Animal Care and Use Committee Structure, Application and Review Procedure

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<tr>
<th>Office of Administrative Responsibility:</th>
<th>Research Ethics Office (REO)</th>
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<td>Approver:</td>
<td>Vice-President (Research)</td>
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<tr>
<td>Scope:</td>
<td>Compliance with this university procedure extends to all academic, support and excluded staff, postdoctoral fellows, and academic colleagues as outlined and defined in the Recruitment Policy (Appendix A and Appendix B: Definitions and Categories); undergraduate and graduate students; emeriti; visitors to campus, including visiting scholars; third party contractors; and volunteers who use animals for research, teaching or testing.</td>
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**Overview**

Ethics approval must be obtained before any use of animals for research, teaching or testing is undertaken and maintained for the duration of the animal use.

**Purpose**

– Define the structure of Animal Care and Use Committees (ACUCs) at the University of Alberta.

– Define the decision making and review requirements for ethics review of animal use.

– Describe the basic procedures for application for and ethics review of animal use.

**PROCEDURE**

1. **STRUCTURE OF ANIMAL CARE AND USE COMMITTEES AND GENERAL CONSIDERATIONS**

   a. The University of Alberta, through the Vice-President (Research) and the University Animal Policy and Welfare Committee (UAPWC), shall establish such number of ACUCs as determined appropriate. ACUCs will be organized around models of animal use and their composition will conform with the requirements outlined in the Canadian Council for Animal Care (CCAC) Policy Statement: Terms of Reference for Animal Care Committees.

   b. It is the shared responsibility of the **Principal Investigator (PI)**, the **animal services unit** providing housing and/or veterinarian oversight and ACUC to ensure the ethical conduct of animal care and use and to promote animal welfare consistent with CCAC requirements. Whether a PI personally works with animals or not, s/he is responsible for the animal care and use performed by his/her staff and trainees.

   c. ACUCs shall apply the principles adopted in the **Animal Ethics Policy** in review of an animal use application. ACUCs should be aware of, and be willing to consider and suggest, a range of approaches to promote the ethical conduct of animal use. No animal use application will require approval from more than one ACUC. ACUC may request additional veterinarian and facility input if necessary. Each ACUC will accept, and rely on, the reviews of the other ACUCs.
d. ACUCs shall function impartially, provide a fair and constructive review with respect to an application and provide reasoned and appropriately documented opinions and decisions. ACUCs should make their decisions on the ethical acceptability of animal use in an efficient and timely manner, and shall communicate all decisions in writing, in print or by electronic means. The deliberations of ACUCs are confidential.

e. Ethics review will be based on fully detailed animal use applications submitted for review through the on-line research ethics system. The animal use applications will include the information defined in the CCAC Guidelines on: Animal Use Protocol Review and the CCAC Policy Statement: Terms of Reference for Animal Care Committees.

f. REO will provide administrative support for ACUCs.

2. DECISION MAKING AND REVIEW REQUIREMENTS

a. ACUC must ensure that each animal use application has been found to have scientific or pedagogical merit through independent peer review before approving the application.

i. In the case of research funded through a competitive peer review process, confirmation of funding or a score in the fundable range will typically be accepted as evidence of peer review. Such merit review will be acceptable for five years from the date of review or such other time as ACUC may decide.

ii. For teaching applications, evidence of a priori consultation with, or involvement of, the relevant animal services unit in the development and approval of the course content and methods must accompany evidence of pedagogical review by the academic unit. ACUC may request additional review.

iii. For animal use applications that are not linked to peer reviewed funding, a REO administrator will select reviewers from a bank maintained in the office and will consult with the PI’s Department Chair and/or Associate/Vice Dean (Research) to select reviewers as required. On these animal use protocols, the PI will be asked to suggest the names of a minimum of two subject matter experts to add to the bank of reviewers. REO will coordinate an impartial peer review process, following which the anonymized reviewers’ comments will be provided to the PI. If the reviews do not warrant any changes to the animal use application, ACUC will complete its review. If changes are recommended, the application will be returned to the PI for appropriate action and the PI’s Department Chair and/or Associate/Vice Dean will be asked to verify that the PI has addressed any concerns before ACUC completes its review.

