

Contents

| | |
|---|----|
| Purpose / Scope..... | 1 |
| Rationale..... | 2 |
| Policy Statements..... | 2 |
| General..... | 2 |
| Animal Use Protocol Scope..... | 3 |
| Animal Use Protocol Submissions..... | 4 |
| Animal Use Protocol Review & Approval Determination..... | 5 |
| ACC Review Decisions..... | 6 |
| Post Approval..... | 7 |
| Special Animal Use Protocols-Pilot Studies..... | 7 |
| Stock vs Experimental Breeding Animal Use Protocols..... | 8 |
| Special Animal Use Protocols - Temporary Animal Holding AUPs..... | 9 |
| AUP Reporting Requirements..... | 10 |
| References..... | 10 |
| Revision History..... | 10 |
| Glossary..... | 12 |
| Exclusions..... | 14 |

Purpose / Scope

The objective of this policy is to outline criteria for the generation, review, and approval of Animal Use Protocols (AUP) including Continuing AUPs, associated with Western’s animal-based science program to ensure alignment with current Federal, Provincial, and Institutional regulatory policies and guidelines.

The purpose of an AUP is to provide clarity on live animal use, including anticipated welfare impact, for reference by internal and external stakeholders – animal health, husbandry and OHS professionals, national and provincial regulators, and the ACC.

This policy pertains to “all proposed animal-based research, teaching, and testing activities involving any nonhuman vertebrate or a cephalopod that is either a subject of scientific inquiry, or is supporting science either directly (animal model of disease or biological process; euthanized animals for tissue collection), or indirectly (used as sentinels, for training, or for food for research animals), including:

- any work categorized as CCAC’s Category of Invasiveness ‘B’ through ‘E,’

- activities within laboratory animal facilities, extra-vivarium spaces, and in natural or semi-natural habitats,
- collaborations with external institutions involving a member of Western's Research Community,
- herd and colony animals, and
- animals in non-degree/diploma/certificate credit courses (e.g., professional development/continuing education workshops) provided by faculty or other institutional personnel under the aegis of a certified institution."¹

For details pertaining to *Annual Protocol Renewals*, *Protocol Modifications* and associated ACC review processes, reference:

- POL-002-B-Animal Use Protocols Policy-Annual Protocol Renewals
- POL-002-C-Animal Use Protocols Policy-Protocol Modifications
- PROC-002-A-Procedure for Full ACC Reviews
- PROC-002-B-Procedure for Delegated Reviews

See Appendix 2 for exclusions to this policy.

Rationale

The Canadian Council on Animal Care's *Terms of Reference for Animal Care Committees* (ACC) states that "no animals be held for display or breeding purposes, or for eventual use in research, teaching or testing projects, without prior ACC approval of a written Animal Use Protocol," which is mirrored by Ontario's *Animals for Research Act* and *Tri-Agency's Agreement on the Administration of Agency Grants and Awards by Research Institutions*.

Policy Statements

General

Pursuant to existing Western University policies, since the AUP is considered the intellectual property of the researcher, it must be made available only for confidential use by authorized individuals and not for unauthorized distribution.

AUPs must be submitted by Faculty members of Western University deemed eligible to hold a research account, Lawson appointed scientists, or an Institutional Veterinarian unless otherwise approved by the ACC.

AUP-holders must remain in good standing with their respective institutions.

¹ CCAC Requirement for Submitting an Animal Use Protocol. Addendum to the CCAC policy statement on: terms of reference for animal care committees (2018). Retrieved 14FEB2019 from [https://www.ccac.ca/Documents/Standards/Policies/Requirement-for-Including-Animals-and-Animal-Based-Activities-in-a-Protocol-\(ADDENDUM\).pdf](https://www.ccac.ca/Documents/Standards/Policies/Requirement-for-Including-Animals-and-Animal-Based-Activities-in-a-Protocol-(ADDENDUM).pdf)

The ACC must receive confirmation that the AUP is part of a research program found to have scientific or pedagogical merit.

Animal Use Protocol Scope

AUP form content must align with regulatory requirements, e.g., CCAC's Terms of Reference for Animal Care Committees, CCAC guidelines on: animal use protocol review (1997), Animals for Research Act R.S.O. 1990.

All animal-based science activities involving live animals must be fully disclosed within an AUP, and must include the animal-related impact in a manner that all members of the ACC understand.

