Goal

The goal of the post approval monitoring (PAM) program is to collaboratively and collegially ensure that animal-based work at Western and affiliated institutions aligns with approved *Animal Use Protocol* elements and conforms to all regulatory and institutional requirements.

Mandate

The Canadian Council on Animal Care (CCAC) requires that institutional animal care committees assume ownership for the creation and execution of a post-approval monitoring policy that defines associated roles and responsibilities, and establishes appropriate procedures to address non-compliance response.

Non-Compliance Response Defined

Non-compliance is defined as either procedural or ethical in nature. Procedural non-compliance refers to outstanding administrative and training requirements, as well as animal procedures that produce limited distress or pain requiring correction. (For a complete definition, link to Procedural Non-Compliance.) Ethical non-compliance refers to animal procedures causing pain or distress not pre-approved in the *Animal Use Protocol* that require immediate intervention to alleviate animal distress. (For a complete definition, link to Ethical Non-Compliance.) If the distinction between procedural and ethical non-compliance is unclear, the Protocol Support Veterinarian (PS Vet) will consult with the Animal Care and Veterinary Services (ACVS) Director to determine the appropriate process.

Roles & Responsibilities

PAM Sources - Post approval monitoring (PAM) relies upon information from a variety of sources, listed below. For detailed roles and responsibilities associated with each source, click on the associated links:
1. Animal Health Program
2. AUS Site Visits
3. Veterinary Rounds
4. Compliance Officers
5. Facility Managers
6. Ad Hoc Veterinary Visits
7. AUS Administrative Officers
8. ACVS Research Education Trainers
9. Regulatory Site Visits
10. Non-Arms-Length Managed Areas - Annual Certification

Post Approval Monitoring Office - *Protocol Support Vet & Protocol Support RLAT*
(Registered Lab Animal Technician) – To ensure response appropriateness and consistency across the city, PAM response is centralized through the PAM office. The PS Vet, under the leadership of the ACVS Director, is directly accountable in this role to the Animal Use Subcommittee (AUS). PAM sources forward post approval monitoring information to the PS Vet / PS RLAT.

AUS PI Rep - To facilitate first-level collegial resolution, the PS Vet/PS RLAT works collaboratively throughout the process with AUS PI Reps, (if one is available). AUS PI Reps are animal user faculty members who act as peer liaisons between the animal users within their departments/areas and the AUS.

Non-Compliance Response Processes

While unique processes exist for procedural and ethical non-compliance response, both processes are intended to be undertaken in a collaborative and collegial manner that is supportive of animal-based research while ensuring appropriate and timely issue resolution. In accordance with CCAC requirements, non-compliance issues will be suitably documented and reported to the AUS by the PS Vet. Link to non-compliance response flow charts for detail.

Procedural Non-Compliance Response Overview

*Step 1 – Collaborative Issue Resolution -*The PS Vet / PS RLAT and/or the associated AUS PI Rep contact the Principal Investigator (PI) involved in procedural non-compliance, and undertake to inform and support timely issue-appropriate resolution. This collaborative process may be repeated at the discretion of PS Vet, AUS PI Rep, and/or AUS Chair / Chair designate, and may involve the following elements:

I.   ***Protocol Drift –*** Due to its very nature, research may become unintentionally divergent from the original *Animal Use Protocol (AUP)* resulting in protocol drift. Issues identified as involving protocol drift require *Protocol Modification* form submission that updates the *Animal Use Protocol*; otherwise, the research laboratory must realign with the previously approved elements.

II.   ***Outstanding AUP Form and Institutional Animal User Training–*** AUS administrators and Research Education Trainers will follow the notification processes outlined within issue specific documents entitled, *Procedural Non-Compliance – Administrative –*
   o   *Institutional Animal User Training*
   o   *Animal Use Exceeds Authorized*
   o   *Annual Renewals*
   o   *Full Renewals*

III.   ***Animal Procedural and Records Adjustments –*** For issues involving animal procedures that produce limited distress or pain requiring correction, and/or inadequate animal

records, ACVS veterinarians will work with the PI/animal users to facilitate the appropriate procedural/record-keeping adjustments.

