Post-Approval Monitoring (PAM)

SOP

According to the Guide for the Care and Use of Laboratory Animals (The Guide - Office of Laboratory Animal Welfare OLAW), "Continuing IACUC oversight of animal activities is required by federal laws, regulations, and policies. A variety of mechanisms can be used to facilitate ongoing protocol assessment and regulatory compliance. Post approval monitoring (PAM) is considered here in the broadest sense, consisting of all types of protocol monitoring after the IACUC's initial protocol approval (page 33, The Guide)." A major goal of the PAM program is to increase communication between investigators, IACUC, animal program staff and to foster an educational partnership among these groups to ensure animal welfare in a collegial manner.

In order to be in compliance with Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy), and OLAW, Howard University IACUC implements a post-approval monitoring (PAM) system that includes continuing protocol review; bi-annual laboratory inspections; veterinary or IACUC observation of animals and of selected procedures; and external regulatory inspections and assessments performed by a PAM coordinator. Thus, IACUC, veterinary, animal care, and compliance staff and the PAM coordinator may all conduct PAM with a goal of assuring that research is being conducted according to what is written and approved by the IACUC. The coordinator acts on behalf and at the request of the IACUC. The role of the coordinator is to confirm, by observation, that all animal care and use activities are performed in accordance with approved IACUC protocols, institutional policies and federal regulations. This document primarily defines the responsibilities of the PAM coordinator.

Roles

- The Principal Investigator (PI) and laboratory staff will work with the PAM coordinator to observe and confirm that monitored procedures agree with the approved protocol.

- The PAM coordinator will work with the PI and laboratory staff to observe activities, to prepare accurate reports, and if necessary, to provide training and recommendations for maintaining compliance.

- The PAM coordinator will also monitor animal activities in Veterinary Services.

Personal Protection:

The PAM coordinator will wear the personal protective equipment (PPE) described in the IACUC-approved protocol for the specific activity or laboratory being observed.

Policy Expectations

I. PAM Reporting Model:

a. The PAM coordinator will report issues directly to the IACUC in the form of updates at IACUC meetings.

b. The PAM coordinator reports to the IACUC and is independent of Veterinary Services.

c. The PAM coordinator is not a member of the IACUC.

II. Selection of Protocols for Review:

All active IACUC-approved protocols will receive, at minimum, one annual PAM review.

Additional PAM coordinator reviews may be scheduled for:

a. Allegations of misuse, neglect, or inappropriate protocol application reported to the IACUC, or

b. Active protocols or procedures identified by the IACUC at the time of protocol approval.

IV. Process of Monitoring:

a. Routine PAM Visit: The PAM coordinator will schedule the initial site visit with the PI or laboratory personnel. Follow-up visits for the purpose of confirming resolution of a concern will be conducted.

b. The PAM coordinator will e-mail the PI at least 5 business days before the initial visit. This e-mail serves as the introduction of the site visit process and the coordinator who will perform the PAM. This email will provide guidelines defined by the IACUC for the visit.

c. During each visit, the PAM coordinator will compare procedures conducted in the laboratory with those listed in the approved protocol.

d. The Guide lists the following examples of effective PAM monitoring strategies:

- examination of surgical areas, including anesthetic equipment, use of appropriate aseptic technique, and handling and use of controlled substances
- review of protocol-related health and safety issues
- review of anesthetic and surgical records
- regular review of adverse or unexpected experimental outcomes affecting the animals
- observation of laboratory practices and procedures and comparison with approved protocols.

V. Information Communicated to the PI or Laboratory Manager:

a. At the conclusion of the visit, the PAM coordinator will conduct an exit interview with the PI or PI-designee.

b. A description of the discrepancies between the procedures performed in the laboratory and those listed in the approved protocol, or procedural plan will be e-mailed to the PI and the IACUC members for review. The IACUC members will have 5 business days to call for full-committee review (FCR) of the discrepancies at an upcoming IACUC meeting. If FCR is not requested, the coordinator will e-mail the list of discrepancies to the PI. When noncompliant concerns are noted, the PAM coordinator will advise the PI or PI-designee on ways to rectify the issues and of the communication options available to discuss the discrepancies with the IACUC (i.e., by way of a memo to the IACUC or attendance at the IACUC meeting to discuss the concern(s)).

c. When no concerns are noted during the site visit, the PAM coordinator will send a memo to the PI and IACUC describing the procedure(s) monitored and commending the PI and laboratory staff for their continued full compliance with the IACUC.

