

**Post Approval Monitoring for the Animal Research Facility at VA Pittsburgh
Healthcare System (VAPHS)**

Policy #A-009

VA Pittsburgh Healthcare System
Pittsburgh, PA 15240

Service Line(s):
Research and Development (R&D)
Department

Signatory Authority:
Dr. Steven Graham, ACOS

Effective Date:
September 15, 2020

Responsible Owner:
Associate Chief of Staff/R&D

Recertification Date:
December 2021

1. PURPOSE AND AUTHORITY

- a. Post approval monitoring (PAM) of Institutional Animal Care and Use Committee (IACUC)-approved protocols is performed at the VA Pittsburgh Healthcare System (VAPHS) to proactively identify problems and to document regulatory compliance and adherence to IACUC-approved protocols. A PAM could be performed in addition to the annual Continuing Reviews of currently approved IACUC protocols and in addition to the regulatory compliance audits performed by the VAPHS Research Compliance Officer.
- b. This Policy sets forth mandatory procedures and processes to ensure compliance with VHA Directive 1200.07, Use of Animals in Research, November 23, 2011.
- c. This policy applies to all VAPHS and Veterans Research Foundation employees (including those with WOC appointments) working with animals within the VAPHS Animal Research Facility (ARF).

2. PROCEDURES

a. **Background**

A continuing program to audit approved animal use protocols is an essential component of a comprehensive Animal Care and Use program and is recommended by the Guide for the Care and Use of Laboratory Animals, 8th Edition. Such a program provides a method of ensuring institutional regulatory compliance, facilitating research activities, and giving investigators an opportunity to discuss problems, concerns and/or changes needed in active projects. The process entails review of study documents, inspection of individual laboratories and selected procedures performed, and agents used therein. Also, this process provides the opportunity to meet with personnel actively engaged in animal-based research, giving a personalized review of relevant IACUC policies, observations of techniques and provision of specific training.

The goal of the PAM program is to selectively review active IACUC protocols on a regular basis.

b. Selection of Protocols

Protocols can be selected from the following categories:

- 1) Category C, D and E protocols.
- 2) Studies involving USDA regulated species, such as rabbits or non-human primates.
- 3) Studies or groups that have had past compliance issues and need regular close oversight.

PAM may include, but is not limited to, review of documents (e.g., the protocols compared to the cage cards), inspection of laboratories, and observation of animal-related procedures, especially if surgical procedures are included in an approved Animal Component of Research Protocol (ACORP). Additionally, a PAM activity could also include a meeting with a new PI to review their approved protocol, and review of Quality Assurance (QA) audits. Inspections of animal research practices are conducted by a qualified veterinarian, the ARF Supervisor, or another qualified member of the IACUC. Focus is placed on surgical procedures, post-anesthesia care, and manipulations that have the potential to cause pain or stress. The PAM Document Review Checklist is used to ensure that all training is up to date, and documentation of ACORP activities is appropriate and accurate.

The IACUC will select a PAM activity to be performed four times a year during IACUC meetings. If a protocol is reviewed as the PAM activity, the IACUC will use a random drawing with the limitations that no protocol is reviewed more frequently than every two years. If there is reason for concern about a particular protocol, the committee is free to select it specifically. A PAM for a study will also be performed on as needed basis.

c. PAM Process

(1) Notification of PAM

The PI will receive a notification email from the IACUC Coordinator approximately 1 month in advance that the protocol will be audited. If an inspection/observation is used to complete the PAM, the notification will include a timeframe to schedule the audit, as well as a copy of the PAM Documentation Review checklist. This allows the PI enough time to gather relevant information as outlined in the checklist, review the protocol, and prepare for the meeting.

(2) PAM Review/Inspection

For PAM, review of documents, inspections of laboratories and/or observation of procedures will be conducted at the discretion of the Veterinarian/Inspector. Review

of a PI's IACUC-approved study can take place at any time and the reviewer can contact the PI with questions that arise during the assessment. If an inspection and/or observation of a procedure is to be conducted, it will be scheduled for a time that is mutually agreed upon by the PI and Veterinarian. The session may take place in the PI's office, laboratory, a nearby conference room, or during a planned experiment if a procedure will be monitored. All results of the PAM are conveyed to the PI and he/she is informed that the results will be discussed at the next convened IACUC meeting.

(3) Review of PAM Results

The IACUC Coordinator will provide a review of the PAM results to the IACUC members at the next convened committee meeting. The IACUC will discuss any deficiencies that are identified and will determine whether the research program is meeting expected standards or if compliance action is required.

The outcome of the evaluation will be recorded in the IACUC minutes and communicated to the PI. The R&D Committee will be informed of the results in the form of the meeting minutes.

Investigators who disagree with the audit results and/or recommendations may appeal to the IACUC.

A hard copy of the final report of PAM will be maintained in the protocol folders located in the IACUC Coordinator's office. The reports will be retained indefinitely, and a copy of the report will be sent to the PI.

(4) PAM at Other Institutions with VA Funding

PAM of research activities that are conducted outside the VAPHS program but are in a program that is Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) accredited (i.e., University of Pittsburgh) will require permission of that institution for inspection of laboratories. If that is not forthcoming, an interview-based PAM (as currently conducted by the University of Pittsburgh IACUC) will be conducted. If there is cause for concern about a given laboratory, PAM will be initiated in conjunction with the compliance office of the institution where the activity is being conducted.

3. ASSIGNMENT OF RESPONSIBILITIES

- a. **Veterinarian/Inspector** – Person who performs the PAM; reviews documents, inspects the laboratories and/or observes procedures that are conducted on a study
- b. **IACUC Coordinator** - Provides a review of the PAM results to the IACUC members at the next convened committee meeting

4. DEFINITIONS

Post Approval Monitoring (PAM) - A continuing program to audit approved animal use protocols; an essential component of a comprehensive Animal Care and Use program

5. REFERENCES

- a. VHA Handbook 1200.07, Use of Animals in Research, November 23, 2011.

6. REVIEW

This policy is reviewed at recertification, when there are changes to the governing document (for example, national policy or an accreditation body mandate), and any regulatory requirement for more frequent review.

7. RECERTIFICATION

This Policy is scheduled for recertification fifteen (15) months from the Effective Date. In the event of contradiction with national policy, the national policy supersedes and controls.

8. SIGNATORY AUTHORITY

//signed copy on file //

Gretchen Haas, MD
Chair, Research and Development Committee
Date Approved: September 15, 2020

//signed copy on file //

Steven Graham, MD, PhD
Associate Chief of Staff Research and Development Department
Date Approved: September 15, 2020

NOTE: *The signature remains valid until rescinded by an appropriate administrative action.*

DISTRIBUTION: SOPs are available at: <https://www.va.gov/pittsburgh-health-care/research/safety-security/animal-research/>