Postapproval Monitoring (PAM) Program

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Aims of PAM

PAM aims at comparing the activity actually performed with those approved by the IACUC/AEC. It also provides opportunities to refine research animal procedures.

Why PAM?

Apart from reviewing and approving animal experimental protocol, the Institutional Animal Care and Use Committee (IACUC) or Animal Ethics Committee (AEC) also takes the responsibility to oversee all approved animal activities. The Hong Kong’s Code of Practice for Care and Use of Animals for Experimental Purposes (the Code) requires the role of such oversight. The oversight, i.e. the PAM, was also implemented into the 2010 eighth edition of the Guide for the Care and Use of Laboratory Animals (the Guide) as a new section.

The goal of PAM is to maintain compliance with regulations and guidelines in order to ensure the welfare of research models.

Components of a PAM program

No two PAM programs are identical. Each institution needs to tailor their own program. However, some common components are listed as follows:

- Audit of approved protocol and other legislation documentations
- Audit of medical records
- Inspection of animal use areas, including laboratories and procedure/surgical rooms
- Audit of training records
- Announced and unannounced observation of procedures
- Investigation of reported animal welfare concerns
- Animal facility inspection

Who performs PAM?

In the Code, AEC members are required to conduct inspections of all animal housing and laboratory areas regularly, and must maintain records. The Guide mentioned that the IACUC/AEC, veterinary, animal care, and compliance staff may all conduct PAM.

Given the demanding work load in a PAM program, plus the fact that the IACUC/AEC personnel is likely to dedicate more time on their full time job, compliance staff may be employed to perform PAM in reporting to the IACUC/AEC. Persons with veterinary background are knowledgeable to examine surgical areas, including anesthetic equipment, use of appropriate aseptic technique, and handling and use of controlled substances. Persons with scientific background and animal research experience understand the science aspects of protocols and communicate effectively with the researchers. Investigators may have more respect to personnel who have research experience. No matter if it is the dedicated compliance staff or the IACUC/AEC member or the facility veterinarian, one must be knowledgeable in animal care and use compliance in order to run a successful PAM program. It is not uncommon that the same compliance staff will also be responsible on other related tasks such as training the IACUC/AEC members and providing consultation during the protocol review process.

Follow-up and reporting

The PAM team will generate a report on the monitoring findings. Contents of the report may include departures from the protocols, relevant policy, guidelines, and local legislation. The team may also propose the corresponding corrective measures. Corrective measures include a modification of the protocol, reverting procedures to those approved by the IACUC/AEC, retraining of persons conducting the procedures, and enhanced environmental control on surgical areas, among others. It is also important to emphasize that the purpose of providing the corrective measures is mainly educational and not a policing and penalizing activity.

HKUST PAM

PAM in HKUST is just beginning. In the absence of dedicated PAM staff, the animal care staff act as the eyes of the team to
identify potential non-compliance during their animal caring and husbandry routine checks in APCF. Observations made by the animal care staff and any information provided by other sources can lead to an investigation by a senior APCF staff. Investigation on any Adverse Event Reports (AER) and the PAM program development are both expected from the newly formed AEC.

We have also developed SOP O-029 Reporting and Investigating an Allegation on Breaching APCF Rules. It is currently in draft format but once approved, it will detail how breaches of APCF SOPs be handled.