

Approval Date: April 26, 2019

Parent Policy: [Animal Ethics Policy](#)

## Animal Care and Use Non-Compliance Procedure

<b>Office of Administrative Responsibility:</b>	Research Ethics Office (REO)
<b>Approver:</b>	Vice-President (Research)
<b>Scope:</b>	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 <b>animals</b> for research, teaching or testing.

### Purpose

- Provide guidance on how to maintain compliance with approved animal use protocols.
- Identify levels of non-compliance, remedial action and consequences.

### **PROCEDURE**

#### 1. GUIDANCE PRINCIPLES FOR MAINTAINING COMPLIANCE

- a. A **principal investigator (PI)** is responsible for ensuring that his/her animal use protocol (AUP) is complete and detailed so that his/her research team, the Animal Care and Use Committee (ACUC) and the **animal services unit** all understand all the elements of the proposed animal care and use – what will be done, when and why, who will do the work and how.
  - b. All research team members must have animal use training appropriate for the procedures and techniques they will perform and they must have access to all relevant AUP materials and standard operating procedures (SOPs) (see *Institutional Animal User Training Program Procedure*).
  - c. SOPs must be kept up-to-date (see *Animal Care and Use Standard Operating Procedures: Definition, Creation, Approval and Management Procedure*).
  - d. Animal use protocols and amendments must be submitted for ACUC approval well before the research is expected to start or before changes are implemented.
  - e. ACUC approvals are valid for one year. Protocol renewals must be resubmitted for review on an annual basis, and generally must be submitted at least two months before the expiry date for a regular renewal and at least three months in advance for fourth-year full renewals, to allow time for ACUC review and revisions.
  - f. A PI must submit an amendment to ACUC if s/he wants to make changes to an existing animal use protocol. Multiple changes and/or changes which are more likely to cause a change in animal welfare are more likely to be referred to the full ACUC. Any changes to an approved protocol must be reviewed and approved by ACUC before being implemented.
  - g. The research team must perform only those procedures described in the approved animal use protocol. All members of the research team must have access to the approved animal use protocol and all related
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procedures. Procedures must only be performed as many times as approved for the experimental design described in the animal use protocol.

- h. All procedures performed on an animal must be recorded on a document (e.g. cage card) that is accessible by the veterinarian and animal support services staff.
- i. The PI is responsible for ensuring that post-procedure animals are monitored according to the schedule outlined in the approved protocol. The PI should consult with the veterinarian to determine if the monitoring schedule can be modified before submitting an amendment.
- j. The PI is responsible for developing and following a reliable humane endpoint monitoring system as described in the approved animal use protocol and for ensuring that staff and trainees working with animals can recognize signs of animal distress and/or compromised health that necessitate intervention or euthanasia.
- k. The PI is responsible for timely communication with the veterinarian regarding the health status of post-procedural animals. If an animal develops any complications following a procedure, the research team must promptly communicate those complications to the veterinary staff.
- l. The PI must ensure that only research staff listed on the approved animal use protocol perform procedures on animals and s/he is responsible for updating the personnel listed on his/her animal use protocol.

## 2. PROTOCOL NON-COMPLIANCE

- a. Research processes are dynamic and animal use in research poses particular challenges. Concerns may arise for a number of reasons, including knowledge gaps, protocol drift, inadequate record-keeping, equipment failures, communication problems and human error and may be identified by a PI, research team member, veterinary or animal care staff, ACUC members and others. Many of these concerns can be resolved quickly and effectively through collaborative work by the animal services unit staff, veterinarians, and the research team and then reported to ACUC via the Post-Approval Monitoring log.
- b. Protocol non-compliance occurs when the animal use protocol approved by ACUC is not followed. Examples of non-compliance that might be termed protocol drift include accounting errors that result in the use of more animals than approved in the AUP, performing unapproved procedures, using unapproved anesthetics, making unapproved changes to approved animal procedures, failure to provide analgesics as approved, administering unauthorized agents, or unauthorized or untrained persons participating in a research project. Failure to submit an annual renewal of an AUP or failure to make changes or to address concerns as required by ACUC may also constitute non-compliance.
- c. The University Animal Policy and Welfare Committee (UAPWC) is the body responsible for determining and working to correct breaches of compliance with approved animal use protocols and SOPs. When an issue of protocol non-compliance arises, UAPWC has delegated to ACUCs the responsibility to bring the issue to the attention of the PI and to devise means to bring the matter into compliance.
- d. If concerns about protocol non-compliance are verified, ACUC can require corrections and impose specific conditions for continued animal use, as needed, per University policy and **Canadian Council on Animal Care (CCAC)** requirements. A clearly minor and unintentional misinterpretation of an institutional requirement that has not created a welfare problem for an animal is an example of where verified protocol non-compliance might lead to an explanation and correction of the situation and no other action will be required.

