**Introduction**

The goal of the post approval monitoring (PAM) program is to ensure that animal-based work at Carleton University aligns with approved Animal Use Protocol (AUP) elements and conforms directly to all regulatory and institutional requirements. By doing this, the PAM program reduces risk to the institution and provides ongoing support to the research community. The program provides an opportunity to improve and refine animal welfare and concomitant high quality reproducible data as well as to ensure transparency. A collaborative and collegial approach with researchers promotes open communications with the ACC and by extension, the CCAC, the animal care staff and Senior Administration. It is managed and supported by the Animal Care Committee (ACC), with work of the program supported by the ACC and Animal Care and Veterinary Services.

There are several elements to the PAM program at Carleton University:

* Veterinary & ACVS Rounds
* ACC Annual Site Visits
* Post Approval Reviews
* Non-Compliance Response

**Veterinary and ACVS Rounds**

Veterinary and ACVS rounds provide a venue for strengthening the capacity of researchers and their staff and students to conduct animal related activities in accordance with their respective approved AUPs and in compliance with applicable regulations. Rounds will be performed by the University Veterinarian and/or a trained and qualified ACVS technician.

The primary objectives of veterinary rounds are to fully understand the work being conducted, to support research by maintaining open dialogue with animal users at the lab level, to offer assistance in correcting protocol drift, to offer advice concerning procedural refinements or additional training requirements, and to learn what refinements scientists have initiated that can be shared with Carleton’s research community. In the event of ‘protocol drift,’ every effort will be made to ensure the collegial development of a strategy to correct any drift. Follow-up monitoring and mentoring will be offered in all cases if deficiencies are identified.

ACVS technicians check all animals daily for signs of disease and physical and behavioural abnormalities. Health issues can be due to infectious agents, genetic abnormalities, environmental problems, or experimental procedures. In the event of an unexpected complication during the course of the study, animals that are sick or distressed are flagged and the Principal Investigator and Veterinarian notified. A Medical Record (Appendix 1) is generated and maintained until the case has been resolved.

**Annual ACC Facility Visits**

CCAC Terms of Reference requires formal ACC facility visits by ACC member teams to all sites where live animals are used. Each area must be visited at minimum once per year to better understand work being conducted, to meet with those working in animal facilities and areas and discuss their needs, and to monitor animal-based work according to AUPs and Standard Operating Procedures (SOPs).

Site visit reports will be produced and presented to ACC by the site visitors and a written response will be required, where necessary, from those responsible for animal areas. The ACC coordinator will contact PIs in advance as required to coordinate lab visits.

**Post Approval Review**

The Post Approval Review will review current practices and procedures associated with approved AUPs and SOPs to which research personnel have been assigned. The committee will review the AUP and determine the skill sets required as described and ensure that training has been completed and recorded for each user as per CCAC guidelines. Additionally, the PAM Review review can provide an opportunity to improve overall conditions and training for the end users thereby improving the student and research staff experience.

When a protocol or the entire lab is selected for review, the ACC Coordinator will coordinate the visit with the PI. The members of the panel will meet beforehand to discuss the protocols under review. A checklist will ensure that the process is as straightforward and consistent as possible to minimize the impact to the lab. The approach will be collaborative and comments on the process will be accepted and taken into consideration as the process unfolds.

**Non-Compliance**

This process deals with noncompliance of approved policies and procedures as well as animal welfare concerns that might arise at Carleton University; it applies to all animal users, staff and students. If researchers, staff or students have concerns about the care and use of animals or are concerned about a procedural (not affecting animal welfare) or ethical (concerning animal welfare) breach, refer to details below for minor and serious concerns.

For minor concerns, or first time occurrences, the observer is encouraged to talk to the individual(s) involved and detail their concern. If the observer is not comfortable in approaching the individual(s) their concern should be brought to the attention of the ACC chair or the University Veterinarian.

In the event of serious concern, a verbal report should be made to the ACC chair and/or the University Veterinarian; completion and submission of a Non-Compliance Form is also appropriate, this form can be submitted to the ACC chair or the University Veterinarian or ACC.

All concerns requiring a Non-Compliance Form (Appendix 2) will be followed up with the student and PI and a report generated which will be communicated to the ACC, excluding the names of the student or staff member. If the ACC feels it is appropriate the concerns will be forwarded to the corresponding PI, Department Chair and/or the VP Research. Once follow up has been completed, the individual whom submitted the form will be notified of the resolution.

*Details outlined above do not supersede collective agreements.*

Appendix 1: ACVS Medical Record

|  |  |  |  |
| --- | --- | --- | --- |
| **INFORMATION** | | | |
| Date: |  | Protocol # |  |
| Principal Investigator |  | Animal ID |  |
| Student |  | Room Number |  |

|  |  |  |
| --- | --- | --- |
| **OBSERVATIONS** | | |
| Observations |  | Initial/Date |
|  |
| Treatment |  |  |
| Follow-up/Outcome |  |  |

Appendix 2: Non-Compliance Form

|  |  |  |  |
| --- | --- | --- | --- |
| Date of Report |  | | |
| Date of Non Compliance |  | Time of Non Compliance |  |
| Reported By: |  | Position |  |
| Reported To: |  | Position |  |

|  |
| --- |
| Description of Non-Compliance |
|  |
| Discussion: |
|  |
| Recommendations and Action |
|  |

|  |  |  |  |
| --- | --- | --- | --- |
| Date |  | Signature |  |