b. All new animal use protocols and fourth year renewals of ongoing protocols will be reviewed by full ACUC.

c. Annual review of ongoing protocols may be done by a subcommittee of ACUC consisting of the ACUC Chair or designate (a scientific member of ACUC), a veterinarian and one community member for up to three annual reviews. At any time a subcommittee member can stipulate that the protocol go to full ACUC review.

d. While the disposition of any individual review rests solely and exclusively with either ACUC, or in the event of an appeal, with UAPWC, ACUCs are accountable to UAPWC for ensuring their processes are consistent with University of Alberta policy and procedures. In the event of a disagreement about the interpretation or application of policy, procedures or guidelines, the Vice-President (Research) shall have final authority.

e. To change approved animal use, except where necessary to eliminate any unanticipated harmful effects to the animals, the PI must submit, and receive ACUC approval for, an amendment to his/her animal use application.

f. The ACUC Chair may, in exceptional circumstances, convene a subcommittee consisting of at least him/herself, a veterinarian and a community representative to review and approve interim animal use on the understanding that a fully detailed animal use application will be reviewed by full ACUC at its next meeting.

3. NEW AND ONGOING ANIMAL USE PROTOCOL REVIEW

a. All applications for animal ethics review at the University of Alberta will be managed through the on-line research ethics system. A PI should choose the ACUC best qualified to review his/her application. The receiving ACUC may redirect an application that would be more suitably reviewed by another ACUC and shall notify the PI as necessary. An animal use application will be checked for operational implications by the animal services unit(s) that will provide veterinarian oversight for the proposed animal use. The animal use application will then be received by an ACUC Specialist and, following an administrative review and in consultation with the ACUC Chair, be assigned for review by ACUC.
b. Applications for animal ethics review will be distributed to all members of ACUC. They may be reviewed by the committee as a whole and/or by specific assigned reviewers, as well as the ACUC Chair or Associate Chair, the veterinarian and the community member(s), and are discussed by all members present at the ACUC meeting.

c. If the ACUC Chair, the veterinarian or one of the primary reviewers determines additional expertise is necessary for appropriate review, ad hoc reviewers will be asked to review the animal use application.

d. At the discretion of the ACUC Chair, the PI will be invited to attend the ACUC meeting at which his/her new or fourth year renewal application is being considered, in order to clarify details of the proposed animal use.

e. If ACUC determines that changes are required, those requirements will be communicated in writing to the PI by the ACUC Specialist. Once the PI has made changes, the ACUC Chair will issue the approval if s/he is satisfied the requirements have been met, or will refer the application to full ACUC or members of the ACUC if not satisfied. ACUC will make decisions by consensus wherever possible. See Animal Care and Use Roles and Responsibilities Procedure for additional details.

f. Ethics approval for animal use is issued for twelve (12) months at a time or for such shorter period of time specified in the approval.

   i. Where animal use requires ongoing ACUC approval, it is the responsibility of the PI to ensure that an annual report and application for renewal is made in sufficient time before the expiry date of the approval to permit review and incorporation of any changes required by ACUC before approval. Annual reports are reviewed by specific assigned reviewers and are distributed to all ACUC members and discussed at full meetings of ACUC.

   ii. A complete renewal, including a fully updated animal use application, must be submitted after three consecutive renewals or when otherwise deemed necessary by ACUC.

   iii. If the PI does not provide an annual report by the approval expiry date, the protocol will normally be closed and no further animal work will be allowed. ACUC, the animal services unit and REO will work with the PI to find an appropriate resolution to any affected animal care and use.

   iv. To facilitate animal ordering and financial administration, the Research Services Office and the animal services unit(s) will be notified by REO when an application is approved and when approval is renewed or expires or the application is closed.

