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 Concordia University’s Animal Research Ethics Committee (AREC)

Members of the AREC are appointed by the Vice-President, Research and Graduate Studies (VPRGS). Terms are typically for a period of no less than 2 years and no more than 4 years, normally renewable up to a maximum of 8 years.

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

- a minimum of 3 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 AREC;

- 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 2 community members, to represent the interests and concerns of the general community, and who have no past or present affiliation with Concordia, and who are not involved in animal use for research, teaching or testing;

- the Manager of Concordia University’s Animal Care Facility (ACF);

- a representative of Environmental Health and Safety office; and

- 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 AREC shall comply with the University’s Policy on Conflicts of Interest in Research (VPRGS-5), whether such conflicts are real, potential or apparent. AREC 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.
Mandate and Authority of the AREC

AREC shall:

1. Require all animal users to complete, and submit for approval, the Animal Use Protocol (AUP), for new protocols, or the Animal Use Protocol Renewal Request (AUPRR) for ongoing protocols.

2. Ensure that no research or testing project or teaching program (including field studies) involving animals commences without prior AREC approval of an AUP and guarantee that no animals are acquired or used before such approval, regardless of the source of funding, if any.

3. Ensure that no research or testing project or teaching program (including field studies) involving animals continues without AREC conditional approval of an AUP or AUPRF.

4. The Office of Research (OOR) will not release research funds until AREC has issued its approval and all other compliance requirements have been satisfied. 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.

5. Ensure that no animals be held for breeding purposes, or for eventual use in research, teaching or testing projects, without prior AREC approval of the appropriate protocol.

6. 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, AREC accepts evaluation from the federal and provincial granting agencies as evidence of peer review.

7. Review and assess all animal use protocols, with particular emphasis on the Canadian Council on Animal Care’s (CCAC) Guide to the Care and Use of Experimental Animals, and 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. AREC 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.

8. Review all protocols annually. Applications for renewal are submitted by completing the
AUPRF. Protocols may be renewed up to 3 times, after which a new AUP must be
submitted for full review.

9. Review any requests for modifications of an approved protocol and additional appendices
submitted under an approved protocol.

10. Document all AREC discussions and decisions in the committee minutes.

11. Ensure that all researchers have the opportunity to become familiar with CCAC
guidelines and policy statements, and federal or provincial statutes that may apply, as
well as institutional requirements.

12. 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.

13. Ensure that appropriate care is provided to animals in all stages of their life and in all
experimental situations.

14. 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).

15. 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 AREC, regardless of whether they proceed to a large-
scale protocol.

16. Stop any objectionable procedure if the AREC considers that unnecessary distress or pain
is being experienced by an animal.
17. 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.

18. Ensure that an animal is euthanized humanely if pain or distress caused to the animal cannot be alleviated.

19. 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.

20. Implement and maintain 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 SOP.

21. AREC will determine what PAM procedures are appropriate for field studies on a case-by-case basis and ensure appropriate follow-up.

22. Ensure that animal housing and use take place in appropriate facilities, with minimal transportation of animals, and where oversight of animal care is possible.

23. Oversee all areas where animals are housed and/or used, conduct visits to these areas and document findings of the visits.

24. Ensure that the ACF Manager, veterinarians, Environmental Health and Safety, and the Chair of the AREC have access at all times to all areas where animals are housed and/or undergo procedures.

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

The primary objective of the OOR, Consulting Veterinarians, and the ACF is to support researchers in performing high-quality research, while also ensuring compliance with all relevant regulations and guidelines. More specifically:
The OOR shall:

25. Advise researchers regarding the application of the Policy on the Ethical Use of Animals in Research and Teaching (VPRGS-13) (the “Policy”) and these Procedures.

26. Make the AUP and the AUPRF templates available to researchers.

27. Receive and process submitted AUPs and AUPRFs and advise researchers as to any missing required information prior to consideration by the AREC.

28. Provide staff support to the AREC.

29. Keep records of all AUP and AUPRF submissions to the AREC.

30. 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.

31. 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. For research activities, the “Process for Scientific Merit Review”, detailed in Appendix A, will be implemented. For teaching activities, the “Process for Pedagogical Merit Review”, detailed in Appendix B, will be implemented.

32. Upon direction of the AREC and VPRGS, implement actions that may be required to address concerns regarding the use of animals.

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

33. 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.

34. Ensure adequate animal care and staffing of the ACF.
35. Ensure AREC approval for all animals ordered and/or used in the ACF as well as areas where animal research is carried out.

36. Serve as a member of the AREC and provide regular updates on the activities within the ACF.

37. 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.