Step 2 – AUS Issue Resolution Meeting – All procedural non-compliance issues not resolved through Step 1 will be forwarded to the AUS Chair or designate, who will request a meeting to discuss issue resolution with the PI/animal user involving the ACVS Director, PS Vet, and associated AUS PI Rep.

Step 3 – Full AUS and/or ACGSC Meeting - All procedural non-compliance issues not resolved through Step 2 will be referred to the full AUS, and/or the University Council on Animal Care (UCAC) working group, the Animal Care Governance Steering Committee (ACGSC).

Ethical Non-Compliance Response Overview

Step 1 – Communication & Immediate Intervention
   I.   Once an ethical non-compliance issue is confirmed, the PS Vet will attempt to contact the PI/animal user, AUS Chair, ACVS Director and AUS PI Rep before beginning any intervening process not previously agreed upon.
  II.   In the event that immediate euthanasia is the only appropriate intervention, and contacting an ACVS veterinarian would cause undue delay, the associated Facility Manager/Compliance Officer may provide humane euthanasia.
 III.   The PS Vet will work with the ACVS team and associated facility management to resolve the situation using one or more of the following responses:
   a. PI/animal user will be requested to immediately stop objectionable procedure(s);
   b. Response team member(s) will immediately provide appropriate therapy and relief;
   c. If pain or distress cannot be alleviated, team member(s) will ensure humane euthanasia of animal(s);
   d. If serious threat to health and safety of personnel is suspected, the PS Vet will contact the appropriate institutional OH&S.
  IV.   Facility management/ACVS staff involved in the response will provide the PS Vet with:
   a. Verbal/written action confirmation **within 1 business day;**
   b. Written report to PS Vet detailing actions taken **within 5 business days.**

Step 2 – Unresolved Issue: Communication, 'On Hold' Process Implementation & Resolution Meeting
   I.   The PS Vet will inform the AUS Chair, ACVS Director, AUS PI Rep, and the Dean/Director of the PI's/animal user's research institute;
  II.   The PS Vet will request that the:
   a. AUS Administrative Officer places the *Animal Use Protocol* 'On Hold';

    b.   Associated Facility Manager ensures no animal ordering and no animal use will be undertaken by the PI/animal user within the facility;

III.   The AUS Chair/designate will convene a meeting with the ACVS Director, PS Vet, and AUS PI Rep within 2 business days. The PS Vet will document meeting content;

IV.   The AUS Chair or designate will convey meeting outcomes to the PI/animal user.

Step 3 – Unresolved Issue: Appeal to AUS

I.   The PI will be invited by the AUS Chair to explain the rationale to the AUS during an interim committee meeting convened for this purpose;

II.   The *Animal Use Protocol* will remain 'on hold' until the ethical issue has been resolved, or until the AUS determines the appropriate recourse;

III.   Senior administration will be informed of meeting results.

Step 4 – Unresolved Issue: Senior Institutional Administration

Unresolved or persistent breaches of compliance or threats to the health and safety of personnel or animals that cannot be promptly corrected by the AUS working with concerned animal users and ACVS veterinarians will be referred to institutional senior administration for resolution: the Animal Care Governance Steering Committee, and the University Council on Animal Care.

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CCAC PAM Policies

CCAC's Post Approval Monitoring Policy – According to the *Terms of Reference of the Canadian Council on Animal Care* (CCAC):

> Each institution must establish procedures for post-approval monitoring of animal use protocols, and must define the roles and responsibilities of the members of the animal care and use program in the monitoring process…the committee must work with the members of the veterinary and animal care staff to ensure compliance with its decisions and with the conditions set out in approved protocols.[1]

CCAC's Non-Compliance Response Policy - According to the CCAC, the Animal Use Subcommittee (AUS) is responsible, "*… for determining and working to correct breaches of compliance with approved animal use protocols and SOPs... in a collegial manner with the animal users and attempt to correct deficiencies collaboratively.*"[2] In the event that the AUS is unable to correct breaches of compliance in conjunction with concerned animal users and veterinary and animal care staff, senior administration must become involved in the resolution process.

