1. Purpose

   Describe the objectives of the Animal Ethics post-approval monitoring program.

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

2. Scope

   This procedure applies to all Athabasca University researchers who use animals for research.

3. Definitions

   | Animal | Any living non-human vertebrate and any living invertebrate of the class Cephalopoda, including free-living and reproducing larval forms, used for research purposes by Athabasca University researchers. |
   | Athabasca University Animal Care Committee (AUACC) | The Committee responsible for the ethics review and post-approval monitoring of all animal use by Athabasca University researchers. |
   | Canadian Council on Animal Care (CCAC) | The national organization responsible for setting and maintaining standards for the ethical use and care of animals used in science. |
   | Peer Review for Scientific Merit | The review of the research proposal by two or more researchers, who have the technical expertise to assess the science of the protocol and are at arm’s length from the research team and the AUACC. |
Principal Investigator (PI)  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 as described in an approved animal use protocol.

Researcher  Anyone who conducts research activities. Includes, but is not limited to, faculty, undergraduate and graduate students, post-doctoral fellows and other personnel involved directly or indirectly in research, including research assistants/associates, technical and support staff, adjunct professors, visiting professors, and institutional administrators.

Science Animal Support Services (SASS)  Animal facility, established and operated by partner institutions (i.e. University of Alberta) as an ongoing administrative unit to provide veterinary and animal care staff, infrastructure, training, oversight and other resources to support the use of animals in research, teaching and testing by University researchers.

4. Guiding Principles
Post-approval monitoring enables Principal Investigators (PIs), the AU Animal Care Committee (AUACC), the Science Animal Support Services unit (SASS) 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 collaborative and collegial processes relying on information from many sources, including animal use applications, animal health programs, AUACC site visits, veterinary rounds, incident reports, self-assessments, laboratory visits by staff engaged in the 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 upon 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.
4.1 Post-Approval Monitoring Objectives

a. PIs, AUACC, the Science Animal Support Services Unit and senior administration share responsibility for ensuring that animal care and use performed by University staff and researchers is consistent with AUACC decisions and institutional and CCAC standards.

b. AUACC representatives are not necessarily 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 AUACC 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. They agree to undertake their animal care and use in practice as approved in principle by AUACC when they sign the final version of the animal use application, and they are responsible for the conduct of their staff and researchers.

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 in a collegial manner and attempt to correct deficiencies collaboratively.

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 AUACC who 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.
h. Breaches of compliance or non-compliance with University policy and procedures may constitute research misconduct and serious incidents or chronic cases will be reported and may be pursued according to the Research Integrity Policy.

4.2 Post-Approval Monitoring Activities

Post-approval monitoring procedures shall not be unduly cumbersome or intrusive, but are a natural extension of many animal care and use activities that are already in place, such as day-to-day observation of animal health and application of endpoints, assistance provided by AUACC personnel to animal users with their animal use applications, including processes for amending applications, site visits and discussions of animal use protocols by AUACC members and veterinary assistance and follow-up for new procedures and/or procedures more likely to result in animal pain and distress.

The following post-approval monitoring activities shall be incorporated into existing practices:

i) Self-assessment – the Research Ethics Office will provide the PI with a self-assessment form which they may complete and append to the animal use application upon initial approval of a new animal use protocol, after any major amendments and upon fourth year renewals.

ii) Veterinarian reports – veterinarians will complete a short report after visiting a lab or attending a procedure. Each report shall be appended to the relevant animal use application.

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

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

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

The Post-Approval Monitoring Program will also involve lab visits, which may be random and unannounced or for cause.

The Animal Care and Use Consultant in the Research Ethics Office at the UofA 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 the AUACC Chair.

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

Administrative support for the Post-Approval Monitoring Program shall be provided by the Research Ethics Office at the UofA and will be regularly monitored by the Ethics Office at Athabasca University.

5. Applicable Legislation and Regulations

The care and use of animals in research is to be carried out in accordance with federal and provincial legislation and regulation, including the most recent versions of the following.

- **Canadian Council on Animal Care (CCAC)**
- **Tri-Agency Agreement on the Administration of Agency Grants and Awards** (2012, December and as amended from time to time.
- **Animal-Based Projects Involving Two or More Institutions (CCAC)**
- **Animal Protection Act** (Government of Alberta)
- **Animal Protection Regulation** (Government of Alberta)
- **Agreement on Animal Research Ethics Review** between the Governors of the University of Alberta and the Governors of Athabasca University (2019, and as amended from time to time).
- **Athabasca University Animal Ethics Policy**
- **Athabasca University Research Integrity Policy**
- **Athabasca University Breach of Research Integrity Procedures**
- **University of Alberta Animal Ethics Policy**

6. Related Procedures/Documents

- **Animal Care Committee Roles and Responsibilities Procedure**
- **Animal Care and Use Appeal of an AUACC Decision Procedure**
- **Animal Care and Use Standard Operating Procedure**
- **Animal Care and Use Non-Compliance Procedure**
- **Animal User Training Procedure**

**History**

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<td>May 22, 2019</td>
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