The University of Pennsylvania’s Institutional Animal Care and Use Committee (IACUC) and Office of Animal Welfare (OAW) is charged with implementing a Post Approval Monitoring (PAM) program that meets the criteria set by the federal regulations, which stipulates that

AWR§2.31(d) (5)
“The IACUC shall conduct continuing reviews of the [activities involving research animals] at appropriate intervals as determined by the IACUC.”

The PHS Policy requires institutions to comply with the performance-based standards in the Guide for the Care and Use of Laboratory Animals (Guide).

“(PAM) is considered here in the broadest sense, consisting of all types of protocol monitoring after the IACUC’s initial protocol approval.... Methods [of PAM] include continuing protocol review; laboratory inspections (conducted either during regular facilities inspection or separately); veterinary or IACUC observation of selected procedures; observation of animals by animal care, veterinary, and IACUC staff and members; and external regulatory inspections and assessments.”

The IACUC has developed the following policy to help the research community understand and prepare for post approval monitoring visits by the OAW Compliance Liaisons (CLs). This policy is relevant to all individuals at the University associated with an IACUC-approved protocol and use animal models in their research.

The PAM program aims to enhance the animal care and use program by:

- Providing a resource to the research community by disseminating information and answering questions.
- Creating an atmosphere for collegial dialogue and exchange of information between the individuals conducting the research and the IACUC.
- Establishing a relationship of advocacy between the laboratory, Office of Animal Welfare, and the IACUC.
- Acknowledging compliant laboratories on campus, resolving unintentional noncompliances, assisting laboratories with maintaining compliance with the institutional policies and guidelines, and identifying and preventing protocol drift.

While the Principle Investigator is ultimately responsible for overseeing the research being performed in the laboratory, they are strongly encouraged to invite all personnel affiliated with the protocols who perform the animal use procedures to attend these scheduled PAM visits.

The OAW’s goal is to visit laboratories using the following schedule:

APPROVED 3/4/2015
Once annually
- USDA species, pain category C (Penn A) procedures
- Non-USDA species, pain category D (Penn B) procedures

Twice annually
- USDA species, pain categories C & D (Penn B & C) procedures
- Non-USDA species, pain category E (Penn C) procedures
- Satellite housing areas—all species

The PAM program uses the following documents as standards, references, and guidance:

- The Guide for Care and Use of Laboratory Animals
- Animal Welfare Act & Regulations
- PHS Policy on Humane Care and Use of Laboratory Animals
- USDA Animal Care Policy Manual
- Guide for Care and Use of Agricultural Animals in Research and Teaching
- ULAR SOPs
- IACUC Policies, Guidelines

This Policy will cover the following topics:
- Scheduling a PAM Visit
- Preparing for a PAM Visit
- Types of PAM Visits
- Conducting the PAM Visit
- Post PAM Visit: Correspondence
- Resolution Process and IACUC review

SCHEDULING A PAM VISIT

An email will be sent by a CL to the PI, the Co-PI, protocol contact, and a secondary contact, if applicable, as listed on the relevant protocols to be reviewed. This email will include:

1. A brief explanation regarding the reason for the visit.
2. The primary focus for this visit requested by the IACUC (e.g., survival surgery, tumor production).
3. The Compliance Checklist (Appendix A) and any other relevant guidelines to be discussed or reviewed.

These visits are typically scheduled in one hour intervals; however, shorter or longer visits may be requested depending on the scope of the visit (record review, procedural observations, etc). This will be arranged at the convenience of the laboratory to allow flexibility with personnel schedules.
PREPARING FOR A PAM VISIT

The CL will review all relevant protocols and IACUC policies and guidelines prior to the PAM visit. The CL will compare procedures described in the approved protocols with current regulatory guidance and standards. This review and comparison may help identify items that may need to be updated or clarified even before the visit. Topics that may be discussed during these visits can be found on the Compliance Checklist. The PI and laboratory personnel are strongly encouraged to review all IACUC protocols, relevant IACUC policies and guidelines, and the checklist prior to a PAM visit.

TYPES OF PAM VISITS

Regardless of the type of PAM visit, the goal of the PAM program is to find evidence of good performance and to confirm continued compliance. When contrary circumstances are discovered, the goal is to resolve any issues in a timely manner with help and guidance from the CLs, OAW, and IACUC.

