

Guidelines for Submission of an Amendment to an Existing Animal Welfare Protocol

1.0 Introduction:

Approved Animal Welfare Protocols occasionally need to be amended to reflect changes such as addition of new personnel, changes in animal numbers or strains, or changes in animal procedures. These amendments must be approved by the Animal Welfare Committee (AWC) prior to their implementation. Depending on the magnitude of the amendment and the implications for animal welfare, the Principal Investigator (PI) may be required to submit a *Request to Amend an Approved Animal Welfare Protocol Form*, or may be required to make a new submission using the *Animal Welfare Approval Form*.

2.0 Purpose:

To provide guidance to researchers and the Animal Welfare Committee (AWC) with respect to the process for submitting a request for an amendment to an existing approved Animal Welfare Protocol.

3.0 Procedures for Minor, Moderate, Substantial and Major Amendments:

The decision as to which form the PI must complete in order to amend an existing approved Animal Welfare Protocol, and the process for reviewing the requested amendment rests with the AWC, and is normally delegated to the Protocol Review Subcommittee. Changes that negatively impact animal welfare, or involve multiple changes in a number of areas, are normally referred to the full AWC. Changes that deviate substantially from the approved protocol are more likely to require completion of a new protocol submission. The number of amendments throughout the history of the protocol will also be taken into consideration. A few examples of the process for submitting minor, moderate, substantial and major amendments, and the level of review, follow. For further guidance on submitting an amendment, please contact the AWC Coordinator, the University Veterinarian, or the AWC Chair, as appropriate.

3.1 Minor Amendments Involving a Change in Personnel

Amendments involving a change in personnel involved in animal procedures may be requested by sending an email to the AWC Coordinator. The request will be reviewed by the AWC Coordinator and the University Veterinarian normally within one week following receipt of the request. Personnel who are being added to an existing protocol are not approved to perform animal procedures until confirmation of completion of the Animal Research Ethics, Facility Orientation, and Animal Handling, at a minimum. Personnel who are being added to an existing protocol must successfully complete the Animal Research Ethics prior to acceptance for Animal Handling training.

Principal Investigators are responsible for ensuring that all those in their team who will handle animals are appropriately trained and competent to undertake procedures that require safety training. Please contact Safety Services for training in WHMIS, laser safety, radiation safety, X-ray safety and other safety training inquiries as applicable.

3.2 Minor Amendments Involving a Change in Behavioural Testing

Amendments involving a change in behavioural testing that do not involve a change in the number of approved animals, do not involve a change in the Category of Invasiveness (COI), and that do not result in an increase in the pain or discomfort to the animals involved in the study may be requested by sending an email to the AWC Coordinator. The request will be reviewed by the AWC Coordinator and the University Veterinarian normally within one week following receipt of the request.

3.3 Minor Amendments that Require Submission of a *Request to Amend an Approved Animal Welfare Protocol Form*

Examples of minor amendments that require submission of a *Request to Amend an Approved Animal Welfare Protocol Form* (<https://www.ulethbridge.ca/research/animal-ethics-guidelines-forms>) include, but are not limited to, the following:

- Minor modifications to procedures
- Change in supplier of animals
- Change in strain of animal, or addition of strains without changes in the total number of approved animals, and where there is no anticipated change to endpoints

The completed *Request to Amend an Approved Animal Welfare Protocol Form* is to be submitted to the AWC Coordinator. The request will be reviewed by the Protocol Review Subcommittee normally within one week following receipt of the request.

3.4 Moderate Amendments that Require Submission of a *Request to Amend an Approved Animal Welfare Protocol Form*

Examples of moderate amendments that require submission of a *Request to Amend an Approved Animal Welfare Protocol Form* (<https://www.ulethbridge.ca/research/animal-ethics-guidelines-forms>) include, but are not limited to, the following:

- Changes in drug(s) used, where the effects on the animal are equivalent
- Change in a procedure in a live animal, where the effects on the animal are equivalent
- Changes in the use of hazardous agents and/or processes
- Small pilot studies that complement the existing research (note: All pilot studies will be reviewed by the full AWC)
- Change to timeline prolonging the animals' participation in the research study

The completed *Request to Amend an Approved Animal Welfare Protocol Form* is to be submitted to the AWC Coordinator. The request will be reviewed by the Protocol Review Subcommittee normally within one week following receipt of the request. At the discretion of the Protocol Review Subcommittee, moderate amendments may be referred to the full AWC for review, which will add further time to the review process.

