

Procedure Title:	Animal Use Protocols
Procedure ID:	#OP 9-902B
Manual Classification:	Section 9 – Applied Research
Linked to Policy:	#9-902
Approved by Senior Management Team:	January 10, 2022
Revision Date(s):	Original: September 25, 2019 Revision: January 10, 2022
Effective Date:	February 1, 2022
Next Review Date:	January 2025
Contacts for Procedure Interpretation:	Vice President Applied Research and Innovation

1.0 – Purpose

The purpose of this procedure (the “**Procedure**”) is to outline the procedures for the submission, review and approval of Animal Use Protocols associated with educational and research activities involving live animals.

Terms not defined in this Procedure have the same meaning found in the College's Access to Information and Protection of Privacy Policy.

2.0 – Procedure

2.1 - Overview

The Canadian Council for Animal Care (CCAC) states that “all proposed animal-based research, teaching and testing activities must be clearly described in an animal protocol, which must be approved by an institutional animal care committee before any animal-based work can begin” (CCAC, 2018). All activities involving live animals must be covered at all times by an Animal Use Protocol (AUP). An AUP provides details about animal care and use for educational activities or research projects, including animals on display for events, animals involved in fieldwork off-campus, and animals occupying College space.

2.2 – Animal Use Protocols

- a) An approved AUP shall be in place before an educational or research activity involving animals can be carried out.
- b) AUPs will be approved for one year and must be renewed annually for up to three consecutive times after which a complete new proposal must be submitted.
- c) AUP renewal must take into consideration developments in the reduction, replacement and refinement of animal use as well as changes in standards and guidelines.
- d) Major modifications of existing AUPs, including nature of invasive procedure, changes in animal species, and changes in the use of anaesthetics, must be subjected to the same level of review and information requirements as new application (CCAC,1997).
- e) AUPs must address the following points in a clearly presented form that all members of the ACC can readily understand:

- Project title and descriptive keywords or brief protocol description as defined in the CCAC Animal Use Data form
- Principal investigator, and all personnel who will handle the animals
- Proposed start date and end date of protocol
- Course codes and a description of pedagogical merit (if applicable)
- Lay summary
- An indication of the use of bio hazardous, infectious, biological, or chemical or radioactive agents in living animals and if so an indication of the institutional approval of this use
- Category(ies) of invasiveness as defined in the CCAC Guide and Purpose of Animal Use (PAU) as defined in the CCAC Animal Use Data Form;
- An indication of whether the study is acute or chronic
- Species and numbers of animals to be used and justification thereof
- A description of possible replacement, refinement and / or reduction alternatives, and justification if these are not to be employed, or a description of the applicant's efforts to find such alternatives
- Anesthesia and analgesia, including dosages and methods of use; justification for not using anesthesia or analgesia, if relevant;
- A description detailing the procedures that are carried out on the animals
- A description of the endpoint(s) of the experimentation
- The method of euthanasia, if used; justification for any physical euthanasia methods, or for any methods that deviate from those described in the CCAC guidelines on: euthanasia of animals used in science 2010
- A description of how the animals will be disposed of if they are not to be euthanized
- Any other information considered important or necessary and pertinent, including information or results derived from any relevant previous protocols.

2.3 – AUPs for Research Activities

- a) After the submission of a research proposal an AUP may be submitted at any time.
- b) An early submission is recommended even if the outcome of the proposal and amount of funding is not yet known.
- c) A PI who chooses to wait until final proposal approval takes the risk of delay in being able to start the research due to the time required to complete the AUP review process.

2.4 – Preparation and Submission

- a) The Animal Care Committee (ACC) Coordinator will send a notification to Fleming College community members detailing AUP requirements for educational and research activities involving animals at least two months prior to ACC meetings.
 - The ACC Coordinator will remind PIs with approved AUPs that are nearing their annual approval date to submit their AUPs to the ACC Coordinator.
 - If an approved AUP has reached its renewal limit (three years) and requires submission of a new AUP, the ACC Coordinator will remind the PI at least two months prior to scheduled ACC meetings.

- b) The PI will inform ACC Coordinator of planned AUP submission and submit the AUPs and all supporting documentation electronically at least four weeks prior to scheduled ACC meetings.
- c) The ACC Coordinator will initially review all submitted AUPs for completion.
 - The ACC Coordinator will return AUPs to the PI that require significant revisions and will work together with the PI to clarify information in the AUP.
 - Incomplete AUPs will not be forwarded to the ACC until completed.
- d) For new AUPs and existing AUPs that have exceeded their renewal limit, the ACC Coordinator will inform the Merit Review Committee (MRC) and provide the MRC with the AUP and supporting documentation. (See Procedure 9-902C Scientific Merit Review of Animal Use Protocols for details).
 - The process for Pedagogical/Scientific Merit review are outlined in the Pedagogical and Scientific Merit procedure (Procedures 9-902C and 9-902D). The ACC Coordinator will inform the PI about the outcome of the pedagogical/scientific merit review and forward completed AUPs and all supporting documentation at least two days prior to scheduled ACC meetings to ACC members for review.

