# The Guide for Preparation of Animal Utilization Protocols



**Animal Research Ethics Board** 

General Information	. 4
Approval Process	. 4
Steps to Follow	. 4
Stages of the approval process	. 5
Section 1 – Project Title	. 6
Section 2 – Principal Investigator	. 6
Section 3 – Associate Scientists, Research Staff & Training/Experience	. 6
Training/Experience	. 7
Section 4 – Funding	. 7
Section 5 – Lay Description	. 8
Sample Lay Descriptions	. 8
Section 6 – Justification of Animal Use	. 9
A. Alternatives?	. 9
B. Why use animals?	. 9
C. Why this species?	. 9
D. How many animals?	. 9
E. Basis for estimated animal use	. 9
Section 7 – Summary of Species, Animal Numbers, & Classification of Experiments	. 9
Summary of Species	. 9
Categories of Invasiveness	. 9
Classifications	10
Section 8 – Experimental Procedures & Summary	10
Objectives	10
Rationale	10
Purpose of Animal Use	11
Proposed Experiments	11
Procedures Summary	11
Housing and Handling	11
Summary of Substances Administered and Fluids Sampled	12
Summary of Surgical Procedures	12
Disposal of Animals	12
Section 9 – Project & Facilities Management	12
Source of Animals	12
Housing of Animals	13
Special Care	13
Isolation/Containment/Quarantine	13
Other Arrangements	13
Location of Procedures Outside of an Animal Facility	13
Animal transport	13

# **Table of Contents**

Enrichment	14
Veterinary Intervention	14
Potential Hazards	14
Section 10 - Endpoints	14
Sample Monitoring Criteria	15
Section 11 - Keywords	16
Extra Forms and Required Information	15
Services Available	16
Contact Numbers	16

## **General Information**

This document is a detailed instruction manual to assist investigators in preparing an Animal Utilization Protocol (AUP) for submission to the McMaster University Animal Research Ethics Board (AREB). Prior to receiving approval to use animals in research, investigators are required to provide a full description of their proposed experiments involving animals in sufficient detail to allow AREB to adequately assess the ethical considerations relating to animal use. An AUP is typically comprised of a standardized form with a variety of attachments and supporting information related to the specific project proposed. All required forms are available through the Health Research Services website (Forms - Health Research Services (mcmaster.ca). Further information on completing these forms and the AUP submission process can be obtained from the AREB Coordinator (905-525-9140, Ext. 22469 or princd1@mcmaster.ca).

## **Approval Process**

An AUP must be approved through the following process before research, testing or teaching projects involving animals or animal tissue are initiated.

In accordance with the requirements of the *Animals for Research Act of Ontario* (1980) and the Guidelines of the *Canadian Council on Animal Care* (CCAC), the President of McMaster University has constituted an Animal Research Ethics Board (AREB) to review all research, testing and teaching activities involving the use of animals or animal tissue. The AUP is intended to provide AREB with information about activities in individual laboratories and classrooms which the Board needs in order to meet its legal and ethical responsibilities.

For animal-based collaborations with other groups or institutions, a copy of the other institution's approved protocol is required.

#### **Steps to Follow**

- 1) Attain approval for biohazards, isotope use, radiation, chemical hazards, animal use in patient areas and safety issues by appropriate committees. It is the responsibility of the Principal Investigator (PI) to initiate approval of his or her project from each relevant committee before requesting AUP approval.
- 2) Consult Veterinary Staff before preparing the AUP so that information on endpoint issues and other veterinary matters can be addressed prior to AREB consideration.
- 3) Submit the draft AUP electronically to the AREB Coordinator (princd1@mcmaster.ca), Health Research Services (HRS). AUP renewals will be sent directly to AREB. For new AUP submissions, HRS will ask the Animal Facility (AF) Veterinary Staff to review the draft AUP, and recommendations will be communicated to the PI. Once the PI has incorporated the veterinary recommendations into the AUP, it can be submitted electronically to princd1@mcmaster.ca according to the AREB deadline schedule. The deadline for submission of the revised AUP to AREB is the second-to-last Tuesday of a given month. Allow adequate time for this review process.

Any changes to an AUP (procedures, species, personnel, etc.) must be documented through submission of an Amendment Form and approved by AREB before implementation. AUP approval by AREB is valid for a period of four (4) years, subject to annual review.