Moderate amendments involving changes in the use of hazardous agents and/or processes requires submission of a Hazard Assessment Form (<https://www.ulethbridge.ca/research/animal-ethics-guidelines-forms>) to Safety Services, and will add further time to the review process, depending on the nature of the hazardous agent.

3.5 Substantial Amendments that Require Submission of a *Request to Amend an Approved Animal Welfare Protocol Form*

Examples of substantial amendments that require submission of a *Request to Amend an Approved Animal Welfare Protocol Form*

(<https://www.ulethbridge.ca/research/animal-ethics-guidelines-forms>)

include, but are not limited to, the following:

- Change to endpoints
- Addition of animal species/strains that are known to have specific housing/care requirements (e.g. isolator housing) or health problems (e.g. immune-compromised)
- Change in the anesthetic agent or in the use of analgesic agents
- Change in method of euthanasia
 - A change from a non-physical to a physical method will generally require review by the full AWC.
 - A change from a recognized to a new or not normally recommended method will usually require review by the full AWC.
- New procedure/manipulation, particularly ones that are judged to result in increased potential for pain and distress
- An increase in the animal number greater than 20%

- Addition of a new D procedure to a D protocol.
 - Exception: Addition of a new transgenic to a protocol already approved for use of transgenics.
- Changes in the duration, frequency or number of procedures performed (generally related to CCAC Category of Invasiveness “D” protocols)
 - The probability and degree of increased distress for the animal will be the deciding factor.
- Change in humane points of intervention
 - Changes in humane points of intervention likely to produce an alteration in animal welfare will be more likely to require full AWC review.

The completed *Request to Amend an Approved Animal Welfare Protocol Form* is to be submitted to the AWC Coordinator. The request will be reviewed by the Protocol Review Subcommittee normally within one week following receipt of the request. At the discretion of the Protocol Review Subcommittee, substantial amendments may be referred to the full AWC for review, which will add further time to the review process. Some substantial amendments may result in a request to the PI to submit a completely new *Animal Welfare Approval Form* (<https://www.ulethbridge.ca/research/animal-ethics-guidelines-forms>).

Substantial amendments involving changes in the use of hazardous agents and/or processes requires submission of a Hazard Assessment Form (<https://www.ulethbridge.ca/research/animal-ethics-guidelines-forms>) to Safety Services, and will add further time to the review process, depending on the nature of the hazardous agent.

3.6 Major Amendments

Major amendments will normally require submission of a new *Animal Welfare Approval Form* (<https://www.ulethbridge.ca/research/animal-ethics-guidelines-forms>). Please contact the AWC Coordinator when requesting major amendments so that the requirement for completion of a new *Animal Welfare Approval Form* can be determined.

Examples of major amendments include, but are not limited to, the following:

- 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 approved animal welfare protocol.
- A change from non-survival to survival surgery.
- Addition of a neuromuscular blocking agent to a surgical procedure.
- A change in the degree of invasiveness of a procedure or

discomfort to an animal (e.g. B→C or D, or C→D).

- Withholding, or reducing substantially, the use of analgesics or other drugs or procedures which provide comfort or safety for an animal or handler.
- Addition of an “E” Category of Invasiveness procedure.
- At the discretion of the AWC, amendment requests for new studies involving multiple new behavioural and/or surgical procedures may require a new animal welfare protocol.

The completed *Animal Welfare Approval Form*, if required, is to be submitted to the AWC Coordinator. The request will be reviewed at the next full AWC meeting, normally from one to four weeks following receipt of the request.

Major amendments involving changes in the use of hazardous agents and/or processes requires submission of a Hazard Assessment Form (<https://www.ulethbridge.ca/research/animal-ethics-guidelines-forms>) to Safety Services, and will add further time to the review process, depending on the nature of the hazardous agent.

4.0 Emergency/Provisional Amendment Approval under Extraordinary Conditions:

The AWC recognizes that in a research environment, unforeseen circumstances may arise. In this case, an emergency/provisional approval may be provided by the AWC Chair or the University Veterinarian following contact (phone or email) by the PI. Appropriate paperwork must be subsequently submitted to the AWC Coordinator in a timely fashion.

5.0 Changes that can be made at the Next Protocol Annual Renewal:

The following amendments can be submitted on the *Annual Renewal for the Use of Animals in Research and Teaching* form, and do not require submission of an amendment mid-year:

- 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 in the Category of Invasiveness (COI) (e.g. from C→B)
- Information on altered use of animal tissues post euthanasia