

ACC Administrative Procedure Series	004
Title	Post Approval Monitoring (PAM) Program
Version Date	June 10, 2020
Approval Date	October 7, 2020
Approved By	Animal Care Committee

1.0 Purpose

This administrative procedure describes the Animal Care Committee’s (ACC) post approval monitoring program for animal-based research conducted at the University of Ontario Institute of Technology (Ontario Tech). Through the post approval monitoring program, all animal utilization protocols (AUP) are monitored post approval to ensure that the project aligns with the regulatory and institutional requirements.

2.0 Mandate

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

3.0 Ontario Tech Post Approval Monitoring Program

As per CCAC requirements, Ontario Tech has established procedures for post-approval monitoring of animal use protocols, and has defined the roles and responsibilities of the members of the animal care and use program in the monitoring process. To this end, Ontario Tech established the Post Approval Monitoring (PAM) Committee to work collaboratively and collegially with Principal Investigator (PI)/animal users to provide guidance and ensure that animal-based work involving research or teaching at Ontario Tech aligns with approved Animal Utilization Protocol (AUP) elements and conforms to all regulatory and institutional requirements.

4.0 General Membership of the PAM Committee

Members include:

- a) Chair and/or Co-Chair of the Animal Care Committee (ACC);
- b) A consultant veterinarian;
- c) Biosafety and/or Health and Safety Officer;
- d) Representative from the Office of Research Services;
- e) Community Member;
- f) Other person(s) invited by the Chair.

5.0 Responsibilities of the PAM Committee

5.1 Overarching Responsibilities

To foster a collaborative working relationship with animal PI/animal user by clearly outlining the objectives of the PAM program and offering supportive information throughout the PAM process. This can be done in the following ways:

- a) Ensuring that all laboratories and facilities housing or using animals are visited twice per year.
- b) Further educating the PI/animal user community in the value of maintaining compliance and improving efficiency with respect to the 3'R's (Replacement, Refinement and Reduction).
- c) Monitoring visits where the PAM committee will participate in face to face visits with PI/animal users to observe research and teaching projects under the purview of the ACC and review animal care use, conditions, monitoring and training as per the approved AUP, in keeping with the Ontario Tech PAM Checklist.
- d) During exceptional conditions (e.g. publicly declared emergencies), the PAM committee will strive to have at least one of its members to visit the animal facilities. However, if in person inspections are not possible under exceptional conditions, the PAM committee may conduct a virtual tour of the animal facility with the PI/animal users, if possible.

5.2 Additional responsibilities of the PAM Committee include:

- a) Maintain records of visits and follow up as required.
- b) Present all report findings at the next ACC meeting for review (including cases of non-compliance) and discussion.
- c) Forward issues and recommendations made by the PI/animal users to the Ontario Tech ACC.
- d) Share findings with and making recommendations to the PI/animal user or course instructor.
- e) Increase frequency of PAM monitoring as necessary.
- f) Investigate concerns expressed by the public and university community.

6.0 PAM Committee Support

The Office of Research Services (ORS), via the Research Ethics Officer, will provide administrative support to the PAM committee, including:

- a) Coordination of PAM visits with PI/animal users and the PAM Committee;
- b) Scheduling meetings, preparing agenda(s), documentation and minutes;
- c) Maintaining records, reports and other documentation;
- d) Coordination of reporting requirements and approvals;
- e) Providing guidance and regulatory documents;
- f) Facilitation with the development of administrative procedures, forms and policies related to the PAM program.

7.0 Post-Approval Monitoring Report

Following the monitoring visit, the PAM Committee will write and approve a report outlining, as applicable, the following:

- a) General Comments;
- b) Recommendations;
- c) Commendations;
- d) Issues of Minor or Serious Non-Compliance;
- e) Timeline for Response; and
- f) Timeline for Action.

The final PAM report will be maintained with ORS and a copy of any PAM report will be provided to the:

- PI/animal user(s);
- Animal Care Committee;
- Applicable Dean;
- Vice President of Research and Innovation (VPRI).

8.0 Non-Compliance

Non-compliance is any action or activity associated with the conduct or oversight of research and teaching involving the care and use of animals that fails to comply with the approved AUP, and/or federal and provincial regulatory requirements, and/or institutional policies and procedures. Non-compliance may be unintentional or willful and defined as either:

- 1) Minor Non-Compliance; or
- 2) Serious Non- Compliance.