Forms are available to request annual review of the AUP without revision or with minor revisions (Annual Review Form) at Forms - Health Research Services (mcmaster.ca).

## Animal Utilization Protocol (AUP) **Approval Process** Allow 1 to 1-1/2 months Submit AUP electronically to AREB Coordinator for initial review New AUP submissions assigned for Veterinary Consult, and recommendations sent electronically to Principal Investigator Stage 1 for incorporation into AUP Pre-AREB AUP renewals sent directly to AREB Principal Investigator to submit revised AUP electronically to AREB Coordinator incorporating veterinary recommendations (written justification required if veterinary recommendations not incorporated) Allow 3 weeks AUP prepared by AREB Coordinator for AREB Meeting Stage 2 AREB AREB recommendations sent electronically to Principal Investigator 30-day deadline Principal Investigator to email revised AUP to AREB Coordinator incorporating AREB recommendations for final approval (written justification required if AREB recommendations not incorporated) Stage 3 Post-AREB Copy of approved AUP sent to Principal Investigator

#### Stages of the approval process

AREB Coordinator

Health Research Services (HRS) Tel: (905) 525-9140, Ext. 22469 Room: HSC-3H9 • Email: <u>princd1@mcmaster.ca</u>

## **Section 1 – Project Title**

Include a clear, descriptive and correctly spelled project title.

Type of project – check <u>all</u> applicable categories. A *New Project* is defined as being a project having no direct connection to a previously approved protocol. AREB recommends that new investigators consult with the AREB Coordinator to assess the requirement for additional support in preparing their first AUP.

A *Research Pilot Study* is defined as a limited and usually short-term project typically using less than 10 animals. However, a pilot study can be written as a component of a more extensive *New* or *Ongoing* project.

Please note that *Teaching* projects must be accompanied by a completed *Teaching Addendum* (available from Forms - Health Research Services (mcmaster.ca) in which pedagogical justification for the project is requested.

## **Section 2 – Principal Investigator**

Ensure complete and up-to-date contact information is entered for the PI responsible for this AUP. PIs are required to hold a faculty position at McMaster University. Use the PI's institutional email address and full mailing address. Identify which course the PI has taken beside PI Training.

Please note that all PIs will be required to sign and date the final *AREB approved* copy of the AUP at the top of page 1. Your signature indicates that:

- 1) Animals used in this research or teaching project will be cared for in accordance with the principles contained in The Care of Experimental Animals A Guide for Canada (published by the CCAC), and the regulations of the Province of Ontario (OMAFRA) under the *Animals for Research Act*, 1980.
- 2) You have considered alternative procedures that do not involve the use of living animals.
- 3) You will use the minimum number of animals consistent with objectives of described research/teaching program.
- 4) You have carefully selected the species that you propose to use.
- 5) You are familiar with the Standard Operating Procedures (SOPs) quoted in this AUP.
- 6) You will use techniques and facilities that are in accordance with OMAFRA and the CCAC.
- 7) You will notify AREB of any revisions to this AUP.
- 8) You will keep copies of approved AUPs, revisions and amendments in a file accessible to your research staff.

## Section 3 – Associate Scientists, Research Staff & Training/Experience

All associates, research staff, and students working on this project must be listed in this section. Amendments may be filed to an approved protocol to add new staff members. In addition to the PI's contact telephone number, at least one emergency contact number must be provided in this list. Since emergencies requiring after hours contact typically relate to animal health issues, the person whose contact number is listed should also be designated as "working with animals" and have all appropriate training. If more space is required in the form to include all personnel working on the project, please attach a separate page with all the requested information. A note should be placed on the form in this section to indicate that addition details are attached.

#### **Training/Experience**

AREB requires <u>all personnel</u> to attend the following AREB-endorsed animal use courses:

- **OR** (*Orientation*) General overview of the function of the animal facilities. No specific training in animal manipulations.
- **AH** (*Animal Handling*) Familiarization with handling and restraint of laboratory species. General introduction to injections and collecting blood (*if handling animals*).

In addition to the above mandatory courses, AREB requires that personnel involved in animal studies attend courses that are appropriate to the proposed project.