VI. Information Provided to the IACUC:

a. Written Report: The following items will be reported to the IACUC by means of a (monthly) Trends Report. The Trends Report will be included in the IACUC meeting packet for member review. Full disclosure of all information related to each item must be included in the trends report:

1. A list of protocols for which no discrepancies were identified, or

2. Unapproved personnel who performed procedures proficiently and who posed no recognized welfare risk to the animal, or

3. Outdated cage cards, incorrect cage cards, improperly labeled cage cards, or

4. Housing locations not listed in the protocol (for non-VS sites), or

5. Procedure locations not listed in the protocol, or

6. Anesthetics/analgesics: unapproved regimen or route of administration, outdated agents, improper clinical use, or

7. Any modifications to approved procedures, or

8. Other procedural deviations, or

9. Incidents of animals that were distressed according to the Guide (p. 121), when that distress was clearly related to mechanical system failure.

10. Items listed in the OLAW Notice concerning reportable conditions, or too vague must define.

11. Recurrent deficiencies, even those not listed in the OLAW Notice, or

12. Allegations of misuse and the subsequent investigation

VII. Process of Sharing Information Concerning the Review:

a. As previously indicated, whenever possible, the PAM coordinator shall conduct an exit interview with the PI or PI-designee before leaving the laboratory. The goal of the exit interview is to confirm accuracy of the observations and to assure a complete understanding of concerns, when applicable. According to PHS Policy, any procedure observed during the site visit that is not included in the IACUC-approved protocol must be stopped immediately. If desired, the PI may submit an amendment to the IACUC requesting approval of a new procedure; however, the procedure may not be performed until final IACUC approval is granted. If the unauthorized action continues, the entire protocol, or the specific procedure may be suspended by the IACUC. "The IACUC may suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with applicable provisions of the Animal Welfare Act, the *Guide*, the institution's Assurance, or IV.C.1.a.-g. of this Policy.[11] The IACUC may suspend an activity only after review of the matter at a convened meeting of a quorum of the IACUC and with the suspension vote of a majority of the quorum present.

If the IACUC suspends an activity involving animals, the Institutional Official in consultation with the IACUC shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to OLAW."

a. Issues that pose an immediate threat to animal welfare will be referred to the Attending Veterinarian for immediate resolution.

b. Issues representing potential noncompliance will be reported to the IACUC.

c. The PAM coordinator will send a final written report of the monitoring results to the PI and the IACUC:

1. Compliant Activity Report

2. Potentially Noncompliance Report

d. In cases where the PI desires to initiate corrective actions prior to the IACUC meeting, the PAM coordinator may assist the laboratory with completing PI-initiated corrective actions by coordinating required training and/or form preparation (i.e., the IACUC amendment process). Corrective action may include modifying an existing protocol, reverting to procedures already listed in the protocol or training/retraining. The PI may communicate the internal action by either means noted above.

VIII. Reporting to the IACUC:

According to PHS Policy:

a. If necessary, prior to the IACUC meeting, the PAM coordinator will meet with the IACUC Chair to discuss the observations and potential recommendations for consideration by the IACUC.

b. The PAM coordinator will report the observations to the IACUC.

c. The PI will be provided the opportunity to:

1. Attend the IACUC meeting to present an argument to or answer questions posed by the Committee, or

2. Provide written correspondence to the IACUC.

3. Request a designated IACUC team to independently observe the procedural concerns raised by the PAM coordinator.

d. The PI or any person, including an IACUC member, who has a direct or indirect conflict define of interest with the issue being discussed, may remain in the room to discuss the incident with the Committee, but he/she must leave the room during the final deliberation and vote.

IX. Process of Follow-up (post-IACUC decision):

a. The IACUC Chair will report the decision to the PI within 2 business days of IACUC meeting.

b. On occasion, additional site visits may be a part of the follow-up process.

c. The PAM coordinator may revisit the laboratory following the initial site visit to confirm the effectiveness of the corrective action. The time of the follow-up visit will be coordinated with the PI and not to exceed 1 week of the request from the PI.

d. In most cases, issues will be addressed by:

1. Modifying an existing IACUC-approved protocol, or

2. Reverting to the procedure(s) listed in the IACUC-approved protocol.

X. Process of Addressing Concerns:

Investigators who disagree with the IACUC decision may appeal to the IACUC in writing or in person.

XI. Recordkeeping:

a. A copy of the final compliance monitoring report will be kept in the file of the protocol associated with the activity. For SOP-related and procedural plan-related activities, the reports will be kept under the name of the SOP or procedural plan.

b. All information will be entered into the Compliance Database (TBD) (maintained by the ORRC) to determine institutional trending and for follow-up purposes.