8.1 Minor non-compliance

Any action or omission in the conduct or oversight in the care and use of animals that does not have the potential to place the animal(s) in greater distress than previously anticipated, however

the action/omission fails to conform to all regulatory and institutional requirements. Examples of minor non-compliance include, but are not limited to:

- Minor protocol drift: Procedure is not covered by or deviates from an approved protocol; however, procedures performed have no negative animal impact (no distress – minor distress);
- Animal use exceeds authorized numbers;
- Expired protocol involving continued animal use, e.g. failure to submit annual renewals before study expiry;
- Failure to complete incident reports;
- Incomplete/inadequate animal records, e.g. room-level animal procedure logs;
- Incomplete animal training for study personnel listed on the AUP or subsequent amendments.

8.2 Procedures for Resolving Minor Non-compliance

Written Notification: The PI/animal user will receive a written notification within 24 hours from when a minor non-compliance issue has been identified by the PAM committee. The PI/animal user will be asked to acknowledge the receipt of the notification within 48 hours and provide a written plan to the PAM committee within 10 business days from when the notice was received. The written plan must include approximate timelines, for addressing the issue(s) of minor non-compliance.

Resolution of Minor Non-Compliance: For minor non-compliance issues that have been resolved by the PI/animal user as expeditiously as possible, the issue will be followed up by a PAM reassessment. When minor non-compliance issues are not, or cannot be resolved for any reason, the ACC Chair will decide the appropriate recourse.

9.0 Serious Non-Compliance

9.1 Serious non-compliance:

Any action or omission in the conduct or oversight in the care and use of animals that places the animals in greater distress than approved and/or fails to conform to all regulatory and institutional requirements, Examples of serious non-compliance include, but are not limited to:

- Conducting research or teaching activities with animals without first obtaining ACC approval;
- Inadequate supervision/training in research or teaching involving procedures;
- Failure to report incidents;
- Major protocol drift, that is not pre-approved and that places the animals in pain or distress; or
- Serious threats to the health and safety of personnel or animals requiring immediate

- veterinarian or designate intervention;
- Unresolved repeated issues of minor non-compliance.

9.2 Procedures for Resolving Serious Non-Compliance:

Written Notification: The PI/animal user, Dean and VPRI will receive a written notification within 24 hours from when a serious non-compliance issue has been identified by the PAM committee. The PI/animal user will be asked to acknowledge the receipt of the notification received from the PAM committee and provide a written plan within 24 hours. The written plan must include approximate timelines for addressing the issue(s) of serious non-compliance.

Resolution of Serious Non- Compliance:

- a) If the PI/animal user does not respond within 24 hours, the AUP is suspended immediately. The VPRI will be notified and any issues of major non-compliance will be reassessed by the PAM committee.
- b) When a written plan is received from the PI/animal user, the ACC will review and make a decision about the plan and provide possible actions within 24 hours of receipt. If necessary, the ACC can request for revisions to the written plan where the PI/animal user has 24 hours to provide a revised written plan to the ACC for review. If required, a face-to-face meeting will be held between the ACC Chair and/or Co-Chair, consultant veterinarian and PI/animal user to work to resolve the situation. When the ACC has accepted the plan, the ACC may request for the possible actions below.
 - i. PI/animal user will be requested to immediately stop objectionable procedure(s) and provide remediation, as appropriate;
 - ii. In the event that immediate euthanasia is the only appropriate intervention as decided by the ACC Chair and/or Co-Chair, and contacting the veterinarian would cause undue delay, the Facility Manager or PI/animal user will be directed to provide humane euthanasia in accordance with approved SOP's.
 - iii. The ACC and consultant veterinarian will meet to determine the appropriate recourse.
 - iv. The ACC may place the AUP(s) under suspension until the serious issue has been resolved. Suspension of an AUP means that all activities involving animals will be reviewed and possibly suspended. The AUP will be followed up by a PAM reassessment. Suspension of activity will be promptly reported to the ORS to ensure appropriate funding agencies and regulatory agencies are notified, as appropriate.

11.0 Misconduct

The PAM committee recognizes its responsibility to ensure that all research and scholarship undertaken meets the highest scientific and ethical standards, including duties of honest and

thoughtful inquiry, rigorous analysis, and accountability. To this end, if necessary an issue of non-compliance may be referred for investigation under the Procedure on the Responsible Conduct of Research and Scholarship policy.

12. References

- 1) Canadian Council on Animal Care (CCAC) standards and guideline documents
- 2) PAM Checklist, Ontario Tech
- 3) Procedure on the Responsible Conduct of Research and Scholarship, Ontario Tech
- 4) Process for Reconsideration or Appeals of Decisions of the ACC, Ontario Tech