



## PROCEDURES FOR THE ETHICAL USE OF ANIMALS IN RESEARCH AND TEACHING

As per *Policy on the Ethical Use of Animals in Research and Teaching* (VPRGS-13)

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These Procedures are related to the *Policy on the Ethical Use of Animals in Research and Teaching* ([VPRGS-13](#)) and establish institutional standards concerning:

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### **Composition of the Concordia University Animal Research Ethics Committee (UAREC)**

Members of the UAREC are appointed by the Vice-President, Research and Graduate Studies (VPRGS). Terms are typically for a period of no less than two years and no more than four years, normally renewable up to a maximum of eight years.

The composition of the committee will include at least the following:

- a minimum of three faculty members experienced in animal care and use, representing Concordia departments that routinely engage in animal use, who may or may not be actively using animals during their term on the UAREC
- a veterinarian experienced in experimental animal care and use
- a faculty member whose normal activities do not depend on or involve animal use for research, teaching or testing
- at least two community members, to represent the interests and concerns of the general community, and who have no affiliation with Concordia, and who are not involved in animal use for research, teaching or testing
- the Manager of Concordia's Animal Care Facility (ACF)
- a representative of Environmental Health and Safety
- a graduate student who uses animals in their research

Of the Faculty members, one will be appointed as Chair and another as Vice-Chair by the VPRGS. If the Chair is absent, the Vice-Chair will serve as chair for the duration of that absence. The Chair and Vice-Chair, should not normally serve in this capacity for more than four years.

All members of UAREC shall comply with the University's *Policy on Conflicts of Interest in Research* ([VPRGS-5](#)), whether such conflicts are real, potential or apparent. UAREC members shall not review their own protocols. Without limiting the generality of the forgoing, the Chair and Vice-Chair must not be directly involved in the management of the ACF or involved in conducting such a large number of protocols that it would interfere with their duties as Chair.

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### Mandate and Authority of the UAREC

#### UAREC shall:

1. Require all animal users to complete, and submit for approval, the Animal Use Summary Protocol Form (AUSPF), for new protocols, or the Animal Use Summary Protocol Renewal Form (AUSPRF) for ongoing protocols.
2. Ensure that no research or testing project or teaching program (including field studies) involving animals commences without prior UAREC approval of an AUSPF or AUSPRF and guarantee that no animals are acquired or used before such approval, regardless of the source of funding, if any. The Office of Research (OOR) will not release research funds until UAREC has issued its approval. If approval expires and the animal user is not pursuing renewal, the OOR will hold the funds until such approval has been obtained. Also, animal purchases will require an approval number before their completion.
3. Ensure that no animals be held for breeding purposes, or for eventual use in research, teaching or testing projects, without prior UAREC approval of the appropriate protocol.
4. Ensure that research projects and teaching activities do not progress to ethics review unless they have received a favorable review for scientific merit. For the purposes of research projects, UAREC accepts evaluation from the federal and provincial granting agencies as evidence of peer review.
5. Review and assess all animal use protocols, with particular emphasis on the CCAC's *Guide to the Care and Use of Experimental Animals*, the *Ethics of Animal Investigation* policy statement and the *CCAC guidelines on: animal use protocol review* as well as on all other CCAC guidelines and policy statements. UAREC may require further supportive information from the researcher or meet with the researcher to ensure that all members of the committee understand the procedures to be used on the animal. The committee must also ensure that all procedures comply with CCAC guidelines, and, if at variance with those guidelines, require justification for the discrepancy on scientific and ethical grounds.
6. Review all protocols annually. Applications for renewal are submitted on an AUSPRF. Protocols may be renewed up to two times, after which a new AUSPF must be submitted for full review.

