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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 Renewals*, *AUP Modifications*, *Pilot Studies*, *Breeding Colonies*, and associated ACC review processes, see the Reference section below.

See Appendix 2 for exclusions to this policy.

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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*.

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Policy Statements

General

The holding of live animals and their use in research, teaching or testing projects must only take place following approval of the associated Animal Use Protocol (AUP) by Western's Animal Care Committee (ACC).

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, affiliate-appointed scientists, or an Institutional Veterinarian.

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

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

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¹ CCAC. Requirement for Submitting an Animal Use Protocol. Addendum to the CCAC policy statement on: terms of reference for animal care committees (2020). Retrieved 28MAR2024 from https://ccac.ca/Documents/Standards/Policies/Requirement_for_submitting_an_animal_protocol-ADDENDUM.pdf



Animal Use Protocol Scope

AUP form content must align with regulatory requirements, e.g., CCAC's Terms of Reference for Animal Care Committees (2006), 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 can understand.

Animal-based scientists and all personnel who will handle live animals must be disclosed and their animal-based activities specified within the AUP.

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

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 *Pilot Studies Policy* (POL-002-D)); and
 - breeding colonies (see *Breeding Colonies Policy* (POL-002-E)).
- *Exceptions may be considered by the ACC Chair.

As directed by the ACC Chair, a separate AUP must be submitted for:

- each distinct disease model, e.g., sepsis, diabetes; and/or
- 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.

Within each AUP a prospective estimate of animal numbers must be disclosed based on the following developmental stages:

- All born mammals capable of independent breathing,
- Hatched birds and reptiles capable of breathing,
- Fish larvae capable of independent feeding, and
- Amphibian larvae (tadpoles) capable of independent feeding.

Pilot studies must be undertaken in accordance with the *Pilot Studies Policy* (POL-002-D) – See *Glossary below*.

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 the *Multi-Jurisdictional Animal-Based Science Policy* (POL-015).

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Animal Use Protocol Review & Approval Determination

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).”²

Final AUP approval may only be granted following confirmation of question resolution, e.g., Institutional OHS, operational space, and other external reviews, e.g., Scientific or Pedagogical Merit.

AUP approval by the ACC is but one among other institutional approvals required prior to the initiation of animal-based work. All other required institutional / external approvals and mandated training must also be obtained prior to the start of any related study.

Reviews

New and Full Renewal AUPs require Full Review as described within the *AUP Review Processes for Principal Investigators* (GUID-002).

During the AUP review process, the reviewing Institutional Veterinarian must consider whether an Animal Welfare Assessment/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 ‘E;’ or
- Morbidity/mortality rate that exceeds standard expectations for this type of project or species.

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

- All AUPs receiving interim approval will be forwarded to the Full ACC for final review and approval.

The Full ACC must be informed at the next convened meeting of AUP submissions that were approved using the Delegated review procedures through attachments to the meeting package.

- At the request of an ACC member, a subsequent review will be undertaken.

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.

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.

² 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



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.

Disapproved – 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.

Closed – Full stoppage of a previously approved AUP by the ACC because it has expired, at the request of the AUP Holder, 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.

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

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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 initial approval month, and must undergo annual review (see the *Annual Renewals Policy* - POL-002-B) by the ACC.

- A maximum of three one-year Annual Renewals is permitted.
- A Full Renewal AUP must be submitted following Year 4 for projects requiring continuation (See below).
- For completed studies, the PI must notify the ACC via email or within the Annual Renewal form.

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 proposed changes to approved procedures must be submitted via AUP Modification as well as approved by the ACC before they take place (see the *AUP Modifications Policy* - POL-002-C).

AUP Holders must ensure that individuals listed in their AUP have full access to the currently approved AUP version, 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 associated with their AUP and any relevant SOPs.

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).

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Temporary Animal Holding AUPs

Temporary animal holding AUPs must be held by an Institutional 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 Chair, or
- other circumstances, as supported by an Institutional Veterinarian and approved by the ACC Chair.

The degree of animal-based science activities permitted will be determined by the ACC Chair.

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Transfer of Animal Use Protocols

AUP transfer requests must be submitted to the ACC (acc@uwo.ca).

Both parties – initial and subsequent AUP Holder – must be aware of the transfer before it is processed.

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AUP Reporting Requirements

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

Actual animal use numbers must be disclosed through reporting mechanisms provided by the institution, e.g., software system, and made readily available to those responsible to submit mandated annual reports to national and provincial regulators (see POL-003).

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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
 - CCAC policy statement on: scientific merit and ethical review of animal-based research (2013)
- University Senate MAPP 7.12
- Animal Care Committee policies and procedures
 - Animal Use Protocols – Annual Renewals (POL-002-B)
 - Animal Use Protocols – AUP Modifications (POL-002-C)
 - Animal Use Protocols – Pilot Studies (POL-002-D)
 - Animal Use Protocols – Breeding Colonies (POL-002-E)
 - AUP Review Processes for Principal Investigators (GUID-002)

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Revision History

Version	Date dd/mm/yyyy	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	08-10-2020	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	10-11-2020	Add section – ‘Submission Delays for Continuing AUPs;’ update APP1	LT
04	14-04-2022	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	19-01-2022	Update AUP Scope & Breeding sections; Remove reference to ‘Closure Form’	LT, LC, JM, BB, SK
06	11-07-2024	Remove procedural, Pilot Study and Breeding AUP elements (relocated in other docs). Update animal number disclosure requirements; approval requirements.	LT, LC, JM

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

Delegated Review – The review process followed by the Animal Care Committee (ACC) whereby reviews and approvals may be performed electronically and can generally involve a subset of ACC members with applicable expertise. AUP forms eligible for Delegated Review include Annual Renewals (see POL-002-B) and Minor AUP Modifications (see POL-002-C). For details see ‘AUP Form Review Processes for Principal Investigators’ (GUID-002).

Full Review - Review of Animal Use Protocol (AUP) forms – a combination of pre-meeting online review via the ACC’s AUP management system, face-to-face meeting discussions and approval determination, and post-meeting final review and approval, as needed - by either the full ACC or an AUP Review Working Group, as per the AUP Form Review Processes for Principal Investigators (GUID-002)

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 - AECF Policies & Procedures

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.



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).³

³ CCAC Requirement for Submitting an Animal Use Protocol. Addendum to the CCAC policy statement on: terms of reference for animal care committees (2018).