Procedures for Animal Use Protocols

Procedure Number: PROC-002

Version Number: 01

Category: Administration

Subject: Procedures for the submission, review and approval of Animal Use Protocols associated with the animal-based science program within Western's research community

Approving Authority: Animal Care Committee

Responsible Office: Animal Care Committee Office

Related Policy: Animal Use Protocols (POL-002)

Approval Date: August 9, 2018

Effective Date: November 1, 2018

Revised: October 8, 2015

Animal Use Protocol Formal Review Process

AUP Facilitation Service, AUP Full/Annual Renewal Reminders and Systems Access Set-Up

The Animal Care Committee (ACC) Coordinator and Institutional Veterinarian will set aside times within their work calendars to provide AUP Facilitations for Principal Investigators (PIs) requesting this service in advance of Animal Use Protocol (AUP) submission.

The ACC Coordinator or designate will
- Send at least two emails or phone reminders to PIs with approved AUPs that are nearing their expiry or annual approval date to remind them to submit their Full or Annual Protocol Renewal form to the ACC,
- Email all PIs who have communicated their intention to submit a new AUP to offer an AUP facilitation in advance of formal AUP submission

The Principal Investigator will
- If desired or as requested by the ACC, request an AUP Facilitation via auspc@uwo.ca

The ACVS Systems & Communications Coordinator will
- Support PIs and their designates in obtaining all required access to the eSirius Animal Use Protocol Management system
- Offer and provide training on navigating the eSirius system to ACC members, PIs and their approved designates

AUP Submission and Form Workflow Assessment

The Principal Investigator will
- Submit the Animal Use Protocol, Annual Renewal or Protocol Modification form to the ACC via the eSirius Protocol Management system
    - Submission may take place following the AUP Facilitation (see above)

The ACC Coordinator or designate will
- Review form content and determine one of the following review workflows:
    - Full Review
    - Designated Review
- Return an AUP that is either missing substantial details, or requires significant revision to the PI within eSirius requesting updates prior to resubmission
    - Significantly incomplete AUPs will not be forwarded to the ACC until completed.
- Any AUP with an 'unfinished' or 'pending' status having a workflow date beyond six months will be removed from the eSirius AUP management system, unless otherwise directed by the ACC Chair.

AUP Review Processes

Full Review for Full Animal Use Protocols (see APP1 AUP Full Review flow chart)

The ACC Office receives full AUPs up to and including the first day of the month preceding the target full ACC Meeting, which normally take place on the second Thursday of every month. Please note that Researchers are encouraged to take advantage of the AUP Facilitation Service to help in the preparation of their AUP prior to submission to the ACC Office

- ***AUP Receipt -*** AUP is received by the ACC Coordinator via eSirius

- ***AUP Pre-Meeting Initial Assessment -*** ACC Coordinator performs a preliminary review of the AUP for completeness
    - If significantly incomplete, the ACC Coordinator returns the AUP form to the PI via eSirius and informs the PI via email or telephone

- ***AUP Pre-Meeting Review -*** At least seven days prior to each meeting, the ACC Coordinator forwards AUPs to all ACC Members via eSirius requesting pre-meeting review. The following have specified roles in the review process
    - Two ACC members are appointed to each AUP to act as primary Presenters and Reviewers (at least one having a strong science background) for each AUP, who will be responsible to:
        - Perform a thorough review – in addition to animal ethics, form completion and readability will be assessed;
        - The Presenter presents the AUP content and review details during the associated ACC monthly meeting.

- In the event that this individual is unavailable during the meeting, the Presenter will pre-arrange with the Primary Reviewer to assume this responsibility.
- In the event that both the Presenter and Primary Reviewer are unavailable for the scheduled meeting, the Institutional Veterinarian involved in pre-meeting review will assume the Presenter role.
    - If unavailable, persons in attendance at the meeting will be solicited for this role.
- o Animal User Trainer for Training Requirements assessment
- o Animal Care (AC) Facility Supervisors for husbandry- and facility-specific elements
- o Communications Coordinator for lay summary assessment (for media relations purposes)
- o For other external reviews, see External Reviews Process below.

- *ACC Reviewer Submission -* All reviews are due from assigned ACC Members by the date specified at the time of AUP distribution.

- *ACC Meeting Agenda Finalization -* Agenda for ACC Meeting is finalized and all AUPs and related documentation are posted to the eSirius online agenda by the ACC Office at least two days prior to the meeting.