Visit types can include a review of the general protocol or specific procedures, for cause or follow up with reported animal welfare concerns, record review, procedural/surgical observation, or a site visit follow-up. While this is not a comprehensive list, these are the more common types of PAM visits performed at Penn. Examples of what may be reviewed or questions that may be asked during these visits can be found in the Compliance Checklist (Appendix A).

General Protocol Review/Specific Procedure Review
Advance review of an approved protocol will assist with understanding the scope of the laboratory’s research goals and approved IACUC activity. The CL will bring any notes to a PAM meeting regarding items that may have been flagged during this post approval protocol review. Finally, the CL will request any records pertaining to specific procedures to review for consistency with protocols. Record reviews may involve confirmation of adherence to drug regimens and documentation of animal health observations per protocol, and controlled drug substance records, etc., though this is not an all-inclusive list.

Procedural/Surgical Observation
These visits involve the observation of any activity on a live animal, including nonsurgical procedures, imaging, behavioral assessments, euthanasia and surgical procedures.

Site Visit Follow-up
During a site visit follow-up, specific items noted during IACUC or other external agency site visits may be discussed and resolution plans may be established or reviewed. Records for specific animals or procedures may be requested for review. The CL performing the follow-up visit will outline the requested records in their scheduling email.
Reported Animal Welfare Concerns/Adverse Event Follow-up (For Cause)
During these visits, the CL may inquire about a recently reported animal welfare concern or adverse event. Details regarding the concern or how the adverse event was managed will assist the CL with gathering information for IACUC review.

CONDUCTING THE PAM VISIT

Conducting the Review
The discussion will be professional and cordial, and not intended to impede any research being conducted. The scope of the visit will encompass one or more of the above categories (Types of PAM Visits) and will be provided to the PI prior to the visit. The CLs will use the Compliance Checklist as an outline for conducting this visit. Certain laboratories, depending on procedures being performed, will be visited annually or biannually as outlined in the introduction of this Policy.

Exit Briefing
A synopsis of the overall laboratory performance and potential concerns will be openly discussed to confirm the accuracy of the observations made during the review with all personnel in attendance. Following the visit, the CL will communicate promptly with the PI and personnel at the briefing with a written post-visit correspondence. The CL will work with the PI and laboratory personnel to develop and implement a resolution plan (e.g., protocol amendment submissions, retraining). These issues and resolution plans will be summarized in a post-visit correspondence email as described below.

POST-PAM VISIT: CORRESPONDENCE

Post-Visit Correspondence
An overview, as well as any recommendations from the PAM visit, will be summarized in a “Post-Visit Communication” email from the liaison. This correspondence will typically be sent out within 48 hours of the visit. The PI should keep the CL updated with plans and completed action items as they occur.

RESOLUTION PROCESS AND IACUC REVIEW
All animal welfare concern investigations and post approval monitoring findings are reviewed by the IACUC Compliance Subcommittee (CSC).

Resolution Process
After receipt of the post visit correspondence email, if any issues were noted, the PI should communicate final resolutions of items noted during the visit, in writing, to the CL. This response should provide timelines for the corrective actions noted in the correspondence email. This information will be helpful when the CL presents their verbal PAM summary to the IACUC Compliance Subcommittee. Proactive resolution plans designed in good faith with or
without the assistance of the CLs are viewed favorably by the IACUC. The CL will be in touch with the PI or designated contact throughout the resolution process.

IACUC/CSC Review
On a weekly basis, the CLs will present the IACUC Compliance Subcommittee (CSC) with summary of PAM visits from the past week, any concerns noted, and the proactive resolution plan being implemented by the PI based upon the suggestion(s) of the CL and CSC. Once the CL reviews the PAM visit with the CSC, several steps may be taken. Brief details of these steps are included below.

1. The CSC finds the established resolution plan adequate and requires no additional information or follow-up.
2. The CSC requires additional information. The CL will be in touch to gather the information through email or an in-person visit. This information will be presented back at the next CSC meeting.
3. The CSC requires additional resolution plan action items. These action items will be detailed by the CL via email. As with the original action items, the PI should respond with a plan to implement these action items. Continued communication with the CL is key when creating and implementing these resolution plans.

The CSC will determine if the issue requires a full IACUC review and if any issues are reportable to regulatory agencies (OLAW, AAALAC). The PI will be contacted by the CL if more information or additional action items are needed as part of the resolution plan. The CLs will also notify the PI if any issue will be reviewed by the full IACUC. The IACUC Chair or OAW Director will notify the PI if any issue is reportable.