Animal-based scientists and all personnel who will handle live animals, to include everyone's specific animal-handling involvement, must be identified and maintained within the AUP.

The AUP must clearly describe the experiences of the animals from arrival to endpoint.

New and Continuing AUPs must include a project overview focused on the research question - the main reason the study is being conducted, the direct implications or applications of the study and projected animal use.

A separate AUP must be submitted for:

- each distinct species;
- level 'E' category level of invasiveness;
- animals housed and used at Containment Level III;
- studies deemed to be Pilots (see *Special Animal Use Protocols – Pilot Studies* section);
- breeding colonies (see *Breeding vs. Experimental AUPs* section); and
- at the discretion of the ACC.

As directed by an ACC leader, a separate AUP must be submitted for:

- each distinct disease model, e.g., sepsis, diabetes;
- a significant change(s) in animal utilization or the direction of the animal-based science activity, e.g., increase in category of invasiveness, procedures and timelines do not align with the previously approved AUP.

Exemptions to these requirements must be granted by the ACC Executive in advance of AUP submission.

Animal numbers disclosed within each AUP must include the following developmental stages:

- born mammals capable of breathing, including animals euthanized prior to weaning
- hatched birds and reptiles capable of breathing
- fish larvae capable of independent feeding
- amphibian larvae (tadpoles) capable of independent feeding.

Pilot studies must be undertaken in advance of new, large-scale AUPs when novel approaches, new species, new methods, or products are being tried.²

AUP Holders who wish to undertake animal-based science activities either completely or partially outside of Western and/or Lawson through collaboration with one or more external institutions, must follow Policy: *Multi-Jurisdictional Animal-Based Science (POL-015)*.

Animal Use Protocol Submissions

AUPs must be submitted to the ACC using the ACC's AUP software system with sufficient time to allow for review and approval prior to its expiry (either Annual or Continuing), or the date at which the animal-based scientist wishes to start the proposed work.

- For Annual Renewal details, see *Animal Use Protocols-B-Annual Renewals (POL-002-B)*

AUP Holders must undergo AUP facilitation in instances where AUP content requires significant updates as identified during the AUP review process.

Submission Delays for Continuing AUPs

Should an AUP Holder fail to submit the Continuing AUP by the required deadline (60 days in advance of expiry), the ACC Office will notify the ACC Chair or designate.

Should an AUP Holder fail to submit the form by the full 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 Continuing AUP is not submitted within four weeks of the AUP expiry date, the ACC Executive may 'Close' the AUP requiring AUP holders to submit a new AUP.

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.

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

If the Continuing AUP has been submitted, but remains in review beyond the expiry date,

- And approved within 30 days beyond the expiry date, a lapse will be recorded and relayed to the ACC Chair.
- And not approved within 30 days beyond the expiry date, as determined by the Executive or ACC leader, the AUP may be 'Closed' with a new AUP submission required.

² CCAC. Terms of Reference for Animal Care Committees. (2006) Section 3(n). Retrieved 14FEB2019 from https://www.ccac.ca/Documents/Standards/Policies/Terms_of_reference_for_ACC.pdf

If animals are present beyond expiry, specific 'on hold' measures will be applied by the Executive or ACC Leader on a case-by-case basis, e.g., animal procurement, 'on study' animal restrictions.

For all scenarios, applicable Institutional groups will be notified.

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

Animal Use Protocol Review & Approval Determination

New and Continuing AUPs require Full ACC Review involving the Full ACC Committee.

- See *Procedures for Full ACC Review* (PROC-002-A)

Interim Review - Under exceptional circumstances and as directed by the ACC Chair or designee, the AUP Review Working Group may review an AUP on behalf of the full ACC, as per the ACC Working Group Terms of Reference.

- The Delegated Review Process will be followed (See *Procedures for Delegated Review* (PROC-002-B))
- All AUPs receiving interim approval by the AUP Review Working Group will be forwarded to the Full ACC for final review and approval.

The ACC must 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)."³

During the AUP review process, ACC reviewers will consider whether an ACC-directed evaluation is appropriate for the following situations:

- Potential concerns re. animal welfare impact; the ACC requests an animal health professional to confirm that specific AUP element(s) is/are proceeding with expected morbidity/mortality;
- Category of Invasiveness (COI) of 'D' or 'E;' or
- Morbidity/mortality rate that exceeds standard expectations for this type of project or species.