38. Oversee the standards of husbandry as well as all facilities and equipment where animals are housed and/or used.

39. Ensure a regular schedule of visits to all rooms where animals are housed and/or used, including those outside the ACF, is followed.

40. Have access at all times to all areas where animals are housed and/or used.

41. Develop and/or collaborate in the development of SOPs for all activities and procedures that involve animals.

42. Advise on procedures for euthanasia.

The Consulting Veterinarian(s) shall:

43. Exercise their professional judgment, and consult with AREC when necessary, in treating animals, removing them from a study or euthanizing them.

44. Contribute to all aspects of the animal care program such as development of SOPs, training initiatives, and overseeing facility maintenance and management.

45. 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 AREC. 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; and

d. all due consideration is given to animal welfare, including environmental enrichment.

46. Inspect and report to the VPRGS on the ACF and areas in which animals are used at least twice per year.

47. Be available for urgent consultations related to animal health and welfare.

48. Have access at all times to all areas where animals are housed and/or used.

Meetings and related processes of the AREC

49. Meetings of the AREC are held at least 3 times 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.

50. 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.

51. AREC 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.

52. At each meeting, the AREC 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 AREC minutes and written reports from a
consulting veterinarian to the VPRGS. The Manager of the ACF will respond to any AREC recommendations in writing.

53. Six weeks prior to a meeting, researchers will be solicited for AUPs. Researchers are eligible for three 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.

54. In the case that a researcher has a previously approved protocol, and the researcher does not apply for a renewal of their AUP (if eligible) or submit an AUPRF, the existing approval shall be revoked, and animals seized and placed under the supervision of the ACF Manager until they can be either donated or euthanized.

55. 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 AUP for review by the AREC. Received funding will not be released until approval for the use of animals in the project from the AREC. An AREC meeting will normally be held in May or June, to accommodate any protocols received.

56. While additional meetings will be called throughout the year, when necessary, the AREC 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 AREC.

Protocol Review Process

57. Protocols submitted prior to the regularly scheduled AREC meetings will be reviewed by either a newly scheduled AREC meeting or, in exceptional situations where an AREC meeting cannot be promptly scheduled, an interim approval procedure, as follows:

a. protocols will be forwarded to all members of the AREC, requesting their recommendation on the protocol (approval, conditional approval, queries, not approved) and including any relevant comments or questions;

b. the Chair of the AREC 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; and

c. interim approvals are subject to discussion and final approval at the next regular meeting of the committee.

58. Following the review process, the AUP or AUPRF 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: in the case of renewals only, 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 a prescribed time. Responses will be reviewed by the Chair of the AREC, the Manager of the ACF and the Consulting Veterinarians. Once all concerns have been met, Full Approval will be granted.

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 AREC in a meeting, or to meet with a representative of the AREC, in order to provide guidance to the researcher in designing their protocol(s) appropriately. Responses will be reviewed at the next AREC 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 AUP. The researcher may be invited to join the AREC in a meeting, or to meet with a representative of the AREC, 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 AREC will occur via the Research Ethics Unit of the OOR with accurate and complete records of this correspondence being maintained.
59. Minor changes to a protocol may be submitted by e-mail; major changes to a protocol require the submission of a new AUP or AUPRF, as appropriate.

   a. Administrative amendments – These can include amendments to the research team, updating personnel status or training, changing or updating grant information, etc. These amendments will be approved by the Ethics Unit in the OOR.

   b. Minor Amendments – These amendments must not alter the approved level of invasiveness, and can include using a different strain, life stage or sex of animal for an approved procedure, an increase of less than 20% in the animals used, use of a different drug that does not change the invasiveness of the procedure, change in supply source or housing location etc. These amendments will be reviewed by the core committee of the AREC, which is comprised of at least one of the veterinarians, the ACF manager, at least one of the community representatives, and the Chair of the AREC.

   c. Major Amendments – These include, but are not limited to, new projects or surgeries never before performed in the lab, applying a new surgical approach or medical treatment, withholding of analgesics, changes in procedures resulting in greater pain, distress, or a higher degree of invasiveness, increasing the number of animals used by more than 20%, applying the protocol to a new species. These amendments must be reviewed and approved by the full AREC.

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.

**Appeal Mechanism**

60. Appeals are to be submitted to the VPRGS who shall then convene an appeal committee, entitled the AREC 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.
61. 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 AREC’s decision. The case for the AREC’s decision shall be presented by the Chair of the AREC and shall include complete minutes of the decision regarding that particular protocol. The AREC will render a final judgment after hearing both sides.

