Policy: Animal Use Protocols

Category: Administration

Subject: Requirements for Animal Use Protocols associated with the animal-based science program within Western’s research community

Approving Authority: Animal Care Committee

Responsible Office: Animal Care Committee Office

Related Procedures: Procedures for Animal Use Protocols

Effective Date: 07OCT2015

Previous Approval Dates:

Revised:

Purpose
The objective of this policy is to outline criteria for the generation, review and approval of Animal Use Protocols (AUP) associated with Western’s animal-based science program to ensure alignment with current federal and provincial and other institutional regulatory policies.

Rationale
Canadian Council on Animal Care’s Terms of Reference for Animal Care Committees (ACC) states that “no animals be held for display or breeding purposes, or for eventual use in research, teaching or testing projects, without prior ACC approval of a written Animal Use Protocol”.

Ontario Ministry for Agriculture and Food and Rural Affairs’ (OMAFRA) Animals for Research Act states “Every animal care committee....shall be responsible for co-coordinating and reviewing, (a) the activities and procedures relating to the care of animals; (b) the standards of care and facilities for animals; (c) the training and qualifications of personnel that are engaged in the care of animals; and (d) procedures for the prevention of unnecessary pain including the use of anaesthetics and analgesics, in every research facility in connection with which the animal care committee is established, having regard to the requirements of this Act and the regulations.”

Additionally, OMAFRA’s Animals for Research Act states “The operator of a research facility shall, prior to conducting any research project in which animals are to be used, file, or cause to be filed, with the animal care committee a research project proposal setting forth the nature of all procedures to be used in connection with such animals, the number and type of animals to be used and the anticipated pain level that any such animal is likely to experience.”

The Tri-Agency’s Agreement on the Administration of Agency Grants and Awards by Research Institutions states that an institution shall:

- Allow access to research funds only after the institution’s animal care committee or another animal care committee designated by the Institution has approved the research, unless the activities involving animals will only take place in the future, in which case a part of the funds may be released to cover only expenses to be incurred before animals are used; and
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Ensure that approval by the animal care committee is maintained for the duration of research activities involving the use of animals and that, subject to (ii), funds are available to the Recipient only while this ongoing requirement is met.

Scope
This policy applies to all animal-based scientists within Western’s Research Community who use animals for research, teaching, testing, breeding or display.

Policy
Animal Use Protocol (AUP) form content, review and approval policies and processes must be developed and undertaken in accordance with all Federal, Provincial, and University policy statutory requirements and guidelines with particular reference to CCAC’s guidelines on animal use protocol review (1997); if any AUP content is at variance with the aforementioned guidelines, scientific and ethical justification must be required and approved by the Animal Care Committee (ACC).

Pursuant to existing policy of the University and of the broader scientific community, since the AUP is considered the intellectual property of the researcher, it must be made available only for confidential use by authorized individuals and not for unauthorized distribution.

AUPs must be submitted by Faculty members of Western’s Research Community, an ACVS Veterinarian or LHSC-Lawson appointed scientist, unless otherwise approved by the ACC.

All animal-based science and displays must be fully disclosed within an AUP.

AUP form completion support – AUP Facilitation – must be available to animal-based scientists.

AUPs must be submitted using eSirius, the web based AUP management system in use by the ACC.

All AUP documentation, including supportive information as requested by the ACC to ensure that all members of the ACC understand the AUP’s animal impact, must be submitted to the ACC with sufficient time to allow for review and approval prior to either expiry date, renewal date, or the date at which the researcher wishes to start the proposed work.

For collaborative projects involving PIs from two or more institutions in which the animal-based work is divided between the animal facilities of these institutions, the ACC must receive a written Animal Use Protocol detailing the animal-based work to be undertaken within the facilities for which it is responsible.

- This AUP must also provide a brief description of the project as a whole.
- Any interactions between the institutions relative to the animal-based work (e.g. transfer of animals from one institution to another, special requirements to ensure the health and welfare of the transferred animals, etc.) must be understood and accepted by the Animal Care Committees of each of the institutions involved.