- *ACC Meeting*
    - o The Presenter for the AUP will be responsible during the ACC meeting to:
        - Present a brief AUP summary;
        - Highlight key Reviewer questions;
        - Identify outstanding issues; and
        - Recommend one of four meeting approval options (see Post- Meeting Review & Approval below):
    - o The ACC Chair will lead a discussion opportunity for attending ACC members to come to consensus;
    - o ACC members will come to consensus; and
    - o The ACC Coordinator will record discussion elements involving clarification requests and other directives within meeting minutes.

- *Post-Meeting Review*
    - o *AUP is Approved -* The ACC Coordinator forwards an approval notification to the PI, PI Designates and related AC Facility Supervisors
    - o *AUP is Approved Pending Clarification -* All questions generated by ACC review (including external reviews, as available) and during the ACC Meeting are compiled and forwarded by the ACC Coordinator to the PI via eSirius for clarification and comment. Once answers are received from the PI, the AUP is returned to reviewers who requested to view the clarifications.
    - o *AUP is Tabled –* The ACC or its Executive determines next steps:
        - a. require an AUP facilitation, and/or
        - b. forward ACC questions directly to PI, and/or
        - c. other actions as determined by the ACC

The ACC Chair notifies the PI of ACC requirements (auschair@uwo.ca). The ACC Coordinator follows the ACC directive, as per steps above. Once the PI has updated the AUP, the Coordinator forwards the AUP to the ACC for review.

- o *AUP is Not Approved* - The ACC Coordinator will request direction from the ACC.

- **Final Approval -** Once final approval is received, an approval notification is forwarded to the PI, Animal User Trainers, AC Facility Supervisors, Research Development Services Grants Office, and the ACC Chair.

Designated Review (see APP2 AUP Designated Review flow chart)

Review

- Upon receipt, the ACC Coordinator or designate
    - o performs a preliminary review of the form for completeness
    - o forwards the form via eSirius to the ACC Reviewer Working Group requesting review within 5 business days
- Reviewers submit their review questions and comments through eSirius Review fields to the ACC Coordinator
    - o If ACC reviewers deem the form not ready for designated review, the form is returned to the PI for further clarification.
- Working Group reviewers assess the form, and determine its approval status

Post-Review Follow-Up

- If 'Approved,'
    - o The ACC Coordinator or designate notifies the PI of the approval. The form will now have ethical approval and may require other external approvals before animal work can begin (See External Reviews Process below).
- If 'Approved Pending Clarification'
    - o The ACC Coordinator forwards the outstanding concerns/questions to the PI.
    - o The PI updates and then forwards the form back to the ACC via eSirius.
    - o Upon receipt of the PI's responses, the reviewers either approve the clarifications
    - o The ACC Coordinator or designate sends approval notice to the PI, or if the first response was not sufficient, returns the AUP to the PI for further clarification.
    - o Once approved, the form will now have ethical approval and may require other external approvals before animal work can begin (see External Reviews Process below)
- If 'To be sent for Full Review,'
    - o The ACC Coordinator or designate forwards the AUP through the Full Review Workflow.

Final Approval

- Once final approval is received, an approval notification is forwarded to the PI, PI Designates, Animal User Trainers and/or related AC Facility Supervisors, as required.
- For Annual Renewals approval is granted on the AUP's annual renewal date.

External Reviews Process

- Following or concurrent with ethics review of an AUP form, the ACC Coordinator will assess, depending on the institutions involved and other AUP content, which external reviewers are required to give approval before animal work may begin.
- The ACC Coordinator sends AUPs to external reviewers for non-ethics review, as appropriate:
  - All merit reviews will be routed through the Merit Review Committee,
    - Scientific Peer Review as per Scientific Merit Review Policy (POL-013) and using forms within Scientific Merit Review Procedures (PROC-013)
    - Pedagogical Merit Review as per Pedagogical Merit Review Policy (POL-014) using forms within Pedagogical Merit Review Procedures (PROC-014)
  - Occupational Health & Safety (OH&S) Review

Expiring Animal Use Protocols (See APP3-Process for Expiring AUPs)

Six and four months in advance of AUP expiry date
- The ACC Coordinator sends email reminder notifications to PI
- Requested submission date is 10 weeks prior to AUP expiry

Three months prior to requested submission date (~12 weeks prior to AUP expiry)
- The ACC Coordinator notifies the ACC Chair of AUPs that have not communicated Full Renewal intention with ACC Office
- ACC Chair to follow up with PI, including ACC Chair email describing potential impacts, and AUP facilitation service deadline