2.5 – Peer Review

- a) The ACC members will review and approve AUPs during ACC meetings which will be scheduled twice per term during the Fall and Winter semester (4 meetings per year). AUPs that require approval prior to scheduled meetings may be approved by an ACC Subcommittee.
- b) The ACC Chair will be responsible during ACC meetings to:
 - Present a brief summary of the AUP
 - Solicit feedback from Committee members
 - Identify outstanding issues
 - Inform Committee members of Merit Review outcome
 - Inform Committee members of Animal User Training status
- c) The ACC Chair will lead the discussion for ACC members to come to consensus.
- d) The ACC members will be responsible during ACC meetings to:
 - Provide feedback during the AUP review process and voice concerns
 - Take into consideration Merit Review outcome
 - Take into consideration Animal User Training status
 - Come to consensus
- e) The ACC Coordinator will record a summary of all concerns and discussions during the AUP review and approval process in ACC meeting minutes, including clarification requests and other directives. The ACC Coordinator will provide pertinent information in writing to the PI.
- f) The ACC shall apply protocol review criteria in a fair and consistent manner, including
 - Potential benefit of the research/teaching activity
 - Replacement alternative to animal use
 - Animal model selection
 - Reduction of animal use/numbers

- Refinement of experimental techniques to minimize or eliminate physical and/or psychological distress
 - Setting endpoints
 - Physical restraint
 - Invasive/stressful procedures
 - Training and competence of individual performing euthanasia
 - Appropriate approval for the use of hazardous agents
- g) ACC members shall base the protocol review on CCAC guidelines on: animal use protocol review (1997).

2.6 – Post-Meeting Review and Approval

- a) The outcome of the AUP review will be communicated in writing within two weeks following the ACC Committee meeting. The following scenarios can apply:
- AUP is approved: The ACC Coordinator will inform the PI in writing of AUP approval within two weeks. *Outcome:* the animal-based activity can start as planned.
 - AUP is approved pending clarification/minor adjustments: The ACC Coordinator will forward all questions and/or requested adjustments generated during the ACC meeting to the PI in writing within two weeks and copy the ACC Chair. The PI will have to respond to concerns and/or make requested adjustments and return the AUP for final approval to the ACC Coordinator. Approval-pending AUPs may receive final approval by the ACC Chair or an ACC Subcommittee. *Outcome:* the animal-based activity can start taking into consideration requested adjustments.
 - AUP is tabled: The ACC Coordinator will forward all questions and ACC requirements to the PI in writing within two weeks. Once the PI has updated the AUP, the ACC Coordinator will forward the AUP for approval. Tabled AUPs required approval from the ACC or, depending on timeframe, interim approval by the ACC Subcommittee. AUPs approved by the Subcommittee require full ACC approval during the next ACC meeting. *Outcome:* The animal-based activity cannot start until the ACC concerns have been addressed.

2.7 – Amendments and Annual Renewal

- a) Minor amendments of approved AUPs can be reviewed and approved by an ACC Subcommittee.
- b) Major amendments require regular ACC approval or, depending on timeframe, interim approval by the ACC Subcommittee.

3.0 – Related Documents

- Animals for Research Act, R.S.O. 1990, c. A.22
- Canadian Council on Animal Care: Ethics of Animal Investigation
- Canadian Council on Animal Care guidelines on: Animal use protocol review
- Canadian Council on Animal Care guidelines on: The care and use of wildlife
- Canadian Council on Animal Care guidelines on: Euthanasia of animals used in science
- Canadian Council on Animal Care: Social and Behavioral Requirements of Experimental Animals (SABREA)

- Canadian Council on Animal Care: Categories of Invasiveness in Animal Experiments
- Canadian Council on Animal Care: Requirement for submitting an animal protocol. Addendum to the CCAC policy statement on: terms of reference for animal care committees.
- Policy #9-902 Animal Care and Welfare
- Operating Procedure #9-902A: Animal Care Committee Terms of Reference
- Operating Procedure #9-902C: Scientific Merit Review of Animal Use Protocols (AUPs)
- Operating Procedure #9-902D: Pedagogical Merit Review of Animal Use Protocols (AUPs)
- Operating Procedure #9-902E: Post Approval Monitoring (PAM)
- Operating Procedure #9-902F: Animal User Training Program
- Operating Procedure #9-902G: Reporting of Concerns
- Operating Procedure #9-902H: Animal Husbandry
- Appendix A: Approval Process Flowchart for Animal-based Activities