Procedural Non-Compliance

Procedural - Administrative

I. Protocol Modification Submission Required
- *Protocol Drift:* Procedure is not covered by, or deviates from an approved protocol; however, procedures performed have no negative animal impact (May involve Item IV. below);
- *Animal Use Exceeds Authorized Numbers*;
- *Expired Protocol Involving Continued Animal Use* - Annual & Full Renewals;

II. Inadequate Animal Records, e.g. room-level animal procedure logs
III. Outstanding Personnel CCAC-mandated Animal Training

Procedural – Limited Animal Impact

IV. Animal Procedural Adjustment That May Require Protocol Modification Submission

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[1] Canadian Council on Animal Care. Terms of Reference for Animal Care Committees. P.4
[2] Canadian Council on Animal Care. Terms of Reference for Animal Care Committees. P. 3-4

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- Animal procedures that produce limited distress or pain requiring correction – due to inaccurate or ineffective analgesics, anesthetics, euthanasia methods, or other animal procedures, e.g. extra injections, or inappropriate anesthesia regimes.
- May involve protocol drift, which requires *Protocol Modification* form submission (See Item I.)

Ethical Non-Compliance

- Animal procedure causing pain or distress not pre-approved in the *Animal Use Protocol* and requiring immediate ACVS veterinarian or designate intervention;
- Serious threats to the health and safety of personnel or animals.

Post-Approval Monitoring Sources

1. Animal Health Program

- A standardized approach to sick animal reporting undertaken by Facility Managers and staff. Where no Facility Manager exists (Thames Hall, Huron, etc.) this will be performed by research staff;
- *Record-Keeping:* A sick animal/mortality log, maintained in each animal holding facility, will contain:
  - o Animal identification by PI, protocol #;
  - o Date, nature of condition, and any action (including treatments) ;
  - o Indication of ACVS notification;
- Log will be inspected by ACVS veterinarians and AUS during their visits;
- ACVS veterinarians will respond when notified, and will make notation in the log;
- Facility Managers will include information from the log in their monthly reports to ACVS;
- Those involved in sick animal response - facility management and their staff, registered veterinary technicians, veterinarians – will inform the PAM office of ethical or procedural non-compliance.

2. AUS Site Visits

- CCAC Terms of Reference requires formal AUS site visits by AUS member teams to all sites where live animals are used;
  - o Minimum one visit per year per area;
- CCAC's Purpose for Animal Care Committee Site Visits:

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To better understand work being conducted…meet with those working in animal facilities and ...areas and discuss their needs, to monitor animal-based work according to approved protocols & SOPs; to assess any weaknesses in the facilities, and to forward… recommendations or commendations to the person(s) responsible for the facilities and for animal use.[3]

- Every AUS member is expected to participate in 2- 3 visits per year;
- *AUS Site Visit Reports* - Site visit reports will be regularly produced and presented to AUS by the PS Vet;
- Written response will be required from those responsible for animal areas;
- Site visit reports should be jointly followed up by senior administration and the AUS;

AUS Site Visit Process Detail:

- The PS RLAT will coordinate AUS Site Visits as follows:
  - o Contact Site Supervisor and/or Facility Manager in advance;
  - o Contact PIs in advance as required to organize their research staff's attendance at the labs being visited;
  - o Arrange required AUS members and provide them with the necessary documentation
  - o In Conventional facilities, groups will ideally consist of the AUS Chair or Vice-Chair or ACVS Director; the AUS PI Rep for the site being visited; the PS Vet or other ACVS veterinarian; another member of the AUS who is a scientist; and a community member;
  - o Due to entrance requirements, visits to barrier units will be composed of fewer individuals;
  - o Documentation may include past CCAC, OMAFRA, Veterinary Rounds, and AUS Site Visits, as well as summaries of *Animal Use Protocols* undertaken at the site being visited;
- The PS Vet or other ACVS veterinarian will prepare a draft report for team members to review then circulate the final report to the AUS, ACVS Director, Facility Manager, senior administration responsible for the facility, and will notify PIs directly of the component of the report that pertains to them.