4. AMENDMENTS TO AN APPROVED ANIMAL USE PROTOCOL

   From time to time, approved animal use protocols may need to be amended to incorporate new procedures or design, new animal numbers or strains, changes in personnel and other changes to the animal use. Amendments to an approved animal use protocol must be completed using the on-line research ethics system and must be approved by the same ACUC that provided the original approval before amendments can be implemented. Regardless of the scope of the amendment(s) and the implications for animal care and use, the PI must submit an amendment or the ACUC may require the PI to submit a new animal use protocol. Multiple changes and/or changes which are more likely to cause a change in animal welfare will be subject to a higher level of scrutiny.

   a. Administrative amendments, including funding changes and personnel/contact information changes can be submitted at any time and will be received by the ACUC Specialist on behalf of ACUC. If the ACUC Specialist believes an amendment is not administrative, it may be referred to the University Veterinarian to determine if it requires ACUC Chair or subcommittee review. Administrative amendments are documented in the on-line research ethics system.

   b. Minor amendments that have little or no impact on the approved animal use may be approved by the ACUC Chair. These include reduction in number of animals used, changes which reduce the invasiveness or stress on the animal, changes in animal procedures or drugs used where the effects on the animal are equivalent, small increases in animal numbers, addition of or changes animal strains that are not known to have specific housing/care requirements and changes in anesthetic or analgesic made on the recommendation of a veterinarian to improve the welfare of an animal, particularly as documented in the Post-Approval Monitoring Log. At any time, the ACUC Chair can send the amendment to full ACUC, or a subcommittee thereof, for review. Minor amendments are reported and documented in the minutes of the following ACUC meeting.
c. Major changes to the approved animal use protocol must be reviewed by ACUC and may require submission of a new animal use protocol application. All major amendments of animal use protocols will be reviewed by at least a sub-committee of ACUC, including the Chair, the veterinarian and a community member. At the discretion of the subcommittee or any member thereof, the amendment may be referred for review and discussion at a meeting of the full ACUC.

i. Changes which may be reviewed by a sub-committee include: changes in species, strain (with health implications), age and genetic manipulation that will alter the animal procedures, introduce different endpoints, or trigger specific housing/care requirements; large increase in animal numbers; change in housing or procedure location; change in anesthetic agent or use of analgesic agents; changes in method of euthanasia from a non-physical to a physical method or from an approved to a conditionally approved method; a new procedure or manipulation, particularly ones judged to result in increased potential for pain and distress and change in duration, frequency or number of procedures performed.

ii. Major changes to an existing animal use protocol that require review of the protocol at a full meeting of ACUC include any protocol in which multiple changes are made; the addition of category D procedures to a category D protocol; addition of new Category E procedures to any protocol; a considerable increase of the number of animals required versus the number in the original protocol; a change of species; use of more invasive or more frequent procedures and use of entirely new procedures.

iii. Major changes that will normally require submission of a new animal use protocol include a change in the main objective of the study or direction of research; a change from non-survival to survival surgery; an increase in the category of invasiveness; a major change in experimental procedures and withholding or reducing substantially the use of analgesics or other drugs or procedures which provide comfort or safety for an animal.

DEFINITIONS

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<td>Principal Investigator (PI)</td>
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<td>Animal Services Units</td>
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FORMS

No Forms for this Procedure.

RELATED LINKS

Should a link fail, please contact uappol@ualberta.ca.
Agreement on the Administration of Agency Grants and Awards by Research Institutions (Government of Canada)

Animal Protection Act (Government of Alberta)

Animal Protection Regulation (Government of Alberta)

Canadian Council on Animal Care Guidelines (CCAC)

On-line Research Ethics System (University of Alberta)

Recruitment Policy (Appendix A) Definition and Categories of Academic Staff, Postdoctoral Fellows, Academic Colleagues and Excluded Academic Staff (UAPPOL)

Recruitment Policy (Appendix B) Definition and Categories of Support Staff (UAPPOL)

Research and Scholarship Integrity Policy (UAPPOL)

Research Ethics Office (University of Alberta)

University Animal Policy and Welfare Committee (University of Alberta)