

PURPOSE

The purpose of Post-Approval Review (PAR) of Animal Use Protocols (AUPs) is to conduct an in-person assessment of protocol activities to determine consistency of practices and procedures with those identified in approved protocols and Standard Operating Procedures (SOPs).

BACKGROUND

The Canadian Council on Animal Care's (CCAC) mandate directs institutions to "establish procedures for post-approval monitoring of animal use protocols and to define the roles and responsibilities of the members of the animal care and use program in the monitoring process" [from the CCAC Terms of Reference for animal care committees (2007)]. Post-approval review of AUPs complements the existing UACC Post-Approval Monitoring Program (PAMP), a process that presently encompasses (but is not limited to) the following: 1) Assistance to animal users from the Research Services and Ethics Office to maintain protocol compliance and to assure an efficient protocol modification process; 2) Assistance to animal users from UACC members (i.e. Animal Welfare Veterinarian, Facility Veterinarian) on new procedures or procedures likely to cause more animal pain or distress, and development of suitable humane intervention point checklists and clinical monitoring schedules; 3) Regular facility inspections by UACC Facility Inspection Committee; and 4) Day-to-day assistance to animal users from UACC veterinarians and animal care staff to assure consistency of practices with approved protocols and institutional policy and procedures, and to assure suitable training. The addition of the PAR of AUP to the existing UACC PAMP provides a forum for continuing education and for the collegial exchange of expertise.

ROLES AND RESPONSIBILITIES

Animal Users – Research trainees and technicians (RTs) and the principal investigator (PI) collaborate with the University Veterinarian (UV) to enable a PAR meeting. The PAR meeting will involve a review of protocol procedures, the direct observation of protocol procedures, and a discussion of AUP elements such as training, monitoring, and SOPs.

Facility Managers (FM) and Staff – FM and staff provide facility access and are encouraged to provide information requested by the UV.

University Veterinarian (UV) – The UV is responsible for prioritizing PAR meetings. The UV works with the PI and RTs to coordinate a PAR meeting, review and observe protocol procedures, prepare meeting notes, and conduct a follow-up meeting with the PI and RTs if necessary on any recommendations or need for further training. The UV also provides

operational oversight and overall management of the PAMP. The UV reports to the AREB and to the UACC and updates the UACC on immediate issues of concern.

University Animal Care Committee - The committee provides oversight to the PAMP, receives reports and updates, and recommends changes to procedures or suggests corrective actions (by way of the UACC Executive) on ongoing and unresolved matters of concern.

PROCEDURES

1. Selection of Protocols for Review

- a. All active protocols are subject to regular review. Protocols identified as Category of Invasiveness (CofI) "D" and "E" will undergo review at least once before the annual expiry date of the protocol. Protocols identified as CofI "B" or "C" will undergo review at least once in the four-year lifetime of the protocol. CofI "A" protocols do not undergo PAR.
- b. Protocol selection is random (except for "For Cause" reviews), but PIs holding multiple protocols may have several protocols reviewed simultaneously to enhance PAR efficiency.

2. Process of Review

- a. The UV will coordinate the PAR and prioritize protocols for review. The PI will receive an e-mail notification to schedule a PAR meeting. Scheduling is contingent upon when the protocol procedure is performed and the availability of the PI and his/her RTs. The PI must attend the PAR discussion, but PI attendance during observed procedures is not mandatory.
- b. The UV will read the protocol and accompanying modifications, annual renewals, and SOPs for PAR in advance of the scheduled meeting.
- c. The on-site review of an AUP will involve discussion on the training level of personnel listed on the protocol, consistency of observed procedures with procedures identified on the approved protocol, anaesthesia/analgesia, surgery, and post-surgical care as appropriate, euthanasia method, clinical care and monitoring activities, record keeping, an evaluation of the space where animal use occurs, environmental enrichment, and discussion of relevant UACC and institutional policies and procedures. This discussion will also identify any important changes in UACC or CCAC policies, procedures, and guidelines as appropriate.
- d. If necessary, the animal technical staff providing care for the animals listed on the protocol may participate in the review or may be consulted by the UV prior to the review.
- e. At the conclusion of the review, immediate concerns are discussed with the PI and research trainees/technicians. The UV will draft PAR Meeting Notes (Appendix I) to identify the key continuing education and evaluation elements of the PAR meeting.
- f. If necessary, an in-person follow up meeting will be scheduled to discuss items of concern.

