

Post-Approval Monitoring (PAM) FAQs

Q: What is Post-Approval Monitoring?

A: Post-Approval Monitoring, or PAM, is a process by which the IACUC can ensure that investigators are adhering to their approved protocols and are in compliance with the regulations. PAM is designed so that the IACUC can effectively establish improved communication and collaboration with the investigators. This will result in improved animal welfare and research implementation. PAM can also help prevent serious non-compliance issues from arising, or can help correct non-compliance issues that have occurred. It is important and ideal for the IACUC to correct non-compliance issues before regulatory agencies find problems and potentially suspend research.

Q: Why are the Semi-annual inspections not enough in terms of IACUC monitoring?

A: The semi-annuals allow the IACUC to broadly assess a laboratory's compliance with regulatory and institutional regulations. Adherence to the details of an approved protocol are not assessed during the Semi-annuals. PAM visits will allow for the assessment of a laboratory's adherence to their protocols.

Q: How often will PAM visits occur?

A: Each laboratory/PI will be visited approximately one time every 2-3 years

Q: How will PAM visits be beneficial for me and my laboratory?

A: PAM visits have the potential to allow for improvement in animal welfare and techniques, thus potentially improving research results. These visits will also give the investigator and lab personnel the opportunity to ask questions or seek assistance from the IACUC. In addition, these visits will allow for preparation before other inspections (semi-annual, USDA, AAALAC)

Q: Will I be notified before a visit occurs?

A: Yes, these will be announced visits. The PI will be notified via email, and the visit will be scheduled approximately one week in advance.

Q: Is Post-Approval Monitoring required by law?

A: To maintain compliance with OLAW and AAALAC, each institution should have a post-approval monitoring program in place to allow for continual review of activities. In order to maintain our OLAW assurance and AAALAC accreditation, it is imperative that we comply with all the guidelines and recommendations. Complying with these guidelines will allow our institution to maintain a high standard of research and animal welfare and decrease the number of noncompliance incidents.

Q: Will I be notified if my laboratory is in compliance with what the IACUC expects?

A: Yes, shortly thereafter, a letter will be emailed to the PI stating the outcome of the visit and listing any issues that need correction.

Q: How will I know what the expectations of the IACUC are?

A: See the PAM Checklist for guidance on what will be asked/observed during a PAM visit.

Q: What are some of the procedures that will be observed during a PAM visit?

A: Procedures observed could be anything described in the protocols, such as a surgical procedure, anesthesia protocols, blood collection, injections, restraint methods, postprocedural care, etc. The personnel listed in the protocol should be qualified to perform the procedures.

Q: Who will be conducting the PAM visits?

A: The IACUC Chair or one of the designees

Q: Are all research personnel listed on the IACUC protocol expected to be available during a PAM visit?

A: The PI is expected to be present and ideally all the personnel, especially the personnel performing specific procedures. But if there are scheduling conflicts, all the personnel do not need to be present during a visit.