

Purpose / Scope

The objective of this policy is to outline requirements for annual review of Animal Use Protocols (AUPs) (hereto referred to as 'Renewals') to ensure alignment with current National, Provincial and Institutional regulatory policies and guidelines.

Rationale

In its *Guidelines on Animal Use Protocol Review*, Canadian Council on Animal Care (CCAC) states that, 'Each protocol must be reviewed annually and must take into consideration changes in standards and guidelines, and developments in the replacement, reduction, and refinement of experimental animal use.'¹

Policy Statements

Annual Renewal Scope

Animal-based science is subject to annual review by the Animal Care Committee (ACC). AUPs may be renewed a maximum of three times, at which point a new AUP must be submitted (See POL-002-A for more details). For AUPs that have been completed, a Closure Form must be submitted (PROC-002-A, APP2).

Animal-based science activities are contingent on the maintenance of 'approved' status under associated AUPs.

Annual Renewal reviews must include the following elements:

- Retrospective
 - number of animals used in preceding year
 - brief progress report describing:
 - complications, including unpredicted outcomes, any animal pain or distress
 - adequacy of endpoints and refinements made relative to protecting animals from pain, distress, or mortality
 - progress with respect to 3Rs
 - any other changes from the original AUP
- Prospective
 - number of animals required for upcoming year, with justification
 - updates to the AUP to align with the upcoming year's plans

¹ Canadian Council on Animal Care. CCAC Guidelines on Animal Use Protocol Review (1997) - Sect. 1

Annual Renewal Submission & Associated Timelines

Annual Renewal Forms must be submitted using the ACC's software system 60 days in advance of the expiry.

To assist the AUP Holder, the AUP software system will send reminders at different time points prior to the expiry date.

Submission Delays

Should an AUP Holder fail to submit the form by the annual expiry date despite reminders/follow-up notifications, a notice that AUP approval has expired will be issued to the AUP Holder and his/her department/division Chair. The AUP will be put 'on hold', as determined by the ACC or its Executive as per the *Concerns Policy* (POL-004). The AUP Holder must provide the ACC with documentation regarding the reasons for the lapse and steps taken to prevent future lapses.

If the Annual Renewal form is still not submitted within two weeks of the AUP annual expiry date, the ACC may 'Close' the AUP requiring AUP holders to submit a new AUP.

- Exceptions to this may be granted for extraordinary circumstances, as supported by the ACC Chair or other ACC leader. In these instances, the AUP Holder must provide in writing sufficient reasoning for not submitting the Annual Renewal on time.

If the Annual Renewal form is submitted after the expiry date but before AUP 'Closure,' this will result in a lapse in ACC approval, which will be documented.

If the Continuing AUP is submitted after the expiry date but before AUP 'Closure,' this will result in a lapse in ACC approval, which will be documented.

Any Concerns not readily resolved by accountable parties associated with Annual Renewals and related processes and timelines must be forwarded to the ACC Executive for consideration as per the *Concerns Policy* (POL-004).

Annual Renewal Review & Approval Determination

The ACC must continue to assess AUPs with respect to whether animal use is acceptable "ethically and in practice and must decide whether the animal-based methods are appropriate for the proposed work, with careful consideration of the Three Rs (replacement, reduction and refinement of animal use)."²

Submitted documentation must be reviewed either via Full ACC Review or Delegated Review processes.

ACC decisions must align with the criteria outlined within the *Animal Use Protocols Policy-A* (POL-002-A).

² CCAC. CCAC policy statement on: scientific merit and ethical review of animal based research. Sect.2. Retrieved 26MAR2019 from https://www.ccac.ca/Documents/Standards/Policies/Scientific_merit_and_ethical_review_of_animal-based_research.pdf

Once the Annual Renewal submission is reviewed and there are no outstanding issues, an ACC approval notification will be issued.

Annual Renewals Requiring Full ACC Review

Annual Renewals involving category of invasiveness 'D' and 'E' that have involved live animal work during the previous year must be reviewed via the Full ACC Review process as outlined within the *Procedure for Full ACC Review PROC-002-A*.

Annual Renewals Eligible for Delegated Review

Annual Renewals involving the following may be reviewed via the Delegated Review process, as outlined within the *Procedure for Delegated Review PROC-002-B*:

- Category of Invasiveness 'B' and 'C' with minimal changes to the animal use plan; animal numbers that are less than previous year's; and/or
- Category of Invasiveness 'D' and 'E' where **no** animal work was performed in the previous year.

Delegated Review of Annual Renewal forms must involve at minimum an Animal-Based Scientist, Institutional Veterinarian and Community Representative; reviewer allocation must be based upon AUP form content with respect to animal health and welfare impact.

On a monthly basis, all Renewals that have been approved by Delegated Review during the previous month must be made available to the full ACC.

References

- OMAFRA's Animals for Research Act, R.S.O. 1990
- Canadian Council on Animal Care
 - Terms of Reference for Animal Care Committees (2006)
 - Requirement for submitting an animal protocol (2020)
 - Frequently Asked Questions (2020)
 - CCAC guidelines on: animal use protocol review (1997)
 - Ethics of Animal Investigation (1989)
 - Categories of Invasiveness in Animal Experiments
- Animal Care Committee policies and procedures

Revision History

Version	Date	Description of Changes	Author
00	07-10-2015	New Policy	LT / LC



01	11-04-2017	Updates to definitions for Major & Minor Protocol Modifications, and Protocol Review Types to align with CCAC recommendations (2015)	LT / LC
02	08-10-20	Split POL-002 into three distinct policies: AUPs (A), Annual Renewals (B) & Protocol Modifications (C); Update References; update formatting; Remove Roles & Responsibilities	LT / LC / EB

AUP Review Working Group – This standing working group of the ACC reviews AUP forms with the exception of those reviewed by the full ACC or designates. The AUP Review Working Group consists of six roles to include Animal-Based Scientist, Community Representative, Institutional Veterinarian, Technical Representative, Non-Animal User, and the ACC Officer as per the Terms of Reference for ACC Working Groups. Participation is on a rotational basis for roles represented by more than one individual.

Categories of Invasiveness – Levels assigned to AUPs in accordance with CCAC policy. Experiments involving:

- A – Most invertebrates or 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 – Procedures causing severe pain at or above the pain tolerance threshold of unanaesthetized conscious animals