Submitted documentation must be reviewed using the appropriate workflow for review and approval in accordance with its Protocol Review Type.

Any AUP with an ‘unfinished’ or ‘pending’ status must have a workflow date less than six months, or it will be removed from the eSirius AUP management system, unless approved by the ACC Chair.

AUPs must be approved prior to the procurement and/or use of animals in animal-based science and display activities.
Final approval of AUPs by the ACC must be undertaken only when the following reviews have been completed and approved by responsible parties:

- Reviews/Approvals undertaken by the ACC - Ethics Review
- Reviews/Approvals undertaken by parties external to the ACC -
  - For all AUPs, as applicable, Animal Care (AC) Facility Supervisor Review
  - For AUPs involving research, Scientific Peer Review
  - For AUPs involving any hazardous and new agent, material, and imaging device - Occupational Health & Safety Review
  - For Teaching AUPs, Pedagogical Merit Review

When requested by the ACC, a Principle Investigator (PI) must submit a Pilot Study to be completed and reported upon to ACC in advance of the total animal work as outlined within a full AUP submission.

For Pilot Studies,

- a peer review of scientific merit must be undertaken when a PI intends to use a Pilot Study to explore a new research direction that is not covered within the context of an existing peer-reviewed research program.
- ACVS Veterinarians must be actively engaged in monitoring and evaluation of experimental subjects during the duration of a Pilot Study and in the identification and refinement of endpoints and monitoring sheets.
- a subsequent complete AUP must not be submitted before the completion of the Pilot Study, the results of which must be included in the new AUP. These results must include the appropriateness of the endpoints and monitoring criteria as developed in consultation with an ACVS veterinarian.

All AUPs must be reviewed by an ACVS Veterinarian, or competent designate, to ensure alignment with current veterinary and regulatory standards of practice related to animal-based procedures outlined in the AUP under review.

All AUPs must be reviewed by Animal Educators to ensure all personnel have sufficient training related to animal-based procedures outlined in the AUP under review.

All AUPs must be reviewed by the AC Facility Supervisor or designate associated with the animal holding and/or use areas listed within the AUP. Once approved, an AUP is valid for a maximum of four years to the last day of the month of the initial approval, and must undergo yearly renewal via an Annual Protocol Renewal form. A maximum of three one-year renewals is permitted.

On a monthly basis, all AUP forms that have been approved by designates of the ACC during the previous month must be made available to the full ACC.

Animal-based science and displays must only continue while the associated AUPs maintain an ‘approved’ status.

Assurances to funding agencies must be provided by an ACC designate via Research Western’s Grants Office following ACC AUP approval.

An AUP holder must submit an amendment to the approved AUP using a Protocol Modification to inform the ACC of any and all changes in advance of introducing any such changes to ensure that documentation aligns with practice.

All Protocol Modifications must be approved by the ACC prior to implementation.
As determined by the ACC, where a Protocol Modification involves a significant change(s) in animal utilization or the direction of the research, teaching, or testing, a full AUP submission must be required.

PIs must accept responsibility for procedures performed on animals associated with their AUPs.

PIs must ensure that individuals listed in their AUP have full ongoing access to their AUP and have full understanding of their roles as outlined within.

PIs must ensure that all individuals to perform any animal-related procedures approved within their AUPs will complete all related CCAC and institutional mandatory training and will be competent to perform these procedures in advance of undertaking them.

All ACC-approved AUPs must be included in Western’s Post Approval Monitoring Program.

Regulatory information from AUPs must be sent annually to CCAC and OMAFRA using regulators’ Animal Use Data Forms.

Any concerns not readily resolved by accountable parties associated with Animal Use Protocols and related processes and timelines must be forwarded to the ACC Executive Team for consideration.

