



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 UACC Coordinator, Chair, and the University Veterinarian are available to provide assistance with amendment submission and to help determine whether specific changes constitute an amendment or a full resubmission.

The UACC reserves the right to request an amendment be resubmitted as a new submission protocol if the proposed changes would significantly alter the global aims of the original approved protocol.

Administrative Amendment:

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 (the 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 strains 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 of animal numbers to a maximum of 5% (level A-C protocols only).
- Typographical corrections and changes to contact information.

Minor Amendment - UACC Subcommittee:

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:

- Addition of animal strains that are not known to have specific housing/care requirements or health concerns.
- Change in drug(s) used, where the effects on the animal are equivalent.



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- 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 in a procedure in a live animal, where the effects on the animal are equivalent. (i.e.: changes in dosing of experimental compounds, additional similarly-acting compounds or antagonists, alterations to time points).
- Changes in the use of hazardous agents.
- Increases in approved animal use 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 strains that are known to have specific housing/care requirements or health concerns.
- Change in procedure or new procedure(s)/manipulation(s) that are judged to result in increased potential for pain and distress (including changes to study endpoints).
- A change from non-survival to survival surgery.
- Increases in approved animal use numbers (rodent, fish and wildlife) greater than 25%
- All increases in approved animal use numbers for large mammals.

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.
- Major changes to the original approved experimental protocol (i.e.: the addition of novel or invasive surgeries or procedures that significantly extend the scope of animal use and/or increase the level of invasiveness.)
- Addition of a level E category of invasiveness procedure. This will generally require the submission of a pilot protocol.

In all cases a thorough scientific justification for the amendment needs to be provided.

All administrative and minor amendments are reported to the full University Animal Care Committee in the monthly Subcommittee reviews report for review and approval.