

Guidelines for Submission of a New Animal Welfare Protocol for Ethics Review

1.0 Introduction:

In accordance with the Canadian Council on Animal Care (CCAC) Guidelines, the Tri-Council Agreement on the Administration of Agency Grants and Awards by Research Institutions, and the University of Lethbridge policy, ethics approval must be obtained before any use of animals in research, teaching or testing is undertaken. Any research, teaching or testing conducted using University facilities, or undertaken by individuals connected to the University involving animals must be reviewed and approved by the University Animal Welfare Committee (AWC).

2.0 Purpose:

To provide guidance to researchers and the AWC with respect to the process for submitting a new Animal Welfare Protocol for ethics review.

3.0 Tri-Council Agreement on the Administration of Agency Grants and Awards by Research Institutions

The University of Lethbridge has obligations under the Agreement with the Natural Sciences and Engineering Research Council of Canada (NSERC), the Social Sciences and Humanities Research Council of Canada (SSHRC) and the Canadian Institutes of Health Research (CIHR) federal granting agencies that bind the University and researchers affiliated with the University conducting animal-based research to the following requirements as they pertain to Animal Welfare ethics review:

3.1 Notification of delays in obtaining ethics certification

The University must inform the federal granting agency of a delay, and explain the reason for the delay, if AWC approval for animal-based research has not been obtained within one year of the funding award date, in which case the agency may defer, or even hold back, the researcher's installment/annual commitment if the agency judges that the need for funds has not been demonstrated or the issues identified. Researchers are therefore reminded to submit protocols for animal welfare ethics review in a timely manner for the release of funds, or request a deferral of the installment/annual commitment from the agency. The total of all deferral periods cannot exceed two years.

3.2 "In principle approvals" for research projects that will involve the use of animals in future years

As per the Agreement, the University agrees to release research funds to researchers planning to conduct animal-based research only after the AWC has approved the research. This review and approval can be a formal review of the detailed protocol and

the related continuing review process, or the review can be a two-stage process if the activities involving animals will only take place in a future fiscal year. Researchers are therefore reminded of the need to obtain “in principle” approval of the research protocol for activities up to the start of the work involving animals so that funds may be released on a pro-rated basis.

3.3 Ongoing ethics certification

The University must ensure that in the absence of valid ethics approval for ongoing research involving animals, it withhold agency funding installments until approval is obtained. Researchers are therefore reminded of the need to submit the annual renewal reports for their approved protocols in a timely manner so that ethical review can occur in order to meet this requirement of valid ethics approval for ongoing research.

4.0 Procedure for Submitting a New Animal Welfare Protocol for Ethics Review:

Applications for animal use in research, teaching or testing conducted under the auspices of the University of Lethbridge must be submitted on *The University of Lethbridge Animal Welfare Approval Form* (<https://www.ulethbridge.ca/research/animal-ethics-guidelines-forms>). Applications for animal use must be submitted and approved prior to beginning animal procedures.

4.1 The Principal Investigator (PI) must complete, sign and send an electronic copy of the *Animal Welfare Approval Form*, and supporting documentation, to the AWC Coordinator in the Office of Research & Innovation Services.

4.1.1 All new submissions require completion of a hazard assessment report (<https://www.ulethbridge.ca/research/animal-ethics-guidelines-forms>). This report must be submitted to Safety Services for review and approval before the corresponding protocol is given final approval by the AWC.

4.1.2 Scientific merit must be demonstrated through an independent peer review for all animal-based research projects before the corresponding protocol is given final approval by the AWC.

4.2 Applications received two weeks prior to the next AWC meeting will be considered at that meeting.

4.2.1 Intake of applications is ongoing throughout the year.

4.3 Review of the application will take place at a meeting of the full AWC. The AWC will discuss the protocol, detailed recommendations will be recorded, and a decision made before the meeting is adjourned.

- 4.3.1 Following review, protocols will be assigned to one of the following categories:
- Approved (full approval, no conditions, no requirement for additional information or clarification);
 - Conditional Approval (additional information/clarification is required prior to full approval);
 - Hold (protocol has numerous/major concerns that cannot be immediately addressed); or
 - Denied (protocol is found to be ethically unacceptable, or has received negative peer review for scientific merit)
- 4.4 The AWC Coordinator will notify the PI by email of the AWC decision on the protocol normally within one week following the AWC meeting at which the decision was made.
- 4.5 The PI will address the identified issues, and send the requested revisions by email to the AWC Coordinator.
- 4.5.1 If no response has been received from the PI three months after the PI has been notified of AWC recommendations regarding the protocol, the protocol shall be declared withdrawn and no longer considered for ethics review.
- 4.5.2 Protocols that have been categorized as withdrawn must be submitted as a new application for further ethics review consideration.
- 4.6 The AWC Coordinator will forward the PI's revisions, within one week of receiving them, by email to a protocol review subcommittee for review.
- 4.7 The protocol review subcommittee will review and send their comments by email to the AWC Coordinator, normally within one week of receiving the PI's revisions.
- 4.8 The AWC coordinator will notify the PI by email of the comments of the protocol review subcommittee normally within one week of receiving them from the subcommittee.
- 4.9 Steps 4.5 to 4.8 will be repeated until all issues have been addressed to the satisfaction of the protocol review subcommittee and the PI.
- 4.9.1 If the issues cannot be resolved to the satisfaction of the protocol review subcommittee (acting on behalf of the AWC) and the PI, the PI has the right to [appeal](#) the decision to the VP Research.
- 4.10 The PI will be notified of the date of full approval by email from the AWC Coordinator.

5.0 Conditions of Approval for a New Animal Welfare Protocol:

- 5.1** Each approved protocol will be assigned a protocol number to facilitate protocol management, and acquisition and tracking of animals associated with the protocol.
- 5.2** Ethics approval of an Animal Welfare Protocol is issued for one year at a time, in accord with the *CCAC Terms of Reference for Animal Care Committees*.
- 5.3** Protocols may be approved for up to 3 renewals (i.e. maximum 4 years), subject to the submission, review and approval of the completed *Annual Renewal for the Use of Animals in Research and Teaching* form.
 - 5.3.1** Annual renewals are due by the anniversary of the initial approval date of the original new protocol submission.
 - 5.3.2** The AWC Coordinator will email the *Annual Renewal for the Use of Animals in Research and Teaching* form four to six weeks before the anniversary of the protocol's approval date to the PI for completion and return by the PI for review by a protocol review subcommittee.
 - 5.3.3** The review of the annual renewal will follow the process as per steps 4.7 to 4.9.
 - 5.3.4** The PI will be notified of the approval of the annual renewal by email from the AWC Coordinator.
 - 5.3.5** Approval of the annual renewal will be brought to the attention of the full AWC for its information.
 - 5.3.6** In the absence of substantial changes to the protocol over the time period involved, approval of ongoing research will be *pro forma*.
- 5.4** Submission of a new full protocol for ethics review is required after a maximum of 3 consecutive renewals.

6.0 Interim Approvals

- 6.1** The AWC may delegate the responsibility of interim approvals to a protocol review subcommittee, consisting of the AWC Chair, the University Veterinarian, a Community Representative, and the AWC Coordinator.
- 6.2** Interim approvals shall only be used infrequently, and the request for interim approval must be accompanied by a rationale from the PI for the request.

- 6.2.1 The decision to conduct an interim review and approval will be at the discretion of the AWC Chair, the University Veterinarian, and the AWC Coordinator, who will review and discuss the PI's request.
- 6.3 The interim review process, including all communications between the protocol review subcommittee and the PI, will be documented and subsequently subject to discussion and final approval at a full meeting of the AWC.