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## Purpose / Scope

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

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## Rationale

In its *Guidelines on Animal Use Protocol Review*, the 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.'<sup>1</sup>

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## 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).

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

Annual Renewal reviews must include the following elements:

- Retrospective
  - *Animal Use* - Number of animals used in preceding year;
  - *Progress* – AUP status and brief update on progress made in achieving specific AUP aims;
  - *Complications* - Unanticipated adverse events, morbidity or mortality, the causes, if known, and how these problems have been resolved;
  - *Progress* - Progress with respect to 3Rs, e.g., refinements considered relative to protecting animals from pain, distress, or mortality; and

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<sup>1</sup> Canadian Council on Animal Care. CCAC Guidelines on Animal Use Protocol Review (1997) - Sect. 1 Retrieved 28MAR2024 from [https://ccac.ca/Documents/Standards/Guidelines/Protocol\\_Review.pdf](https://ccac.ca/Documents/Standards/Guidelines/Protocol_Review.pdf)

- Prospective
  - Number of animals required for upcoming year;
  - Justification is associated with the full AUP.
  - Future plans.

## Annual Renewal Submission & Associated Timelines

Annual Renewal Forms must be submitted using the ACC’s software system well in advance of the expiry, and as outlined within the reminder notice.

## 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).”<sup>2</sup>

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

Annual Renewals must be reviewed as outlined within the *AUP Review Processes for Principal Investigators* (GUID-002).

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

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## 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
  - Animal Use Protocols (POL-002-A)
  - AUP Review Processes for Principal Investigators (GUID-002)

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## Revision History

Version	Date <i>dd-mm-yyyy</i>	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

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<sup>2</sup> CCAC. CCAC policy statement on: scientific merit and ethical review of animal based research. (2013) Sect.2. Retrieved 28MAR2024 from [https://ccac.ca/Documents/Standards/Policies/Scientific\\_merit\\_and\\_ethical\\_review\\_of\\_animal-based\\_research.pdf](https://ccac.ca/Documents/Standards/Policies/Scientific_merit_and_ethical_review_of_animal-based_research.pdf)

02	08-10-2020	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
03	11-04-2024	Align with current Annual Renewal form content with reference to CCAC's ToFR for ACCs; remove procedural elements; point to new guidance document for processes	LT / LC / JMc