

UND IACUC Post-Approval Monitoring Guidelines

Standard:

The goal of post-approval monitoring (PAM) is to work with, and in support of, research staff members and to confirm accurate and consistent protocol performance in a collegial and unobtrusive manner.

Background:

Post approval monitoring is required by federal laws, regulations, and guidelines, though the exact form it takes is somewhat flexible. Post approval monitoring includes continuing IACUC oversight of animal activities, providing an assurance to regulatory agencies as well as the research institution, ensuring that animal experiments are monitored for compliance with approved IACUC protocols. The University of North Dakota IACUC PAM Team confirms consistency with approved protocols and program policy, working collaboratively with research personnel to satisfy this federal requirement.

Roles:

Investigators and research personnel: Will work in conjunction with the PAM Team to facilitate observation of procedures and document compliance with approved protocols. Will submit amendments for corrective actions resulting from the PAM visit in a timely manner.

PAM Team (Attending Veterinarian and member of IACUC, as well as the IBC-IACUC Coordinator, when available): Will work with the investigator and research personnel to observe activity, prepare accurate reports, and if necessary, facilitate training and provide recommendations for maintaining compliance. The Office of Research Compliance & Ethics (RC&E) maintains PAM records, uploads them to investigator protocols in the online protocol system, and corresponds with the IACUC.

Institutional Animal Care and Use Committee (IACUC): Shall provide operational oversight of the PAM Team and the post-approval monitoring program, ensure that the IACUC receives reports or updates on items of concern, and provide training recommendations as required to ensure compliance.

Required Protective Measures:

The PAM Team, as well as other visitors, shall wear the Personal Protective Equipment (PPE) prescribed for the specific activity/procedure of the laboratory.

Expectations:

- I. Selection of Protocols for Review:
 - a. All active protocols involving the use of animals are subject to PAM monitoring.
 - b. All active protocols involving the use of animals in USDA Category D or E may be subject to more frequent monitoring on a random basis, or at the discretion of the IACUC and Attending Veterinarian.

- c. In general, the PAM Team or designee will schedule monitoring sessions with the Principal Investigator or other research personnel in advance.
- d. "For cause" monitoring may be conducted at any time, with or without advance notice to the Principal Investigator or research personnel.

II. Process of Monitoring:

- a. The PAM Team shall make an appointment for visits (follow-up visits may also be scheduled).
- b. The PAM Team shall use the IACUC-approved "Post-Approval Monitoring Checklist" for the PAM visits.
- c. Training documents (i.e., laboratory personnel training record) may be requested during the PAM process.
- d. Procedure logs may be requested during the PAM process. During each monitoring session, the PAM Team will compare procedures conducted in the laboratory with those listed in the approved protocol. Documented discrepancies between procedures performed in the lab and those listed in the protocol will be brought to the attention of the Principal Investigator.
- e. Items that will be reviewed are listed on the "Post Approval Monitoring Checklist" and include the following sections:
 - i. Protocol and Personnel
 - ii. Study Procedures
 - iii. Anesthesia
 - iv. Surgery
 - v. Post-Surgical Care
 - vi. Euthanasia
 - vii. Record Keeping
 - viii. Laboratory
- f. At the discretion of the PAM team, research procedures may be placed on hold if animal welfare issues are observed.

Animal misuse, mistreatment, or neglect (welfare issues), and discrepancies which result in animal welfare concerns (deliberate animal misuse, mistreatment, or neglect, or those that involve willful disregard for appropriate animal care) will be immediately reported to the IACUC in accordance with Public Health Service Policy. RC&E staff, in conjunction with the IACUC Chair, will gather information to present to the IACUC for review and, if necessary, further investigation.

Process of Sharing Information Concerning the Review:

- I. The PAM Team shall discuss monitoring results with the Principal Investigator and other research personnel before leaving the laboratory. Issues that pose an immediate threat to animal welfare shall be referred to the Attending Veterinarian or other veterinarian for immediate resolution.
- II. The PAM Team may send a written draft report of the monitoring results to the Principal Investigator and other research personnel. The investigators will have an opportunity to respond to the draft report before the final report is prepared.

- III. The PAM Team presents a biannual report to the UND IACUC committee regarding any visit findings.
- IV. The PAM Team shall send a final written report of the monitoring results to the Principal Investigator on behalf of the IACUC Chair.
- V. Follow-Up Process:
 - a. The PAM Team will follow up on any issues that require protocol modifications, orientation of new personnel, or training. The PAM Team will support the laboratory corrective action by facilitating the required training.
 - b. The principal investigator is responsible for submission of any amendments requested by the PAM Team. Amendments must be submitted within 30 calendar days of receipt of the final report from the PAM Team.
 - c. On occasion, additional monitoring sessions may be part of the follow-up to assist with proper corrective actions.

Recordkeeping:

- I. The visit information shall be recorded by the PAM Team for use as institutional trending or follow-up, and determination of general training or information needs.
- II. A copy of the final compliance monitoring report shall be kept with the investigator's protocols and in the Office of Research Compliance & Ethics.

References:

The UND IACUC post-approval monitoring guidelines are based on Northwestern University's IACUC Post-Approval Monitoring documents.