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## REVIEW AND APPROVAL OF ANIMAL USE PROTOCOLS

### PURPOSE

1. The purpose of these procedures are to describe the Animal Care Committee's (ACC) review and approval process for animal-based research conducted at the University of Ontario Institute of Technology (UOIT).

### DEFINITIONS

2. For the purposes of these procedures the following definitions apply:

**“Animal Care Committee (ACC) Coordinator”** is the Research Ethics Officer at UOIT who is responsible for the coordination of all animal care related activities and provides support to the ACC.

**“Animal Utilization Protocol (AUP)”** is the application form which animal users are required to complete and submit to the ACC for review. The AUP form is intended to provide the ACC with information about activities in individual laboratories and classrooms. This information is required for the ACC to meet its legal and ethical responsibilities.

**“Canadian Council on Animal Care (CCAC)”** is a national peer review agency responsible setting and maintaining standards for ethical use and care of experiment animals used in research, teaching and testing in Canada.

**“Ontario Animals for Research Act”** all experiment animals used in research, teaching and regulatory testing in Ontario fall under the auspices of the Ontario Animals for Research Act. The Chief Veterinary Inspector of the Ontario Ministry of Agriculture, Food and Rural Affairs (OMAFRA) oversees compliance to this Act.

**“Major modification”** are substantive issues which in the opinion of the committee, constitute as ethical, scientific or regulatory issues that are barriers to approval and must be satisfactorily addressed prior to issuing study approval major modifications required. To name a few, these issues can relate to technique, study design and/or animal welfare.

**“Minor modification”** are less substantive issues that require resolution or clarification, but are not immediate barriers to approval.

**“Principal Investigator (PI)”** in research involving animals, is the person who is a University member and leads a research project. The PI is also responsible for overseeing all aspects of the research project.

**“University Member”** means any individual who is:

- Employed by the University;
- Registered as a student, in accordance with the academic regulations of the University;
- Holding an appointment with the University, including paid, unpaid and/or honorific appointments; and/or
- Otherwise, subject to University policies by virtue of the requirements of a specific Policy and/or the terms of an agreement or contract.

### **SCOPE AND AUTHORITY**

3. These procedures apply to all animal-based research and teaching carried out under the authority of UOIT.
4. **Responsibility**  
The Animal Care Committee (ACC) Chair, Co-chair, ACC members, Principal Investigator (PI) and ACC designate are responsible for executing this procedure.
5. The Vice-President Responsible for Research, or successor thereof, is the Policy Owner and is responsible for overseeing the implementation, administration and interpretation of these Procedures.

### **PROCEDURES**

All new animal-based research and teaching carried out under the authority of UOIT, shall be subject to an ethics review from the ACC to ensure compliance with the Canadian Council on Animal Care (CCAC) and the Ontario Animals for Research Act. Research may not commence until the ACC has approved the protocol and an approval letter has been issued.

#### **6. Initial Animal Utilization Protocol (AUP) Submission**

- 6.1. Initial AUP submissions are pre-reviewed by the ACC Coordinator for completeness. The PI is notified if there are any missing elements to the AUP submission. Once AUP submissions are deemed as complete, a review of the AUP is organized in consultation with the ACC Chair. There are also opportunities for animal users to request for pre-submission consultations to address administrative or veterinary concerns. AUPs are reviewed at a convened ACC meeting with review materials circulated in advance to all ACC members for review and comment.

#### **7. ACC Review Process**

- 7.1. The ACC will review AUPs in a fair, equitable and consistent manner. As described in the CCAC policy statement on Scientific Merit and Ethical Review of Animal-based Research (2013), all proposed AUPs would undergo two levels of review.
  - a) An independent, expert peer review of the scientific merit of the research program or project; and
  - b) A review by the full ACC to assess if the proposed animal use is acceptable and whether the proposed animal-based methods are appropriate.