AUPs categorized as Level 'E,' those involving cats, dogs, pigs and NHPs and those requiring significant revisions, e.g., Deferred AUPs, must undergo initial review by an ACC leader or the ACC's Executive and, as specified by the full ACC, must undergo an ACC-directed evaluation per the *Visits by Animal Health Professional* policy and procedures.

Final approval of AUPs by the ACC must only be granted following confirmation of associated approvals, e.g., Scientific or Pedagogical Merit, Multi-Jurisdictional Animal-Based Science, Institutional OHS.

³ 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

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

ACC Review Decisions

The ACC has the authority to approve (as submitted or pending clarification), defer, or disapprove a submitted AUP based upon the following criteria:

Approved – The AUP is ethically sound based upon the Three Rs Tenet; animal health and welfare considerations have been addressed appropriately; form content is clear and consistent. No further form revisions are required.

- The effective date of the initial approval will be set as the meeting date.

Approved Pending Clarification – Animal procedures, their consequences, and associated interventions are clear and appropriate, which facilitates a comprehensive ethics review in consideration of the Three Rs Tenet. Minimal revisions are required, e.g., minor editorial, graphical corrections.

- The effective date of the initial approval is the date on which the ACC Chair, or designee, has reviewed and accepted all changes to the AUP.

Deferred - Defer a decision on the AUP and continue the deliberation of the AUP at a future meeting. Animal procedures, and/or procedural consequences, and/or associated interventions are not clear and/or inappropriate, and/or major revisions are required, which does not facilitate a comprehensive ethics review in consideration of the Three Rs Tenet.

- The effective date of the initial approval will be set as the meeting date at which the AUP is re-reviewed by the full ACC and approved as submitted, or the date on which the ACC Chair, or designee, has reviewed and accepted all changes to the AUP and supplementary documents required by the ACC.

Not Approved – The AUP does not meet minimum standards with respect to regulatory requirements and/or ethical standards in consideration of the Three Rs Tenet, and/or the AUP Holder is not in good standing with the Institution, and where revisions are unlikely to enable the ACC to reach a positive determination. NOTE: If the recommendation under delegated review is to disapprove the AUP, a final decision must be made by the full ACC at a convened meeting.

- The AUP is 'cancelled' in the system as at the ACC decision date.

Closed – Full stoppage of a previously approved AUP by the ACC because it has expired, or at the request of the ACC (This decision normally arises in response to a Non-Compliance, per the *Concerns* Policy (POL-004)). The AUP is 'archived' in the system; final disposition of the animals will be determined by the ACC Executive.

- The AUP is 'expired' in the system as at the ACC decision date.

Appeals to ACC decisions will follow the ACC's Terms of Reference.

Post Approval

Post-Approval AUP Form Requirements

Animal-based science must only continue while the associated AUPs maintain an 'approved' status.

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

- A maximum of three one-year Renewals is permitted.
- A Continuing AUP must be submitted following Year 4 for projects requiring continuation (See below).
- For studies that have been completed, the PI must notify the ACC via email or within the Annual Renewal form.
 - The AUP will be expired in the software system.

All ACC-approved AUPs are enrolled in Western's Post Approval Monitoring Program, as per the *Post Approval Monitoring Program Policy* (POL-005).

Post-Approval Responsibilities of AUP Holders

AUP Holders must ensure that procedures performed on animals directly align with approved AUP content. Any changes to approved procedures must be submitted for review by the ACC via a Protocol Modification or a new AUP form.

AUP Holders must ensure that individuals listed in their AUP have full ongoing access to their AUP, have full understanding of their roles as outlined within, have received mandated institutional animal user training and are competent to perform these procedures in advance of undertaking them independently, as per the *Institutional Animal User Training Program Policy* (POL-017). All users must understand the use of monitoring sheets for invasive procedures and any relevant SOPs.

Special Animal Use Protocols-Pilot Studies

Criteria for Pilot Studies

An AUP Holder must submit a Pilot Study when the intended animal use is to evaluate the appropriateness, feasibility and suitability of a particular animal model, procedure, or study design to meet defined scientific objectives.

