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Purpose / Scope

The objective of this policy is to outline the Animal Care Committee’s criteria for preparing for and undertaking a ‘Pilot Study’ Animal Use Protocol (AUP) associated with Western’s Animal Ethics & Care Program.

For the purpose of this policy, Pilot studies refer to limited studies for which veterinarian oversight is required.

Rationale

Within the Canadian Council on Animal Care’s guidelines on the Animal Use Protocol (AUP), the CCAC (Canadian Council for Animal Care) outlines the importance of undertaking a Pilot Study when the expected frequency, severity, and signs of morbidity or mortality for a study are unknown. During the Pilot Study phase, the CCAC encourages Institutional Veterinarians to engage directly with research teams to identify refinements in health monitoring, interventions, and endpoints as well as provide expertise in the development of new methods involving live animals.

Under Section 3 – Responsibility, subsection n), CCAC’s *Terms of Reference for Animal Care Committees* policy, ACCs are responsible to:

Encourage the use of pilot studies with few animals when new approaches, methods or products are being tried, before approving new, large-scale protocols.

Ensure that animal users report on the results of any pilot studies, no matter whether they wish to pursue the study immediately or not, in order to preserve important data on various approaches to animal-based studies, whether they work well or not.¹

Guideline 2 from *CCAC guidelines: Identification of scientific endpoints, humane intervention points, and cumulative endpoints* states:

When there is insufficient evidence to establish scientific endpoints prospectively, pilot studies must be conducted to identify the earliest point that the scientific activity can be terminated. Pilot studies must focus on determining welfare-appropriate endpoints, not on generating useable scientific data. The results of the pilot must be presented to the animal care committee before the protocol proceeds.²

CCAC's *Guidelines on Animal Use Protocol Review* (1997) provide additional direction on the use of Pilots prior to full AUP submission to assist in determining appropriate animal numbers, endpoints, restraint and invasive or stressful procedures.³

Policy Statements

Determination of the Need for a Pilot Study

Pilot Studies must be undertaken in advance of submission of full Animal Use Protocols (AUPs) in the following instances where:

- A high degree of uncertainty or concern regarding procedural elements or outcomes (morbidity/mortality) requires further procedural clarification or potential refinement, or
- Unclear or unknown procedural consequences or animal monitoring parameters exist.

Post-AUP approval the ACC may direct that an AUP, or portion thereof, be performed as a Pilot Study when procedural elements and/or outcomes (morbidity/mortality rates) have significantly greater negative animal welfare impact than was predicted in the AUP.

Pilot AUP Development & Submission

PIs (Principal Investigator) should request an AUP Facilitation involving ACC administrative staff and an Institutional Veterinarian (via acc@uwo.ca) **prior to** Pilot AUP form submission.

¹ Canadian Council on Animal Care. Terms of Reference for Animal Care Committees (2006). Retrieved 05OCT2023 from https://ccac.ca/Documents/Standards/Policies/Terms_of_reference_for_ACC.pdf

² Canadian Council on Animal Care. CCAC guidelines: Identification of scientific endpoints, humane intervention points, and cumulative endpoints. Retrieved 17OCT2023 from https://ccac.ca/Documents/Standards/Guidelines/CCAC_guidelines_scientific_endpoints.pdf

³ Canadian Council on Animal Care. Guidelines on Animal Use Protocol Review (1997). Retrieved 05OCT2023 from https://ccac.ca/Documents/Standards/Policies/Terms_of_reference_for_ACC.pdf

- Pilot Study AUPs must be prepared using the ACC's AUP software system with sufficient time to allow for review and approval.
- A Pilot AUP will undergo the same review process as a full AUP (see *Full AUP Review Procedures*).
- Ethical considerations will be assessed by ACC reviewers during the ACC review process.

Pilot studies must be limited to the fewest number of animals necessary to determine welfare-appropriate monitoring and endpoints and/or to clarify refinements for new procedural elements.

As a reminder, peer review of scientific merit must be in place for Pilot Study AUPs before evaluation by the ACC.

In instances where a portion of the AUP requires a Pilot Study, a stand-alone Pilot AUP must be developed, per the AUP Scope section of the Animal Use Protocols Policy-A.

Undertaking a Pilot Study

Once approved, a Pilot AUP is valid for the period identified within the AUP and up to a maximum of four years to the last day of the month of the initial approval, and must undergo annual review by the ACC.

Institutional Veterinarians or their designates must be actively engaged in monitoring and evaluation of experimental subjects during Pilot Studies with a view to identifying refinements to procedures, housing, and care as well as health monitoring, interventions, and endpoints.

