

**Appendix 1a – Experimental Procedures**

Office of Research – Research Ethics Unit – GM 900 – 514-848-2424 ext. 7481 – oor.ethics@concordia.ca – www.concordia.ca/offices/oor.html

This Appendix should **not** contain extensive text regarding the background and general objectives of the research. Rather, this Appendix should contain only enough context to provide a detailed description of procedures to be used with animals.

Each Appendix 1a should capture the description of similar sets of experiments that use the same procedures and similar experimental design.

You should submit more than one version of Appendix 1a when there are sets of experiments to be conducted that differ substantially in the sets of procedures used, and when this can enhance the AREC’s understanding of the procedures to be conducted and their impact on the welfare of the animal.

If a laboratory-specific Standard Operating Procedure is submitted with this Appendix, it should only contain descriptions of procedures that are to be approved as part of this Appendix.

**1.**  **Basic Information**

Study Title:

Principal Investigator:

Department:

Protocol Number (if assigned; e.g. 30000123):

**To be used by the office of research only**

Experiment Number:

**2. Experimental Procedures**

a) Please describe the animals required for the experiment in the table below:

 In the Source column, please indicate how the animals are obtained (for example, commercial supplier, donated, wildlife/field studies, Concordia colony, purchased or other), and wherever possible, the name, address, and phone number of the supplier. If you plan to re-use animals as part of your research, for each row in the table, you may indicate that you will obtain the animals from both a commercial supplier, as well as un-used or “spare” animals from another laboratory at Concordia (For example: “Charles River and spares”). If you intend to use or generate genetically modified animals for this experiment, please complete a copy of “Appendix 2: Genetically Modified Animals” for each strain, in addition to the table below.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Quantity** | **Species/Strain** | **Weight/Age** | **Gender** | **Source** |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

b) Please describe each procedure to be conducted on the animals listed above.

 Where appropriate, please attach or refer to the Standard Operating Procedures that describe the procedures. The description of procedures should include a description of the sequence and timeline of multiple procedures to be conducted which will allow the AREC to appreciate the cumulative overall experience of the animal. When there are variations in what procedures are conducted in different experiments or conditions, ensure that you describe the most invasive timeline and sequence of procedures. Please include a visual timeline or representation for complex sequences of procedures.

 List all non-surgical manipulations & show recovery time between procedures (injections, special diets, sample collection). Each experiment must state study endpoint or the conditions for which endpoints will be met in the case of a survival study.

 For wildlife field studies, please provide details of the pursuit, capture, housing, handling and restraint procedures. Furthermore, please describe the type of trap to be used, as well as its potential to injure animals.

 For experiments involving surgical procedures, please describe:

* A brief technical description of the surgical procedures including preparation
* Monitoring, including assessment of pain and distress, during and after surgery
* Pain/distress management. Note that analgesics must be given to animals prior to recovery from anaesthesia and for a minimum of 24 hours following surgery. Thereafter, animals must be assessed, and if there is continuing pain or distress, analgesics will be continued in conjunction with appropriate care.
* The antibiotic to be administered, the dosage and route of administration. Systemic antibiotics are not routinely required if aseptic surgical technique is used. Researchers are encouraged to reduce the use of systemic antibiotics in perioperative care. Veterinary staff is to be consulted to determine procedures that may reduce the use of systemic antibiotics. See AREC-07 Survival Surgery and Invasive Procedures in Rodents.
* Instrumentation of the animals during and after surgery, such as IV lines and catheters

c) What is the highest category of invasiveness to which animals could be exposed as part of this experiment?

 Please refer to the CCAC website (<http://www.ccac.ca/en_/standards/policies/policy-categories_of_invasiveness>) for complete descriptions and examples of each category of invasiveness.

 [ ]  A: Experiments on most invertebrates or on live isolates

 [ ]  B: Little or no discomfort or stress

 [ ]  C: Minor stress or pain of short duration

 [ ]  D: Moderate to severe distress or discomfort

 [ ]  E: Severe pain near, at, or above the pain tolerance threshold of unanesthetized conscious animals

d) Please choose the applicable classification(s):

 [ ]  Acute: Utilizing an animal for a brief period (less than 24 hours), followed by euthanasia or return of the animal to source, or humanely euthanizing an animal upon receipt or after a brief housing period during which time no manipulations other than standard management procedures are performed, i.e. anesthetized without recovery, euthanized for tissue collection, etc.

