

Administrative SOP Title :	004 SOP: UOIT Post Approval Monitoring Program
Approved By:	UOIT Animal Care Committee
Approval Date:	May 15, 2013

Post Approval Monitoring Program

1.0 Purpose

The goal of the post approval monitoring program is to collaboratively and collegially ensure that animal-based work involving research or teaching at UOIT aligns with approved Animal Use Protocol elements and conforms to all 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 post-approval monitoring program that defines associated roles and responsibilities, and establishes appropriate procedures to address issues of non-compliance.

3.0 UOIT Post Approval Monitoring Program

As per CCAC requirements, UOIT 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, UOIT established the Post Approval Monitoring (PAM) Committee to work collaboratively and collegially with PI/animal users to provide guidance and ensure that animal-based work involving research or teaching at UOIT aligns with approved Animal Use Protocol 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 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 Post Approval Monitoring Process. This can be done by:

- 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) Minimum Monitoring Visits: 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 UOIT PAM Checklist.

5.2 Additional responsibilities of the PAM Committee include:

- Maintaining records of visits and follow up as required.
- Presenting all report findings at the next ACC meeting for review (including cases of non-compliance) and discussion.
- Forwarding issues and recommendations made by animal PI/animal users to the UOIT ACC.
- Sharing findings with and making recommendations to the PI/animal user or course instructor.
- Increasing frequency of PAM monitoring as necessary.
- Investigating concerns expressed by the public and university community.

6.0 PAM Committee Support

The Office of Research Services, via the Ethics and Compliance Officer, will provide administrative support to the PAM committee, including:

- Coordinating PAM visits with PI/animal users and the PAM Committee;
- Scheduling meetings, preparing agenda(s), documentation and minutes;
- Maintaining records, reports and other documentation;
- Coordinating reporting requirements and approvals;
- PI/animal user;
- Providing guidance and regulatory documents;
- Facilitating the development of SOP's, 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:

- General Comments;
- Recommendations;
- Commendations;
- Issues of Minor or Serious Non-Compliance;

- Timeline for Response; and
- Timeline for Action.

The final PAM report will be maintained in the Office of Research Services 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, Innovation and International.

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 animal use protocol, and/or federal and provincial regulatory requirements, and/or institutional policies and procedures. Non-compliance may be unintentional or wilful 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 – Annual & Full Renewals;
- Failure to complete incident reports;
- Incomplete/Inadequate Animal Records, e.g. room-level animal procedure logs;
- Incomplete Animal Training for any person listed on the protocol or subsequent amendments.

8.2 Procedures for Resolving Minor Non-compliance:

- **Written Notification:** The PI/animal user will receive a written notification identifying the minor non-compliance from the PAM committee. The PI/animal user will be asked to acknowledge the receipt of the notification and provide a written plan, including approximate timelines, for addressing the issue(s) of minor non-compliance.
- **Resolution of Minor Non-Compliance:** All minor non-compliance issues are to be resolved by the PI/animal user as quickly as possible. However, if the issue of minor non-compliance is not, or cannot be resolved for any reason, the ACC Chair will decide the appropriate recourse. Any issues of minor non-compliance will be re-assessed at subsequent PAM visits.

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 will receive a written notification identifying the serious non-compliance; the notifications will also reference the policy *Integrity in Research and Scholarship*. The PI/animal user will be asked to acknowledge the receipt of the notification and provide a written plan including approximate timelines for addressing the issue(s) of serious non-compliance within 24 hours.
- **Resolution of Serious Non- Compliance:**
 - The PI/animal user will receive a written notification and will be contacted by the ACC Chair and/or ACC Co-Chair regarding the issues of serious non-compliance. If required, a face to face meeting will be held between the ACC Chair and/or Co-Chair, Veterinarian and PI/animal user to work to resolve the situation using one or more of the following responses:
 - PI/animal user will be requested to immediately stop objectionable procedure(s) and provide remediation, as appropriate;
 - If serious threat to health and safety of personnel is suspected, the Biosafety Officer and Occupational Health and Safety Officer will be contacted.
 - 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 directed to provide humane euthanasia in accordance with approved SOP's.
 - The ACC and Veterinarian will meet to determine the appropriate recourse.
 - The ACC may place the Animal Use Protocol(s) under suspension until the serious issue has been resolved. Suspension of an AUP means that no activities involving animals' or including animal ordering or animal use related to the suspended AUP(s) will be undertaken by the PI/animal users. Suspension of activity will be promptly reported to the Office of Research Services to ensure appropriate funding agencies and regulatory agencies are notified, as appropriate.

10.0 Appeal Process

The ACC and the PI/Animal Users should use every means possible to work constructively and collegially to resolve any issues of non-compliance to ensure the most appropriate means for using and caring for animals. If however, a disagreement should occur related to decisions of non-compliance the PI/Animal User may appeal a decision by following the *Process for Appeal of Decisions of the ACC*.

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 *Integrity in Research and Scholarship* policy.

11.0 References:

1. CCAC Post-Approval Monitoring 2006 Resource Vol. 29 No. 1
2. CCAC Website: Post Approval Monitoring (<http://www.ccac.ca/en/about/f.a.q>)
3. CCAC Policy Statement for Senior Administrators 2008
4. UOIT PAM Checklist
5. Integrity in Research and Scholarship
6. Process for Appeals in Decisions of the ACC