PIs (Principal Investigator) and Institutional Veterinarians must work collaboratively to undertake the Pilot Study.

Planning Phase

PIs/lab members must notify the Institutional Veterinarians (acvsvet@uwo.ca) of their proposed timelines for initiating the study and arrange to meet with an Institutional Veterinarian to discuss Pilot roll-out plans.

- At this time, the Institutional Veterinarian will relay their expectations regarding their level of direct involvement.

Active Pilot Study Phase

PIs/lab members and the Institutional Veterinarian, or designate, must work collaboratively towards refining techniques and ensuring appropriate health monitoring and interventions.

- During and post observation, the Institutional Veterinarian, PI (Principal Investigator) and lab members will meet to review the AUP and determine identified refinements.

During the Pilot Study the Institutional Veterinarian has been granted authority by the ACC to provide interim approval for procedural refinements.

- The Institutional Veterinarian will document all veterinarian-approved intra-Pilot changes and make it available to the ACC Executive.

- During the Pilot Study the Pilot AUP does not need to be updated via AUP Modification due to obligatory veterinarian oversight; however, the Institutional Veterinarian may request an AUP Modification at their discretion.

Post-Pilot Study Completion Phase

The Institutional Veterinarian and PI (Principal Investigator) will work collaboratively to determine Pilot completeness.

- If the technique has been mastered, the procedural consequences (e.g., morbidity and mortality) are known and the appropriate monitoring is established, then the work completed under the Pilot can be incorporated into a full AUP or modified onto an existing AUP.
- Alternatively, the Pilot may reveal that the model or some aspect therein is not feasible to use.

Following Pilot Study completion, the PI (Principal Investigator), lab participants and the Institutional Veterinarian must complete the *Post-Pilot Study Report* collaboratively.

- The report must include the appropriateness of the endpoints and monitoring criteria as developed in consultation with an Institutional Veterinarian.
- All required changes to procedures, must be summarized in the final *Post-Pilot Study Report* and implemented in subsequent AUP submissions, as applicable.

The *Post-Pilot Study Report* must be provided to the ACC Executive for consideration.

The *Post-Pilot Study Report* must be appended to a new AUP or modification to an existing AUP that includes the piloted procedure.

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)
 - CCAC policy statement on: scientific merit and ethical review of animal-based research
 - CCAC guidelines: Identification of scientific endpoints, humane intervention points, and cumulative endpoints
- Animal Care Committee
 - POL-002-A Animal Use Protocols Policy
 - PROC-002-A / PROC-002-B – Full / Delegated Review Procedures
 - ACC Working Groups Terms of Reference – AUP Review Working Group

Revision History

Version	Date <i>dd-mm-yyyy</i>	Description of Changes	Author
00	09-11-2023	New Policy	ACC Executive

Glossary

For full terms and definitions, see the *AECP (Animal Ethics & Care Program) Glossary of Terms* on the [AECP Policies & Procedures](#) page of the Animal Care Committee's OWL Site.

Animal Care Committee (ACC) Executive – An ACC Working Group, as per the ACC Terms of Reference, that provides real-time feedback and support to institutional stakeholders accountable for the animal ethics and care program; provides leadership for animal ethics reviews; acts as front-line responders to Concerns brought to its attention, as outlined within the Concerns Policy (POL-004); receives updates from ACC designates regarding their mandated activities; provides direction and support to other ACC Working Groups; and relays decisions to the Full ACC.

Animal Morbidity - Any sick animal whose condition warrants humane intervention.

Animal Mortality - Any animal that has died under any circumstance or condition, with the exception of one that has reached its experimental endpoint as outlined within the related AUP. Includes animals found dead and animals requiring early euthanasia as their humane intervention.

Animal Use Protocol (AUP) - The Animal Care Committee's (ACC) mandatory animal ethics form that contains details of a PI (Principal Investigator)'s intended live vertebrate and cephalopod animal use, which must be reviewed and approved by the ACC in advance of Animal-Based Science activities (see AECP Policies & Procedures POL-002).

Animal Use Protocol (AUP) Facilitation – An AUP development and refinement service provided to Principal Investigators by the Office of the ACC and/or an Institutional Veterinarian. Normally, this service is offered virtually.

Pilot Study – A study focused on refining animal-based procedures that requires oversight by an Institutional Veterinarian. Pilot studies are required in situations where:

- a high degree of uncertainty or concern regarding procedural elements or outcomes (morbidity/mortality) requires further procedural clarification or potential refinement, or
- unclear or unknown procedural consequences or animal monitoring parameters exist, or
- when procedural elements and/or outcomes (morbidity/mortality rates) have significantly greater negative animal welfare impact than was predicted in the AUP.