Definitions

- **Accountable Parties** – Individuals directly responsible for AUP preparation, review or approval: PI and PI staff, ACC designates involved in AUP review, Departmental Research Offices, ACVS support staff.
- **Animal Care Committee (ACC)** – A subcommittee of the University Council on Animal Care; the institutional animal care committee “responsible for overseeing all aspects of animal care and use and for working with animal users, animal care personnel and the institutional administration”; responsible to ensure animal ethics and care for animal-based science and animal displays directly associated with Western’s Research Community is in accordance with all regulatory and institutional policies and guidelines.
- **ACC Coordinator** – An administrative role dedicated to providing the ACC and PIs and their staffs with support for ACC and AUP-related activities, as outlined by CCAC.
- **ACC Executive Team** - A subset of the ACC tasked with performing preliminary assessments of concerns and related evidence brought forward to the ACC; developing recommendations for Project Refinements and Action Plans; and assigning a specific PI Rep to incidents as they arise. This subset must include at least one ACC and ACVS leader, an ACVS veterinarian, ACC Community Rep, an ACC Coordinator, and an experienced animal-based scientist on the ACC, if not represented by the ACC leader.
- **Animal Care (AC) Facility Supervisor** – A trained, competent individual responsible for the oversight of an area or facility that houses research animals who is accountable to the ACVS Director as regards animal health and welfare related matters.
- **AC Facility Supervisor Review** – The review of animal facility and husbandry-related elements of an AUP by Facility Supervisors responsible for oversight of animal facilities identified within an AUP. Each animal care facility supervisor may seek additional information directly from the PI or via the eSirius AUP review process regarding facility, hazards, animal husbandry and procurement requirements in advance of proceeding with the animal project. PIs are encouraged to directly contact the facility supervisor associated with the animal housing area identified within his/her AUP in advance of AUP submission.
• **Animal Displays** – All displays of animals that can be encountered by Western’s community and/or public at large. Displays may include aviaries, fish ponds, and fish tanks within classrooms. Excluded from this requirement are displays in private offices, e.g. fish tanks, caged birds.

• **Animal Educators** – Designates of the ACC who administer and provide CCAC-mandated Animal Care and Use ethics and hands-on training.

• **Animal Use Protocol (AUP)** – The ACC’s mandatory animal ethics form that contains details of a AUP holder’s intended live vertebrate animal care and use, which must be reviewed and approved by the ACC in advance of animal-based science or public viewing of displayed animals.

• **AUP Facilitation** – An AUP pre-review service provided to PIs or their designates through in-person dialogue with the ACC Coordinator, an ACVS Veterinarian and/or the ACVS Systems Administrator with the goal of clarifying ACC expectations regarding AUP content, and training PIs and their staff on the eSirius AUP management system.

• **Authorized Individuals** – All persons listed in an AUP, ACC members, Animal Care staffs

• **Categories of Invasiveness** – Levels assigned to AUPs in accordance with CCAC policy. Experiments involving:
  - o **A** – Most invertebrates or live isolates
  - o **B** – Little or no discomfort or stress
  - o **C** – Minor stress or pain of short duration
  - o **D** – Moderate to severe distress or discomfort
  - o **E** – Procedures causing severe pain at or above the pain tolerance threshold of anaesthetized conscious animals

• **CCAC** – The Canadian Council on Animal Care is a not-for-profit organization, created in 1968 to oversee the ethical use and care of animals in science (research, teaching and testing) throughout Canada.

• **Concerns** – Anything raised to any member regarding animal health and/or welfare, human safety, and AUP-related issues. Concerns will be reviewed by an ACC Executive Team, as appropriate. Concerns will be communicated to the PI before they are classified as either Incidents or Non-Compliance.

• **Designate** – An individual who is adequately trained and appropriately experienced with the animals under his/her care/oversight, and who is authorized to act on behalf of either the ACC, VP-Research, ACVS Director, ACVS Veterinarian, a Principal Investigator, or an Animal Care Facility Supervisor.