Two months prior to AUP expiry (Two weeks prior to the ACC meeting held during the month before the expiry date)
- The ACC Coordinator notifies the ACC Chair of any AUPs not received and those received but delayed within the full review process and due to expire
- The ACC Coordinator adds to next ACC Executive meeting Agenda

Between two and one month(s) prior to AUP expiry
- ACC Executive develops action plan
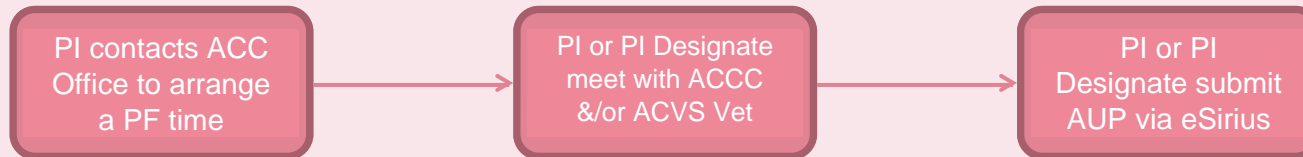- ACC Chair emails PI, AC Facility Supervisor action plan

At AUP expiry date
- Actions are taken as per ACC plan developed previously
- The ACC Chair notifies the AC Facility Supervisor
- As directed, AC Facility Supervisor updates cage cards, e.g. transfer to ACC's Holding AUP
- The ACC Coordinator informs Research Development Services Grants Office
- The ACC Coordinator completes and submits to the ACC Executive a Concern Report as per the *Concerns Identification, Project Refinement, and Corrective Response Policy* (POL-004)

Revision History

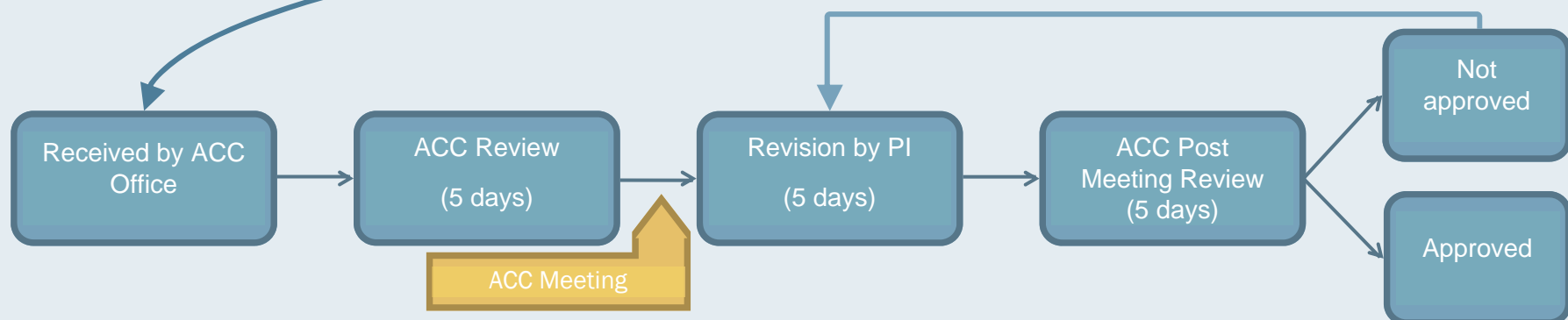| Version	Date	Description of Changes	Author
00	07-10-17	New procedure	LC/LT
01	09-08-18	Remove definitions; Simplify review process to 'full' and 'designated'; update external reviews to incorporate new merit review policies and procedures; add process for expiring AUPs	LT/LC

Animal Care Committee
APP1-AUP Full Review Process Flow Chart
Procedure for Animal Use Protocols
PROC-002
Approval Date: 09AUG2018
Effective Date: 01NOV2018

Step 1: AUP Facilitation (optional) & Form Submission

PI contacts ACC Office to arrange a PF time → PI or PI Designate meet with ACCC &/or ACVS Vet → PI or PI Designate submit AUP via eSirius

