

SOP:	109.5	Non-Compliance and Response
Version Date:	10-2024	
Review By:	10-2027	
Subject:	To define non-compliance and to describe the process by which approved projects with identified non-compliance concerns are resolved.	
Related Documents	SOPs 106; 107; 108; RS 111	

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.

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.

Post Approval Monitoring (PAM): 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.

PAM 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 Research Ethics Officer or the Animal Care Coordinator typically act as the PAM liaison.

Principal Investigator(s) (PI)/Animal User(s): responsible for ensuring all research and teaching involving animals have an approval Animal Use Protocol (AUP) prior to initiation of the project, that the methods used when conducting the research or teaching adheres to the approved AUP, and that any non-compliance issues are brought forward to the AREB Chair.

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.

Non-Compliance Response Process

1. In accordance with CCAC policy, the AREB is ultimately responsible to handle non-compliance concerns, and may appoint compliance officers (e.g., Consulting Veterinarian or Animal Care & Ethics Staff); However persistent breaches of compliance must be reported to the AREB, and any breaches of compliance that cannot be solved by the AREB or appointed compliance officer must be reported to the senior administrator.

2. All compliance concerns should be undertaken in a collaborative and collegial manner that is supportive of animal-based research while ensuring appropriate and timely resolution. Communication must be professional and based on mutual respect.
3. Compliance concerns will be addressed according to their classification: procedural or ethical. See below for descriptions and specific response actions.
4. Principal Investigator (PI)/animal user(s) may appeal, in writing, to the AREB on areas of the PAM report or follow-up requirements they disagree with. If unresolved, the PI/animal(s) may proceed through the Office of Research Services' formal appeals process.

Procedural Non-Compliance

1. Procedural non-compliance may consist of any outstanding administrative or training requirements, as well as any animal procedure(s) that result in unexpected distress or pain, which require correction.
2. Procedural non-compliance may consist of, but is not limited to, the following:
 - a. Protocol Alignment:
 - i. *Protocol Drift*: when observed procedures deviate from, or are not covered by, an approved protocol and do not have a negative impact on animals.
 - ii. *Exceeded Animal Use Numbers*: when the number of animals observed exceeds the number of animals authorized.
 - iii. *Expired Protocol*: when protocols have not been renewed and involve continued animal use.
 - iv. *Animal Users*: when there are additional animal users from those listed on the approved protocol.
 - v. *No Protocol*: when research is occurring without an approved protocol.
 - b. Inadequate Animal Records:
 - i. Animal care and welfare logs
 - ii. Animal procedure logs
 - iii. Other animal records
 - c. Outstanding Animal User Training:

- i. Animal users who have not completed the animal user training (Animal User Training Parts I and II) or whose training has expired.
- d. Procedural Adjustment(s):
 - i. Procedures that result in unexpected distress or pain in animals may require correction due to inaccurate or ineffective analgesics, anesthetics, euthanasia methods, or other procedures that require a protocol modification submission.

Procedural Non-Compliance Response Process

1. Following the protocol audit, the AREB Chair will gather all information and provide points of non-compliance to the PAM liaison within five (5) business days.
2. The PAM liaison will provide a written PAM report that details non-compliance issues to the PI and to the senior administrator within five (5) business days.

Step 1: Collaborative Resolution

1. The PAM liaison will aid in informing and supporting the timely issue-appropriate resolution of compliance concerns. The collaborative process may be repeated at the discretion of the AREB Chair and the PI/animal user(s), and may involve the following elements:
 - a. Protocol Alignment: Issues identified as involving protocol alignment will require the submission of the appropriate protocol modification form by the PI/animal user(s) to realign with the previously approved elements.
 - b. Inadequate Animal Records: the PAM liaison will work with the PI/animal user(s) to facilitate proper record keeping.
 - c. Procedural Adjustment: the Consulting Veterinarian and PAM liaison will work with the PI/animal user to correct the procedures producing distress.
2. All collaborative resolution procedural non-compliance issues must be addressed by the PI, in writing to the PAM liaison, within five (5) business days.
3. The PAM liaison may add additional comments to the document and will submit the written summary to the AREB Chair within five (5) business days after receiving the report from the PI/animal user(s).
4. After receiving the written report, the AREB Chair will determine whether all issues have been resolved or if further intervention is required.
5. If issues are resolved after Step 1, the AREB Chair will submit a letter of resolution to the PAM Liaison within five (5) business days. The PAM Liaison is responsible for sending the letter to the

PI/animal user(s) within five (5) business days of receipt.

6. If the issue remains unresolved after Step 1, the process will proceed to Step 2.

Step 2: AREB Subcommittee Resolution Meeting

1. All procedural non-compliance issues not resolved through Step 1 will be put forward to an AREB Subcommittee Resolution Meeting. The purpose of this meeting is to discuss the issue resolution between the PI/animal user(s) and an AREB Subcommittee. The subcommittee should consist of, minimally: the AREB Chair or Vice-Chair, Consulting Veterinarian, one (1) community member, one (1) member with appropriate expertise, and Animal Care & Ethics Staff representative. Administrative support will also be present.
2. The Subcommittee Resolution Meeting should be scheduled within five (5) business days from the time it is determined that Step 1 did not lead to resolution.
3. Administrative support will record the meeting minutes, and the AREB Chair will provide a written copy of the decided course of action to the PI/animal user(s) and senior administrator within five (5) business days.
4. All AREB non-compliance issues involving a subcommittee resolution meeting must be addressed by the PI/animal user(s), in writing, to the AREB Chair, within five (5) business days.
5. After receiving the written report from the PI/animal user(s), the AREB Chair, in consultation with the AREB Subcommittee, will determine whether issues are resolved, or if further intervention is required.
6. If the issue remains unresolved after Step 2, the process will proceed to Step 3.