3. Veterinary Rounds

- The primary objectives are to seek to understand the work being conducted; meet with those working in research in order to support research by maintaining an open dialogue with animal users; seek to understand research at the lab level or in the case of field studies, in their natural habitat; offer animal procedure/drug administration refinements.

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[3] Canadian Council on Animal Care. Terms of Reference for Animal Care Committees. P.11

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1. Laboratory Animals

- ACVS veterinarians will perform announced rounds of city wide laboratories/sites.
- Rounds will include observation of animal procedures and holding areas where live animals are used or housed, to evaluate record keeping and to discuss AUP approved activities.
- This responsibility rests primarily with the PS Vet; however, in order to accomplish the task in a timely manner, all ACVS veterinarians will participate;
- ACVS veterinarians will determine which rounds will take place in priority order according to AUP annual approvals in the month prior, or as deemed necessary by either the AUS, ACVS veterinarians, Facility Managers, and Researchers, as follows:
    - o Protocols in which concerns were expressed via the PAM process to the AUS or ACVS veterinarians within previous protocol year
    - o Category of Invasiveness
    - o Ethically sensitive species: non-human primates, dogs, cats
- ACVS veterinarians will visit each site on their own and will familiarize themselves in advance with applicable CCAC, OMAFRA, AUS Site Visit, and Veterinary Rounds reports;
- ACVS veterinarians will discuss resolution strategies of any non-compliance issues with the appropriate party as soon as possible;
- ACVS veterinarians will submit a report of their findings and any actions to the AUS, ACVS Director, and the PAM office;
    - o Reports will be submitted to the monthly AUS meeting
    - o Follow up to any outstanding concerns will be performed by the PAM office (PS Vet or PS RLAT) and subsequently reported to the AUS at the next available monthly meeting following resolution.
    - o All ethical non-compliance will be *immediately* reported to the AUS.
        - Reference the *[Post-Approval Monitoring Policy -Veterinary Rounds for Laboratories](#)*

2. Field Studies

- Subjects will be studied in their natural habitat & documented by video medium provided by the research group
- An AUS appointed arms length representative (ACVS veterinarian or PS RLAT) will observe the procedures which have been documented by video medium.
- A follow up discussion will be held with the research group directly involved.
- *Animal Use Protocols* involving field studies will undergo veterinary rounds a minimum of once every four years. Protocols that introduce additional procedures via modification

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may require additional veterinary rounds. Animal Use Protocols selected for rounds will be prioritized based on the following criteria:
- o Category of Invasiveness
- o Cultural sensitivity of species
- o Protocols in which concerns were expressed via the PAM process to the AUS or ACVS veterinarians within previous AUP year
- o Novel and/or non standard animal procedures or contexts
- A report will be generated and submitted to the PAM office:
  - o Reports will be submitted to the monthly AUS meeting
  - o Follow up questions will be forwarded to the PI
  - o Final report will be appended to the AUP
- Reference the *Post Approval Monitoring Policy -Veterinary Rounds for Field Studies*

4. Compliance Officer

- A Compliance Officer will perform regular rounds within the Lawson Health Research Institute (LHRI) animal holding facilities and procedure areas, as described in their associated position descriptions;
- Periodic scheduled lab visits will be accompanied by the Researcher or researcher designate wherever possible;
- In the event that scheduled lab visits are not possible, unscheduled visits will be performed to ensure appropriate animal care and use;
- In consultation with the PS Vet under the approval of the ACVS Director, the Compliance Officer may act as an agent of the AUS by intervening as necessary to eliminate animal suffering;
- In the event that immediate euthanasia is the only appropriate intervention, and contacting an ACVS veterinarian would cause undue delay, the Compliance Officer may provide humane euthanasia;
- Regular reports will be submitted to the AUS, PS Vet, LHRI supervisor, and senior administration;
- The Compliance Officer will participate as non-voting members in monthly AUS meetings to present related reports and answer questions.

