals on this study. Include the Principal Investigator on the list.

*Protocol Contacts***:** The Protocol Contact will be cc'd on emails to the PI concerning IACUC and protocol compliance issues. This includes Annual Status Reports and 3rd Year Renewal Notifications. Please mark if personnel will be directly involved with work on animals.

*Occupational Safety Designee***:** This person will be responsible for assuring that all participating personnel are adequately informed and trained with regard to potential occupational hazards associated with animal work. For additional information regarding the Animal Hazards Program, contact the University Health Clinic at 407-2790.

Project Role: List the duties this person will perform relating to the animal studies.

Section 5:
Hazardous Agents include, but are not limited to:

1. **Infectious Agents** including bacteria, chlamydiae, fungi, rickettsias, viruses, parasites, prions, human blood, body fluids, tissues or cell cultures. **Recombinant DNA and the creation (but not acquisition) of transgenic animals**.
2. **Radiation** including x-rays, lasers, sealed sources and radioisotopes.
3. **Hazardous Chemicals** such as toxic, carcinogenic, mutagenic or teratogenic substances; sterilant or anesthetic gases.

Please list the hazardous agents that may be included in this project, and describe how it will be dealt with to reduce the safety hazards (e.g. will involved personnel be vaccinated if a project includes animals with rabies; how will infected cadavers be disposed,…) . In certain cases the committee may request a more detailed addendum.

Section 7:
The primary aim of the lay summary is describing your work to the non-scientific world. The summary should briefly describe the major goals of the research and why the animal model you chose is the appropriate model. This should be written in non-technical language. All abbreviations/acronyms should be defined on first use. Be clear and concise; several sentences to one or two short paragraphs should be adequate.

Section 8:
Describe the scientific aims of this project. Justify the project in terms of its potential value in advancing scientific knowledge and/or the benefits of the study to human and/or animal health. Provide sufficient information to indicate that the potential new knowledge from the project justifies the use of animals, improvement of animal management or production, or achievement of educational objectives.

Section 9:

Use this section to record the materials and methods used. This is the 'how' of the protocol.

Provide a complete and accurate description of what procedures will be performed on/with the animals. Include the rationale/purpose of the procedures described. Answer in lay language or language understood by a person unfamiliar with your area of research (define all acronyms). Jargon should be avoided or explicitly explained.

1. Specify the number of animals in each experimental group, including control animals. Be certain to detail the regulatory classification of each animal group. This should correspond to the information you will provide later in the **Humane Use Animal Categories, Justification for Number Requested, and Justification for Species sections** of this application.
2. Provide a step-by-step description of all procedures, their frequency and time points over the course of the experiments.
3. Describe the rationale/purpose for the procedures and address possible temporary or permanent affects to the animal's physiology/behavior.
4. Include how long the animals will be maintained. Include dose, route of administration and frequency of any drugs to be administered.

Describe methods used in behavior studies (including use of noxious stimuli or other methods of positive or negative reinforcement).

Section 10:

All vertebrate animals used for research or teaching must be assigned to a USDA pain and distress category on the protocol under which they are used. Procedures that could cause pain or distress in humans should be assumed to cause pain or distress in other animals. This document provides definitions and examples of the USDA pain and distress levels to ensure that animals are listed on their protocol

under the correct USDA pain and distress category. The IACUC will make the final decision about the correct pain category assignment for each protocol.

- Assign each animal listed on a protocol to one of the following USDA pain and distress categories: B, C, D or E. For definition and examples of USDA pain and distress categories, see Appendix 1.
- List each animal under the highest pain and distress category that will apply to the animal at any time while the animal is listed on the protocol, even if it is for a short duration of time.
- Do not include non-research related veterinary care in determining USDA pain and distress category.
- If a procedure is done on an animal (e.g. tail snip or euthanasia), list the animals as category C or greater. This includes animals used for breeding if they are later euthanized. Thus, breeding mice should be placed in category C rather than category B. List breeding animals as category B only if no procedures are done, including euthanasia.
- Genetically engineered animals:
  - Place animals in category C if the phenotype produced by the genetic alteration is unknown. Amend the category if the investigator or veterinary staff recognizes phenotype-related pain or distress.
  - Place animals in category D if the phenotype is expected to cause, pain or distress that will be alleviated by IACUC approved methods.
  - Describe any new information regarding the phenotype, including adverse events, and adjust the pain and distress category as necessary during the annual review.