Step 3: Senior Institutional Administration

1. All procedural non-compliance issues not resolved through Step 2 will be referred to the senior administrator for resolution. At this point, the senior administrator may decide to freeze research funding and/or require that research activities cease, unless doing so presents health and welfare issues to the animals.

Ethical Non-Compliance

1. Ethical non-compliance pertains to all serious threats to the health and safety of animals and includes any animal procedure causing pain or distress that was not approved by the AREB when the Animal Use Protocol was reviewed, and that requires immediate intervention.

Ethical Non-Compliance Response Process

1. Ethical non-compliance must be addressed immediately.

2. If ethical non-compliance is confirmed during a site visit, the Consulting Veterinarian will attempt to contact the PI/animal user(s) and the AREB Chair before beginning any intervening process not previously agreed upon, should those stakeholders not be present during the site visit.
3. If the ethical non-compliance was reported to the AREB by an animal user, the Consulting Veterinarian or Animal Care Coordinator will immediately provide appropriate therapy and relief to the affected animals, if necessary.
4. The AREB Chair will work with the PAM liaison to resolve the situation using one or more of the following responses:
 - a. PI/animal user(s) will be requested to immediately stop the objectionable procedure(s);
 - b. The Animal Care Coordinator or Consulting Veterinarian will immediately provide appropriate therapy and relief to the affected animals;
 - c. If pain or distress cannot be alleviated, the Animal Care Coordinator or Consulting Veterinarian will provide humane euthanasia of the affected animal(s);
 - d. If a serious threat to health and safety of personnel is suspected, the Animal Care Coordinator or Consulting Veterinarian will contact the Health, Safety and Environment (HSE) Office.
5. The PI/animal user(s), working with the Animal Care Coordinator or Consulting Veterinarian involved in the response, will provide the AREB Chair with:
 - a. Written communication describing the action(s) that will be taken to resolve the ethical non-compliance within one (1) business day; and
 - b. A written report detailing the actions that were taken to resolve the ethical non-compliance within three (3) business days.
6. After receiving the written report, the AREB Chair, in consultation with the PAM liaison and the Consulting Veterinarian, will determine whether the issues are resolved or if further intervention is required.
7. The AREB Chair will provide the senior administrator with a report documenting the non-compliance within five (5) business days.
8. If the issue remains unresolved after Step 1, the process will proceed to Step 2.

Step 2: Communication, 'On Hold' Protocol and Resolution Meeting

1. All ethical non-compliance issues not resolved through Step 1 require the AREB Chair to inform the PI/animal user's Out of Scope Supervisor, Animal Care Coordinator, Research Ethics Officer,

and the senior administrator, of the non-compliance, and explain that the Animal Use Protocol be placed ‘on hold’ until further notice.

2. ‘On Hold’ Animal Use Protocols require the Department Chair and Animal Care and Ethics Staff to ensure that:
 - a. All affected animal use protocols be identified as ‘on hold’;
 - b. Facility/field access is denied to the PI/ animal user(s) and research staff on the protocol;
 - c. No new animals are ordered, procured or accessed in the wild;
 - d. No animals used for breeding will be transferred;
 - e. No animals leave the animal facility for research; and
 - f. Animals are cared for by the animal care staff.
3. The AREB Chair will convene an AREB resolution Subcommittee meeting with, minimally: the Consulting Veterinarian, PAM liaison, PI/animal user(s), one (1) community member, and one (1) AREB member with appropriate expertise, along with administrative support. This meeting should be held within five (5) business days after receiving the written report regarding non-compliance, as identified in Step 1, to address the non-compliance issue and to define a course of action for the PI/animal user(s).
4. Administrative support will record the meeting minutes, and the AREB Chair will provide a written copy of the decided course of action to the PI, their Out of Scope Supervisor, Animal Care Coordinator, and the senior administrator, within three (3) business days thereafter.
5. If the PI/animal user(s) agree to the terms set by the AREB in the resolution subcommittee meeting, they will be granted re-access to the facility and will provide the AREB Chair with a written report detailing the actions taken to resolve the non-compliance within five (5) business days thereafter. Note that the AUP is still on-hold, and no data-gathering activities should be conducted at this time.
6. Within ten (10) business days following the AREB resolution subcommittee meeting, the AREB Chair, Consulting Veterinarian and PAM liaison will re-inspect the facility to determine whether the issues have been resolved, or if further intervention is required. If no further intervention is required, the AUP can be re-activated.
7. If the non-compliance issue has been resolved, an unannounced, follow-up PAM inspection including, minimally, the AREB Chair, University Consulting Veterinarian, PAM liaison, one (1) community member, and one (1) AREB member with appropriate expertise will occur within

sixty (60) days.

8. If the non-compliance issue has not been resolved, the resolution process will continue to Step 3.

Step 3: Senior Institutional Administration

1. All ethical non-compliance issues not resolved through Step 2 will require that the AREB Chair place the Animal Use Protocol ‘on hold’ again and refer the issue to the senior administrator responsible for the animal care and use program. At this point, the senior administrator may decide to freeze research funding and/or require that research activities cease, unless doing so presents health and welfare issues to the animals.

Yearly Non-Compliance Reporting

1. Non-compliance numbers will be reported in the AREB Annual Report(s).

Previous Versions

SOP Number	Date Effective	Summary of Changes
109.0	09-2011	
109.1	01-2014	
109.2	11-2016	Minor administrative edits.
109.3	10-2019	Clarification to personnel roles and timelines.
109.4	10-2021	Staff position terms updated
109.5	10-2024	Reviewed, minor updates