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7. Review any requests for modifications of an approved protocol, and additional appendices submitted under an approved protocol.
8. Document all UAREC discussions and decisions in the committee minutes.
9. Ensure that all researchers have the opportunity to become familiar with the CCAC's *Guide* and *Ethics* statement and all other CCAC guidelines and policy statements, and federal or provincial statutes that may apply, as well as institutional requirements.
10. Ensure that researchers report any unanticipated problems or complications, as well as the steps they have taken to address the problem(s), to the Manager of the ACF.
11. Ensure that appropriate care is provided to animals in all stages of their life and in all experimental situations.
12. Ensure that the pertinent Standard Operating Procedures (SOPs) necessary to meet the needs of the researchers are established and implemented by the ACF (see mandate below).
13. Encourage the use of pilot studies with few animals when new approaches, methods or products are being tried, before approving new, large scale protocols. Researchers must report the results of pilot studies to UAREC, regardless of whether they proceed to a large scale protocol.
14. Stop any objectionable procedure if the committee considers that unnecessary distress or pain is being experienced by an animal.
15. Stop immediately any use of animals that deviates from the approved use, any non-approved procedure, or any procedure causing unforeseen pain or distress to animals.
16. Have an animal euthanized humanely if pain or distress caused to the animal cannot be alleviated
17. Recommend to the OOR that access to research funds be restricted if a researcher has been found to be using procedures that deviate from the approved procedures, or that cause unnecessary distress or pain to an animal.

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18. Implement a Post-Approval Monitoring (PAM) program that covers all animals used under the auspices of Concordia, review PAM reports, and, if appropriate, require that changes be made to animal use practices in light of the reports. The procedure for PAM visits to on-site laboratories is described in the PAM form. UHREC will determine what PAM procedures are appropriate for field studies on a case-by-case basis and ensure appropriate follow-up.
19. Ensure that animal housing and use take place in appropriate facilities, with minimal transportation of animals, and where oversight of animal care is possible.
20. Oversee all areas where animals are housed and/or used, conduct visits to these areas and document findings of the visits.
21. The Chair of AREC shall have access at all times to all areas where animals are housed and/or used.

### **Mandate of the OOR, Consulting Veterinarians, and the ACF**

#### **The OOR shall:**

22. Advise researchers regarding the application of the *Policy on the Ethical Use of Animals in Research and Teaching* ([VPRGS-13](#)) and these Procedures.
23. Make the AUSPF and the AUSPRF available to researchers.
24. Receive and process submitted AUSPFs and AUSPRFs and advise researchers as to any missing required information prior to consideration by the UAREC.
25. Provide staff support to the UAREC.
26. Keep records of all AUSPF and AUSPRF submissions to the UAREC.
27. Inform researchers of directives and communications related to the use of animals in research or teaching received from the CCAC as well as from public and private funding agencies.

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28. Ensure that unfunded research, internally funded research, and any other research that has not received peer review, and all teaching activities involving animals are reviewed for scientific merit. If such research or teaching activities are submitted, the OOR on behalf of the VPRGS will, in consultation with the Faculty of Arts and Science Research Committee, convene an independent panel, with appropriate expertise, to assess the scholarly merit of the research.
29. Stop providing research funds to any researcher who has been found to be using procedures that deviate from the approved procedures, or that cause unnecessary distress or pain to an animal.

**The Manager of the ACF shall, on behalf of the VPRGS:**

30. Ensure that all animal care and animal experimentation are conducted in accordance with CCAC guidelines and policies, as well as any federal, provincial and institutional regulations that may be in effect.
31. Ensure adequate animal care and staffing of the ACF.
32. Ensure UAREC approval for all animals ordered and/or used in the ACF as well as areas where animal research is carried out.
33. Serve as a member of the UAREC and provide regular updates on the activities within the ACF.
34. Provide researchers with training appropriate to the use of the ACF and verify the qualifications of animal care personnel and animal users, who should receive appropriate training according to the CCAC *guidelines on: institutional animal user training*, 1999.
35. Oversee the standards of husbandry as well as all facilities and equipment where animals are housed and/or used.
36. Ensure a regular schedule of visits to all rooms where animals are housed and/or used, including those outside the Animal Care Facility, is followed.

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37. Develop and/or collaborate in the development of SOPs for all activities and procedures that involve animals.
38. Advise on procedures for euthanasia.

