

SOP:	106.7	Post Approval Monitoring (PAM): General
Version Date:	10-2024	
Review By:	10-2027	
Subject:	To describe the process by which AREB approved projects are monitored for ethical and CCAC compliance and to ensure approved protocols are adhered to and best practices are developed for problematic procedures. Post Approval Monitoring is a combination of policies, practices and procedures designed to manage risk, and a series of institutional safeguards to prevent difficulties and address them when they occur. Typically, this involves the completion of a site visit, and an audit of each approved protocol.	
Related Documents	SOPs 107; 108; 109; 303	

Researcher Responsibilities and Requirements

1. All animal care personnel including, but not limited to principal investigators (PIs), instructors, students, and animal care staff are responsible for communicating directly with the Consulting Veterinarian on a regular basis about animal health, behavior, and welfare.
2. Researchers must inform the AREB of, and provide the rationale for, any discontinuation of a project before the expected date of completion.
3. Researchers must immediately report anything that may warrant protocol review to the AREB, Office of Research Services, Animal Care Coordinator, or Consulting Veterinarian. This includes, but is not limited to, proposed amendments to protocols, reporting any unexpected morbidity/mortality, non-compliance with endpoints, areas they feel need refinement following protocol approval, changes to study personnel and deviations from approved SOPs.

AREB Responsibilities and Requirements

1. The AREB must monitor all approved projects to ensure compliance with university, provincial, federal, and CCAC guidelines.
2. The AREB may request and discuss information on any aspects of the project with investigators at any time.
3. The AREB must track to completion the outcomes of any recommendations that arise due to protocol audits or site visits.
4. If the AREB believes that circumstances have arisen such that a research project is not being, or cannot be, conducted in accordance with the approved protocol, the AREB may withdraw approval.

Post-Approval Monitoring Procedures

Post-approval monitoring of animal use protocols is a collegial process that involves researchers, AREB, animal care staff and the Consulting Veterinarian and is comprised of several components:

- a. Each approved protocol is subject to at least one scheduled in-person protocol audit per year as described in SOP 108 (Protocol Audits)
 - b. Unannounced in-person protocol audits may be conducted at any time
 - c. Day-to-day communication between animal users and animal care staff to ensure procedural compliance including provision of further animal care training if required
 - d. Daily animal health checks by researchers and/or animal care staff
 - e. Animal Welfare Assessments as defined in the AUP
 - f. Assessments made by the Consulting Veterinarians during semiannual visits
 - g. Regular discourse between animal users and the Consulting Veterinarians
 - h. Regular review of research-related SOPs and annual renewal reports
 - i. Maintenance of Incident Reports for unexpected animal mortalities with follow-up to identify issues and implement safeguarding measures
 - j. CCAC Regular and Interim Assessment Visits
5. In extraordinary circumstances (for example, ongoing public health restrictions) post approval monitoring procedures may be conducted virtually.

Previous Versions

SOP Number	Date Effective	Summary of Changes
106.0	07-2010	Date created
106.1	09-2011	
106.2	11-2014	
106.3	11-2016	Minor administrative edits
106.4	10-2019	Update frequency of vet. visits
106.5	02-2021	Expansion of Post Approval Monitoring Program
106.6	10-2021	Staff position terms updated
106.7	10-2024	AWA added