POLICY NUMBER: A-009

TITLE: Post Approval Monitoring for the Animal Research Facility at VA Pittsburgh Healthcare System

1.0 PURPOSE

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. PAM is performed in addition to the annual Continuing Reviews for every approved IACUC protocol and in addition to the audits performed by the VAPHS Research Compliance Officer.

2.0 REVISION HISTORY

R&D Approval Date	Revision #	Change	Reference Section(s)	Effective Date
July 24, 2018	1.2	Change IACUC Program Assistant to IACUC Coordinator	Sections 6.1 and 6.3	July 27, 2018
June 27, 2017	1.1	Minor modifications to wording	Section 5.0	June 30, 2017
June 14, 2016	1.0	None	N/A	June 17, 2016
May 26, 2015	1.0	Minor modifications to wording.	All	May 29, 2015
January 14, 2014	N/A	NEW POLICY		January 16, 2014

3.0 SCOPE

This policy applies to all Research personnel working with animals within the VAPHS Animal Research Facility (ARF).

4.0 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 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.

5.0 SELECTION OF PROTOCOLS

Protocols are 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 inspection of laboratories and animal-related procedures, especially if surgical procedures are included in an approved Animal Component of Research Protocol (ACORP). Inspections of animal research practices are conducted by a qualified veterinarian, the ARF Supervisor, or other 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 protocol four times a year for PAM during IACUC meetings using 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. With this approach, approximately ten percent of active protocols receive PAM annually.

6.0 PAM PROCESS

6.1 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. 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 sufficient time to gather relevant information as outlined in the checklist, review the protocol, and prepare for the meeting.

6.2 PAM Inspection

For PAM, inspections of laboratories and/or procedures will be conducted at the discretion of the Veterinarian/Inspector. The inspection will be conducted at 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 inspection are conveyed to the PI and he/she is informed that the results will be discussed at the next convened IACUC meeting.

6.3 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.

6.4 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 particular 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.

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Gretchen L. Haas, PhD
Research and Development Committee Chair

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Steven H. Graham, MD, PhD
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