5. Facility Managers

- CCAC Terms of Reference for Animal Care Committees (ACC) requires Facility Managers to
'Ensure adequate animal care and management of the animal facilities…keep the other ACC members updated on the activities within the animal facilities."[4]

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[4] Canadian Council on Animal Care. Terms of Reference for Animal Care Committees. P.10

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- Facility Managers are the primary monitors of daily activities within their facilities and will address, and refer to the PS Vet when appropriate, all non-compliance matters;
  - o Animal care staff is responsible to report non-compliance issues to their Facility Manager.
- In consultation with an ACVS veterinarian under the approval of the ACVS Director, Facility Managers may act as agents of the AUS by intervening as necessary to eliminate animal suffering;
- In the event that immediate euthanasia is the only appropriate intervention, and contacting an ACVS veterinarian would cause undue delay, the Facility Manager may provide humane euthanasia.
- Facility Managers will be familiar with and meet the requirements as outlined in the AUS document "Animal Care Facilities – Site Supervisors / Managers' Responsibilities," and will:
  - o Maintain up-to-date AUP records on site;
  - o Ensure animal care staff is informed of animal procedures per protocol within the animal facilities;
  - o Inform the PS Vet of non-compliance issues;
  - o Prepare and submit monthly facility update reports to the PS Vet for the AUS;
  - o Participate as a non-voting member of the AUS;
  - o Inform animal care staff and PIs of upcoming announced site visits;
  - o Provide follow-up report content to associated staff and PIs, as applicable;
  - o Follow up on issues noted in reports from ACVS veterinarians, AUS, OMAFRA, CCAC, etc.

6. Ad Hoc Veterinary Visits

- ACVS veterinarians will make periodic visits - scheduled and unscheduled - to ensure appropriate animal care and use and to aid in resolution of any issues at the request of a PI, Facility Manager, or AUS;
- ACVS veterinarians will provide a report to the AUS via the PS Vet.

7. AUS Administrative Officers

- As per the related notification process (see below), the following administrative compliance associated with Animal Use Protocol forms and related review and approval processes, non-compliance issues will be managed by the AUS Administrative Officer (AUS AO) or designate:
  - o Expired *Animal Use Protocols* involving continued animal use –
    - ▪ Annual - Reference *Procedural Non-Compliance – Administrative-Annual Renewals*

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- ▪ Full Renewals – Reference *Procedural Non-Compliance – Administrative-Full Renewals*
  - o Animal use exceeding authorized numbers – Reference *Procedural Non-Compliance – Administrative-Use Exceeds Authorized*
- AUS AO or designate will note any such issues on the associated *Animal Use Protocol*;
- Where there are issues that cannot be resolved, AUS AO or designate will inform the PS Vet;
- AUS AO and designate will support the PS Vet, as required, in *Animal Use Protocol* form facilitation.

8. ACVS Research Education Trainers

- ACVS Research Education Trainers will notify the PS Vet of:
  - o Outstanding CCAC-mandated animal-related training for personnel listed on *Animal Use Protocol* forms – Reference *Procedural Non-Compliance – Administrative – Institutional Animal User Training*;
  - o Animal procedural/ethical concerns.
- Research Education Trainers will support the PS Vet, as required, in training assessments, certificate production and distribution, and associated database entry (training records & service charges).

9. Regulatory Site Visits

- Unannounced visits by OMAFRA veterinarian
- Announced visits by CCAC

10. Non Arms Length Managed (NALM) Areas - Annual Certification

- Applies to all research areas where:
  - o Animal holding or housing extends beyond 12 hours
  - o Oversight of animal care is performed directly by research staff (considered non arms length).
- Announced NALM visits will be performed by a representative from the PAM office (PS Vet / PS RLAT) on a yearly basis.
- All researchers requesting to hold animals within a NALM site must receive certification by the AUS in advance of initial site use as well as annual recertification.
- Accompanied by research staff, the PS Vet / PS RLAT will tour and assess the area.
- A report will be generated and submitted to the PAM office:
  - o Reports will be submitted to the monthly AUS meeting & Western's OH & S officers.