The following is a listing of other courses available through the CAF:

- **EP** (*Endpoints*) Approaches to setting effective endpoints other than death which are required when it is anticipated that animals will or potentially die.
- InjAn (Injectable Anaesthesia) Injectable anaesthesia course on laboratory species.
- GasAn (Gaseous Anaesthesia) Gaseous anaesthesia course on laboratory species.
- **SS** (*Survival Surgery*) Four-part course on preparation of animal, surgeon and equipment for aseptic surgery and post-operative recovery principles.
- **IM** (*Immunology Procedures*) Proper techniques to be used on animals for monoclonal and polyclonal antibody production. Includes blood collection using intravenous procedures and fluid replacement techniques.
- **TN** (*Transgenics*) Specific training in proper procedures to be used when housing and breeding transgenic rodents, including monitoring for phenotypic abnormalities and setting and monitoring for endpoints other than death.
- **BL** (*Blood Collection*) Practical sessions demonstrating and allowing practice on acceptable blood collection procedures in species used.
- **Brd** (*Breeding Colony Training*) Training on proper procedures for maintaining a rodent breeding colony.
- **Bio** (*Biohazard Training*) Training on proper procedures to follow in order to use Biohazard rooms.

Identify which courses have been taken or describe the relevant experience for <u>each</u> person named within the proposal. Extra pages can be attached as required. For further details regarding training courses available on-line, please visit the Central Animal Facility website at <u>Home</u> (<u>mcmaster.ca</u>) (or call Ext. 22365). For further information on the availability of other animal training programs, please visit the CCAC website at <u>http://www.ccac.ca/</u>.

## **Section 4 – Funding**

Provide details of the funding awarded or pending for the animal work in the proposed project. If the funding agency does not provide scientific review of the animal components of the project (e.g. internal or private contract funds), a separate *Scientific Review Form* is required. This form,

available at <u>Forms - Health Research Services (mcmaster.ca)</u>, will be processed by the responsible department to ensure that the project has scientific merit. All research projects must be reviewed for scientific merit, therefore, departmental review and approval is required for all projects not funded through agencies which conduct external peer review. Contact the AREB Coordinator for further details.

## **Section 5 – Lay Description**

AREB may need to release this abstract to the Public Relations Office in order to provide information to the public about animal use at McMaster University. Provide a lay abstract of <u>250</u> words or less in <u>simple language</u> (preferably at a grade 7 reading level). A program to rate the reading level of text is available at <u>http://www.standards-</u>

<u>schmandards.com/exhibits/rix/index.php</u>). This lay description is a CCAC required element to ensure lay member comprehension. With minimal technical jargon, outline the objectives of the project, the experimental approach and highlight the significance of the expected results to human and/or animal health.

#### **Sample Lay Descriptions**

#### Example 1

Heparin is a blood thinner used alone or in combination with clot digesting agents for the treatment or prevention of blood clots in the heart, lungs or brain. Its administration, however, can be associated with bleeding. To prevent this complication, we have developed novel blood thinning agents which are expected to produce less bleeding. To test this possibility, we plan to compare these new agents with standard blood thinners commonly used in clinics. Accordingly, anaesthetized rabbits will be injected with new agents or standard blood thinners, and we will measure blood loss from small incisions made in the ear. Because bleeding is a complex process that involves the interaction of blood cells and the clotting factors with the vessel wall, these studies have to be done in animals and cannot be done in test tubes. We anticipate that these new clot thinning agents will have a minimal effect on bleeding and could replace the currently recommended inferior therapies for the treatment of clots in humans and animals.

#### Example 2

To experience abdominal symptoms, such as cramps or diarrhoea, in association with emotional stress is a common and natural experience. In some individuals, these responses to stress are severe and persistent and result in a clinical syndrome called "Irritable Bowel", the most common gut disorder in our society. Because this disorder is not accompanied by any structural damage to the bowel, and because the disorder occurs in relation to stress, there is a tendency for some to consider it to be exclusively a behavioural problem and to overlook the possibility that the gut itself may have become abnormal as a result of the stress. The proposed studies will attempt to provide evidence that chronic stress alters gut function. Three different forms of stress to produce persistent changes in gut function in the rat will be examined. The results of these studies may establish that chronic stress alters gut function. It is hoped that this knowledge will influence attitudes towards the disease and improve therapy.

## Section 6 – Justification of Animal Use

As part of justifying the use of live animals in research, PIs must search for alternative approaches that could be applied to the proposed project. The project must also adhere to the *Three R's of Replacement, Reduction and Refinement* as proposed by Russell & Burch.

Indicate that you have reviewed the relevant information on selecting alternatives to animal use at <u>CCAC - Canadian Council on Animal Care: Three Rs and Ethics</u> by checking the box in this section.

