

PURPOSE

The purpose of Post-Approval Review (**PAR**) of Animal Use Protocols (**AUPs**) is to compare research and teaching activities conducted under an approved protocol with the written procedures contained in that AUP. PAR includes an evaluation of documents, record keeping and any necessary site visits to observe procedures. This gives assurance that research and teaching practices and procedures do not deviate from those identified in approved AUPs, and that all documentation is in compliance.

BACKGROUND

Post-Approval Review is part of the overall University Animal Care Committee's (UACC) Post-Approval Monitoring Program (**PAMP**); see *UACC Procedures on Post-Approval Monitoring Program*. It is understood that a range of discrepancies between practice and AUP can occur for varying reasons. Such discrepancies may include:

- Personnel performing procedures are not listed on the approved AUP;
- Procedures performed are not listed on the approved AUP;
- Medications used are not noted in the AUP, are different from those listed in the AUP, or are not used in accordance with the AUP;
- Procedures listed in the AUP to promote animal welfare are not being performed, or documented, as approved in the AUP;
- Surgeries are not performed using aseptic technique;
- Euthanasia procedures differ from those listed in the AUP;
- Personnel do not demonstrate sufficient skill or lack training to appropriately perform procedures described in the AUP;
- Supporting documentation for animal care, monitoring, and/or other procedures are incomplete or unavailable;
- Conditions are not safe for humans and/or animals;
- Materials or medications are out-of-date.

ROLES AND RESPONSIBILITIES

University Animal Care Committee (UACC) and Animal Research Ethics Board (AREB) – The UACC is a University Committee that reports to the Vice-President Research. The AREB is a standing committee of the UACC that conducts ethical review of all AUPs. The AREB provides oversight of the PAMP, receives reports and updates, and recommends changes to procedures or suggests corrective actions on ongoing and unresolved matters of concern.

Animal Users – The Principal Investigator (**PI**) and designated research group members, authorized investigators, Course Director (**CD**) and instructors collaborate with the Post Approval Review Veterinarian (**PARV**) and provide documentation and clarification as required.

Post-Approval Review Veterinarian (PARV) – The PARV is an Animal Care and Research Support Veterinarian (**ACRSV**) and UACC member responsible for prioritizing and conducting PARs. The PARV works with the PI/CD to coordinate PAR meetings, reviews and observes AUP procedures, and completes a report of observations and recommendations. The PARV is accountable to and communicates directly with the AREB and also reports directly to the University Veterinarian (**UV**).

PROCEDURES

1. Selection of Protocols for Review

All active AUPs are subject to PAR. However, the primary focus of PAR will be on AUPs that:

- Involve surgical procedures
- Are Category of Invasiveness Level D or E
- Involve PIs, CDs, or labs that have had prior compliance issues
- Involve PIs, CDs, or labs that have been designated for a ‘For Cause’ Review. ‘For Cause Review’ may be requested by UACC members and UACC Support staff in response to specific concerns brought to the attention of the PARV or other UACC members. External agencies (e.g., Canadian Council on Animal Care (CCAC), Tri-Council agencies) may also request a ‘For Cause’ review.

2. Process of Review and Reporting

- a. The PARV will coordinate the PAR and prioritize AUPs for review. The PARV will review the AUP and note specific items of interest for observation, review or discussion.
- b. The PI/CD will receive an e-mail notification to schedule a PAR meeting. The PARV may request additional information or documentation prior to the meeting. Scheduling may be contingent upon when the protocol procedure is performed and the availability of the PI/CD and research group members. The PI/CD must attend PAR discussions, but PI/CD attendance during observed procedures is not mandatory.
- c. UACC members or animal care staff may be asked to participate in the review.
- d. The PAR will involve discussion and review of the following, where applicable (refer to the appended PAR Checklist and Report form)*:
 - Personnel and Training
 - Procedures
 - Anesthesia
 - Surgery
 - Post-procedural monitoring and care
 - Medication Use and Storage
 - Record keeping
 - Humane Intervention Points
 - Euthanasia
 - Equipment and Practices
 - Occupational Health and Safety pertinent to the AUP

PAR discussion will also identify any important changes in UACC or CCAC policies, procedures, and guidelines as appropriate.

- e. At the conclusion of the PAR, observations, recommendations, and deadlines are reported to the PI/CD. The PI/CD is responsible for communicating these observations, recommendations, and deadlines to research group members/instructors. In most cases, including Minor and Regular Recommendations, issues raised will be addressed collaboratively through additional training, improved record-keeping, reverting to procedures in an approved AUP, or submission of a modification to the AUP for AREB approval. The PARV will assist the PI in coordinating/providing additional training or AUP modifications if these actions are necessary.
- f. Reports for 'For Cause' review will be submitted to the AREB Chair and UV and included in the AUP file for review by the AREB at the next scheduled AREB meeting.
- g. Serious and Major Recommendations, or Animal Welfare concerns, i.e. misuse, mistreatment, neglect, or willful disregard for appropriate animal care, will be reported immediately to the AREB Chair and University Veterinarian, and shall be referred to the Vice-President Research in accordance with compliance procedures and policy (e.g., Responsible Conduct of Research). Any issues of veterinary care that pose an immediate threat to animal welfare will be referred directly to the Animal Care and Research Support Veterinarians or Facility Veterinarian for immediate resolution. As per CCAC guidelines, concerns qualifying as Major Animal Welfare Incidents must be reported to the CCAC within ten days of their occurrence.
- h. Continued non-compliance or instances of ethical non-compliance will be addressed according to *UACC Procedures on Animal Use Non-Compliance*.
- i. At each semi-annual UACC meeting the PARV will report major trends noted in PARs and suggest general educational development or informational needs within the university's– Animal Care and Use Program (ACUP)?.

4. Recordkeeping

- a. A PAR database will be maintained to track active protocols that have undergone or require PAR.
- b. The PARV will retain all documentation and communication associated with a PAR (e.g., e-mail, meeting notes) in the AUP file on the UACC shared server.

Approved by the UACC, December 2, 2020