

PROCEDURES

New and ongoing animal-based research, teaching or testing shall be subject to continuing ethics review in compliance with the guidelines of the Canadian Council on Animal Care (CCAC) and requirements of the University Animal Care Committee (UACC).

For the purpose of this document, Principal Investigator (PI) refers to both principal investigator of research projects or course director of teaching animal use protocols.

OVERVIEW OF ANIMAL USE PROTOCOL (AUP) REVIEW PROCESS

- All new AUPs, AUP forms filed after four years (4 year AUP), and annual review of all ongoing AUPs that are CCAC Category of Invasiveness (CI) Level "D" or "E" will be reviewed by the full Animal Research Ethics Board (AREB).
- Annual review of ongoing AUPs that are CCAC CI Level "B" or "C" and that have not had major changes to the AUP will be reviewed by a Designated Member Review process: A subcommittee of the AREB consisting of three persons; Chair of the AREB or designate (researcher member of UACC); the University Veterinarian or delegate; and one community representative of the UACC, for up to three annual reviews. At any time one of the Designated Members can stipulate that the AUP should receive full AREB review. The fourth year the AUP must undergo review by the full AREB.
- If the annual review of a CI Level B or Level C AUP includes a major modification then the annual review will be reviewed by the full AREB, rather than the AREB subcommittee, as per the [CCAC guidelines on: animal use protocol review](#) which indicate: *“Renewal applications should permit ACCs to review proposed modifications to the original protocol, if any, and the justification for the changes. Major modifications, including changes in animal species, category of invasiveness, the nature of the invasive procedure(s), or significant changes in the use of anesthetics/analgesics must be subjected to the same level of review and information requirements as a new application.”*
- Requests for modifications to an AUP will follow the *UACC Procedures on Submission of a Modification to an Existing Animal Use Protocol*.
 - Provisional approval of new AUPs judged to be CI Level “B”, “C” or “D” may be granted following review by the AREB Chair, the University Veterinarian or delegate, and a community representative provided all AREB subcommittee members agree to issuing the provisional approval and evidence of scientific merit review is confirmed. If the AREB subcommittee agrees to provisional approval but the research study has not undergone an external peer review of its scientific merit, then scientific merit review must first be established by the OVPR Scientific Merit Review Committee for Animal-Based Research. At least two positive peer reviews must be received, before provisional approval by the AREB subcommittee is issued. The AUP will be reviewed by

the full AREB at the next scheduled meeting. If the AREB subcommittee agrees to provisional approval of a teaching AUP, then pedagogical merit review must first be established by the Office of the Vice-Provost Teaching, Learning, and Student Experience Pedagogical Merit Review Committee for Animal-Based Teaching and Training (PMRC). Provisional approval by the PMRC Chair must be received, before provisional approval by the AREB subcommittee is issued.

- AUPs that do not involve any live animal handling or manipulation (CCAC CI Level “A” protocols) or other exempt activities (i.e. live animal use not under the CCAC mandate) will (at minimum) be reviewed and approved by a UACC Veterinarian (or delegate) and a Biosafety Officer. An approved copy of the Exempt Activity form will be documented and filed in the UACC AUP records. Annual review of these AUPs is not required; although, submission of a new Exempt Activity form is recommended by the ACRS every 4 years.

ONGOING ANIMAL USE PROTOCOLS

AREB approval of animal-based research AUPs is issued for one year at a time, in compliance with the CCAC guidelines and the UACC Terms of Reference. Late submission or approval of annual renewal forms does not extend the expiry date. Requests to change the original expiry date must be approved by the AREB Chair.

If the research or teaching AUP continues beyond one year, the PI must submit a completed “Annual Review Form” to ACRS at least one month prior to the expiry date of the AUP.

1. For annual review of ongoing AUPs, a reminder message with the Annual Review Form will be sent to the PI 9 weeks prior to the expiry date. A second reminder message will be sent 6 weeks prior to the expiry date of the AUP. **It is the responsibility of the PI to submit the Annual Review Form at least one month in advance of the expiry date to ensure sufficient time for review and approval by the AREB prior to the expiry date of the AUP.**
2. If an Annual Review Form / response to AREB Notice of Ethical Review (NER) is not received and approved by the AREB by the expiry date of the AUP, the status of the AUP will change to “suspended”, and no new animal use will be allowed. Animals from breeding colonies/herds will not be available for use under the expired AUP and breeding will cease. Experimental animals in a facility that are not currently undergoing treatment will be transferred to a Facility Holding AUP (see further details below). If animals are currently undergoing experimental treatment/procedures, continuance of the experiment is permitted only with AREB Chair approval.
3. If animals are held under an AUP that is declared suspended due to non-response from the PI, authority is given for their disposal by the University Veterinarian (or delegate) or for the transfer of animals to an approved Facility Holding AUP (Facility Manager listed as the PI). Any animal on a Facility Holding AUP may not be used for research or teaching until approval for that use is obtained from the AREB. The PI of the suspended AUP is responsible for all per diems associated with the housing, care and maintenance of all animals transferred from the suspended AUP to the Facility Holding AUP. The PI is

responsible to submit a response to NER or Annual Review Form for approval before these animals are transferred back to the PI's AUP from the Facility Holding AUP.

4. If an Annual Review Form or response to an AREB NER is not submitted as required, the University Veterinarian (or delegate), in consultation with the AREB Chair is fully authorized to do one or more of the following as deemed appropriate:
 - Hold the review or approval of current or future submissions by the PI until the status of the expired study has been addressed.
 - Notify the funding agency, industry sponsor or the appropriate regulatory authority of the expiry of the ethics approval for the study.
 - Notify Financial Services Division and Research Excellence and Innovation and/or Research Acceleration and Strategic Initiatives (RASI) to advise that the study is no longer approved and that no further associated funds should be released.
 - Terminate the study and notify the PI, Department Head, and Associate Dean Research (or equivalent). If a graduate student is involved in the study, the graduate student and Associate Dean, College of Graduate and Postdoctoral Studies, will also be notified.

5. If an Annual Review Form or response to AREB NER is not received by one month following the expiry date of the AUP, the AUP will be considered "closed" by the UACC and no further animal use will be allowed. The PI is responsible to submit a new AUP for approval before any animals are transferred from the Facility Holding AUP or any new animal use may proceed.

New Animal Use Protocols

For new AUPs that are reviewed by the AREB and are either (a) conditionally approved (requiring a response and approval by the AREB Chair or AREB Chair and UACC Veterinarian) or (b) not approved (requiring a response and review again by the full AREB), the PI must submit a response and revised AUP within three months from receipt of the AREB NER.

After two months, if a response (addressing the specific conditions of the AREB or a request for additional response time) is not received, ACRS will send a reminder to the PI. If a response is not received within three months, the AUP will be considered as "not proceeding" and will be closed. The PI will receive a notification to be informed of this change in status. If the project is to proceed, another new AUP must be submitted to the AREB for review.

These procedures are effective as of May 31, 2023.

Date Created: 01 October 2011		Written by: Diane Martz and Amanda Plante
Procedure Review and Revision History		
Revision Number	Review/Revision Date	Reviewer
1	31 October 2011	UCACS
2	19 November 2012	UACC
3	26 May 2016	UACC
4	11 June 2018	UACC
5	20 November 2018	UACC
6	02 June 2022	UACC
7	31 May 2023	UACC