

Animal Welfare Protocol Post-Approval Monitoring

This document describes the University of Lethbridge Post-Approval Monitoring (PAM) program to monitor the work with animals in Animal Welfare Protocols (AWP) following Animal Welfare Committee (AWC) approval. This program includes facility site visits when procedures are being performed, evaluation of document and record keeping, a comparison of the actual activities being performed and those that are approved on the protocol, and the use of endpoint monitoring, Annual Renewals and Facility Assessments.

1.0 Background

- 1.1 In accordance with the Canadian Council on Animal Care (CCAC) policy statement on *Terms of Reference for Animal Care Committees*, institutions conducting animal based research, teaching or testing must establish procedures for post-approval monitoring of animal welfare protocols, and must define the roles and responsibilities of the members of the animal care and use program in the monitoring process.
- 1.2 It is understood that at any research institution examples of non-compliance are common, but arise for diverse reasons. Some of the reasons are innocuous, for example, details of methods show spontaneous variation, so called “protocol drift”, over time in multi-year studies. In these cases, explaining the nature of the variation to the investigator or trainee is a sufficient remedy. At the opposite extreme are very infrequent examples of major infractions in which stressful, painful, or invasive procedures are performed deliberately without animal welfare approval. The latter ethical violations must be reported to the responsible senior university administrator who will compel compliance. Between these extremes are many other types of violation, each requiring attention in a collegial and cooperative manner involving all parties.

2.0 Responsibilities

- 2.1 The institutional AWC is the body responsible for determining and working to correct breaches of compliance with approved AWP and Standard Operating Procedures (SOP).
- 2.2 Researchers working with animals are responsible for ensuring that work is undertaken in practice as approved in principle by the AWC, and meets institutional and CCAC standards.
- 2.3 The University Veterinarian, animal care staff and researchers share in the responsibility for monitoring the health and welfare of animals.
- 2.4 Senior administrators are responsible for ensuring that animal care and research takes place in practice according to AWC decisions, institutional and CCAC standards.
- 2.5 All must work in a collegial and respectful manner to attempt to correct deficiencies collaboratively.

3.0 Policy

- 3.1** All personnel involved with animals in research, teaching and testing must be adequately trained in the principles of laboratory animal science and the ethical issues involved in animal-based work.
- 3.2** The PAM program involves numerous elements including pedagogical review, record keeping; annual facility visits by the AWC; visits by the CCAC assessment team; ad hoc visits by the University Veterinarian; ad hoc observations made on a daily basis by animal care staff, investigators and trainees; and formal site visits by a PAM assessment team.
- 3.3** Animal welfare activities to be reviewed include:
 - 3.3.1 Active protocols and their corresponding amendments.
 - 3.3.2 New procedures and procedures more likely to result in animal pain or distress.
 - 3.3.3 Suspected cases of ethical violations and allegations of non-compliance.
- 3.4** Aspects of protocol compliance that will be reviewed include:
 - 3.4.1 Procedures
 - 3.4.2 Anesthesia
 - 3.4.3 Surgery
 - 3.4.4 Post-surgical monitoring and care
 - 3.4.5 Record keeping
 - 3.4.6 Euthanasia
 - 3.4.7 Laboratory practices
 - 3.4.8 Pain management
 - 3.4.9 Regulatory requirements (e.g. appropriate use of personal protective equipment, storage of controlled drugs, etc.)

4.0 Pedagogical Review

- 4.1** Review of the pedagogical merit of teaching projects involving animals will be performed by an ad hoc committee composed of faculty members who conduct animal-based teaching, faculty animal researchers with AWC experience, faculty who are experienced with the acquisition of live and preserved animals, and other department members as needed.
- 4.2** At least one member of the committee will be from a department different from the one for which the review is being conducted.
- 4.3** The committee will consider the courses currently employing animals in teaching, how such practice has changed in the past two decades, the pedagogical merit of animals in teaching, and the institutional commitment to the ethical practice with animals in its teaching program as well as its commitment to excellence in teaching and hands-on training.

- 4.4 The committee will take into consideration the application of the “Three R’s” in animal welfare before a decision on the current work with animals is rendered.
- 4.5 The committee will communicate the decision to the AWC through the AWC Coordinator.
- 4.6 Pedagogical reviews will be conducted every two years.

5.0 Record Keeping

- 5.1 Record keeping will include a log of all procedures performed on an animal, including surgery, drug administration, food/water restriction, beginning and type of behavioural method, and relevant dates.

6.0 Annual Facility Visits by the AWC

- 6.1 Each of the animal care facilities shall be visited at least once a year by members of the AWC.
- 6.2 Each member of the AWC will participate in at least one facility visit on an annual basis.