- A. **Alternatives?** If alternative techniques are available that do not require the use of animals, you must provide justification for why these alternatives are not appropriate for the proposed project.
- B. Why use animals? Select all justifications that apply to the proposed project, and if necessary, provide further details as to your justification for using animals. Cost is not generally acceptable as a primary consideration for using animals rather than an *in vitro* model.
- C. Why this species? Provide a description of the characteristics of the proposed species that make them appropriate for the current study. These might include structural, behavioural, physiological, biochemical, or other features or considerations (such as availability of species-specific reagents, or the continued use of a well-established model) which make the model compatible with the proposed research objectives.
- D. **How many animals?** Animal numbers are expected to be clearly defined in the proposed experimental procedures and in Section 7, therefore, do not include animal numbers and groups in this section. For projects that *cannot* be planned in detail, provide an explanation of why the numbers cannot be planned in advance.
- E. **Basis for estimated animal use.** Provide a description of how the estimate above was derived.

## Section 7 – Animal Numbers and Classification of Experiments

#### **Summary of Species**

Indicate the species and strain of animals to be used in this project (each strain must be on a separate line). Select from the drop-down list whether the animals are genetically modified – the use of genetically modified animals requires the completion of an applicable *Genetically Modified Animal Form* (available at Forms - Health Research Services (mcmaster.ca)).

#### **Categories of Invasiveness**

- A. Experiments involving tissues without using live animals (see Tissue Utilization Protocol Form available at <u>Forms Health Research Services (mcmaster.ca)</u> for further details).
- B. *Little or no discomfort or stress* [e.g., short-term skilful restraint of animals for observation or examination, blood sampling, non-toxic injections by intravenous, subcutaneous, intramuscular, intraperitoneal, or oral routes (not intrathoracic or intracardiac), acute non-survival studies where animals are completely anaesthetized and never regain consciousness, euthanasia by approved methods following rapid unconsciousness (anaesthetic overdose or decapitation preceded by sedation or anaesthesia), very short periods of food and/or water deprivation.]
- C. *Minor stress or pain of short duration* [e.g., minor surgeries or procedures under anaesthesia (cannulation, catheterization, biopsy, laparoscopy), short periods of food and/or water deprivation

and/or restraint causing minimal distress, behavioural experiments on conscious animals with shortterm stressful restraint (must not cause significant changes in animal's appearance, respiratory or cardiac rate, fecal or urinary output, behaviour or social responses, during or after procedures).]

- D. Experiments which cause moderate to severe distress or discomfort [e.g., major surgical procedures conducted under general anaesthesia, with subsequent recovery; prolonged (several hours or more) periods of physical restraint; induction of behavioural stresses such as maternal deprivation, aggression, predator-prey interactions; procedures which cause severe, persistent or irreversible disruption of sensorimotor organization; the use of *Freund's Complete Adjuvant*; induction of anatomical and physiological abnormalities that will result in pain or distress; the exposure of an animal to noxious stimuli from which escape is impossible; the production of radiation sickness; exposure to drugs or chemicals at levels that impair physiological systems. Note: Procedures used in Category D studies should not cause prolonged or severe clinical distress as may be exhibited by a wide range of clinical signs, such as marked abnormalities in behavioural patterns or attitudes, the absence of grooming, dehydration, abnormal vocalization, prolonged anorexia, circulatory collapse, extreme lethargy or disinclination to move, and clinical signs of severe or advanced local or systemic infection, etc.]
- E. Severe pain which is near, at, or above the pain tolerance threshold of unanaesthetized conscious animals. Not confined to surgical procedures (e.g. noxious stimuli or agents with unknown severe effects, highly invasive experiments, behavioural studies causing severe or unknown degrees of distress, use of muscle relaxants or paralytic drugs without anaesthetics, induction of burns or trauma on unanaesthetized animals, any method of euthanasia not approved by CCAC, any procedure causing severe pain unrelieved by analgesia, any experiment where death is expected as an endpoint in some or all animals). Category E experiments will not be approved unless there is extremely persuasive evidence that the data are critically important to human or animal health and cannot be obtained by any other means.

#### Classifications

The CCAC requires that each experiment in an AUP be classified as either *Acute* or *Chronic*, and that each experiment is assigned an appropriate *Category of Invasiveness*.