Pilot studies must be undertaken in advance of new, large-scale AUPs when novel approaches, new species, new methods, or products are being tried.⁴

⁴ CCAC. Terms of Reference for Animal Care Committees. (2006) Section 3(n). Retrieved 14FEB2019 from https://www.ccac.ca/Documents/Standards/Policies/Terms_of_reference_for_ACC.pdf

When requested by the ACC, an AUP Holder must submit a Pilot Study to be completed and reported upon to the ACC's Executive in advance of an AUP submission describing the entire project or experiment.

For new experimental agents or drugs, a pilot should be performed if the effect of a dose range on animal health and welfare is unknown. If the agent or drug is new to the AUP, and the goal is to test a dose range, within a range for which the effect on animal health and welfare is well-characterized and described in published data, then this does not need to be a pilot.

Peer review of scientific merit must be undertaken when an AUP Holder intends to use a Pilot Study to explore a new research direction that is not covered within the context of his/her existing peer-reviewed research program.

A subsequent complete AUP must not be submitted before the completion of the Pilot Study. These results must include the appropriateness of the endpoints and monitoring criteria as developed in consultation with an Institutional Veterinarian.

Veterinarian Engagement

Institutional Veterinarians must be actively engaged in monitoring and evaluation of experimental subjects during Pilot Studies with a view to identifying refinements in health monitoring, interventions, and endpoints.

AUP Holders must give advance notice of project commencement to the ACC and Institutional Veterinarians. The Institutional Veterinarian and lab staff will develop the timeline for direct observation of procedures and animals; will work collaboratively towards refining techniques and ensuring appropriate health monitoring and interventions.

During and/or post observation, the Institutional Veterinarian, AUP Holder and lab staff will meet to review the AUP and determine identified refinements.

Modifications to Pilot AUPs must be made with direct consultation from an Institutional Veterinarian.

Pilot Study Reporting

A *Post-Pilot Study Report* from the PI must be submitted to the Institutional Veterinarian, who will then add their own evaluation. The veterinarian will forward the report to the ACC's Executive, which will deliberate re. feasibility of a full AUP submission. Recommendations will be relayed to the full ACC, e.g., model / procedural / monitoring refinements.

The Pilot Study Report must be appended to the Pilot AUP and subsequent Full AUP.

Stock vs Experimental Breeding Animal Use Protocols

General

Any breeding colony involving animal models with known phenotypes must be assigned a Category of Invasiveness (COI) commensurate with its degree of severity.

Any breeding colony involving the development of new animal models with unknown phenotypes must be assigned a Category of Invasiveness (COI) 'D' until such time that the phenotype has been clearly ascertained in conjunction with the veterinarian.

- Once confirmed by a veterinarian, the COI must be adjusted via Protocol Modification.

Stock Breeding AUPs

A distinct 'Stock Breeding' AUP must be established for animals bred to maintain the propagation of experimental animals for future generations of animals and focused upon breeding line maintenance only.

- Associated procedures will be limited to breeding, animal identification and genotyping.
- Stock Breeding Purpose of Animal Use (PAU) will be '0.'

Experimental Breeding AUPs

Breeding for the purpose of maintaining the colony may be included in the associated experimental AUP under the following conditions:

- the research question is focused upon gestation, parturition, or perinatal research, or
- the experimental purpose involves phenotyping (unknown phenotype = COI 'D'), or
- animals undergo no experimental procedure other than euthanasia.
 - For situations anticipated to change the animal welfare impact, e.g., aging animals, the ACC Chair will determine if a separate experimental AUP is most appropriate.

Special Animal Use Protocols - Temporary Animal Holding AUPs

Temporary animal holding AUPs must be held by the University Veterinarian and be maintained with an approved status for the ACC to respond to situations requiring its usage.

The temporary holding of animals under these AUPs must only be permitted when:

- an AUP Holder's AUP has been suspended ('on hold') by the ACC, or external regulatory body, or
- the AUP Holder's AUP has already undergone ACC review and has been 'Approved-Pending Clarification,' and where the inability to procure or hold animals would be detrimental to the animal-based science program;
 - in this instance only, a formal request with justification must be submitted by the AUP Holder and approved by the ACC, or
- other circumstances, as supported by the University Veterinarian and approved by the ACC Executive.

No animal-based science activities are permitted under these AUPs.

The status of animals on the holding AUP must be reviewed by the Executive every month.

Transfer of Animal Use Protocols

AUP transfer requests must be submitted via the AUP management system.

When transferring an AUP from one AUP Holder to another, each AUP Holder must be notified in advance of the transfer.

The ACC must pre-approve the transfer request prior to the transfer.