Resolving Compliance Concerns Regarding the Use of Animals

62. The use of animals in research and teaching is governed by SOPs including AREC-06 PAM Program, and AREC-02 General Information, Roles and Responsibilities of the Research Team. The PAM Program includes multiple processes for monitoring the use of animals, and for identifying and correcting aspects of animal usage that may deviate from an approved AUP and/or from regulatory standards. Post-approval monitoring procedures can provide education to investigators and instructors regarding their responsibilities in the conduct of ethical research and teaching with animals. Post-approval monitoring is conducted in collaboration with, and in support of, researchers, PIs and instructors, to review procedures, provide knowledge on best practices, and facilitate the needs of the research and teaching community.

63. This section provides a framework for the researchers, ACF, AREC and the OOR to effectively and collegially assess and resolve concerns related to the use of animals in teaching and research. A key to the success of these procedures is effective, collaborative communications.

64. Roles and Responsibilities

a. Animal well-being is the joint responsibility of research and teaching personnel and ACF personnel.

b. ACF Manager, Staff, and Veterinarian responsibilities:
   
   • Communicate concerns regarding a perceived departure from an approved AUP or ACF procedures directly to principal investigators (“PI”) and their staff, and to the Chair of the AREC when said concerns are repeated, or have a potential to impact animal welfare.
When any of these concerns are not readily resolved directly with the PI and their staff, inform the AREC or its compliance subset, which consists of a Consulting Veterinarian, the Manager of the ACF, and the Chair of AREC.

Respond promptly to concerns regarding animal use or husbandry.

Maintain records of concerns regarding the use of animals that impact animal welfare.

c. The AREC’s responsibilities:

The compliance subset of the AREC will perform a preliminary assessment of concerns brought to the AREC, and will work with the PI to resolve these concerns.

Assess evidence associated with concerns.

Provide technical and consultative support to the PI towards aligning animal-research practices with the approved AUP and/or regulatory standards.

Develop recommendations to resolve concerns in consultation with the PI.

Report concerns that are not resolved within the timeframe recommended by AREC to the OOR and VPRGS.

The Chair of the AREC must:

- maintain an arm’s length position; and

- ensure timely communications between the PI and the ACF staff and AREC as appropriate.
d. Principal Investigator’s responsibilities:

- Communicate and work promptly with ACF staff and the AREC to address concerns in the event of a perceived departure from an approved AUP or regulatory standards.

- Be available to ACF staff and AREC representatives for collegial interaction throughout the process.

- Provide timely responses. Failure to respond or significantly delayed replies will be brought to the attention of the AREC Chair, and documented by the OOR.

- Promptly implement protocol refinements to resolve concerns.

e. The OOR, and the VPRGS:

- Will maintain records of concerns and their resolution and facilitate processes, as appropriate;

- Will provide reasoned responses to concerns that are not resolved by the AREC, including corrective responses to address unresolved concerns, within their purview and/or involve other appropriate individuals or units – such as but not limited to the office of the respective faculty Dean, Employee and Labour Relations, and Legal Counsel; and

- When serious or recurrent concerns are raised, regardless of whether or not they are resolved by the AREC, the VPRGS may involve other appropriate individuals or units – such as but not limited to the office of the respective faculty Dean, Employee and Labour Relations, and Legal Counsel.

65. Procedures for Resolving Concerns

a. The AREC, PIs, ACF Manager and staff and veterinarians must act collegially to readily resolve concerns regarding animal use.
b. All concerns that could impact animal wellbeing are recorded as a component of post-approval monitoring, as described in AREC-06 PAM Program

- Information regarding concerns includes a description, the date of the initial concern, the number of animals affected, morbidity/mortality, suspected cause of any sickness, and the manner in which the concern was resolved. Information may include communications and information provided by the ACF manager and staff, the veterinarian, and the PI;

c. At all times, the degree and timelines of responses to concerns, by the ACF staff and veterinarians, the AREC, the OOR, and the PI must correspond to the potential impact upon an animal’s health and well-being.

Step 1: Routine concerns

a. Concerns are initially communicated by ACF staff or a veterinarian to the PI and researcher, and to the Chair of the AREC. The veterinarian is informed and consulted as appropriate depending on the nature of the concern.

b. Concerns regarding the care of animals by ACF staff should be reported to the ACF Manager, the Chair of AREC, and a veterinarian as needed. The ACF manager first attempts to resolve these concerns. Concerns that are not readily resolved will be considered by the AREC and OOR.

c. ACF staff and veterinarians follow procedures described in ACH-03 Sick, Loose, or Dead Animals, and VET-10 Rodent Health Evaluation and Common Treatment.

