

IOWA STATE UNIVERSITY
Office of Research Ethics
Post-Approval Monitoring Program for the
Use of Animals in Research, Teaching, and
Testing

Program Description

Objective

Iowa State University recognizes that ensuring and documenting compliance with approved animal care and use protocols is an important aspect of the animal care and use program. The purpose of a post-approval monitoring program is to work with investigators to facilitate their animal research, teaching and testing and to be proactive in identifying potential problems in compliance with active Institutional Animal Care and Use (IACUC) approved protocols, with an emphasis on education and training. The program is also designed to help investigators, their teams, and the University prepare for external audits by funding, regulatory, and accreditation agencies.

Background

Post-approval monitoring of IACUC-approved protocols is achieved through several different mechanisms (e.g., the Attending Veterinarian's observation of research, teaching and testing procedures, IACUC inspections, compliance checks coordinated with the Office of Sponsored Programs Administration, etc.). The Post-Approval Monitor (PAM) from the Office of Research Ethics (ORE) is specifically charged with documentation of compliance. The PAM will also focus on meeting with investigators to discuss their research, teaching and testing programs and to offer insight on regulatory and committee requirements, expectations, and recent developments regarding ISU's animal care and use program.

This program provides the following distinct benefits:

- Provides a mechanism for documenting compliance with applicable animal care and use policies, guidelines, and laws
- Serves as an opportunity for dialogue, education, and exchange of information between individuals conducting research, teaching and testing involving animals and the IACUC/ORE
- Assists investigators in preparing for visits by outside evaluators such as USDA inspectors, Office of Laboratory Animal Welfare (OLAW) staff, and AAALAC site visitors

This program is also designed to avoid overlap with the responsibilities of other components of the animal care and use program. The post-approval monitoring program will not interfere with the Attending Veterinarian's oversight of pre-procedural and post-procedural care and guidance to investigators regarding animal handling, immobilization, and anesthesia; the IACUC's inspection of animal housing facilities; or inspection of laboratory spaces by the Biosafety Officer.

Roles

- Investigators and their staff will work with the PAM by allowing the observation of, or verbally verifying, protocol-specific procedures, supported by giving access to study-related records.

- The PAM will discuss protocol-specific research, teaching or testing activities, prepare accurate reports, provide recommendations for maintaining compliance, provide training or information on training options when needed, and assist in the execution of corrective and preventive actions.
- The Director, Office of Research Ethics (DORE), shall provide oversight and management of the PAM and the post-approval monitoring program, assure that the IACUC and the Institutional Official receive reports or updates on items of concern, and provide training support as required to assure compliance.

Scope

The post-approval monitoring program is designed to provide the opportunity to meet with a greater number of investigators and their research teams. As such, any IACUC-approved protocol may be randomly selected for a visit.

In addition to random selection, monitoring visits may also be “directed” by the IACUC or DORE, for example, to assist in the verification of findings in cases of potential noncompliance, to provide verification that corrective actions were implemented in response to noncompliance, to observe a new procedure, or to assist the IACUC in monitoring studies requiring more frequent review, etc.

Furthermore, principal investigators may also request a monitoring visit in order to help keep records and procedures in compliance with federal regulation and institutional policies, or to prepare for an external audit by a sponsor or federal agency. Visits of this nature are encouraged, as a key goal of post-approval monitoring is not to “catch” individual wrongdoing; rather, it is designed to assist investigators in conducting compliant research.

Monitoring process

The post-approval monitoring program will primarily center on a dialogue between the investigators and the PAM. During the visit, the PAM will observe protocol-specific procedures or ask the PI and the laboratory staff who are present to verbally describe their study including animal procedures. The PAM will assist the investigator in identifying any inconsistencies and concerns by comparing observed procedures or verbal reports to information contained in the approved animal use protocol. The visit will also involve review of associated study records including monitoring records, animal use records, etc., to help ensure that all procedures being conducted are included in the protocol.

Additionally, the PAM will help to inform the PI and associated personnel of any new or revised policies made by the IACUC or ORE. Visits may also include observation of any areas where procedures are carried out or animals are housed if the protocol is currently active. A foremost goal of PAM visits will be to provide an opportunity to share information and answer questions.

Deliberate animal misuse, mistreatment, or neglect, or situations which involve willful disregard for appropriate animal care will be immediately reported to the DORE, IACUC Chair, and the Attending Veterinarian. See [Reporting Concerns](#) for additional information.

Recordkeeping

Documentation of PAM visits will consist of a write-up of the topics discussed, any controverted issues relating to what has been approved and discussed, along with confirmation of general areas of compliance. The PI will be asked to verify the accuracy of the information provided and will receive a copy of the PAM visit report for inclusion in their files. Copies of the report will also be provided to the DORE, the IACUC Chair, IACUC Administrator, and the Attending Veterinarian. The IACUC will receive monthly reports regarding PAM activities.

Adopted: September 2008

PAM records shall be maintained for three years following closure of the protocol by the investigator or when administratively closed by the IACUC administrative staff. After a period of three years after the protocol is closed, PAM reports, communication, and notes will be deleted and paper files will be disposed of.