USDA pain levels:

Category B	**Category C**	**Category D**	**Category E**
Animals being bred, acclimatized, or held for use in teaching, testing, experiments, research, or surgery **but not yet used** for such purposes. Non-invasive observation only of animals in the wild.	Animals that are subject to procedures that cause no pain or distress, or only momentary or slight pain or distress and do not require the use of pain-relieving drugs.	Animals subjected to potentially painful or stressful procedures for which they receive appropriate anesthetics, analgesics and/or tranquilizer drugs.	Animals subjected to potentially painful or stressful procedures that are **not** relieved with anesthetics, analgesics and/or tranquilizer drugs. Withholding anesthesia/analgesia must be scientifically justified in writing and approved by the IACUC.

Example (B)	Examples (C)	Examples (D)	Examples (E)
1. Animals being bred or housed, without any research manipulation, including euthanasia. 2. Observation of animal behavior in the wild without manipulation the animal or it's environment	1. Holding or weighing animals in teaching, outreach or research activities 2. Ear punching of rodents 3. Animal behavior studies 4. Routine physical examination 5. Peripheral injections, blood collection or percutaneous catheter implantation 6. Feed studies, which do not result in clinical health problems 7. Routine agricultural husbandry procedures approved by the IACUC in a protocol or SOP 8. Live trapping 9. Research procedures that involve no potential increase in pain or distress on client owned animals that are undergoing clinical procedures 9. Positive reward training or research 10. Tattooing 11. Anesthesia used for restraint for a painless, or momentarily painful, procedure 12. AVAM approved Euthanasia procedures	1. Survival surgery 2. Non-survival surgical procedures 3. Laparoscopy or needle biopsies 4. Retro-orbital blood collection from animals 5. Exposure of blood vessels for catheter implantation 6. Induced infections or antibody production (ascites method) 7. Research procedures that could potentially increase pain or distress on client owned animals (e.g. analgesia studies)	1. Toxicological or microbiological testing, cancer research or infectious disease research that requires continuation after clinical symptoms are evident without medical relief or require death as an endpoint 2. Severe food or water deprivation beyond that necessary for ordinary pre-surgical preparation 3. Application of noxious stimuli such as electrical shock that the animal cannot avoid/escape the stimuli and/or it is severe enough to cause more than momentary pain or distress. 4. Any procedures for which needed analgesics, tranquilizers, sedatives, or anesthetics must be withheld for justifiable study purposes 5. Exposure to extreme environmental conditions 6. Euthanasia by procedures not approved by the AVMA 7. Paralysis of a conscious animal

Provide the total number of animals to be used for the approval term of this protocol (maximum of 3 years).

Section 11b:
Federal laws require that animals which will experience more than momentary pain and distress (such as that associated with a needle-prick) must be provided with appropriate sedatives, analgesics, and/or anesthetics. Withholding of these agents required scientific evidence that such drugs will interfere with the study or harm the welfare of the animal.

Any change from the methods or agents listed herein must be pre-approved by a University Animal Care veterinarian and such approval documented in the animal's record. Permanent changes in palliative therapy must be submitted to the IACUC as an amendment to the protocol.
Clinical signs of pain or distress that will be used to evaluate the need for palliative therapy should be included.

Section 11e:
Please Note: Euthanasia should be performed in accordance with the methods approved by the American Veterinary Medical Association (AVMA) panel on euthanasia. The guidelines can be found on the IACUC Sakai site.
All protocols using live animals must include this section, even if euthanasia is not planned)
Please list all non-University Animal Care locations where Euthanasia will take place.

Section 12:
Federal Regulations and University Policy require assurance that this project does not unnecessarily duplicate research projects/courses performed at this or other institutions, and that the use of alternatives to live animal models and procedures that may cause more than momentary or slight pain/distress to animals have been considered. The information in this section should include adequate information for the IACUC to assess that a reasonable and good faith effort was made to determine the availability of alternative models or methods. If the database search or other source identifies a bonafide alternative method (one that could be used to accomplish the goals of the animal use proposal), the written narrative should justify why this alternative was not used.

Section 13:
It is the policy of the IACUC and University Animal Care to work with the Principal Investigator and their research team to assure that any modifications made to the protocol will not compromise the research aims of the project. Please note, however, that the IACUC policy and federal law has granted intervention authority to the attending/University veterinarian and the IACUC in the event that animal health is jeopardized or approved protocol procedures have been altered without prior

IACUC approval. The IACUC has the authority to suspend work that is in violation of federal regulations.

Print this final page and sign. Please send the signed hardcopy to IACUC Office or you may scan and send as an email attachment. This is the ONLY hardcopy required by the IACUC Office. DO NOT send the entire application Form.