

SOP:	108.6	Protocol Audits
Version Date:	10-2024	
Review By:	10-2027	
Subject:	To describe the process by which approved projects are audited and monitored for ethical and CCAC compliance.	
Related Documents	SOPs 106; 107; 109; RS 111; 114	

Purpose

The Canadian Council on Animal Care (CCAC) requires that all academic institutions that work with animals in science (research and teaching) establish procedures for post-approval monitoring (PAM). As part of the PAM program, protocol audits are typically in-person assessments of animal use protocols to ensure protocols are applied in practice as approved by the Animal Research Ethics Board (AREB). They may be conducted virtually in some circumstances.

The purpose of this SOP is to meet this requirement and to describe the protocol audit process, as part of the PAM program at MacEwan University.

Scheduled Protocol Audits: Roles and Responsibilities

AREB Chair: responsible for participating, as a rotational member, in protocol audits, compiling initial reporting information for the PAM liaison, making decisions on the acceptability of non-compliance responses, and calling AREB subcommittee and full committee meetings when necessary.

AREB Members: responsible for attending a minimum of one (1) protocol audit per year, completing the Protocol Audit form, and participating in any elements of PAM deemed necessary by the AREB Chair.

AREB Protocol Audit Subcommittee: consisting of three (3) or four (4) rotating members of the AREB, including, minimally, one (1) community member, and one (1) AREB member with appropriate expertise; is responsible for participating in one audit for each protocol per year, and for participating in meetings called by the AREB Chair to address non-compliance issues.

Audit Liaison: responsible for acting as a respectful liaison between the AREB and the Principal Investigator/animal users, and for assisting the AREB chair in resolving protocol compliance concerns. The Audit Liaison is typically either the Research Ethics Officer, or the Animal Care Coordinator (Animal Care & Ethics Staff).

Senior Administrator Responsible for the Animal Care and Use Program (Senior administrator): coordinates efforts and ensures that all organizational/institutional responsibilities are met. They ensure that appropriate animal care and use operations are in place to meet the institution's scientific goals of research, teaching, testing or production and that all animal care and use is conducted appropriately, according to institutional and CCAC policies and guidelines.

Principal Investigator(s)(PI)/Animal User(s): responsible for providing all relevant documentation prior to a protocol audit, informing all animal care staff of upcoming protocol audits (when announced),

participating in the protocol audit, providing written follow-up reports to the AREB, and complying with AREB decisions.

Consulting Veterinarian: responsible for providing training to animal users, as deemed necessary by the Protocol Audit Subcommittee or AREB Chair, and intervening on all ethical non-compliance issues.

Protocol Audits

1. All AREB approved protocols are subject to a minimum of one (1) in-person protocol audit per year. More frequent protocol audits may be conducted on protocols identified as presenting higher risks to animal care and welfare.
2. Initiation of a protocol audit may occur at any time if a report of non-compliance with animal procedures has been received.
3. Protocol audits include the review of the protocol and ensure the processes documented in the protocol are reflected in practice.
4. While protocol audits are typically conducted in-person, there may be some exceptional circumstances (for example, remote locations) where protocol audits may be conducted virtually.

Notification of Protocol Audits

1. When a protocol is selected for an audit, the Audit Liaison will coordinate the audit as follows:
 - a. Contact the PI(s)/animal user(s) at least ten (10) days in advance, and provide them with all related documentation (e.g., Protocol Audit checklist) that will be used so that they may organize the attendance of research staff; and
 - b. The Audit Liaison will provide a written protocol audit report including commendations and non-compliance issues, to the PI/animal user(s) and to the senior administrator within ten (10) business days.

Non-Compliance Response Process

1. All compliance concerns should be undertaken in a collaborative and collegial manner that is supportive of animal-based research while ensuring appropriate and timely issue resolution. Communication must be professional and based on mutual respect.
2. Compliance concerns will be addressed according to their classification (procedural or ethical).
3. A PI/animal user(s) may appeal in writing to the AREB on areas of the protocol audit report or follow-up requirements they disagree with. If unresolved, the PI may contact the senior administrator, to justify why they are unable to meet follow-up requirements.

Off-site Facilities

Other Institutions

1. All protocol audits will be conducted by the host institution.
2. The ACCs of collaborating institutions will agree in advance about how protocol audits will be conducted.

Field Studies

MacEwan University Researcher as PI

1. When appropriate, PIs/animal users should demonstrate protocol techniques to the Consulting Veterinarian prior to use in the field.
2. Where appropriate, protocol audits should be conducted by an AREB subcommittee consisting of the AREB Chair or designate, the Consulting Veterinarian, one (1) community member, and one (1) AREB member with relevant expertise. In cases where an AREB Subcommittee protocol audit is not possible, the protocol audit may be completed by the Consulting Veterinarian.
3. For field studies in areas where protocol audits are not possible, PI/animal user(s) are required to submit progress reports to the AREB Chair on their project status every 3-12 months, depending on the nature of the project. Reports should include a visual presentation of each field protocol being monitored (pictures and/or video) along with details of any animal welfare issues or other problems encountered that could lead to non-compliance with the approved protocol.

Other Institution's Researcher as PI

1. The ACCs of collaborating institutions will agree in advance about how protocol audits will be covered.

Previous Versions

SOP Number	Date Effective	Summary of Changes
108.0	11-2013	
108.1	11-2014	
108.2	11-2016	Minor administrative edits
108.3	10-2019	Minor updates to process
108.4	02-2021	Minor administrative edits
108.5	10-2021	Staff position terms updated
108.6	10-2024	Reviewed, minor updates