

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 visiting PAM Team to facilitate observation of procedures and document compliance with approved protocols.

PAM Team (Attending Veterinarian and member of IACUC): 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 PAM Team also maintains PAM records 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, assure that the IACUC receives reports or updates on items of concern and provide training support as required to assure 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 may be 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. Protocols involving less invasive procedures will be monitored at the discretion of the IACUC and Attending Veterinarian.

- d. In general, the PAM Team or designee will schedule monitoring sessions with the Principal Investigator or other research personnel in advance.
 - e. "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. 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. The IACUC 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 shall 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 and/or form preparation (addendum submission).
 - b. 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 in the IACUC Office.

References:

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

Post-Approval Monitoring (PAM) Checklist

Principal Investigator: _____

Protocol Reviews: _____

Protocol Number:

_____ Protocol Title:

_____ Species:

_____ Date of

Monitoring: _____

Procedure Observed: _____

PAM Team Member(s): _____

The Protocol and Personnel

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|---|---|-----|--|
| Y | N | N/A | 1. Do the PI and research personnel have or know how to access the most recent version of the complete protocol, including amendments? |
| Y | N | N/A | 2. Have the investigators and research personnel read the protocol? |
| Y | N | N/A | 3. Are laboratory staff performing the procedure(s) listed on the protocol? |
| Y | N | N/A | 4. Are all personnel currently up to date on Occupational Health Program requirements? |
| Y | N | N/A | 5. Is each room where animals are taken listed on the protocol? |

Study Procedures

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|---|---|-----|---|
| Y | N | N/A | 6. Does the protocol number on the animals' cage card match the IACUC approved protocol number? |
| Y | N | N/A | 7. Are the procedures performed consistent with those approved in the protocol ? |
| Y | N | N/A | 8. Are research personnel appropriately trained to perform these procedures and is documentation of training available? |
| Y | N | N/A | 9. Are investigators/research personnel wearing appropriate Personal Protective Equipment (PPE) and/or other attire (i.e., gloves, masks, etc.) for the species and procedures performed? |
| Y | N | N/A | 10. Are the species, strains, and ages of animals consistent with those in the approved protocol? |
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Post-Approval Monitoring (PAM) Checklist

Anesthesia

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|---|---|-----|---|
| Y | N | N/A | 11. Are the methods of anesthesia in compliance with the protocol? |
| Y | N | N/A | 12. Are anesthetized animals monitored according to the approved methods in the protocol? |
| Y | N | N/A | 13. Are the animals maintained at an appropriate depth of anesthesia for the procedure performed? |
| Y | N | N/A | 14. If inhalant anesthetics are used, are they scavenged appropriately? |
| Y | N | N/A | 15. Are anesthetic machines serviced and calibrated annually? |
| Y | N | N/A | 16. Are analgesic dosages, frequency, and routes of administration accurately recorded? |

Surgery

- | | | | |
|---|---|-----|--|
| Y | N | N/A | 17. Is surgery performed in a location that has been approved by the IACUC? Is there a separate animal preparation and surgical space? |
| Y | N | N/A | 18. Is the method of animal prep appropriate and in accordance with the approved protocol? |
| Y | N | N/A | 19. Is survival surgery performed using sterile instruments, sterile gloves, a surgery mask and aseptic technique? |
| Y | N | N/A | 20. Is an appropriate heat source used to keep the animal warm throughout the surgical procedure? |
| Y | N | N/A | 21. Are incisions closed appropriately and in accordance with the approved protocol? |
| Y | N | N/A | 22. Is there an appropriate/designated recovery area for the animals? |
| Y | N | N/A | 23. Is there only one major surgery performed on each animal (unless prior approval by the IACUC)? |
| Y | N | N/A | 24. Is an identification method in place to indicate which animals have had a procedure performed on them? |

Post-Surgical Care

Post-Approval Monitoring (PAM) Checklist

- Y N N/A 25. Is the post-surgical area in compliance with the approved protocol?
- Y N N/A 26. Are the methods of analgesia (dose, frequency, duration) consistent with the approved protocol?
- Y N N/A 27. Is post-surgical/post-procedural care adequately documented? Is an appropriate heat source used for recovery?
- Y N N/A 28. Are any post-operative problems reported to CCM veterinary staff?

Record Keeping

- Y N N/A 29. Is there an up-to-date and complete surgical/procedure log (i.e., USDA medical record, pink card)? Is the animal's weight recorded at appropriate intervals?
- Y N N/A 30. Are individual animals appropriately identified (cage cards, ear tags, tattoos, etc.)?
- Y N N/A 31. Are medical and post-procedural care progress notes complete and accurate?
- Y N N/A 32. Is medication/anesthetic/analgesic administration accurately documented?
- Y N N/A 33. Are injections, blood collection, and fluid collection amounts dated and documented?

Euthanasia

- Y N N/A 34. Does the method of euthanasia correspond with what is written in the protocol?
- Y N N/A 35. Is death assured by performing an approved physical/secondary method of euthanasia?

Laboratory

- Y N N/A 36. If USDA species are housed in the lab for greater than 12 hours (24 hours for rats and mice), has the lab been approved for this activity by the IACUC?
- Y N N/A 37. Are drugs, suture materials, and other items within their expiration date?
- Y N N/A 38. Are controlled substances stored/logged appropriately?
- Y N N/A 39. If applicable, are sharps containers located within the lab?
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Post-Approval Monitoring (PAM) Checklist

Y N N/A 40. Are there any safety issues or other concerns that pose a threat to human or animal safety, or animal welfare?

Comments/ Clarifications:
