Animal Care and Use Post-Approval Monitoring Procedure

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<tr>
<th>Office of Administrative Responsibility:</th>
<th>Research Ethics Office (REO)</th>
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<td>Approver:</td>
<td>Vice-President (Research)</td>
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<td>Scope:</td>
<td>Compliance with this university procedure extends to all academic, support and excluded staff, postdoctoral fellows, and academic colleagues as outlined and defined in the Recruitment Policy (Appendix A and Appendix B: Definitions and Categories); undergraduate and graduate students; emeriti; visitors to campus, including visiting scholars; third party contractors; and volunteers who use animals for research, teaching or testing.</td>
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Overview

Post-approval monitoring enables Principal Investigators (PIs), animal care and use committees (ACUCs), animal services units and the University to assess animal care and use in practice and to close any gaps between those practices and approved animal use applications. Post-approval monitoring involves a wide range of activities, from PI self-assessments and regular animal health monitoring by the veterinarian and animal care staff to lab visits and formal observation of techniques. An effective post-approval monitoring program is based on relying on information from many sources, including animal use applications, animal health programs, ACUC site visits, veterinary rounds, incident reports, self-assessments, laboratory visits by staff engaged in the University Animal Policy and Welfare Program and other reports.

The Canadian Council on Animal Care (CCAC) requires that the University establish and define a post-approval monitoring program to audit approved animal use applications and to provide continuing education to ensure consistency of practices with approved animal use applications and University policy and procedures. Recognizing that University research is built on scholarly integrity and trust, the starting point for post-approval monitoring is that researchers typically adhere to the activities described in their animal use applications. Consequently, post-approval monitoring will most often involve information exchange about procedures that work well, continuing education about areas that are problematic and assessments of novel issues so that best practices inform all animal care and use.

Purpose

– Describe the objectives of the post-approval monitoring program.
– Describe the components of the post-approval monitoring program and its relationship to the overall animal care and use program.

PROCEDURE

1. POST-APPROVAL MONITORING OBJECTIVES

   a. PIs, ACUCs, the animal services units, and senior administration share responsibility for ensuring that animal care and use performed by University staff and trainees is consistent with ACUC decisions and institutional and CCAC standards.

   b. Neither University Animal Policy and Welfare Committee (UAPWC) nor ACUC representatives are present when animal use protocols are conducted so they must work with PIs and members of the veterinary and
animal care staff to ensure compliance with ACUC decisions and with the conditions set out in the approved animal use application.

c. The most important partner in post-approval monitoring is the PI. S/he agrees to undertake his/her animal care and use in practice as approved in principle by ACUC when s/he signs the final version of the animal use application, and s/he is responsible for the conduct of his/her staff and trainees.

d. The veterinarians and animal care staff are also essential partners in post-approval monitoring as they deliver applied animal user training and provide day-to-day assistance and information with respect to animal care and use and will often be the first to learn of an animal welfare issue.

e. All University staff and students working with animals must work together quickly and collaboratively to correct deficiencies.

f. Deficiencies may arise for a number of reasons, including knowledge gaps, protocol drift, poor record keeping, communication problems and human error. Deficiencies can be corrected through protocol updates or amendments, improved practice, better training and more rigorous attention to detail.

g. In the rare event there are persistent and/or deliberate breaches of compliance that threaten the health, welfare and/or safety of animals or personnel, these issues must be reported to the Chair of ACUC that approved the protocol. Breaches of compliance or non-compliance with approved animal use protocols will be handled according to the Animal Care and Use Non-Compliance Procedure. Serious incidents or chronic cases of non-compliance will be reporting according to the Research and Scholarship Integrity Policy.