#### Acute

Any animal use where animals are euthanized before procedures take place, or where animals are anaesthetized for a procedure, then euthanized while still under anaesthesia (non-recovery).

#### Chronic

Any other animal use (e.g. where animals recover from anaesthesia or are held for a period of time after at least one procedure). If <u>any procedures</u> are performed or <u>any substances</u> are administered to an animal that is subsequently recovered (regardless of the duration of the experiment), the protocol is automatically classified as *Chronic*.

## Section 8 – Experimental Procedures & Summary

#### **Objectives**

Briefly describe the objectives of the experiments proposed – that is, what you plan to achieve with the proposed project.

#### Rationale

Briefly describe the experimental rationale - that is, why you propose to do this work.

#### **Purpose of Animal Use**

Select one item that best describes the purpose of animal use in this proposal and enter the appropriate number into the box.

#### **Proposed Experiments**

Enter a full description of the proposed experiments below or attach a separate file that includes page numbers. Use of an attached file will allow applicants to include rich text formatting and insert diagrams to better explain the proposed experiments.

The Proposed Experiments should provide a concise narrative description of the procedural events experienced by the animals in each experiment. If applicable to the proposed project, you should describe exactly what will be done to the animals in a step-by-step fashion. To reduce repetition, you may refer to well defined SOPs by quoting both the SOP number and title (available at <u>AREB Guidelines - Health Research Services (mcmaster.ca)</u>). If the proposed procedures deviate from the SOP description, you must provide further information on how and why these differ from the established techniques.

The Proposed Experiments should include specific details of all anaesthesia and analgesia, detailed surgical procedures performed, a complete description of all substances administered (including route, dose, volume and potential side effects). In addition, you should provide details as to the volumes and frequency of all fluids sampled or tissues collected, the parameters of any behavioural testing performed, a description of any conditions that may cause distress to the animals (including fasting, food/water restriction, altered environmental conditions, etc.), and a description of the primary method of euthanasia or an account of the final disposition of all the animals in the study.

Include charts and diagrams to clearly show relationships between different activities and to demonstrate the distribution of animals between different procedures. This is especially important in projects where animals may receive more than one treatment or procedure. Note that final approval of the AUP is dependent on a full and accurate account of which procedures are performed on which animals and on how many animals undergo each of the procedures.

Since this AUP <u>must</u> stand on its own, do not refer to previous or other investigator's AUPs for details relating to this protocol. It is also not appropriate to simply provide a copy of a grant application, as the purpose of this AUP is to allow AREB to specifically assess the ethical use of animals.

#### **Procedures Summary**

Applicants must ensure that all items listed in this section are also fully described in the body of the Proposed Experiments.

#### **Housing and Handling**

Describe any special conditions relating to housing and handling of the animals in the proposed experiments. These include the need for special food or water conditions, exposure to stressful environments, and the need for manual or other types of restraint (including holding of animals for administering substances). Briefly describe any need for animal facility staff assistance.

#### Summary of Substances Administered and Fluids Sampled

All substances administered to animals must be listed on a separate row in the table *in addition to* being described in the body of the Proposed Experiments. If using viruses, each virus must be listed and described separately. For projects using cell lines, ensure that these have been tested as appropriate for murine pathogens (please contact the veterinary staff for details). Drugs administered for euthanasia should also be listed in this section. Controlled drugs require a license application (i.e., morphine, demoral, amphetamines, testosterone, buprenorphine, lorazepam, ketamine, somnitol, butorphanol, euthanol, sodium pentobarbital, etc.)

#### Substances Administered

Indicate the substance, dosage, volume, route, needle gauge and frequency of administration (as appropriate). This list should also include anaesthesia, analgesia and euthanasia drugs. Note that controlled drugs (such as narcotics and barbiturates) may require a separate licence application to *Health Canada* (<u>http://www.hc-sc.gc.ca/hc-ps/substancontrol/exemptions/index-eng.php</u>) – please plan accordingly. If the list of substances exceeds the space available in the table, additional pages may be attached.

#### Fluids sampled

All fluids sampled must be listed here in addition to being described in the body of the Proposed Experiments. Details that must be provided include the type of fluid sampled, site/route, volume, needle gauge (as appropriate) and frequency of sampling. Refer to the AF SOPs for the relevant fluid sampling standards for each species.

Indicate if *Freund's Complete Adjuvant* is planned to be used in this project.