- Situations of immediate danger or impact to animal welfare may require immediate response and corrective action by animal care staff or researchers depending on the severity. (e.g.s, severe morbidity requiring immediate euthanasia; unrelenting pain and/or distress, moribund state)

- Situations that present a potential danger to animal welfare if not corrected in an expeditious manner are responded to by animal care staff and researchers with timelines according to the severity of the impact on animal welfare. (e.g.s, high potential for pain and distress amenable to
treatment, ignoring clinical endpoints, Body Condition Scoring of less than 2.0)

- Situations that have no immediate threat to animals must be addressed in a timely manner in order for the PI to comply with approved procedures and regulatory guidelines. Recurring concerns of this nature will be considered by the AREC sub-committee. (e.g. Deficient record keeping, minor deviation from SOPs, overcrowded cages, lack of necessary cage card information, inadequate aseptic technique.)

d. ACF staff and veterinarians have the authority to provide direction for relief to animals experiencing unnecessary pain or suffering within reasonable timelines. The veterinarian or ACF staff will try to contact the researcher and/or emergency contact person prior to taking action, as indicated in ACH-03 Sick, Loose, or Dead Animals.

e. The ACF staff or veterinarian can suggest an action to resolve the concern to the PI and researcher, with a reasonable timeline given for the corrective action of the ACF if it is not possible to contact the researcher or PI.

f. The PI responds to the concern to provide additional information, and to indicate how the concern will be resolved, and how any procedures may be modified as needed. The AUP is updated as needed.

Step 2: Consultation with the AREC compliance subset

a. In cases where broader consultation would be useful to resolve a complex concern or to determine how to best modify procedures, or in cases of disagreement, documents and communications related to the concern are shared with the AREC compliance subset,

b. The PI and the AREC compliance subset share information and collaborate to develop a plan to resolve the concern.

c. If requested, the PI provides a written response which indicates how the concern is resolved, and how procedures will be refined, and the AUP is updated, as appropriate.
d. Repeated concerns that may reflect a demonstrated recurring disregard for animal-related regulatory, veterinary and/or institutional standards and related policies and procedures that impact animal well being may be escalated for consideration by the AREC and OOR, with more rigorous demands to address the matter.

Step 3: Consultation with the AREC and the OOR

a. If a concern is not resolved within the AREC compliance subset, the concern is brought to the full AREC and the OOR

b. The AREC compliance subset provides the full AREC with a record of the concern, and any relevant communications for review, and may also suggest a plan of action. Concerns brought to the AREC must be based upon the records and communications presented.

- PIs must be afforded opportunities to provide the AREC with clarifications and to express any reservations regarding plans of action or modifications to procedures. The PI will be invited to meet with the AREC to discuss the situation, and to determine a plan of action. The AREC develops recommendations, in consultation with the PI, for corrective actions to resolve the concern.

- If the concern is resolved, the PI provides a written response which indicates how the concern is resolved, and how procedures will be refined, and the AUP is updated, as appropriate.

Step 4: Consultation with the VPRGS / Informing the VPRGS

a. If the concern is not resolved between the AREC and the PI following repeated reasonable attempts, the VPRGS is consulted

- A full record of the concern, and the recommendations of the AREC based on the record of the concern and the consultation with the PI, is provided to the VPRGS.
- Principal Investigators must be afforded opportunities to provide the VPRGS with clarifications and to express any reservations regarding plans of action or modifications to procedures.
• The VPRGS consults with the AREC and the PI to determine any modifications to AREC recommendations.

• Under the direction of the VPRGS, the final recommendations to maintain animal welfare are implemented by the PI or the ACF personnel as appropriate.

• Failure to comply will result in corrective actions, implemented by the VPRGS, that may include placing an AUP “on hold” to stop work related to the protocol, suspending the AUP, placing restrictions on use of grant funds, restricting access to the ACF, or other action or requirements.

• In cases that have required consultation with the VPRGS, the AREC normally requires a full AUP submission from the PI, if one is to be submitted, at its next meeting.

• In the cases that have required consultation with the VPRGS, the VPRGS has the discretion of filing a complaint with the respective Faculty Dean under article 29 of the Concordia University Faculty Association.

  b. If a resolution is found but the concerns either originated from recurrent events or were very serious in nature, the VPRGS should be informed and has the discretion of filing a complaint with the respective faculty Dean under article 29 of the Concordia University Faculty Association collective agreement.

Miscellaneous AREC Processes and Responsibilities

66. The AREC must regularly review the Policy and these 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.

67. The AREC must maintain liaison with the CCAC Secretariat, prepare for and participate in site visits in accordance with CCAC scheduling. Through the OOR, the AREC 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.

68. The AREC 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).

69. The AREC 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, AREC members and other interested parties to attend as possible.

Approved by the Dean, Faculty of Arts and Science on November 24, 2014, and revisions approved on January 29, 2016, and January 30, 2018, and May 15 2022.