7.0 Visits by the CCAC Assessment Team

- 7.1 The AWC, researchers, University Veterinarian and animal care staff shall work in a collaborative and collegial manner in preparing for, during and in responding to recommendations in the formal assessment report after the CCAC panel visit.

8.0 Ad hoc Visits by the University Veterinarian

- 8.1 The University Veterinarian will make periodic visits to all parts of the animal facilities and will offer advice on correcting methods to the relevant parties where procedural drift or minor infractions are observed.
- 8.2 Observation of apparently minor infractions made informally shall be dealt with in a prompt, collegial manner.

9.0 Ad hoc Observations Made on a Daily Basis by Animal Care Staff, Investigators and Trainees

- 9.1 Observers of apparent infractions will make a report to their immediate supervisor or their Principal Investigator who will determine an appropriate response.
- 9.2 Sick animals or unexpected deaths will be reported to animal care staff or the University Veterinarian who will document them in a logbook.
- 9.3 Animal care staff and researchers will work in a collegial manner to ensure compliance with approved protocols and institutional and CCAC standards.

- 9.3.1 Where required, animal care staff will work with researchers to ensure they are comfortable handling animals and carrying out procedures successfully, and that they are able to do so in appropriate conditions.
- 9.3.2 Where required, animal care staff will work with researchers to apply endpoints as approved by the AWC to avoid unnecessary distress to animals.

10.0 Formal Assessments by a PAM Team

- 10.1** The PAM assessment team will consist of the PAM Coordinator and one researcher with relevant expertise selected by the AWC.
- 10.2** Additional members with relevant expertise may be added to the PAM assessment team as required.
- 10.3** Assessments will fall into one of two categories.
 - 10.3.1 The PAM assessment team will arbitrarily select 2-3 protocols for assessment every month.
 - 10.3.2 In the event of suspected cases of ethical violations and allegations of non-compliance, the PAM assessment team will conduct a targeted unannounced visit when deemed necessary by the AWC.
- 10.4** The Principal Investigator (PI) or designate identified on the selected protocol will be notified in writing, by the PAM Coordinator, of an impending Preliminary Meeting and asked to provide upcoming date options for a scheduled meeting (Appendix A). This written notification will include the Post-Approval Monitoring Worksheet for all lab team members to review prior to the scheduled Preliminary Meeting.
- 10.5** The PAM assessment team will review pertinent documentation (protocol, amendments, annual renewals, etc.) prior to conducting the site visit.
- 10.6** On the agreed date and time for the Preliminary Meeting, the PAM Coordinator will meet with all members of the lab that will be involved in the selected protocol. During this meeting, a schedule for the PAM assessment team visit(s) will be developed.
- 10.7** On the agreed date(s) and time(s), the PAM assessment team will perform the site visit using the Post-Approval Monitoring Worksheet as a guide for the assessment.
- 10.8** During the visit, the PAM assessment team will compare the procedures being performed with those that are documented in the AWC approved protocol.
 - 10.8.1 If at any time during the visit the PAM assessment team observes serious ethical violations, they will be documented and reported to the University Veterinarian.

10.8.2 Serious ethical violations of approved animal protocols will be reported by the University Veterinarian to the AWC Chair, or in the case of a conflict of interest involving the Chair, directly to the Vice-President Research (VPR).

10.8.2.1 Prior to the report by the University Veterinarian to the AWC Chair, the relevant PI will be asked by the University Veterinarian to provide an explanation of the apparent violation to avoid misinterpretations.

10.8.2.2 The first course of action in every case should involve seeking a resolution in a cooperative and collegial manner.

10.8.3 If the infraction is sufficiently serious, work under the relevant protocol will be immediately stopped by the authority of the VPR upon recommendation from the AWC Chair or University Veterinarian.

10.9 At the conclusion of the site visit, the PAM assessment team will discuss the findings with the PI and lab team to avoid misinterpretations and inaccuracies.

10.10 The PAM assessment team will complete and submit a summary report to the AWC, with a duplicate copy sent to the PI.

11.0 Resolution and Follow-up

11.1 The AWC will meet to review the summary report and develop recommendations for resolution.

11.2 The AWC Chair will communicate the observations and recommendations to the PI in writing (Appendix B) within one week following the AWC resolution meeting.

11.3 The PI will have 60 days following the date of the recommendations letter to implement corrective actions or file an appeal.

11.3.1 Corrective actions can include, but are not limited to, further education, submitting protocol amendments, or improving record keeping.

11.4 The PAM Coordinator will revisit the lab after the implementation deadline for a site visit to confirm and document implementation of corrective actions.