#### **Summary of Surgical Procedures**

Provide a summary of the type of surgical procedures to be performed and the extent of postsurgical monitoring proposed. Note that all chronic experiments require an appropriate endpoint monitoring record form to be consistently used. Surgical monitoring records <u>must</u> be kept and maintained at the animal room level.

#### **Disposal of Animals**

The final disposition of all animals in the study needs to be defined here. If animals will be euthanized by a variety of methods, please check all that apply. The <u>CCAC</u> requires that the use of physical methods of euthanasia is supported with further scientific justification.

Please note that the University Veterinarian is obligated to treat or euthanize animals in distress. The decision of the Veterinarian in this regard is final. Ensure that appropriate arrangements are in place to permit consultation on a 24-hour per day, 7-day per week basis.

#### Section 9 – Project & Facilities Management

To assist in planning and management of animal facility activities, details relating to animal care are required.

#### **Source of Animals**

List all suppliers of animals for the proposed project. Animals ordered from non-approved sources will be coordinated through the AF office and may require biosafety approval and/or

health status monitoring reports. Complete the *Biohazard Utilization Protocol* Form available at <u>http://fhs.mcmaster.ca/safetyoffice/biosafety\_approval.html</u>, and once signed off by the Safety Office, provide the BUP number in this AUP. All animal acquisitions and deliveries must be coordinated through the appropriate animal facility office.

#### **Housing of Animals**

Select the building location and appropriate level of care (e.g. sterile/non-sterile) for animals in the proposed project.

#### Special Care

If any special care is required due to experimental procedures or animal phenotype, these must be described here.

#### Isolation/Containment/Quarantine

For animals requiring specialized isolation or containment, the details must be described here. Please note that this isolation or containment is *in addition to* the standard 1 week acclimatization/holding period required after an animal arrives at the animal facility.

#### **Other Arrangements**

List all other special handling/housing requirements that are required.

#### Location of Procedures Outside of an Animal Facility

Animals removed from the animal facility must be signed out at the animal room level. The location where animal work is performed *must* also be authorized by AREB. Animal work proposed to take place outside of an animal facility (e.g. in laboratories) may raise issues of both aesthetics and safety. Taking animals into public areas such as hallways and laboratories raises potential objections by people not working with animals and increases risk of allergens from animal dander getting into the air system. Therefore, full justification for taking animals outside of an animal facility must be provided. Convenience and the ability to observe animals more frequently are not acceptable reasons. If adequate justification is provided, then animals must be covered and taken directly to an appropriate location to be held for a minimum period of time. Procedures on animals that might disturb others need to be confined in a discreet manner. All locations where animals are taken will be subject to inspection by AREB. Short-term housing of animals outside of an animal facility must be approved in advance.

For projects involving Field Studies, complete the *Field Studies Addendum* available at <u>Forms -</u> <u>Health Research Services (mcmaster.ca)</u>.

#### **Animal transport**

Provide the appropriate details of transport if animal transport to and from areas outside of an animal facility is required. Use of animals in patient areas requires approval before the project commences. The *Approval to Use Animals in Patient Treatment Areas Form* is available at Forms - Health Research Services (mcmaster.ca).

#### Enrichment

If any experimental conditions exist that would preclude the use of standard environmental enrichment in animal housing (e.g. nestlets, tubes, etc.), applicants must fully describe and justify why enrichment cannot be used. Special cage level marking of these conditions must be in place.

#### **Veterinary Intervention**

If any experimental conditions exist that would preclude the use of standard veterinary care (e.g. the use of antibiotics), applicants must fully describe and justify why such veterinary treatments are not to be used. Special cage level marking of these conditions must be in place.

#### **Potential Hazards**

Biohazardous/Infectious Agents – a Biohazard Utilization Protocol (BUP) number is required.

*Chemical/Hazardous Drugs* – an HMIS/GHS score is required. If the HMIS score is 2 or above, the GHS score is 1 or 2 or there is not sufficient information regarding the safety of a chemical/drug, a Chemical/Hazardous Drug Risk Assessment form must be submitted to the applicable animal facility at the time of use.

Isotopes – A Radioisotope License form must be submitted.

## **Section 10 - Endpoints**

Endpoints are required for most *Chronic* studies – consult with Veterinary Staff for clarification. If the proposed project requires several distinct endpoint definitions, attach separate Endpoint forms that can be downloaded from <u>Forms - Health Research Services (mcmaster.ca)</u>.

