

**Animal Use Summary Protocol Form**

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

The Concordia University Animal Research Ethics Committee (AREC) is responsible for the review of all protocols involving the use of animals in research or teaching at, or affiliated with, Concordia University. The role of the Committee is to ensure that the welfare of the animals is a prime consideration in their procurement, care and use, and that the highest ethical standards, as defined by the Canadian Council on Animal Care (CCAC), are observed. The AREC includes principal investigators, faculty members who do not use animals in research, the ACF manager, Animal Care Technicians, and Environmental Health and Safety representative, a student representative and a community representative.

**Sources of Information**

The Concordia Animal Care Facilities Moodle page is your main reference for information related to the ACF and AREC. It contains ACF and AREC Forms, SOPs, CCAC documents, Training information, and Additional resources and videos. Contact the ACF Manager if you need to arrange access to the Moodle site.

It is important that all principal investigators and researchers are familiar with their roles and responsibilities as described in AREC-02: General Information, Roles and Responsibilities of the Principal Investigator and Researchers.

AREC follows procedures described in the Concordia University Policy on the Ethical Use of Animals in Research and Teaching VPRGS-13 and its related Procedures. Please see links below:

http://www.concordia.ca/content/dam/common/docs/policies/official-policies/VPRGS-13.pdf

<http://www.concordia.ca/content/dam/concordia/offices/vprgs/docs/VPRGS-13-procedures.pdf>

**General Instructions**

Please read the instructions in this form carefully. If you are submitting a new AUSPF or planning to use a new procedure, please consult veterinary staff for comments on your proposal prior to submitting it to the AREC. Similarly, if you are completing this form for the first time, you may request an example of an approved AUSPF that uses similar procedures. This should speed up the approval of your AUSPF.

Following the approval of an AUP, the AUP may be renewed annually up to three times.

If you will be conducting sabbatical research at another institution, the AUP forms and animal use certificate from the other institution must be reviewed by AREC prior to the start of the animal use at the other institution.

**Amendments**

Changes to an approved AUP require a request for an amendment to be submitted to the AREC. It may take several weeks for an amendment request to be processed, and so it is important to plan any changes to your procedures well ahead of time. If you are submitting a renewal request or amendment, please make the changes in this form and the appropriate Appendices, and highlight those changes or additions in yellow.

There are three types of amendments:

*Administrative amendments.* These can include amendments to the research team, grants, et c., and will be approved by the Ethics unit in the Office of Research. When new personnel join your lab or you obtain new grant information, you must submit an administrative amendment. To update personnel or grant information, please email Karen Gregg in the OOR and highlight the new information in your most recently approved version of this form. The ACF must also be informed when personnel leave and no longer require access to the ACF.

 *Minor amendments.* These amendments must not alter the approved level of invasiveness, and can include using a different strain or sex of animal for an approved procedure, an increase of less than 20% in the animals used, and use of different drug that does not change the invasiveness of the procedure etc. These amendments will be reviewed by the core committee of the AREC, which is comprised of at least one of the veterinarians, the Animal Care Facility (ACF) manager, at least one of the community representatives, and the Chair of the AREC.

*Major Amendments.* These include new projects or surgeries never before performed in the lab and changes to the level of invasiveness. These amendments must be reviewed and approved by the full committee.

**Scientific Merit Review**

The use of animals needs to have scientific merit, which is typically evidenced by funding obtained from granting agencies for the proposed research. Researchers who do not have funding for the proposed research must declare this prior to submitting the AUP form, and also provide materials that are needed for a scientific merit review when, or prior to, submitting the AUP form. The Office of Research will then arrange a scientific merit review. Similarly, if a new line of research is proposed, that is outside the researcher's program of research that has received funding, then a scientific merit review is also required. See *VPGSR-13 Appendix 1*.

**Pedagogical Review**

The AREC reviews protocols for the use of animals for teaching purposes as a part of courses that students take. The use of animals for teaching requires a review of the pedagogical merit of their use. At the time an AUP form is submitted for teaching purposes, the instructor must also provide the materials that are needed for pedagogical review, and the Office of Research will then arrange for the review to be conducted. See *VPGSR-13 Appendix 2*.

**1. Basic Information**

Study Title:

Principal Investigator:

Department:

Protocol number (if assigned, e.g. 30001234):

**2. Research Team and Contact Information**

 Please list all members of the research team in the table below. *In case of an emergency involving animals used for the research or teaching activities, team members will be contacted one by one until someone is reached, in the order in which they appear in the table below. Please add additional rows to this table as needed.*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Name** | **Role\*** | **Daytime Phone** | **Evening Phone** | **e-mail** | **Internal Address (Building/Rm)**  |
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\*Principal Investigator (PI), Post-doctoral Fellow (PDF), Graduate Student (MA or PhD), Undergraduate (Ugrad), Laboratory Technician (Tech).

**3. Funding Sources**

 Please list all sources of funds that will be used for your research involving animals in the coming year.

|  |  |  |  |
| --- | --- | --- | --- |
| **Funding Source** | **Project Title\*** | **Grant Number†** |  **Award Period** |
| **Start** | **End** |
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\*Please provide the project title as it appears on the Notice of Award or equivalent documentation.

† If you have applied for funding, and the decision is still pending, please enter “applied”. If you intend to apply for funding, but haven’t yet done so, please enter “intend to apply”.

**4. Canadian Council on Animal Care Categorizations**

1. Which of the following best describes the purpose of animal use under this protocol? *Please choose only one.*

 *Please refer to the Canadian Council on Animal Care (CCAC) website for examples of each purpose.*

 <http://www.ccac.ca/Documents/Assessment/Reporting-AUDF.pdf>

[ ]  Studies of a fundamental nature in sciences relating to essential structure or function (i.e. biology, psychology, biochemistry, pharmacology, physiology, etc.)