**The Consulting Veterinarian(s) shall:**

39. Exercise their professional judgment, and consult with UAREC when necessary, in treating animals, removing them from a study or euthanizing them.
40. Contribute to all aspects of the animal care program such as development of SOPs, training initiatives, and overseeing facility maintenance and management.
41. Ensure that procedures, commensurate with current veterinary standards, are established in order to ensure that:
  - a. unnecessary pain or distress to animals is avoided
  - b. anesthesia and analgesia are properly and effectively used. The only exception to this may be when drugs must be withheld as a scientifically-justified requirement of the study, and that this has been approved by the UAREC. Painful studies requiring exemption from the use of either anesthetics or analgesia must be subject to particular scrutiny, not only prior to approval, but also during the experiment
  - c. appropriate post-operative care is provided
  - d. all due consideration is given to animal welfare, including environmental enrichment.
42. Inspect and report to the VPRGS on the ACF and areas in which animals are used at least twice per year.
43. Be available for urgent consultations related to animal health and welfare.
44. Have access at all times to all areas where animals are housed and/or used.

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### Meetings and related processes of the UAREC

45. Meetings of the UAREC are conducted at least twice per year, and as often as necessary to fulfill its mandate and to satisfy that all animal use within its jurisdiction occurs in compliance with institutional, federal and provincial regulations, as well as CCAC guidelines.
46. Meetings will not proceed unless quorum is present. Quorum is defined as fifty percent of the members plus one, including at least one community member and one veterinarian.
47. UAREC will make decisions by consensus whenever possible. If it is impossible to reach a consensus, the committee votes, and an absolute majority of the members present prevails.
48. At each meeting, the UAREC will visit the ACF, and areas in which animals are used, in order to better understand the work being conducted, to meet with those working in the animal facilities as well as animal use areas and to forward any recommendations or commendations to the individual(s) responsible for the facilities and for animal use. Visits of the ACF will be documented through the UAREC minutes and written reports from a consulting veterinarian to the VPRGS. The Manager of the ACF will respond to any UAREC recommendations in writing.
49. Six weeks prior to a meeting, researchers will be solicited for AUSPFs. Researchers are eligible for two renewals of previously approved projects; after which they must submit a new application. Received applications will be discussed at the next meeting. Remaining procedures will be as otherwise described.
50. In the case that a researcher has a previously approved protocol and he/she does not apply for a renewal of their AUSPF (if eligible) or submit an AUSPRE, the existing approval shall be revoked.
51. If a researcher receives grant, contract, or internal funding, and the research proposal indicates that such funding will use animals, the OOR will contact the researcher and request that he/she submit an AUSPF for review by the UAREC. Received funding will not be released until approval for the use of animals in the project from the UAREC. A UAREC meeting will normally be held in May or June, to accommodate any protocols received.



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52. While additional meetings will be called throughout the year when necessary, the UAREC may, exceptionally, undertake an interim approval process as detailed below. These interim approvals are subject to discussion and final approval at the next regular meeting of the UAREC.

### **Protocol Review Process**

53. Protocols submitted prior to the regularly scheduled UAREC meetings will be reviewed by either a newly scheduled UAREC meeting or, in exceptional situations where a UAREC meeting cannot be promptly scheduled, an interim approval procedure, as follows:
- a. Protocols will be forwarded to all members of the UAREC, requesting their recommendation on the protocol (approval, conditional approval, queries, not approved) and including any relevant comments or questions.
  - b. The Chair of the UAREC will review these recommendations and decide on the most appropriate course of action. Approval will be dependent on a significant majority (quorum) from the responses, as well as approval or conditional approval from the veterinarian(s), and at least one community member.
  - c. Interim approvals are subject to discussion and final approval at the next regular meeting of the committee.
54. Following the review process, the AUSPF or AUSPRF will receive one of the following results:
- a. Approval: any pending funding is released. No further input from the researcher is required for one year, except in the case that the researcher wishes to modify the protocol.
  - b. Conditional Approval: any pending funding is released, but full approval is contingent on the researcher meeting particular concerns. These concerns will be provided to the researcher in writing, and he/she will be asked to respond to these concerns within two weeks. Responses will be reviewed by the Chair of the UAREC, the Manager of the ACF and the Consulting Veterinarians. Once all concerns have been met, Full Approval will be granted.