11.4.1 Breaches of compliance that cannot be corrected by the AWC working with the concerned researchers and veterinary/animal care staff must be referred to the VPR who must inform all members of the animal care and use program about sanctions that will be taken by the administration in the event of serious breaches of compliance.

11.5 All documentation associated with the PAM assessment team site visit will be kept on file by the AWC Coordinator.

12.0 Appeals

12.1 PIs who do not agree with the AWC's recommendations may submit a written request for an appeal to the VPR.

12.2 The appeal will be conducted as per the process described in the University AWC Appeal Procedure.

Principal Investigator:

Protocol #:

Title:

[insert date]

Re: Post-Approval Monitoring Visit

Dear [insert name of PI]:

The Canadian Council on Animal Care (CCAC) requires that institutions conducting animal-based research, teaching or testing establish procedures for post-approval monitoring of animal welfare protocols. The institutional Animal Welfare Committee (AWC) is the body responsible for working with researchers who conduct animal-based research, to support compliance with approved animal welfare protocols and standard operating procedures (SOPs).

The University of Lethbridge AWC, as part of its post-approval monitoring (PAM) program, has established a PAM team. The aim of the PAM team is:

- To be collegial and supportive of animal-based research and teaching at the university
- To maintain the maximum degree of flexibility in developing procedures consistent with the standards for regulatory compliance
- To work in a collegial manner with researchers working with animals, and veterinary and animal care staff, to correct deficiencies
- To support the more formal animal welfare education program with investigators and trainees in animal procedures and in animal welfare considerations

Your lab has been randomly selected for a visit from the PAM team for the purpose of collecting evidence of good animal practice and compliance with regulations regarding your animal-based research.

Prior to the PAM team visit, a Preliminary Meeting with the PAM Coordinator will take place. The Preliminary Meeting provides an opportunity for all members of the lab team to communicate any questions or concerns with the upcoming visit, as well as to participate in the selection of the animal-based procedures for observation by the PAM team. During this meeting, a schedule for the PAM assessment team visit(s) will be developed. To schedule a Preliminary Meeting, please email the PAM Coordinator at moira.holley@uleth.ca with the following information:

- Three upcoming date options (time of day, date, month) when all members of the lab team that will be involved with this protocol will be available for the Preliminary Meeting.

The PAM Coordinator will confirm one of the date options provided for the Preliminary Meeting.

During the PAM visit, the PAM team will observe the animal-based procedures that were agreed upon at the Preliminary Meeting. At the conclusion of the visit, the PAM team will summarize its findings with you and your team to ensure accuracy of its observations prior to reporting its findings back to the AWC.

Following the PAM visit, you will be supplied with a copy of the written report as presented to the AWC. This report will outline commendations and/or concerns that require correction, as well as instructions for any necessary follow-up.

The PAM team greatly appreciates your cooperation and looks forward to meeting with you in the very near future. Sincerely,

[insert name]

AWC Chair

cc: AWC Coordinator PAM
Coordinator University
Veterinarian

Principal Investigator:
Protocol #:
Title:

[insert date]

Re: Post-Approval Monitoring Visit

Dear [insert name of PI]:

On [insert date], a Post-Approval Monitoring (PAM) team performed a routine animal welfare program assessment of the institutional Animal Welfare Committee (AWC) approved procedures. We thank you and your laboratory team for the collegial manner of assisting with this assessment.

Monitoring experimental animal procedures post-approval is one method the University of Lethbridge AWC uses to assure the Canadian Council on Animal Care (CCAC) that animal studies are conducted in accordance with approved protocols.

With respect to the procedures observed during the assessment, there were a few issues that require attention:

OBSERVATION:
SUGGESTION:

OBSERVATION:
SUGGESTION:

We realize that on occasion, research may drift from the original proposal – indeed the very nature of research requires original and creative thought – and may become unintentionally non-concordant with the original approval. When non-compliant activities are identified, the research laboratory must either return immediately to the original animal welfare protocol, or suspend the change and submit an amendment request to the AWC for its consideration and approval. Please provide a response to the PAM Coordinator (moira.holley@uleth.ca) and include a plan for correction of the observations that require attention. A follow-up assessment will occur after [insert date 60 days post-date of this letter] to confirm that corrective actions have been implemented.

Thank you for your consideration and response to these items. Our assessment is not intended to be negative, but rather a collegial review of approved activities, and an opportunity for education and information sharing of the research process and expectations for research at the University of Lethbridge. The AWC appreciates your adherence to the procedures in the approved protocol until any proposed amendments are reviewed and approved.

Sincerely,

[insert name]
AWC Chair

cc: AWC Coordinator
PAM Coordinator
University Veterinarian