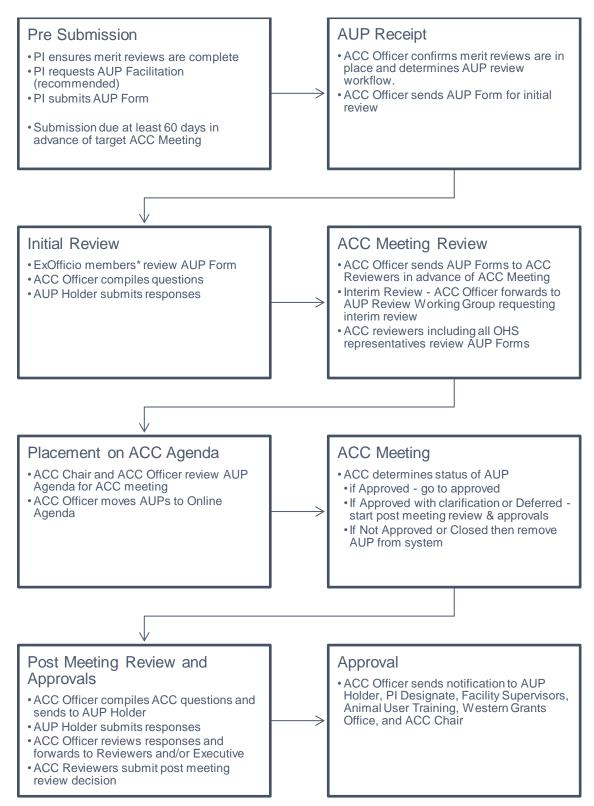


Procedures for Animal Use Protocol Reviews

APP1-Full ACC Review Flow Chart



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PROC-002-A-02 Approved: 08OCT2020 Effective:



APP 2 - AUP Closure Form

Within one month of closure of an AUP, AUP Holders are asked to submit this form to the ACC (acc@uwo.ca).

- 1. PI Name: Click or tap here to enter text.
- 2. AUP Number: Click or tap here to enter text.
- 3. AUP Title: Click or tap here to enter text.
- 4. Species: Click or tap here to enter text.
- 5. Total Animals Used That
 - a. reached experimental endpoint: Click or tap here to enter text.
 - b. met an early euthanasia endpoint: Click or tap here to enter text.
- 6. Animal Disposition Please outline the disposition of animals at AUP closure, e.g., euthanized, transferred to other AUP, adoption: Click or tap here to enter text.
 - a. If transferred to other AUP, provide AUP # & PI name, as applicable: Click or tap here to enter text.
- 7. AUP Closure Date (last day of live-animal use): Click or tap here to enter text.
- 8. Provide a brief update on the progress made throughout the life of the AUP in achieving the specific aims identified within the AUP: Click or tap here to enter text.
- 9. Provide an update on progress made throughout this project with respect to 3Rs alignment:
 - a. **Replacement** Outline the methods and/or animal alternatives considered and/or used to avoid or replace the use of animals: Click or tap here to enter text.
 - b. **Refinement** Outline refinements to procedures that were considered and/or implemented: Click or tap here to enter text.
 - c. **Reduction** Outline how you were able to reduce your animal numbers usage: Click or tap here to enter text.

Western Research

Animal Care Committee

Procedures for Animal Use Protocol Reviews
Full ACC Review

I. AUP Preparations and Submission

- 1) The AUP Holder will, (recommended in advance of AUP submission to the ACC Office),
 - a) request the AUP Facilitation Service to help in the preparation of their AUP prior to submission to the ACC Office (acc@uwo.ca);
 - i. this service is also available for Protocol Modification forms.
 - b) outreach to the associated Facility Supervisor to discuss animal housing and husbandry requirements;
 - c) for hazards, obtain institutional OHS approval for use of hazards within animal-based science;
 - d) ensure merit review (Scientific or Pedagogical) has been undertaken and approved; and
 - e) for Continuing AUPs following a Pilot Study, separately submit to the ACC Office via email (acc@uwo.ca) the required report, per the Policy (POL-002);
- 2) and then will, send the AUP via the online system 60 days in advance of the target full ACC Meeting, which takes place on the second Thursday of every month. (This timeframe facilitates an initial round of targeted ACC reviewer feedback to the PI in advance of full ACC review).
 - a) In instances where the AUP Holder requires an expedited Interim Review, the AUP Holder will submit a request in writing to the ACC Executive outlining the rationale.
 - b) The Executive will review the request and relay its decision to the AUP Holder and the ACC Officer.
- 3) The Institutional Veterinarian will, for Pilot Studies, submit via email to the ACC Office the required Pilot reports, per the Policy (POL-002-A).

II. AUP Receipt

- 4) The ACC Officer will
 - a) receive all AUP forms via the online AUP software system; and
 - b) assess the AUP for completeness, including at minimum ensuring scientific or pedagogical merit is in place.
 - o if significantly incomplete, return the AUP form to the AUP Holder via the online system and inform the AUP Holder via email.

III. Initial Review

- 5) The ACC Officer will within two days of form receipt, forward the form to ex officio ACC members requesting review, as appropriate.
- 6) Ex officio ACC members will within one week of form receipt, review and return the AUP to the ACC Officer
- 7) The ACC Officer will within one week of form receipt, combine reviews, including their own, in the online system, and forward questions to the AUP Holder requesting feedback within one week.



