Queen's UNIVERSITY RESEARCH

UNIVERSITY ANIMAL CARE COMMITTEE

Policy on Protocol Amendments

As per the CCAC Policy Statement on the Terms of Reference for Animal Care Committees: (2006) *It is the responsibility of the ACC to 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 (e.g., 1 or 2 animal users added or removed, a small number of animals added, etc.), as defined by the ACC, can be approved by the Chair of the ACC or a delegate. For any major changes to a protocol, require that a new one be submitted.*

The University Animal Care Committee (UACC) reserves the right to request an amendment be resubmitted as a new protocol submission if the proposed changes would significantly alter the global aims of the original approved protocol or warrant a standalone Pilot protocol.

The UACC Coordinator, Chair, and the University Veterinarian are available to provide assistance with determining whether the proposed changes constitute an amendment or a new protocol submission.

<u>Administrative Amendment:</u>
Administrative amendments are straightforward changes to the protocol which do not affect animal use or welfare. They are to be reviewed and approved by the UACC Coordinator (with consultation of the UACC Chair and University Veterinarian as required). Administrative amendments are usually assessed within 2-3 days of submission.
Examples:

- Change in personnel (addition or removal of protocol associates including students)
- Change in title
- Change in funding source or account information provided it does not impact scientific peer-review
- Adding/removing strain/sex/breed (SSB) without changes to the total number of animals previously approved (provided new strains are not known to have specific housing/care requirements or health concerns)
- Change in supplier of animals
- Increase in total animal numbers to a maximum of 5% (level A-C protocols only)
- Typographical corrections and changes to contact information

<u>Minor Amendment - UACC Subcommittee:</u>
Minor amendments are changes to the protocol which may affect animal use or welfare, but do not increase the category of invasiveness. At the discretion of the UACC Subcommittee, modifications may be referred to the full UACC for review, which will add further time to the review process. Minor amendments are usually assessed within 4-5 days of submission

Examples:

- 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 (the degree of difference 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 UACC)
- Change to a live-animal procedure, where the effects on the animal are equivalent (e.g.: changes in dosing of experimental compounds, additional similarly-acting compounds or antagonists, alterations to time points etc.)
- Changes in the use of hazardous agents
- Addition of animal strains that are not known to have specific housing/care requirements or health concerns
- Increase in total animal numbers (rodent, fish and wildlife) up to 25%

Major Amendment - Full UACC:

Major amendments are changes which affect animal use or welfare, including but not limited to those increasing the original category of invasiveness. The UACC meets once per month, therefore major amendments can only be processed on a monthly basis. Substantial modifications may result in a request to submit a completely new Animal Use Protocol.

Examples:

- Addition of animal species
- Addition of animal strain/sex/breed (SSB) that are known to have specific housing/care requirements or health concerns
- Change in live animal procedure or addition of new procedure(s)/manipulation(s) 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
- Increase in total animal use numbers (rodent, fish and wildlife) greater than 25%
- Any increase in animal number for large mammals
- Transfer request of any non-naïve canine or NHP to ensure cumulative endpoints are taken into full consideration (non-naïve is defined as any animal that has undergone experimental procedures excluding standard maintenance or health exam)

New Protocol – Full UACC:

- A change in the main objective of the study or a change in the direction of the research (hypotheses and objectives) from those described in the grant request and/or in the existing animal use protocol that received scientific merit review
- Major changes to the original approved experimental protocol (e.g.: the addition of novel or invasive surgeries or procedures that significantly extend the scope or complexity of animal use and/or increase the level of invasiveness)
- Addition of a level E category of invasiveness procedure may require the submission of a standalone pilot protocol

In all cases, a thorough scientific justification for the proposed changes must be provided.

All administrative and minor amendments are reported to the full UACC in the monthly Subcommittee reviews report for review and approval.

Revision History:

Date	New Version
09/12/2007	Policy Created and Approved
07/21/2011	Triennial Review; Admin, minor & major amendments defined
11/19/2014	Triennial Review
10/26/2017	Triennial Review
11/18/2019	Revised minor amendment criteria to include an increase in animal numbers up to 25% (with no impact on COI and limited to rodents, fish and wildlife) and major amendment criteria to include all large animal increases
10/27/2022	Triennial Review; Revised to indicate that percent animal increase is based off total number of animals on protocol; New Format
10/22/2025	Triennial Review; Clarified that transfer of non-naïve colony animals constitutes major amendment