- 7.2.** For AUPs that have been funded by a federal or provincial granting agency and have undergone a scientific peer review process, the results may be accepted by the ACC as evidence of scientific merit. For AUPs that have not received a scientific peer review (e.g. internally funded projects, or projects that have been funded by a source where a scientific peer review has not been completed), PIs must follow Administrative Procedure 003 (Peer Review Process) to organize an independent scientific peer review process. Scientific peer reviews must be included in the AUP review package.
- 7.3.** All live animal-based teaching or training activities that require an AUP must undergo a pedagogical merit review. PIs must follow Administrative Procedure 005 (Pedagogical Merit Review for Animals in Teaching).
- 7.4.** ACC meetings are held at least twice annually, or as frequently as necessary to fulfil the responsibility of the committee. At the meeting, the AUP is reviewed and discussed by ACC members to ensure that the animal-based methods are appropriate for the work, meet institutional and CCAC requirements.
- 7.5.** Quorum shall be a simple majority of the committee members; however, quorum must include at least one (1) community representative and one (1) consultant veterinarian. Quorum must be maintained throughout the duration of the meeting.

## **8. ACC Decisions**

- 8.1.** The ACC Chair is responsible for ensuring that a decision is made for every submission reviewed by the committee. The decision must be clearly understood, and the delegation of responsibility for considering any further information prior to issuing approval is clearly agreed. In the event that the duties of the Chair cannot be fulfilled, the Vice-Chair shall be named designate and shall carry out all of the Chair's functions as follows: 1) when the Chair is absent; 2) when there is a conflict of interest; or 3) when designated by the Chair.
- 8.2.** The ACC has the authority to render one of the following decisions about the AUP under review:
  - a)** Approval (as is): No changes are required to the AUP and approval is granted as is.
  - b)** Approval with minor modifications: The AUP is approved, provided that the minor modifications requested by the ACC are addressed. The AUP approval letter will outline the modification required.
  - c)** Deferral (major modifications required): The ACC may defer action if there are questions that must be addressed prior to a decision being rendered. AUPs with a decision of deferral with major modifications required, relate to issues surrounding technique, study design or animal welfare.
  - d)** Minor/Major Modifications: For AUPs requiring minor modifications, the PI responses can be reviewed by the ACC Chair, consultant veterinarian and community member. Whereas, AUPs requiring major modifications, the PI

responses to the modifications are required to undergo a full review at the next convened ACC meeting.

- e) Rejection: An AUP is rejected if the stated research cannot be carried out on ethical or procedural grounds. PIs have the right to request reconsideration and/or appeal the decision of the ACC. (See Administrative Procedure 002 Process for Reconsideration or Appeal of Decisions of the ACC).
- 8.3. The decisions rendered by the ACC will be made by consensus at a convened meeting. In cases where consensus cannot be achieved, a majority vote will be taken. All decisions of the ACC are communicated in writing to the PI post meeting.
  - 8.4. For AUPs with modifications requested, the PI must respond to the ACC correspondence within the body of the letter and provide supporting documentation as necessary. Responses are required within three (3) months from when the ACC correspondence was sent. Failure to respond after three (3) months will result in the automatic closure of the file. If the PI decides to proceed with the research after the file has been formally closed, the PI will be required to submit a new AUP to the ACC for review.
  - 8.5. Research activities may commence once the ACC deems the AUP as ethically acceptable in practice and a written letter of approval is issued by the ACC.

## 9. ACC Documentation

- 9.1. All aspects of the review process and communications in connection with the review and approval of the AUP are documented in the ACC's respective study file. Meeting minutes will capture the review discussion of the AUP, modifications required, category of invasiveness assessment and ACC decision.

## MONITORING AND REVIEW

- 10. These procedures will be reviewed as necessary and at least every three years. The ACC Chair, ACC Vice-Chair and ACC Coordinator are responsible to monitor and review these Procedures.

## RELEVANT LEGISLATION

- 11. Ontario Animals for Research Act

## RELATED POLICIES, PROCEDURES & DOCUMENTS

- 12. Canadian Council on Animal Care (CCAC) standards and guideline documents  
 UOIT Policies and Guidelines: Requirements for Working with Animals Guide  
 UOIT Animal Care Committee Terms of Reference  
 CCAC policy statement on: scientific merit and ethical review of animal-based research, March 2, 2013  
 ACC Administrative Procedure 003 Peer Review Process

ACC Administrative Procedure 002 Process for Reconsideration or Appeal of Decisions of the  
ACC