

Post-Approval Monitoring Program

Summary/Purpose: To ensure research and teaching activities involving live vertebrate animals are conducted in accordance with regulations and are consistent with the IACUC-approved Animal Study Protocol and amendments.

POLICY

Animal Study Protocols will be subject to post-approval monitoring according to selection criteria below.

PROCEDURES

A. Comprehensive site visit

Monitor(s)

Monitor(s) will be IACUC members or persons designated by the IACUC.

Protocol Selection

Protocols will be selected for monitoring based on PI history and/or protocol type. For example:

- PIs with past compliance issues,
- Multiple Survival Surgery (MSS) protocols,
- Pain category D protocols,
- Species requiring satellite housing, i.e., field station,
- Recommendations from Animal Care Staff, and
- Protocols involving USDA-covered species.

Pre-Review

Monitors will review the protocol and amendments using the Post-Approval Monitoring Checklist, formulate additional questions, and highlight areas of interest.

Notification of Principal Investigator (PI)

IACUC staff will notify the PI approximately one month in advance that one or more of their protocols will be reviewed. IACUC staff will call the PI or PI's designee to answer any questions and schedule the review. Other protocol research personnel and student assistants should make every attempt to participate in the review along with the PI.

Protocol Review

The protocol review will be conducted in the PI's office, laboratory or accessible conference room using the Post-Approval Monitoring Checklist and protocol records.

Report of Findings

If necessary, corrective action and timelines will be discussed with the PI at the time of the review. A report including findings, recommendations for improvement, action to be taken, and/or follow-up procedures (as necessary) will be submitted to the IACUC for review and

discussion during a convened IACUC meeting. The Principal Investigator will receive a copy of the final report, which will be filed in the corresponding protocol folder(s).

B. Routine animal care staff inspections

UM's OLAW assurance and AAALAC accreditation documents state that ORSP animal care staff must inspect all animal housing areas. This affords a continuous opportunity to evaluate the research and the animals to detect deviations from approved protocols and amendments. Inspections are documented and maintained by the IACUC office.

C. PI Annual Update forms

The annual update forms are used to verify compliance with approved protocols.