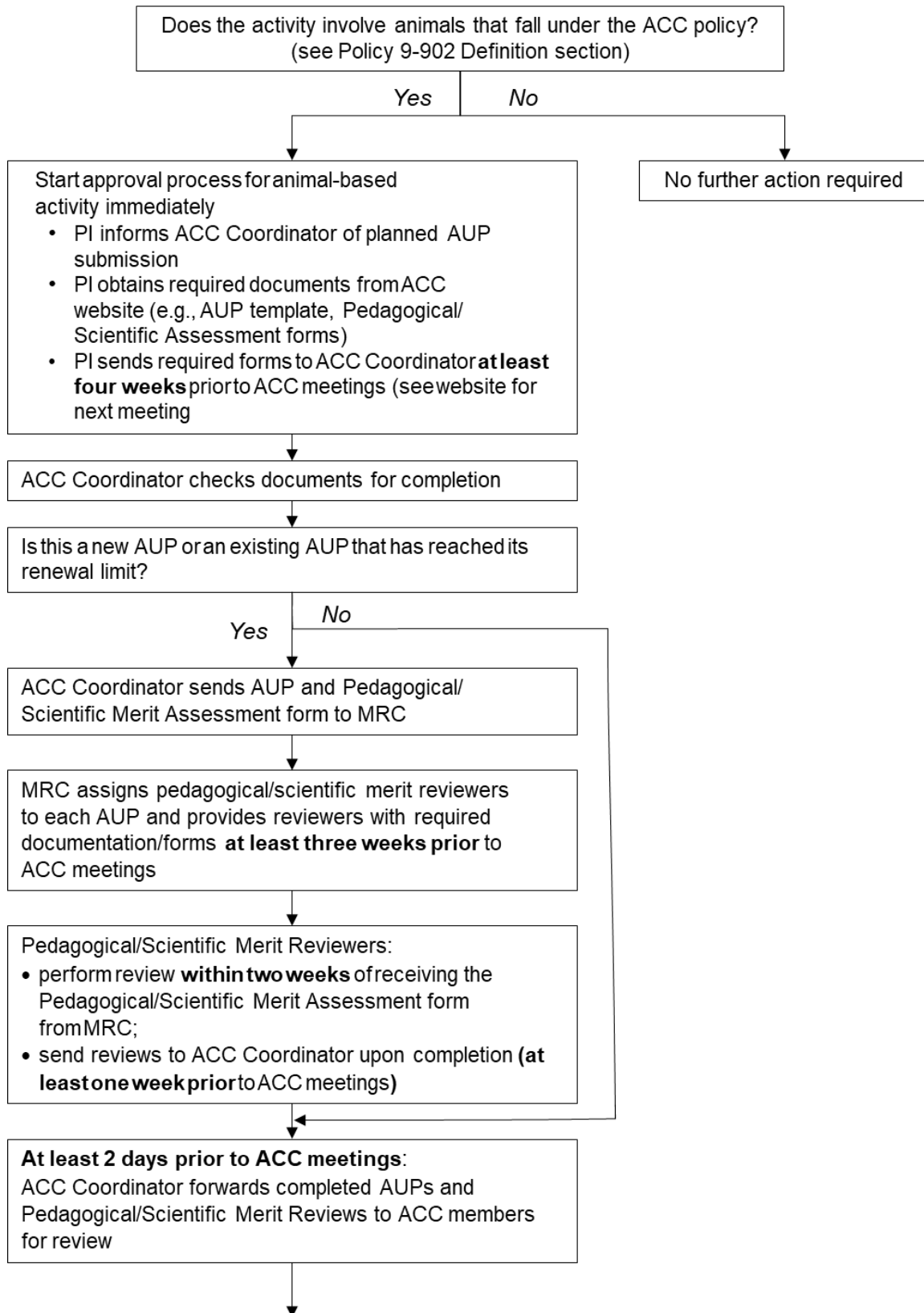
4.0 – History of Amendments & Reviews

Original approved by SMT September 25, 2019

Policy ID revised from 9-902A to 9-902B January 10, 2022.

Revision approved by SMT Jan 10, 2022

APPENDIX A: Approval Process Flowchart for Animal-based Activities



APPENDIX A: cont