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- c. Queries: any pending funds are not released. The researcher must respond within two weeks to a list of concerns and/or questions, which will be provided to the researcher in writing. The researcher may be invited to join the UAREC in a meeting, or to meet with a representative of the UAREC, in order to provide guidance to the researcher in designing their protocol(s) appropriately. Responses will be reviewed at the next UAREC meeting.
  - d. Not approved: any pending funds are not released. The researcher will be provided with a list of concerns, and requested to prepare and resubmit their AUSPF. The researcher may be invited to join the UAREC in a meeting, or to meet with a representative of the UAREC, in order to provide guidance to the researcher in designing their protocol(s) appropriately. Resubmitted protocols will be considered as a new protocol. Correspondence between the researcher and the UAREC will occur via the Research Ethics Unit of the OOR with accurate and complete records of this correspondence being maintained.
55. Minor changes to a protocol may be submitted by e-mail; major changes to a protocol require the submission of a new AUSPF or AUSPRF, as appropriate. All modification requests and responses to conditional approval or queries must be reviewed by the Chair, the Manager of the ACF and a veterinarian. When further clarifications are required, the researcher is contacted for a response, which is then reviewed as previously indicated. Once all issues have been resolved, the most up-to-date version of all documents and correspondence is sent to the Chair for final approval. Minor changes are those that have little or no impact on the welfare of animals and include:
- a. administrative changes to a protocol, such as changes in contact information or lab personnel
  - b. an incremental increase to the number of animals to be used,
  - c. changes in experimental agents such as drugs, anesthetic agents or analgesic agents where the effect on the animal is equivalent
  - d. changes in experimental procedures, provided that such changes do not increase the category of invasiveness

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Major changes are those that have a significant impact on the welfare of animals, including:

- a. changes in the species of animal
- b. changes in the strain of animal that necessitate different housing or care
- c. any change that changes the category of invasiveness of the procedures

### **Appeal Mechanism**

56. Appeals are to be submitted to the VPRGS who shall then convene an appeal committee, entitled the UAREC Appeal Committee (Appeal Committee). The Appeal Committee shall be composed of the VPRGS, or his/her designate, as Chair as well as two other individuals from within the Faculty of the researcher. One of these shall be a faculty member, and the other either a department chair, Dean, or Associate Dean.
57. The appellant will present his/her case, which can involve testimony from other faculty members internal or external to Concordia, regarding the nature of the research and the need for an exception to the UAREC's decision. The case for the UAREC's decision shall be presented by the Chair of the UAREC, and shall include complete minutes of the decision regarding that particular protocol. The Committee will render a final judgment after hearing both sides.

### **Miscellaneous UAREC Processes and Responsibilities**

58. The UAREC must regularly review the *Policy on the Ethical Use of Animals in Research and Teaching* ([VPRGS-13](#)) and its accompanying Procedures as well as SOPs related to the security of the animals and its research facilities. This is done in order to meet new CCAC guidelines or policies and changing needs within the institution, the scientific community, the animal welfare community and society as a whole and undertake revisions as appropriate.
59. The UAREC must maintain liaison with the CCAC Secretariat, prepare for and participate in site visits in accordance with CCAC scheduling. Through the OOR, the UAREC must submit complete and accurate animal use information in the CCAC *Animal Use Data Form* (AUDF) format for all protocols in accordance with the CCAC's annual schedule.

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60. The UAREC must develop, approve, and periodically review a crisis management program for the ACF and areas in which animals are used for the animal care and use program, in conjunction with any general institutional crisis management plan(s).
61. The UAREC should, from time to time, sponsor seminars or workshops on the use of animals in science and the ethics of animal experimentation, and encourage as many animal users, animal caregivers, students, UAREC members and other interested parties to attend as possible.

Approved by the Dean, Faculty of Arts and Science on November 24, 2014

Revisions approved by the Dean, Faculty of Arts and Science on January 29, 2016

Revisions approved by the Dean, Faculty of Arts and Science on January 30, 2018