Procedures for Animal Use Protocol Reviews
Full ACC Review

- 8) The AUP Holder will within one week of form receipt, update the form in response to pre-meeting review questions and/or comments and return the AUP to the ACC Office via the online system.
- 9) The ACC Officer will return to the AUP Holder forms requiring further refinement.
 - a) for Category of Invasiveness Level 'E' AUPs and those involving sensitive species (cats, dogs, pigs, NHPs), forward the AUP to the Executive requesting 3Rs review.
- 10) The AUP Holder will refine the form.
 - a) This process will be repeated until the form is sufficiently ready for submission to the full ACC.
 - b) Ex officio members may be involved in subsequent initial review.
- 11) *The Executive will,* for Category of Invasiveness Level 'E' AUPs and those involving sensitive species (cats, dogs, pigs, NHPs), provide feedback to the AUP Holder with respect to 3Rs alignment.

IV. Interim Review

- The ACC Officer will, as directed by the ACC Chair or other ACC leader for rare instances involving an
 expedited review and interim approval, forward the AUP to the AUP Review Working Group
 requesting initial review.
 - a) The Delegated Review process will be followed to the point of approval determination.
- 2) Following completion of delegated review by the AUP Review Working Group, the ACC Officer will forward the AUP to an upcoming ACC Meeting (Section V).

V. ACC Meeting Review

- 3) The ACC Officer will:
 - a) at least seven days prior to each meeting, forward AUPs to all ACC Members via the online system requesting review, and indicate the review submission deadline; and
 - b) appoint two ACC members to each AUP to act as primary Presenters and Reviewers (at least one having a strong science background) for each AUP.
- 4) ACC Reviewers will perform a thorough review including animal ethics, form completion and readability.
- 5) Ex officio ACC members will assess AUP form changes to confirm that their feedback has been addressed, and indicate approval recommendation, or request to review post-meeting.

VI. ACC Meeting AUP Agenda Finalization

- 6) The ACC Chair or Designee and ACC Officer will:
- a) determine the AUPs assigned to the Agenda for the upcoming ACC Meeting;
- b) at least two days prior to the meeting, post all AUPs under review to the online agenda; and
- c) post to the online Agenda a list of all AUPs approved via Delegated Review during the month leading up to each meeting.



Procedures for Animal Use Protocol Reviews
Full ACC Review

VII. ACC Meeting

- 7) The Presenter for each AUP under review will:
- a) present a high-level AUP summary;
- b) identify outstanding issues requiring discussion; and
- c) recommend one of four meeting approval options (see next section);
 - if this individual is unavailable during the meeting, the Presenter will pre-arrange with the Assigned Reviewer, or during the meeting persons in attendance will be solicited for this role;
- 8) The ACC Chair will lead a discussion opportunity for attending ACC members to come to consensus;
- 9) The ACC will come to consensus regarding the approval status of each AUP (See next Section ACC Decisions); and
- 10) *The ACC Officer will* record discussion elements involving clarification requests and other directives within meeting minutes.

VIII. ACC Decisions

- 11) Through consensus-driven decision-making and in consideration of the 'ACC Review Decisions' (see the Policy), the ACC will assign one of the following statuses to each AUP, Modification, Annual Renewal form under review:
 - **a. Approved** The ACC Officer will forward an approval notification to the AUP Holder and related Facility Supervisors.

b. Approved Pending Clarification

- i. The ACC Officer will within one week forward all questions generated by ACC Meeting Review and during the ACC Meeting to the AUP Holder via the online system requesting revision and/or comment.
- ii. The AUP Holder will within one week update the AUP in response to ACC review feedback and return it to the ACC Office via the online system.
- iii. The ACC Officer will within one week forward the revised AUP to reviewers who requested to act as post-meeting reviewers.
- iv. Reviewers will within one week assess AUP form changes to confirm that their feedback has been addressed, and indicate approval or additional questions for AUP Holder.
- v. This process will be repeated until all concerns are resolved; if not readily resolved, the ACC Officer will forward the AUP to the ACC Executive requesting direction.
- vi. Once all reviewer concerns are resolved, proceed to f. Final Approval.



Procedures for Animal Use Protocol Reviews Full ACC Review

c. Deferred

- The ACC or its Executive will determine next steps, e.g., require an AUP facilitation, and/or forward ACC questions directly to the AUP Holder, and/or other actions as determined by the ACC.
- ii. The ACC Chair or designee will notify the AUP Holder of the AUP status.
- iii. The ACC Officer will follow ACC directives with respect to forwarding the AUP to the AUP Holder, and/or organizing an AUP Facilitation.
- iv. The AUP Holder will follow ACC directives, e.g. AUP Facilitation and updates to the AUP and return it to the ACC Office via the online system.
- v. The ACC Officer will assign the AUP to the next available ACC Executive meeting.
- vi. As determined by the Executive assign the AUP to full ACC Meeting Review (Sect. IV).

d. Not Approved

- i. The ACC Chair will notify the AUP Holder of the AUP status, and request that the AUP be Closed, per the Policy (POL-002).
- ii. The ACC Officer will 'Close' the AUP in the online system.
 - e. **Closed -** The ACC Executive will notify the Full ACC of sanctions arising from Non-Compliance, per the Concerns Policy (POL-004). A full new AUP will be required.
 - f. *Final Approval* Once final ACC approval is received, *the ACC Officer will* ensure all required external approvals are in place, and once confirmed, approve the AUP within the online system, which sends an automatic approval email to the AUP Holder, *and will* forward the approval notification to Institutional Animal User Trainers, Facility Supervisors, Research Development Services Grants Office, and the ACC Chair.

Revision History

Version	Date	Description of Changes	Author
00	07-10-17	New procedure	LC/LT
01	09-08-18	Remove definitions; Simplify review process to 'full' and 'Delegated'; update external reviews to incorporate new merit review policies and procedures; add process for expiring AUPs	LT/LC
02	08-10-20	Reformat; Divide into two distinct procedures docs – PROC-002-A-Full ACC Review, and PROC-002-B-Delegated Review; Move definitions & reminder details into the Policy; Add a flow chart	LT/LC/EB