## 3. CHRONIC PROTOCOL NON-COMPLIANCE OR CONTRAVENTION OF ANIMAL CARE AND USE STANDARDS

- a. Chronic problems of recurring or continued non-compliance may be identified through post-approval monitoring site visits, ACUC site visits or veterinary reports, and must be reported by anyone who is aware of the non-compliance.
- b. The details of the chronic issue(s) will be discussed by ACUC at the next meeting. ACUC will notify the PI in writing of the reported non-compliance. An initial meeting of a subcommittee of ACUC with the PI will be

arranged as soon as possible to resolve the problem. If there is a subsequent recurrence of problems either associated with one particular animal care protocol or with several animal care protocols involving the same PI, a letter will be sent to the PI outlining the concerns and ACUC will arrange to meet the PI at the earliest possible time to conduct a fact finding meeting. In the event that a member of ACUC is the PI named in the incident, any subsequent discussion of the issue and the course of action to be taken will be conducted confidentially by ACUC in the absence of that member.

- c. ACUC may recommend one or more courses of action in dealing with the resolution of chronic non-compliance issues (see Section 6 below). Measures must be taken by ACUC to ensure that humane treatment and animal welfare problems are effectively dealt with and will not reoccur.

#### 4. SERIOUS NON-COMPLIANCE WITH AN APPROVED PROTOCOL

- a. Serious non-compliance includes any situation where:
  - i. Animals suffer pain, or distress that is not consistent with the approved AUP, or
  - ii. The health and welfare of the animals is seriously compromised by inadequate housing, maintenance or monitoring of the animals in question.
- b. In these cases, if the non-compliance endangers additional animals, or if the risk of repeated non-compliance is considered to be high, the initial course of action may include temporary suspension of the animal use protocol. This means that the PI cannot conduct any new research work associated with the suspended protocol until the incident is reviewed by full ACUC. The University Veterinarian in consultation with the Chair of ACUC, will provide written notice to the PI and his/her delegates, relevant Director and/or animal facility manager and ACUC as soon as possible (typically within 1 working day). The University Veterinarian will then communicate to the PI within 72 hours whether ACUC will extend the suspension beyond this initial period. ACUC has a duty to act as expeditiously as possible.
- c. The University Veterinarian, Director of the appropriate animal services unit and Chair and other members of the relevant ACUC will arrange to meet the PI at the earliest possible time to conduct a fact finding meeting and to determine an initial course of action to deal with the situation, including its causes, consequences and how to manage any remaining animals on the animal use protocol. The initial course of action will be developed at the first meeting, and may be elaborated at subsequent meetings or as additional facts concerning the incident emerge. A quorum of ACUC will make the final determination concerning the seriousness of the incident and of subsequent courses of action.

#### 5. UNAPPROVED ANIMAL USE

- a. Failure to obtain ACUC approval for animal use in research, teaching and testing constitutes non-compliance and is a serious contravention of the *Animal Ethics Policy* and CCAC requirements.
- b. This non-compliance may be detected by animal services facility staff or veterinarians, the Post-Approval Monitoring program, ACUC and/or Environment, Health and Safety (EHS) site visits and can be reported by anyone.
- c. The University Veterinarian, Director of the appropriate animal services unit and Chair and other members of the relevant ACUC will arrange to meet the PI at the earliest possible time to conduct a fact finding meeting and to determine an initial course of action to deal with the situation, including its causes and consequences, and how to manage the animals involved. The initial course of action will be developed at the first meeting, and may be elaborated at subsequent meetings or as additional facts concerning the incident emerge.