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- o Follow up to any outstanding concerns will be performed by the PAM office (PS Vet or PS RLAT) and subsequently reported to the AUS at the next available monthly meeting following resolution.
  - o Certificates will be issued for approved areas.
- Reference the *Post Approval Monitoring Policy - Non-Arms-Length-Managed Animal Holding Areas Certification.*

AUS PI Representatives (AUS PI Reps)

- AUS PI Reps are active AUS animal-user faculty members who act as peer liaisons between the animal users and the AUS for their specific area/department;
  - o At times, AUS PI Reps may be asked to assume this role for an area without AUS PI representation.
- AUS PI Reps assist the AUS Chair and PS Vet in resolving PAM concerns that may be raised regarding colleagues' *Animal Use Protocols*.
- The PS Vet may request AUS PI Rep involvement if:
  - o The nature of the issue or the anticipated response of the PI animal use warrants their facilitation;
  - o The PS Vet is unable to resolve an issue on her/his own.
- Matters that cannot be resolved with the PS Vet and AUS PI rep working together will be forwarded to the AUS for consideration.

Non-Compliance Response

Non-Compliance Response Flow Charts - Link to detailed Procedural and Ethical non-compliance response process flow charts.

'On Hold' Process for Ethical Non-Compliance

- Identify cages with 'On Hold' within associated facility
- Facility access denied to PI and research staff on specific protocol
- No animal ordering
- No breeding transfers out to research
- No animals leave animal facility for experiments
- Facility animal care staff manage animals
- Facility management charge out related services to PI

Procedural Non-Compliance

Administrative, Training & Limited Animal Impact

I. Protocol Modification Submission Required

a. Protocol Drift: Procedure is not covered by, or deviates from an approved protocol; however, procedures performed have no negative animal impact (May involve Item III. below);

b. Animal Use Exceeds Authorized Numbers;

c. Expired Protocol Involving Continued Animal Use - Annual & Full Renewals;

II. Inadequate Animal Records, e.g. room-level animal procedure logs;

III. Outstanding Personnel Training

IV. Animal Procedural Adjustment that may require Protocol Modification Submission:

Animal procedures that produce limited distress or pain requiring correction – due to inaccurate or ineffective analgesics, anesthetics, euthanasia methods, or other animal procedures, e.g. extra injections, or inappropriate anesthesia regimes.

This may involve protocol drift, which requires protocol modification form submission (See Item I.)

Protocol Support (PS) Vet informed & determines animal impact; if 'Procedural Non-Compliance,' Vet proceeds with process below; if 'Ethical' impact, PS Vet proceeds with *Ethical Non-Compliance Process.*

If the distinction between procedural & ethical non-compliance is unclear, the PS Vet will consult with the ACVS Director to determine the appropriate process.

PS Vet contacts AUS PI rep to discuss situation & to determine who should act as liaison between AUS & animal user.

AUS PI Rep / **PS Vet**

AUS PI Rep/PS Vet to meet with / contact PI/animal user to discuss procedural issue & communicate required compliance response

AUS PI Rep/PS Vet to provide feedback to one another and AUS Chair/Designate re. PI/animal user response & further follow-up requirements.

This collaborative process may be repeated at the discretion of PS Vet, AUS PI Rep, and/or AUS Chair / Chair Designate.

PS Vet / AUS PI Rep to provide feedback to one another and AUS Chair/Designate re. compliance status:
AUP form submission and/or procedural adjustment

Persistent Breaches of Procedural Compliance
PS Vet to request AUS Chair's or Chair Designate's direct involvement for scenarios involving persistent breaches of procedural compliance

Unresolved

Resolved

Animal Procedural Change or Animal Records

Outstanding Training
Charges to commence 1 month from non-compliance notice on behalf of AUS Chair;
PS Vet to track timeframes & inform Training Coordinator

Administrative Impact Involving Protocol Form Submission

Animal Procedural Change or Animal Records
PI adjusts animal procedure, or updates animal records

Outstanding Training
PI completes training requirements

Administrative & Limited Animal Impact Involving Protocol Drift
PI submits related *Protocol* form to AUS AO

Hands-on Workshop Training
ACVS vets to arrange with animal users/PIs with outstanding training for competence assessment
Charged equal to training workshop

