

Introduction

Approved Animal Use Protocols (AUPs) occasionally need to be amended/modified to reflect changes such as the addition of new personnel, changes in animal numbers or strains, or changes in animal procedures. The Canadian Council on Animal Care (CCAC) requires that each ACC define what constitutes minor and major amendments to approved protocols, and implements a process for review and approval of proposed amendments. The Terms of Reference for the Animal Care Committee (ACC) states that the ACC must ensure that animal users update their protocols with any modifications they intend to make, and approve any modifications to a protocol before they are implemented. Minor modifications as defined by the ACC, can be approved through a designated review consisting of the ACC Chair, community representative and the YukonU Consulting Veterinarian. For any major changes to a protocol, the ACC requires that a new AUP be submitted. Any changes to a AUP must be approved prior to beginning any new activities.

The following details provide guidance to researchers, instructors and the ACC with respect to the process for submitting a request for an amendment to an existing approved Animal Use Protocol (AUP).

For the purposes of the Yukon University ACC, amendments/modifications to an AUP are considered for the category of either minor or major amendments**.

The ACC Coordinator, ACC Chair and the consulting veterinarian are available to provide assistance with amendment submissions and to help determine whether specific changes constitute an amendment or a full resubmission.

**The ACC reserves the right to determine whether a change is too significant to approve as an amendment and must be submitted as a new protocol.

Minor Amendments/Modifications

Minor amendments are reviewed and approved by the ACC Chair, Community representative, Consulting Veterinarian and the Animal Care Coordinator.

These types of amendments may affect animal use or care, but do not change the category of invasiveness, and include but are not limited to.

- Addition of animal strains that are not known to have specific housing / care requirements or health problems (without changes in the total number of animals per year)
- Increase in animal numbers up to 25% (rodent, fish and wildlife).
- Change in drug(s) used, where the effects on the animal are equivalent.

- Change in the anesthetic agent used or in the use of analgesic agents (differences in efficacy, titration, and difficulty in administration of the agent will be considered).
- Change in method of euthanasia (change from a recognized to a new or not normally recommended method will usually require review by the full ACC)
- Change in a procedure on a live animal (where the effects on the animal are equivalent).

Thorough scientific justification must be provided for any of the above amendments.

Administrative amendments are a type of minor amendment, but do not affect animal use or welfare. They are to be reviewed and approved by the ACC Chair, in consultation with the Animal Care Coordinator and the Consulting Veterinarian. Administrative amendments are usually assessed within 2-3 days of submission. Some examples of these include:

- Changes in personnel (adding or removing personnel involved with animal procedures – for example the addition or removal of protocol associates including students).
- Change in study title.
- Change in funding source or account information (provided it does not impact scientific peer review).
- Adding or removing strains without changes to the total number of animals previously approved.
- Change in supplier of animals.
- Change in location of animal accommodation or experimental area.

Major Amendments/Modifications

These types of amendments affect animal use or welfare, including but not limited to those increasing the original category of invasiveness. Some examples of major amendments include:

- Addition of animal species
- Addition of animal strains that are known to have specific housing/care requirements or health concerns.
- Increase in total animal use numbers of greater than 25% (rodent, fish and wildlife).
- Change in drug(s) used.
- Change in live animal procedure or new procedure(s)/manipulations that are judged to result in increased potential for pain or distress (including changes to study endpoints or humane interventions).
- A change from non-survival to survival surgery.

Thorough scientific justification must be provided.

Major amendments are reviewed by the full ACC.

The ACC reserves the right to request the submission of a new, full, complete protocol if it deems that the major amendments are too significant to approve as amendments (such as the change in the main objective of the research, a change in the experimental protocol to a new level of invasiveness, etc.)

All protocol amendments are reported to the full University Animal Care Committee for review and approval.

Procedure

All requests for amendments are submitted to the ACC Coordinator using the [Request to Amend an Approved Animal Use Protocol Form](#). **You must also update affected sections in the original Animal Use Protocol Application (changes must be shown as highlighted, bold or alternate colored text) and submit along with the request to amend form.**