#### 6. ACTIONS AVAILABLE TO UAPWC AND THE ACUC TO ADDRESS NON-COMPLIANCE

- a. ACUC or UAPWC, in the event of an appeal of an ACUC decision, may follow one or more courses of action to address non-compliance and to ensure that humane treatment and animal welfare problems are effectively dealt with and will not reoccur. These may include, but are not limited to:

- i. Implementing measures to correct the problem and prevent recurrence;
  - ii. Counseling, such as meeting with the PI and research team;
  - iii. Issuing warning letters;
  - iv. Mandating specific animal user training aimed at preventing future incidents;
  - v. Monitoring by ACUC or its delegates (Animal Care and Use Consultant, Veterinarian) of research, testing, or training that involves animals;
  - vi. Revoking an Alternate Animal Housing permit;
  - vii. Revoking a PI's privileges to provide animal care or to conduct research, testing, or training procedures that involve animals, pending compliance with specific, ACUC-mandated conditions;
  - viii. Temporary or permanent suspension of one or all of a PI's animal use protocols;
  - ix. Notifying the Department Chair and the Vice/Associate Dean (Research) of its actions;
  - x. Notifying Research Services Office (RSO) that ACUC approval is not in place;
  - xi. Recommending that REO and/or the Vice/Associate Dean (Research) initiate a complaint under the *Research and Scholarship Integrity Policy*;
  - xii. Notifying funding or regulatory agencies, as required.
- b. Depending on the nature of the non-compliance incident(s), suspension of a protocol (temporary or permanent) means that the PI is either prohibited from conducting any *further* research work under the suspended protocol or any *new* research work under the suspended protocol (one of these two options will be spelled out in the meeting with, or letter to, the PI).
- i. In all cases where a protocol is suspended, a quorum of ACUC will outline the steps that must be taken to have the protocol reinstated. Requirements for reactivation of a suspended protocol will vary depending on the nature of the incident(s).
  - ii. Reactivation can occur once ACUC receives written communication indicating that the PI has implemented the recommendations of ACUC or otherwise met the conditions to the satisfaction of ACUC. ACUC also may require follow-up visits and reports on the conduct of the reinstated research protocol by the veterinary staff, Animal Care and Use Consultant, or a subcommittee of ACUC. The PI also may be asked to verify ongoing compliance by providing further information in the form of follow up report(s) or through site visits.
  - iii. In some cases, reactivation may not be advised. If a permanent suspension of animal use is imposed, a PI may only be permitted to transfer grants and activities to another lab or to engage the services of one of the animal services units, which may conduct his/her research without direct involvement by the PI or his/her personnel.
- c. PIs are expected to cooperate fully and expeditiously in the review process. In the event of non-cooperation by the PI with the ACUC Chair, ACUC, University Veterinarian and/or his/her delegates approved by ACUC, ACUC may withdraw approval for all protocols belonging to a PI until the cooperation is received.
- d. If the problems are determined to be largely due to actions of animal support services staff not supervised by the PI, the ACUC will document the problem to the University Veterinarian and Director of the relevant facility, and the Director will take appropriate action to correct, re-train or remove the staff member(s) responsible.
- e. Verified details of the circumstances of serious incidents of non-compliance or chronic non-compliance will be retained on file in the on-line research ethics system and with the Research Ethics Office, and the PI in question will receive a copy.
- f. A formal letter containing the details of ACUC recommendations will be sent to the PI with copies to the Chair, Head or Dean of the PI's academic unit. If ACUC permanently suspends a PI's research protocols, copies also will be sent to the Provost and Vice-President (Academic), and this could lead to a formal complaint under the *Research and Scholarship Integrity Policy*.

7. Non-compliance that cannot be corrected by ACUC working with the concerned animal users and veterinary/animal care staff will be referred to the Office of the Provost and Vice-President (Academic) according to the *Research and Scholarship Integrity Policy*.

## **DEFINITIONS**

Any definitions listed in the following table apply to this document only with no implied or intended institution-wide use. <a href="#">▲Top</a>	
<b>Animal</b>	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.
<b>Principal Investigator (PI)</b>	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.
<b>Animal Services Units</b>	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).
<b>Canadian Council on Animal Care (CCAC)</b>	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.

## **FORMS**

No Forms for this Procedure. [▲Top](#)

## **RELATED LINKS**

Should a link fail, please contact [uappol@ualberta.ca](mailto:uappol@ualberta.ca). [▲Top](#)

[Agreement on the Administration of Agency Grants and Awards by Research Institutions](#) (Government of Canada)

[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)