Animal Care & Use Course Web CT Training
$50 monthly admin. fee applied per person with outstanding training

Expired Animal Use Protocol Form Involving Ongoing Animal Use –
AUP is 'expired.'
PS Vet attempts to convene a meeting with PI to assist with AUP completion.
Service Fee
AUP =$1,000

Outstanding Modification or Renewal Form -
PS Vet or AUS AO initiates form completion on behalf of PI & bills PI for admin services:
Service Fees
MODs =$200
RENEWALS = $250

PS Vet informed of compliance resolution & notes within database

Unresolved

Resolved

Billing & Training Follow-up
PS Vet to request:
1. **Billing -** ACVS Financial AO &/or Training Coordinator to bill PI for services;
2. **Training Records -**Training Coordinator to produce & distribute training certificate, & to update training record in Sirius/eSirius database

AUS Chair or Designate requests meeting with ACVS Director, AUS PI, PS Vet, and animal user to resolve issue.

Unresolved

All unresolved procedural issues will be referred to full AUS Committee and/or Animal Care Governance Steering Committee

Ethical Non-Compliance

Ethical Animal Impact
*Animal procedure causing pain or distress not pre-approved in the *Animal Use Protocol, and* requiring immediate ACVS veterinary intervention;
*Persistent breaches of ethical compliance or serious threats to the health and safety of personnel or animals.

Protocol Support (PS) Vet informed & determines animal impact; if 'Administrative &/or Limited Animal Impact,' Vet proceeds with *Procedural Non-Compliance Process*; if 'ethical impact', PS Vet proceeds with process below.

If the distinction between procedural & ethical non-compliance is unclear, the PS Vet will consult with the ACVS Director and/or AUS Chair to determine the appropriate process.

PS Vet attempts to contact PI/animal user, AUS Chair, ACVS Director & AUS PI Rep before beginning any intervening process not previously agreed upon.

In the event that immediate euthanasia is the only appropriate intervention, and contacting an ACVS vet would cause undue delay, the Facility Manager/ Officer may provide humane euthanasia.

PS vet works with ACVS team & facility management to resolve situation using one or more of the following responses:
1. PI/animal user requested to immediately stop objectionable procedure(s);
2. Response team member(s) immediately provides appropriate therapy & relief;
3. If pain or distress cannot be alleviated, team member(s) ensures humane euthanasia of animal(s).
4. If serious threat to health & safety of personnel is suspected, PS Vet contacts institutional OH&S.

Facility management/ACVS staff involved in response to provide PS Vet with:
1. Verbal/written action confirmation **within 1 business day**
2. Written report to PS Vet detailing actions taken **within 5 business days.**

PS Vet in conjunction with response team determines resolution status.

Unresolved

1. PS Vet **informs** AUS Chair, ACVS Director, AUS PI Rep, & associated Dean/Research Institute Director;
2. PS Vet informs AUS AO's to place Protocol 'ON HOLD.'
3. PS Vet informs facility management that no animal ordering & no animal use are permitted.
4. AUS Chair/designate convenes a **meeting** with ACVS Director, PS Vet, & AUS PI Rep within 2 business days. PS Vet records meeting content.
5. AUS Chair or designate conveys meeting outcomes to PI.

Facility Management ensures appropriate 'ON HOLD' status at facility & cage levels.

Resolved

Unresolved

Appeal to AUS
1. PI is invited by AUS Chair to explain rationale to the AUS committee during an interim committee meeting convened for this purpose;
2. Protocol remains 'ON HOLD' until resolved, or until AUS determines appropriate recourse.
3. Senior administration informed of meeting results.

Follow-Up by PS Vet
1. PS Vet informed of compliance resolution,
2. PS Vet updates those involved in the process (e.g. PI, non-compliance source, response team)
3. PS Vet prepares & appends report to AUP;
4. PS Vet presents report during AUS meeting.

Unresolved

Unresolved or persistent breaches of compliance or threats to the health & safety of personnel or animals that cannot be promptly corrected by the AUS working with concerned animal users & ACVS vets will be referred to Western's senior administration for resolution: Animal Care Governance Steering Committee, or University Council on Animal Care.