#### A. Timing of adverse clinical signs

• If it is expected that the animals used in the project may reach a critical stage where their health may become impaired, provide a description of when this may occur. For example, a statement such as "group 2 animals are expected to show some reduction in body weight within the first three days following surgery but this weight loss is typically recovered within 1 week" would help to ensure that the researchers and the animal care staff are prepared for potential complications relating to the animal's health status.

#### **B.** Clinical signs

• Five specific clinical signs that are appropriate to the planned procedures should be listed in this section. These signs may be used by animal care staff to assist in identifying animals that are approaching a humane endpoint, at which time they may require veterinary treatment. For example, "animals in this study need to be monitored for porphyrin staining, impaired grooming, tachypnia, sudden body weight loss and palpebral ptosis (eyelid drooping)". See list below for suggested clinical signs.

#### C. Humane endpoints

• Describe the clinical endpoints at which the animals will either be humanely euthanized or will begin treatment to relieve discomfort. For example, "Animals presenting with any of the following signs will be considered to be at endpoint: skin abscess, laboured breathing, paresis or paralysis of the hind limbs or tumours that interfere with normal eating/drinking". In this section, also indicate the name and contact information of anyone in the investigator's group who has the authority to euthanize the animals that have reached humane endpoints.

#### **D.** Study endpoints

• Indicate the point in the experiment at which the animals will no longer be needed, that is, when the experimental requirements have been met.

#### E. Contact information for monitoring records

• Indicate the name and contact information for the person responsible for maintaining the monitoring records for this project.

#### F. Frequency of monitoring

• State the frequency of monitoring for the following: 1) while the animal is stable, and 2) during critical periods.

#### G. Monitoring criteria

• Describe the physical criteria that will be recorded on the monitoring sheets. These could include items such as body weight, body condition scores, size of tumours, etc. Attach a copy of a monitoring sheet that provides for the collection of this information. The monitoring sheet should reflect the needs of the project endpoints. Sample monitoring sheets can be found at Forms - Health Research Services (mcmaster.ca). Ensure that you do not list criteria that you do not intend to monitor or record regularly (e.g. weight loss).

#### **Sample Monitoring Criteria**

- Behaviour
- Body condition scoring
- Body temperature
- Body weight
- Grooming
- Respiration rate
- Tumour size

## **Section 11 – Keywords**

Check off all keywords that apply to your work.

## **Extra Forms and Required Information**

All forms are available at <u>Forms - Health Research Services (mcmaster.ca)</u>. The following is a list of supporting documents that may be required for the AUP.

- Tissue Utilization Protocol (TUP)
- Amendments
- Annual Review
- Endpoint Monitoring Checklist
- Genetically Modified Animal Form
- Certification of Animal Care Form
- Chemical/Hazardous Drug Risk Assessment
- Animal Use in Patient Areas
- Field Studies Addendum
- Scientific Review Form
- Teaching Addendum
- MCPTI Animal Imaging Form
- Isotope Licence

## **Services Available**

The following is a non-exhaustive list of services that may be available either at McMaster University or through external sources to support animal research activities. Contact the appropriate animal facility office for further details.

- Animal model development
- Animal monitoring, breeding or other technical services
- Antibody production
- Cell line verification
- Contract services
- Cryopreservation
- Germ free housing
- Imaging
  - o X-ray, SPECT, CT, PET, in vivo bioluminescence/fluorescence
- Irradiation
- Pathogen testing (e.g. MAP testing available at <a href="http://www.radil.missouri.edu/pcraltmap.html">http://www.radil.missouri.edu/pcraltmap.html</a>)
- PCR genotyping
- Rederivation
- Surgical techniques
- Veterinary consultation/advice
- Veterinary pathology and histology services
- IVIS
- Radiolabelling

# **Contact Numbers**

Central Animal Facility	(905) 525-9140, Ext. 22365
Kathy Delaney University Veterinarian	(905) 525-9140, Ext. 22812
Karen Gourlay Director, Animal Facilities	(905) 525-9140, Ext. 22366
AREB Coordinator	(905) 525-9140, Ext. 22469
David Braley Research Institute (DBRI)	(905) 521-2100, Ext. 40702
Health Science Safety Office	(905) 525-9140, Ext. 24956
Environmental & Occupational Health Support Services (EOHSS)	(905) 525-9140, Ext. 24352
McMaster Centre for Pre-Clinical and Translational Imaging	(905) 521-2100, Ext. 75668