[ ]  Studies for medical purposes, including veterinary medicine, that relate to human or animal disease or disorders.

[ ]  Studies for regulatory testing of products, for the protection of humans, animals, or the environment.

[ ]  Studies for the development of products or appliances for human or veterinary medicine, animal nutrition, animal reproduction and/or animal care.

[ ]  Education and Training of individuals in post-secondary institutions or facilities. Please provide the course number:

b) Do you intend to produce antibodies as part of this research?

 *If you answer “Yes”, please contact the Manager, Research Ethics for more instructions on the information to be submitted. Please note that antibody production is subject to guidelines from the Canadian Council on Animal Care.*

 [ ]  Yes

 [ ]  No

**5. Lay Summary**

 Please provide a brief description of the research or teaching activity in everyday language. ***It is extremely important that the summary be understandable by individuals with no discipline-specific training, and by community members of the AREC.*** *Do not use overly technical terms that you would use in a grant application, and provide a brief description that does not exceed about one half to three quarters of a page.*

1. Background, Objectives and Methods

 *Please provide a general description of the methods to be used. Do not include descriptions of specific experiments that will be described in Appendix Ia.*

1. Animal Model

 *Please describe the characteristics of the animal that make the species or strain appropriate for the research or teaching objectives, for example, structural, behavioral, physiological, biochemical or other features and considerations. Cost may not be used as a justification.*

1. Anticipated Impact

 *Please describe how the research or teaching activity is expected to benefit humans or animals, either in terms of immediate applications of the findings or contributions to scientific knowledge.*

**6. Alternatives**

1. Please explain the need to use animals in this research or teaching activity, and why alternatives such as *in vitro* or *ex vivo* systems would be inappropriate to meet your research or pedagogical objectives. It is not sufficient to simply indicate that a replacement alternative is not available.
2. Please describe any alternatives to animal use, such as *in vitro* or *ex vivo* systems*,* that are already incorporated into the research or course design.

**7. Hazards**

1. EHS Certificate Number:
2. Will this study use hazardous chemicals (e.g. isoflurane, acids, corrosives, alcohol)?

 *Please specify whether any chemicals are classified as carcinogenic, mutagenic, toxic for reproduction or harmful to unborn children. For studies involving anesthetic gases, please describe ventilation procedures to protect against human exposure.*

 [ ]  No

 [ ]  Yes (specify):

c) Will this study use biohazardous material (e.g. microorganisms, microbial toxins, cell lines, recombinant DNA, viral vectors)?

 [ ]  No

 [ ]  Yes (specify):

d) Will this study use radioactive material?

 [ ]  No

 [ ]  Yes (specify):

e) Will this study use controlled substances?

 Note that controlled substances must be stored appropriately as indicated in your approval from Health Canada. The use of controlled substances must be logged appropriately. Procedures for controlled substances and logging their use are indicated in EHS-SOP-005 Controlled Substances.

 [ ]  No

 [ ]  Yes (specify):

f) Will this study use any other types of hazard (e.g. lasers, hazardous machines such as cutting equipment or drills, electrical hazards, hazardous processes, noise, UV light)?

 [ ]  No

 [ ]  Yes (specify):

**8. Wildlife certification**

 [ ]  Not applicable

a) Please describe any wildlife permits required to carry out the protocol.

 *For collaborative research at other institutions, please submit a copy of the relevant AUP and the certificate of approval from the other institution. If you have received them, please submit a copy. If you have not yet received them, please state when you expect to receive them and submit a copy when you do.*

b) Please describe the type or degree of potential ecological disruption expected, for example, the consequences to reproduction, or survival of animals studied.

c) Please describe procedures for disposal of animal carcasses, if applicable.

**9. Appendices**

 Complete an Appendix 1a for each set of experiments that use similar procedures to be conducted under this protocol. If the protocol involves either Teaching, Wildlife, or Genetically Modified Animals, check the appropriate box, and complete the corresponding appendix. *All appendices are available on the office of research website (*[*http://www.concordia.ca/research/for-researchers/ethics.html#tab1*](http://www.concordia.ca/research/for-researchers/ethics.html#tab1)*)*

 [ ]  Appendix 1a: Specific Experiments

 [ ]  Appendix 1b: Teaching Activities

 [ ]  Appendix 1c: Wildlife – Specific Experiments

 [ ]  Appendix 2: Genetically Modified Animals

**10. Disposition**

a) What will be done with animals when they are no longer needed for this research?

 *Please note that when an animal’s use in an experiment has been completed, it must be euthanized as soon as possible. It is very important that animals not be left unnecessarily in the ACF after the experiment has finished, both for the welfare of the animal and the proper operation of the ACF. Animals should normally be euthanized within one week of the experimental end date indicated on the cage card.*

 [ ]  Euthanized – method:

 [ ]  Anesthetic/physical method (please specify):

 [ ]  CO2 /physical method (please specify)\*:

 [ ]  Other (if a physical method is used without anesthesia, please provide justification):

 [ ]  Other – please specify (e.g. returned to natural habitat; donated, recycled, reused):

\*As with euthanasia carried out in response to an animal reaching a humane endpoint, if CO2 euthanasia will be used, please provide a justification, and methodology based on CCAC guidance.

**11. Annual Report**

 If this is a renewal of the protocol, please provide an update on the research conducted in the previous year (e.g. refinements, issues, number of animals used or number of animals in surplus).

**12. Signature and Declaration**

I declare that this Animal Use Summary Protocol Form and its appendices accurately describe the proposed animal use.

I will only use animals in accordance with an Animal Use Summary Protocol Form 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 Animal Use Summary Protocol Form. 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 Animal Care Facility 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: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_