Step 2: ACC Office Review

Received by ACC Office → Administrative Review (2 days) → Revision by PI (5 days)
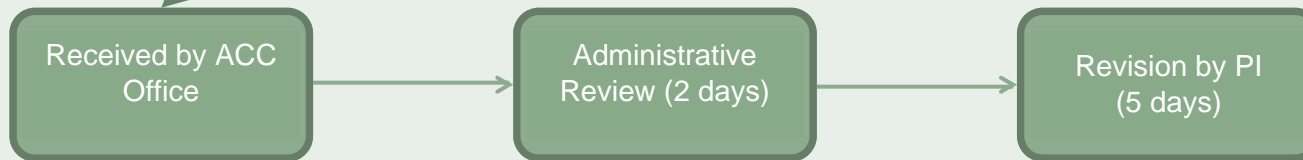
Step 3: ACC Committee Review

Received by ACC Office → ACC Review (5 days) → Revision by PI (5 days) → ACC Post Meeting Review (5 days) → Not approved / Approved

ACC Meeting

Animal Care Committee
APP2-AUP Designated Review Process
Procedure for Animal Use Protocols
PROC-002
Approval Date: 09AUG2018
Effective Date: 01NOV2018

Step 1: AUP Facilitation (optional) & Form Submission

PI contacts ACC Office to arrange a PF time → PI or PI Designate meet with ACCC &/or ACVS Vet → PI or PI Designate submit AUP via eSirius

Step 2: ACC Office Review

Received by ACC Office → Administrative Review (2 days) → Revision by PI (5 days)

Step 3: AUP Review Working Group (WG)

Received by ACC Office → WG Review (5 days) → Revision by PI (5 days) → WG Review (if needed) (5 days) → Not approved / Approved

As requested by WG member To Full ACC

Animal Care Committee
APP3-Process for Expiring Animal Use Protocols
Procedure for Animal Use Protocols
PROC-002
Approval Date: 09AUG2018
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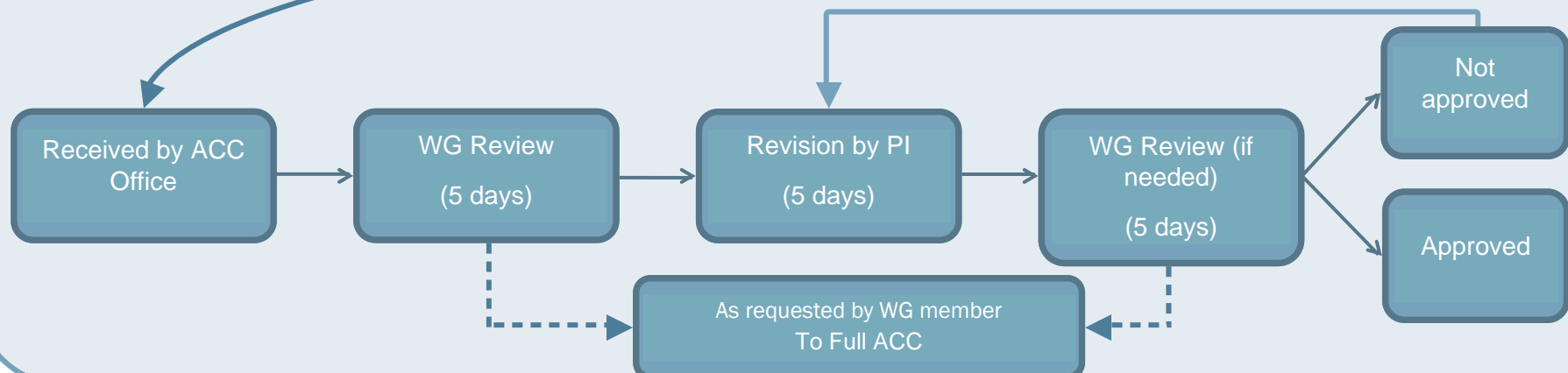
6 and 4 months in advance of expiry date

- Email reminder notifications sent to PI from ACC Office
- Requested submission is 10 weeks prior to Expiry

3 months prior to AUP expiry

- ACC Chair notified of AUPs that have not communicated Full Renewal intention with ACC Office
- ACC Chair to follow up with PI re. potential impacts & AUP facilitation

2 months prior to AUP expiry

- ACC Chair notified of AUPs not received/received initially but delayed in review
- ACC Coordinator adds to next ACC Executive meeting Agenda

Between 2 & 1 month prior to expiry

- ACC Executive develops action plan
- ACC Chair emails PI, AC Facility Supervisor action plan details

Expiry Date

- Action as per ACC plan developed previously
- AC Facility Supervisor notified and cages labelled accordingly
- RDS notified
- ACC Coordinator submits Concern report to ACC Executive