2a. Cause for Review

- a) 'For Cause' reviews will follow from specific concerns or issues brought to the attention of the UV or other UACC member. External agencies (e.g., CCAC, Tri-Council agencies) may also request a 'For Cause' review.
- b) 'For Cause' reviews will involve at minimum a two-membered team that includes the UV and a UACC member.
- c) The UV will request a meeting with the PI and other personnel as appropriate and investigate the specific concern or issue.
- d) Reports for 'For Cause' review including corrective actions and follow-up meetings will be submitted to the PI, AREB Chair, UACC Chair, and UV, and filed in the animal use protocol file for review by the AREB at the next scheduled AREB meeting.

3. Process of Reporting

a. Immediate Reporting

- i. Any departures from the approved protocol, the CCAC guidelines and policies, and institutional policies and SOPs that may constitute significant, serious or continuing violations will be reported immediately to the UACC Chair.
- ii. Any issues of veterinary care that pose an immediate threat to animal welfare will be referred directly to the Facility Veterinarian for immediate resolution.

b. Follow-up with the PI

- i. Shortly following the PAR meeting, the UV will prepare meeting notes and e-mail these to the PI for his/her signature. If necessary, the UV may schedule a face-to-face exit meeting with the PI and appropriate personnel to discuss key observations and offer recommendations to address the concern(s).
- ii. The UV will assist the PI in coordinating/providing additional training or protocol modifications if these actions are necessary. The UV will follow-up to confirm completion of these actions.

c. Document Control

- i. The PI and the UV will retain each a signed copy of the PAR Meeting Notes.
- ii. A copy of the signed Meeting Notes will be filed with the protocol in the Research Ethics Office.
- iii. The UV will report significant observations or concerns from PAR Meeting Notes at each scheduled AREB meeting.
- iv. At each semi-annual UACC meeting the UV will consolidate major trends within PAR Meeting Notes and suggest general educational development or informational needs within the university's animal care and use program.

4. Recordkeeping

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

Approved by UACC, 30 May 2014



PAR MEETING NOTES

I. BACKGROUND INFORMATION

PRINCIPAL INVESTIGATOR	PROTOCOL NUMBER	C OF I
PAR VISIT DATE	DATE OF MEETING NOTES	
PROTOCOL PERSONNEL PARTICIPANTS		

II. EVALUATION

A. DISCUSSION OF RELEVANT PROTOCOL ACTIVITIES AND APPLICABLE UACC POLICIES/PROCEDURES

B. OBSERVATION (SEE CHECKLIST)

OBSERVATIONS	RECOMMENDATIONS

B. SUMMARY EVALUATION AND COMMENTS

IV. SIGNATURES

SIGNATURE OF UNIVERSITY VETERINARIAN

SIGNATURE OF PRINCIPAL INVESTIGATOR

Post-approval Review Monitoring Checklist

- Does the PI/personnel/facility staff have the most recent version of the complete protocol, including amendments? Is it read? Any changes that have not been identified and approved?
- Are the people performing the animal work trained, competent, and listed on the AUP? What training received?
- Are drugs, suture material and other items within the noted package expiration dates? Are controlled substances stored appropriately and records maintained?
- Are animals identified by protocol number and individual numbers or cage/pen cards?
- Are endpoints or humane intervention point monitoring checklists and records available?
- Are medical and post-procedure care progress notes complete and accurate? Medication documented; injections, blood collection, etc documented.
- Are investigators and research personnel wearing PPE and/or other attire (e.g. masks & gloves) appropriate for the level of biocontainment, and for the species and procedures performed?
- Are anaesthetized animals monitored according to the approved method in protocol? Are the animals maintained at an appropriate depth of anaesthesia for the procedure performed?
- Is survival surgery performed in an appropriate surgical area, with use of aseptic technique (sterile instruments, sterile gloves, surgery mask) and adherence to appropriate surgical principles, and with use of an appropriate heat source to keep the animal warm during surgery?
- Appropriate recovery area? Is post-surgical care documented?
- Is the euthanasia method consistent with the approved protocol? Are proper methods of carcass/tissue disposal in place?
- Are the procedures performed consistent with those in the approved protocol?
- Are the methods of analgesia (dose, frequency, duration) consistent with the protocol?
- Are there any safety issues or other concerns that pose a threat to human or animal safety, or animal welfare? Have unforeseen circumstances arisen that may have caused undue distress for the animals involved?