• **Ethics Review** – Ethics review of a proposed AUP by the ACC that focuses on the level of harm to animals as balanced by potential benefits and scientific merit with specific application of CCAC’s 3Rs of undertaking humane animal-based science. The ACC functions as a microcosm of society to review AUP applications by applying the guidelines and policies of the CCAC and using their own expertise, experience, values, and common sense to reach decisions by consensus about what animal-based work should be allowed to proceed and under what conditions.

• **OMAFRA** – Ontario Ministry of Agriculture, Food and Rural Affairs. Provincial regulators of animal-based science. Enforcers of the Animals for Research Act

• **Occupational Health & Safety (OH&S) Review** – A review process external to the ACC under the responsibility of institutional safety officers and Research Western’s Animal Research Safety Consultant. Required for AUPs containing biological, chemical, radioactive, imaging & laser devices.

• **Pedagogical Merit Review** – Peer review for pedagogical merit of proposed animal use in teaching shall consist of, at minimum, a review at a department level to be summarized in the pedagogical
merit review questions contained within the AUP form, and confirmed by the Chair of the Department.

- **Pilot Study** – A study limited to the fewest number of animals necessary to evaluate the appropriateness, feasibility and suitability of a particular animal model, procedure, or study design to meet defined scientific objectives that is compatible with Federal, Provincial, and University regulations, guidelines and policy statements.

- **Principal Investigator (PI)** – A scientist responsible for undertaking animal-based science in alignment with an approved Animal Use Protocol and current veterinary standards of animal care.

- **Protocol Review Type** -
  - **Full Review**: Animal Use Protocol, Annual Renewal and Protocol Modification forms involving the following elements will be automatically considered to require review by the full ACC:
    - All new AUPs
    - All C, D and E level Full Renewal AUPs
    - Pilot studies that involve level ‘E’ category of invasiveness or ethically sensitive species;
    - Interim-approved AUPs
    - Any protocol form upon request by any ACC Member, ACVS Veterinarian, or regulatory body (OMAFRA, CCAC);
    - Annual Renewals as requested by the full ACC and/or ACC Protocol Review Committee;
    - Protocol Modifications involving:
      - Animal procedural changes involving Category of Invasiveness level ‘E’
      - Use of animal models that employ ascites;
      - Multiple major survival surgeries;
      - Food and/or water deprivation resulting in pain or distress as determined by the reviewing ACVS Veterinarian;
      - Animal number increase above 100%
      - Addition of species involving rabbits, pigs, cats, dogs, sheep, NHPs.

  - **Designated Review**: The Designated Review process involves an alternating subset of ACC members including at minimum one ACVS Veterinarian or designate, one ACC Community Rep, and one ACC Chair or Vice Chair; other experts are included as needed.
    - Protocol Modifications involving:
      - Chronic studies containing animal procedural changes;
      - Addition of species that do not include rabbit, pig, cat, dog, sheep, NHP;
      - Animal number increase up to 100%;
      - New agents, materials, or devices.
    - Annual Renewals;
    - Full Renewals of B level AUPs
    - Pilot study Animal Use Protocol submissions, excluding ‘E’ Category of Invasiveness and ethically sensitive species;
    - Interim approval of full AUPs to be used infrequently.

- **Office Review**: The Office Review process is used for requested minor changes to an AUP which neither deleteriously impact animals nor require new skills.
  - The ACC Office may grant approval for:
- Staff & their training requirements
- AUP title change
- Granting information
- Animal Source (except involving transfer of previously 'used' animals between protocols)
- Animal Strain - addition of non-genetically modified strains
- Animal number increase up to 10%
  - An ACVS Veterinarian or designate may grant approval for:
    - Housing or use location change;
    - Euthanasia method change (CCAC acceptable only);
    - Acute procedures on a fully anesthetized animal that will not be recovered;
    - Analgesia & anesthesia regime change;
    - A change to a less invasive, distressful or painful procedure;
    - Transfer of animals between protocols (Protocol Transfers involving previous animal use, excluding breeders, moms & surplus animals)
- Animal Strain – addition of genetically modified strains
- Animal number increase between 11 and 25%

- **Scientific Peer Review** – A review process external to the ACC. Where scientific peer review has not already been documented by the granting agency, the ACC will request confirmation from the Associate Dean of Research (AD-R), or the equivalent, for the associated Faculty that scientific peer review has been undertaken at a faculty level in accordance with CCAC’s policy.
  - The AD-R will provide confirmation of scientific peer review by a minimum of two qualified, arms-length peer reviewers to the ACC office in a timely manner.
  - The AUP may only receive ethical approval once the ACC office has received confirmation of scientific peer review.

