

**University of Manitoba
Guideline 002**

Submission of a New Protocol or an Amendment to an Existing Protocol

**Approved by the Senate Committee on Animal Care (SCAC)
October 14, 2008**

Purpose:

- 1) To provide guidance to Principal Investigators (PI) and consistency across time and committees with respect to the use of an amendment form versus the requirement for a full protocol submission to document changes to existing approved protocols. This document is intended to provide guidance rather than to present a set rules.
- 2) To provide more clarity to the statement found on the amendment form:

An amendment may be used for:

- *minor changes in numbers of animals,*
- *changes, additions, or deletions of species being used,*
- *minor modifications to procedures.*

Submission of a new protocol may be warranted when:

- *there are substantial changes to procedures to be used on live animals,*
- *addition of, or change to, new procedures not reviewed in the existing protocol or another current approved protocol held by the PI,*
- *large changes in requested numbers of animals,*
- *changes in the species of animals.*

Procedures:

The decision to amend a protocol as a regular amendment (standard form), a major amendment (standard form plus additional schedules) or a full protocol submission rests with the veterinarians, with consultation when appropriate. As with full protocol submissions, major amendments would be approved by the ACC. In order to make the process easier for PIs, the ACC will not overturn the decision, i.e. request a full protocol submission following submission of a major amendment to the ACC. The ACC can however, request additional information.

Changes which are more likely to cause a change in animal welfare are more likely to be referred to the appropriate ACC. Multiple changes are more likely to require re-review by the ACC. If any of the reviewers of an amendment express uncertainty or question any aspect of an amendment, he/she can inform the Chair who would, in most instances, recommend that the amendment be reviewed by the appropriate ACC.

1) Changes which would be significant and would normally require a full protocol submission:

- 1.1 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.
- 1.2 A change from non-survival to survival surgery.
- 1.3 The addition of a neural blocking agent to a surgical procedure.
- 1.4 A change in the degree of invasiveness of a procedure or discomfort to an animal (B → C or D; C → D).
- 1.5 Addition of a new D procedure to a D protocol.
Exceptions: Addition of a new transgenic to a protocol already approved for use of transgenics.
- 1.6 Withholding, or reducing substantially, the use of analgesics or other drugs or procedures which provide comfort or safety for an animal or handler.
- 1.7 Addition of an E Category of Invasiveness procedure.

2) Changes which would normally be handled on a case by case basis:

In general, changes in this category have widely varying effects, only some of which would warrant a full protocol submission.

Three options are available:

- i a new protocol submission reviewed by the full ACC,
- ii a major amendment: an amendment form with additional schedules or other information as required, reviewed by the full ACC,
- iii a standard amendment form, reviewed by a sub committee of the ACC.

The option required will normally be based on the number of areas of the protocol which are impacted by the change(s): Numerous changes involving multiple categories are more likely to require a new protocol submission. The number of changes throughout the history of the protocol will also be considered.

Categories are listed below with some statements for clarification.

- 2.1 Change in species/sex/breed/strain/age/genetic manipulation:
 - the degree to which the proposed changes will or potentially alter the procedures involving the animals, introduce early endpoints, or have potential negative effects on the animal will be the deciding factor on how these will be handled.
- 2.2 Change in method of euthanasia:
 - a change from a non-physical to a physical method will generally require re-review by the ACC.
 - a change from a recognized to a new or not normally recommended method will usually require review by the committee.

- 2.3 Change in the duration, frequency or number of procedures performed:
- the probability and degree of increased distress for the animal will be the deciding factor.
- 2.4 Change in the anesthetic agent or in the use of analgesic agents:
- the degree of difference in efficacy, titration and difficulty in administration of the agent will be considered.
- 2.5 Change in early endpoints:
- changes in early endpoints likely to produce an alteration in welfare will be more likely to require review by the ACC.

3. Changes which would normally be appropriate for an amendment:

- 3.1 Changes in personnel involved in animal procedures:
Addition or deletion of associates, or changes in their supervision status.
- the only exception would be when there is a significant reduction in the level of skill competence in the group.
- 3.2 Changes in the use of hazardous agents must be recorded on an amendment. These changes must be cleared through the facility director and the Environmental Health and Safety Office before being instituted. Submission of an amendment does not constitute such clearance.
- 3.3 Change in drug(s) used, where the effects on the animal are equivalent.
- 3.4 Change in a procedure in a live animal, where the effects on the animal are equivalent.

4. Emergency/Provisional amendment approval under extra ordinary conditions

- The ACC recognizes that in a research environment, unforeseen circumstances may arise. In this case, an emergency/provisional approval may be provided by a veterinarian following contact (phone or email) by one of the research teams. Appropriate paperwork must follow in a timely fashion .

5. Changes which can be amended at the next protocol annual renewal

- title change or change in source of funding,
- reduction in numbers of animals used,
- procedures at the higher level are completed and only lower level of invasiveness procedures are being performed; note this may result in a decrease COI placement (from C to B for instance),
- information on altered use of animal tissues post euthanasia.