2. POST-APPROVAL MONITORING ACTIVITIES

a. Post-approval monitoring procedures should not be unduly cumbersome or intrusive. They may be a natural extension of many animal care and use activities that are already in place and should leverage existing information and processes wherever possible. These include, for example, day-to-day observation of animal health and application of endpoints, assistance provided by ACUC personnel to animal users with their animal use applications, including processes for amending applications, site visits and discussions of animal use protocols by ACUC members and veterinary assistance and follow-up for new procedures and/or procedures more likely to result in animal pain and distress.

b. The following are examples of how post-approval monitoring activities will be incorporated with existing practices:

i. Self-Assessment – Following approval of a new animal use application, including major amendments and fourth year renewals, REO will provide the PI with a self-assessment form which s/he may complete and append to the animal use application.

ii. Veterinarian reports – A simple form, created in consultation with the animal services units, will be filled out by veterinarians after visiting a lab or attending a procedure. Each report will be appended to the relevant animal use application.

iii. ACUC facility tours – ACUC’s observations related to animal procedure and housing space made during its annual visits will be appended to individual animal use applications wherever possible.

iv. Animal care reports – These could take many forms, ranging from copies of records maintained by staff in the animal services units to incident reports and post-mortems and will be appended to the animal use applications.

v. Facility Reports – The animal services units can append information on routine or non-routine events, for example, power outages, disease outbreaks, treatment and resolution, and the like.

c. The Post-Approval Monitoring Program will also involve lab visits, which may be random and unannounced or for cause. For instance, studies involving a higher category of invasiveness, complex or novel procedures, alternate animal housing or identified by ACUC as requiring additional follow-up are more likely to receive for cause visits.

3. POST-APPROVAL MONITORING RESOURCES

a. The Animal Care and Use Consultant in REO will support the Post-Approval Monitoring Program, including the reviewers. The Post-Approval Monitoring Reviewers, between 3 and 6 knowledgeable and experienced animal users, will be recruited by the Animal Care and Use Consultant in consultation with ACUC Chairs and Chair of UAPWC.
b. The Animal Care and Use Consultant will be an ex officio member of all ACUCs and will attend all ACUC meetings. In addition, the Post-Approval Monitoring Committee members will be ACUC members and will be encouraged to attend meetings, although they will not be required to review protocols.

c. Post-approval monitoring activities and information will be captured at a protocol level in the on-line research ethics system as much as possible.

d. REO will provide administrative support for the Post-Approval Monitoring Program.

**DEFINITIONS**

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<tr>
<td>Animal</td>
<td>Any living non-human vertebrate and any living invertebrate of the class of cephalopoda, including free-living and reproducing larval forms, used for research, teaching or testing by University staff or trainees.</td>
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<td>Principal Investigator (PI)</td>
<td>A member of the academic staff who is responsible for the design, conduct, supervision and oversight of the care and use of animals in research, teaching or testing as describe in an approved animal use protocol.</td>
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<td>Animal Services Units</td>
<td>Animal facilities established and operated by the University of Alberta as ongoing administrative units to provide veterinary and animal care staff, infrastructure, training, oversight and other resources to support use of animals in research, teaching and testing by University staff and trainees. They currently are: Agricultural, Food and Nutritional Sciences Animal Services (AFNSAS), Health Sciences Laboratory Animal Services (HSLAS) and Science Animal Support Services (SASS).</td>
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<td>Canadian Council on Animal Care (CCAC)</td>
<td>The national organization responsible for setting and maintaining standards for the ethical use and care of animals used in science (research, teaching and testing) in Canada.</td>
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**FORMS**

No Forms for this Procedure.

**RELATED LINKS**

Should a link fail, please contact uappol@ualberta.ca.

- Agreement on the Administration of Agency Grants and Awards by Research Institutions (Government of Canada)
- Animal Protection Act (Government of Alberta)
- Animal Protection Regulation (Government of Alberta)
- Canadian Council on Animal Care Guidelines (CCAC)
- On-line Research Ethics System (University of Alberta)
- Recruitment Policy (Appendix A) Definition and Categories of Academic Staff, Postdoctoral Fellows, Academic Colleagues and Excluded Academic Staff (UAPPOL)
Recruitment Policy (Appendix B) Definition and Categories of Support Staff (UAPPOL)

Research and Scholarship Integrity Policy (UAPPOL)

Research Ethics Office (University of Alberta)

University Animal Policy and Welfare Committee (University of Alberta)