  Scientific peer review will be requested for Pilots involving a new research direction that is not covered within the context of an existing peer-reviewed research program.

- **UCAC** – Western’s Senate committee ultimately responsible for the Animal Ethics and Care program directly associated with Western’s Research Community.

- **Western’s Post Approval Monitoring (PAM) Program** – A CCAC-mandated program undertaken by the ACC. PAM encompasses regular assessment of core AUP elements including but not limited to animal procurement, animal housing and husbandry, animal procedures, animal monitoring, sick animal response, animal health/procedural records, and related documentation.

- **Western’s Research Community** – Institutions and their departments involving animal-based scientists having Animal Use Protocols under the jurisdiction of Western’s Animal Care Committee, the ACC.

**Roles and Responsibilities**

All stakeholders are expected to demonstrate collaborative, collegial communications and commitment to act in good faith.

Animal Care Committee members and associated reviewers are responsible to
- be knowledgeable of and respect institutional, provincial and national regulatory standards
- undertake ethical review of submitted AUPs
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- complete AUP reviews assigned to them within the allocated time
- maintain confidentiality of all material reviewed

Principal Investigator (PI) is responsible to
- treat all animals with respect and dignity
- be knowledgeable of and respect institutional, provincial and national regulatory standards
- ensure that all animal-based work is documented on his/her AUP, and submitted through eSirius for review and approval by the ACC in advance of project commencement
- submit AUP documentation with sufficient time to allow for review and approval prior to expiry dates or prior to project commencement
- undertake the AUP in practice as approved in principle by the ACC
- provide full copies of his/her AUP to those listed within
- ensure their research staff members who directly work with animals are listed in the AUP, apprised of, appropriately trained and competently undertake only those procedures in a manner outlined within the approved AUP
- seek guidance from ACC support staff for the preparation of his/her AUP if unclear on ACC expectations and/or form content
- submit Protocol Modifications for all changes to an approved AUP in advance of implementing these changes

PI Staff is responsible to
- treat all animals with respect and dignity
- be knowledgeable of and respect institutional, provincial and national regulatory standards
- read and understand the Animal Use Protocol(s) within which they are approved by the ACC as animal users
- receive required training in animal ethics and handling prior to undertaking any procedures within an approved AUP
- inform the PI and Animal Care Facility staff of any issues associated with either a departure from or concerns associated with the AUP

ACC Coordinator or designate is responsible to
- be knowledgeable of and respect institutional, provincial and national regulatory standards
- manage all AUP documentation and related review processes
- maintain schedules for review of documentation
- provide guidance to PIs and their staffs for the preparation of AUP documentation when requested
- compile annual regulatory reports associated with AUPs
- provide AUP facilitation services

ACVS Veterinarian is responsible to:
- be knowledgeable of and respect institutional, provincial and national regulatory standards
- provide guidance to and ACC, PIs and their staffs for the preparation of AUP documentation when requested
- complete AUP veterinary reviews within the allocated time
- provide AUP facilitation services
References

- MAPP 7.12 – Policy for the Use of Animals in Research, Testing and Teaching
- MAPP 7.10 – Standardized Training in Animal Care and Use
- MAPP 7.15 – Post Approval Monitoring Program
- Concerns Identification, Project Refinement and Corrective Response Policy Animals for Research Act
- CCAC guidelines on: animal use protocol review (1997)
- CCAC policy statement on: scientific merit and ethical review of animal-based research