 [ ]  Chronic: Maintaining the animal and performing experimental procedures during this time, i.e. feeding trials, antibody production, breeding colony, recovery surgery.

**3.**  **Animal Numbers and Refinement**

a) For the animals undergoing the procedures described in section 2b), please describe the experimental design, explaining how the total number of animals to be used was determined, for example, 5 animals x 3 groups x 2 replicates = 30 animals. You may wish to include a flow chart or table outlining total numbers. Clearly describe all groups in the design for each of the experiments, including control and experimental groups and number of animals per group.

b) Are any additional animals required, for example, to teach surgical techniques, or to compensate for unsuccessful procedures? If so, how many? Please provide a sequential description of how these animals will be used. For example, a certain number of animals might be required to optimize procedures before proceeding with the experiment described above.

c) Is the number of animals proposed for this experiment the minimum number necessary to achieve valid results? Please describe any measures used to reduce the use of animals, by minimizing number of animals and/or maximizing the scientific value of the experiment, as well as any statistical considerations.

d) If mortality is an expected risk of procedures to be used with animals, please indicate the expected mortality rates. Expected mortality rates are important because they identify high risk procedures, and provide a reference level. The mortality rates you provide should be based on mortality expected under best practices, and developed in consultation with the veterinarian.

e) What refinements have been made to husbandry practices and experimental procedures to enhance animal health and welfare and to minimize physical and/or psychological distress? Some examples of potential areas of refinement include refinements in procedures used with animals, reductions in the length of time animals will be used, improvements in husbandry, extra environmental enrichment, anesthesia/analgesia, surgical procedures and euthanasia. For wildlife field studies, please describe any refinements that have been made to minimize stress due to observation, capture, handling and other experimental procedures.

**4. Animal Care**

a) Indicate where the animals will be housed at each stage of the experiment, and where experimental procedures take place.

 There must be justification for housing animals outside the ACF for more than 12 hours. Consult AREC-03 Alternative Housing of Experimental Animals for the relevant policy, and include the Alternate Holding/Housing Request Form to provide your justification. AREC-03 also contains the required Room Log Form for Animal Housing Outside the ACF, for documenting care of animals

 The ACF includes a surgical suite for common use, and the the use of surgical areas outside the ACF must be well justified. Surgery outside the ACF may be necessary when access to specialized laboratory equipment is needed, but the ACF surgical suite should be used whenever possible. If experimental procedures are conducted outside of the ACF, please briefly describe the transportation of animals, and how distress during transportation will be minimized. Note that when animals are transported outside the ACF, the cages must be draped. See ACH-07 Rodent Transport Outside ACF within Loyola Campus.

 Note that university veterinarians and ACF personnel have oversight and access to all locations where animals are housed or undergo procedures.

Animal housing:

 [ ]  Animals will be housed in the Rodent ACF

 [ ]  Animals will be housed in the Aquatic ACF

 [ ]  Animals will be housed elsewhere (Please provide location and justification):

Animal experiments (Provide building name and room numbers):

 [ ]  Experimental procedures will be performed in the Rodent ACF:

 [ ]  Experimental procedures will be performed in the Aquatic ACF:

 [ ]  Experimental procedures will be performed elsewhere (Please provide location and justification):

 [ ]  Wildlife field studies (Please specify where the study will take place, and describe the facilities for any experimental procedures, as well as any arrangements for transporting wildlife from the field to the laboratory):

b) How often will the research team observe or monitor the animals to assess their condition? Please attach any assessment sheets to be used to document observations or monitoring. Please refer to the animals undergoing the procedures listed above, as well as routine observations. For wildlife field studies, please specify how often traps will be monitored (if applicable), and the procedures to be followed if lactating females are trapped. Furthermore, please comment on whether the traps could capture species of animal other than the target, and any complications that could arise if this occurs.