AUP Reporting Requirements

Regulatory information from AUPs must be sent annually to CCAC and OMAFRA using regulators' Animal Use Data Forms.

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

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
 - CCAC policy statement on: scientific merit and ethical review of animal-based research
 - University Senate MAPPs 7.12
 - 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 policy into three: AUPs (A), Annual Renewals (B), Modifications (C); Updates to policy statements: AUP Scope; Appeals, AUP Transfers, ACC Review Decisions, Collaborations, Merit Reviews, Pilots, Personnel on AUPs, Updates to References; Move essential definitions to Appendix; Update formatting; Remove Roles & Responsibilities | LT / LC / EB |

| | | | |
|----|----------|--|---|
| 03 | 10-11-20 | Add section – ‘Submission Delays for Continuing AUPs;’ update APP1 | LT |
| 04 | 14-04-22 | Add AUP purpose; Refine AUP Scope; Add animals required for counting; Add ACC Directed Evaluations criteria during AUP review; Add new section on Breeding vs. Experimental Stock, update Pilot Studies section; Clarify impacts of expired AUPS | LT, RG, RD, LH, LC, JM, JSN, EB, LC |
| 05 | 19-01-22 | Update AUP Scope & Breeding sections; Remove reference to ‘Closure Form’ | LT, LC, JM, BB, SK |

Glossary

For full terms and definitions, see the *AECP 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 Use Protocol (AUP) - The Animal Care Committee's (ACC) mandatory animal ethics form that contains details of a AUP holder'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) Review Working Group – A Working Group of the Animal Care Committee (ACC), per its Terms of Reference, consisting of six roles to include an Animal-Based Scientist, Community Representative, Institutional Veterinarian, Technical Representative, Non-Animal User, and the ACC Coordinator that undertake the reviews of AUPs on behalf of the Full ACC, as per the *Animal Use Protocols Policies* (POL-002 A-C) and *Procedures* (PROC-002 A-B) - [AECP Policies & Procedures](#)

Categories of Invasiveness – Levels of animal impact arising from experimental procedures, as outlined within Canadian Council on Animal Care's Categories of Invasiveness in Animal Experiments (1991) and Guidelines on the care and use of wildlife, Appendix D – CCAC Categories of Invasiveness for Wildlife Studies (2003), as follows:

- **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

On Hold – As determined by the Animal Care Committee (ACC) Executive on a case-by-case basis, actions taken to limit animal-based science activities in the short-term until associated Concerns have been resolved (see POL-004). Limited activities may include one or more of the following:

- Limiting animal-based science activities, including but not limited to:
- No new animal procurement
- No experimental procedures
- No breeding transfers out to research
- No animals leave animal facility for experiments
- Arms-length animal health professional/husbandry staff directly oversee animals

- Fee for related services paid for by the animal-based scientist
- Limiting access to animals by animal-based scientists and their staff, or a sub-set
- Animals may be transferred to the Temporary Animal Holding Animal Use Protocol (AUP), as per POL-002 Animal Use Protocols - AECP Policies & Procedures

Pilot Study – A study limited to the fewest number of animals necessary to evaluate the appropriateness, feasibility and suitability of a particular animal model, procedure, or study design to meet defined scientific objectives and to facilitate optimal animal welfare.

Exclusions

This **excludes** any work that is categorized as CCAC Category of Invasiveness ‘A;’ animal work for and/or by regulatory agencies for regulated monitoring of contaminants or disease, or to obtain abundance estimates or other population variables required for assessing and managing animal populations, e.g.:

- fish being counted at installations such as counting fences and traps, and fish being lethally sampled for regulatory purposes;
- bird banding overseen by the Canadian Bird Banding Council;
- population/abundance estimates; and
- animal work for environmental effects monitoring strategies or other environmental assessments, for example, to assess the health of fish at contaminated sites (this does not involve placing fish in potentially contaminated water to detect contaminants).
- animals held separately and exclusively for commercial purposes unrelated to science;
- service animals, unless the subject of research or involved in teaching;
- pets or display animals kept in offices or public areas, unrelated to teaching or research; and
- third-party, animal-based activities conducted on campus (e.g., e.g., dog or horse clubs using college facilities).⁵

⁵ CCAC Requirement for Submitting an Animal Use Protocol. Addendum to the CCAC policy statement on: terms of reference for animal care committees (2018).