c) Will standard institutional procedures for housing and environmental enrichment be followed? If not, please describe and justify any special requirements, such as non-standard housing, or restrictions to enrichment. Environmental enrichment is a basic standard requirement of housing, and is important for the well-being of the animal. Enrichment includes cage-mates as well as physical materials present in the cage. Reductions in environmental enrichment, such as single-housing and reduced physical enrichment materials, is to be avoided, and reductions in environmental enrichment need to be well justified in the AUP form. See ACH-05 Environmental Nutritional Enrichment in Rats and Mice

**5. Intervention points and Endpoints**

 Intervention points and endpoints are meant to be applied to protect animal health and welfare. They are determined using both scientific goals and animal health considerations. An endpoint is the point at which an experimental animal's pain and/or distress is terminated, minimized or reduced, by taking actions such as euthanasia, terminating a painful procedure, or giving treatment to relieve pain and/or distress. Standard AREC endpoints have been developed and are outlined in the AREC-04 Humane Endpoints and Cumulative Endpoints. Cumulative endpoints are the points at which individual animals should be considered to have reached their lifetime maximum involvement in scientific activities. Relevant information can also be found within the CCAC guidelines on choosing an appropriate endpoint in experiments using animals for research, teaching and testing and veterinarians are available to assist you with this and any other questions.

 When a complication develops following a procedure, or there are problems with the health of an animal, the ACF staff should be consulted immediately, and a veterinarian should be consulted as necessary. Treatment of animals is done consultatively, and in the case of disagreements regarding animal health and euthanasia, the final decision will be made by the ACF staff and/or veterinarians.

a) What clinical conditions or abnormalities could arise, or are expected to arise, as a result of the proposed experiment?

b) If one the conditions or abnormalities described in 5a) arise, what endpoints should be used to determine when to intervene to alleviate an animal’s pain or distress? For mammals, this might include, for example, increased grooming, vocalization or postural changes, or physical changes such as anorexia, dehydration or diarrhea. For fish, postural or equilibrium issues, anorexia, gasping, clamped fins, fin rot, Ich and glancing could be examples of endpoints.

c) What intervention is appropriate, if the animal reaches the endpoints described in section 5b), for example, euthanasia, treatment, or terminating a particular experimental procedure? If CO2 euthanasia will be used, please provide a justification, and methodology that satisfies the conditions set out in the CCAC guidance[[1]](#footnote-1). Please specify any analgesics and anesthetics that will be used, as well as dosages and routes of administration, procedures used to verify that and any other special procedures. For wildlife field studies, please specify the provisions for recovery, treatment or euthanasia of injured animals.

**6. Emergency Care**

 Please note that reasonable attempts will be made to contact and consult the personnel listed on your AUSPF. However, the final decision regarding emergency care is at the professional discretion of the veterinarian or the manager of the ACF. If emergency veterinary care becomes necessary, please provide information, specific instructions, indications, or contra-indications that you feel the veterinarian or ACF manager should be aware of.

 [ ]  Standard veterinary care is appropriate

 [ ]  Other (please specify):

**7. Declaration and Signature**

I declare that this Appendix to the AUSPF accurately describes the proposed animal use.

I will only use animals in accordance with an AUSPF and its appendices approved by the University Animal Research Ethics Committee (UAREC). I will not deviate from this protocol unless the modification has been approved by the UAREC.

I will ensure that only the personnel listed in section 2 conduct procedures involving animals under this AUSPF. I will ensure the personnel have all required training and that they are competent in executing the approved procedures.

If any unexpected problems or complications involving animal health and well-being occur during this study, I will complete an Animal Incident Report and deliver it to the Manager of the ACF within 24 hours of the incident.

I acknowledge that approval will expire on the date specified on the Certificate of Ethical Acceptability for Research or Teaching Involving the Use of Animals. I will not use animals after that date unless I have duly applied for renewal of my approval.

I will ensure that all animals used in this protocol will be cared for in accordance with:

* The CCAC Guide to the Care and Use of Experimental Animals and any other applicable CCAC policy;
* The Concordia University Policy on the Ethical Use of Animals in Research and Teaching (VPRGS-13) and its

 associated procedures.

This form may be submitted by e-mail in MS Word or PDF format to oor.ethics@concordia.ca. E-mail submissions sent from the researcher’s official Concordia address will be deemed equivalent to an ink-on-paper signature.

Signature of Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. [↑](#footnote-ref-1)