

Performance Standard:

The goal of post-approval monitoring (PAM) is to work with, and in support of, research staff members, confirming 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 Institutional Animal Care and Use Committee (IACUC) oversight of animal activities, providing an assurance to regulatory agencies and to the research institution, that animal experiments are monitored for compliance with approved IACUC protocols. The Northwestern University PAM Team confirms consistency with approved protocols and program policy, working collaboratively with research personnel to satisfy this federal requirement.

Roles:

- Principal Investigators and research personnel: Works in conjunction with the visiting PAM Team to facilitate observation of procedures and document compliance with approved protocols.
- PAM Team: Works with the Principal Investigator and research personnel to observe experimental activities, prepare accurate reports, and if necessary, facilitate training and provide recommendations for maintaining compliance. The PAM Team also maintains related records and corresponds with the IACUC.
- IACUC: Provides operational oversight of the PAM Team and the post-approval monitoring program, assuring that the IACUC receives reports or updates on items of concern and provides 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) deemed appropriate for the specific activity/procedure of the laboratory.

PAM Program Expectations:

- I. Selection of Protocols for Review:

- A. All Animal Study Protocols (ASPs) may be subject to PAM periodically, or at the discretion of the IACUC and veterinary personnel.
- B. All active ASPs 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 veterinary personnel.
- C. In general, the PAM Team or designee will contact the laboratory in advance to schedule monitoring sessions.
- 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 procedure observations or an audit of one or more protocols. In either case, follow-up appointments may also be scheduled.
- B. The PAM Team shall use the appropriate “PAM Checklist” during the procedure observation or protocol audit.
- C. Training documents (i.e., laboratory personnel training record) and documents tracking animal health and monitoring 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.
- D. Animal misuse, mistreatment or neglect (welfare issues), and discrepancies which result in animal welfare concerns (i.e., 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 the Public Health Service Policy. The IACUC Office, in conjunction with the IACUC Chair, will gather information to present to the IACUC for review and, if necessary, further investigation.
- E. At the discretion of the PAM Team, research procedure(s) being observed may be placed on hold if animal welfare issues are observed.

III. Process of Sharing Information Concerning the Review:

- A. The PAM Team shall discuss monitoring results with the Principal Investigator and/or 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.

- B. The PAM Team shall send a written draft report of the monitoring results to the Principal Investigator and other research personnel. The Principal Investigator will have an opportunity to respond to the draft report before the final report is prepared.
- C. The PAM Team presents a monthly report to the IACUC regarding any visit findings.
- D. The PAM Team shall send a final written report of the monitoring results to the Principal Investigator.

IV. 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 with corrective action(s) 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.

V. Record Keeping:

- A. 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.
- B. A copy of the final monitoring report shall be kept in the IACUC Office.

Northwestern University

PAM Checklist for Procedure Observations

Principal Investigator: _____

Protocol Reviews: _____

Protocol Number: _____

Protocol Title: _____

Procedure Observed: _____

Species: _____

Date of Monitoring: _____

PAM Team Member(s): _____

The Protocol and Personnel

- | | | | |
|---|---|-----|---|
| Y | N | N/A | 1. Have PI and research personnel read the protocol(s), including amendments, and do they have access to them in their lab space? |
| Y | N | N/A | 2. Are laboratory staff only performing procedures approved on the protocol? |
| Y | N | N/A | 3. Do all protocol approved personnel working with animals have an up-to-date enrollment in the Occupational Health Program? |
| Y | N | N/A | 4. Is each room where animals are taken listed in the approved protocol(s)? |

Study Procedures

- | | | | |
|---|---|-----|---|
| Y | N | N/A | 5. Are the procedures performed consistent with those approved in the protocol? |
| Y | N | N/A | 6. Does the protocol number on the animal's cage card match the IACUC approved protocol number? |
| Y | N | N/A | 7. Does the laboratory maintain documentation of the required training for personnel working with live animals? |

- | | | | |
|---|---|-----|--|
| Y | N | N/A | 8. Are investigators/research personnel utilizing appropriate Personal Protective Equipment (PPE) and/or other equipment for the species and procedures performed? |
| Y | N | N/A | 9. Are the species, strains, and ages of animals consistent with those in the approved protocol? |

Anesthesia

- | | | | |
|---|---|-----|---|
| Y | N | N/A | 10. Are the agents/methods of anesthesia in compliance with the protocol? |
| Y | N | N/A | 11. Are anesthetized animals monitored according to the approved methods in the protocol? |
| Y | N | N/A | 12. Are the animals maintained at an appropriate depth of anesthesia? |
| Y | N | N/A | 13. If inhalant anesthetics are used, are they scavenged appropriately? |
| Y | N | N/A | 14. Are anesthetic machines serviced and calibrated annually? |

Surgery

- | | | | |
|---|---|-----|--|
| Y | N | N/A | 15. Are animal preparation and surgical spaces separate? |
| Y | N | N/A | 16. Is the method of animal prep appropriate and in accordance with the approved protocol? |
| Y | N | N/A | 17. Is survival surgery performed using sterile instruments, sterile gloves, a surgery mask and aseptic technique? |
| Y | N | N/A | 18. Is an appropriate heat source used to keep the animal warm throughout the procedure? |
| Y | N | N/A | 19. Are incisions closed appropriately and in accordance with the approved protocol? |
| Y | N | N/A | 20. Is there an appropriate/designated recovery area for the animals? |

Post-Surgical Care

- Y N N/A 21. Are the methods of analgesia (dose, frequency, route) consistent with the approved protocol?
- Y N N/A 22. Is an appropriate heat source used for recovery?
- Y N N/A 23. Is there an up-to-date and complete surgical/procedure log (i.e., USDA medical record, pink card, lab record)?

Record Keeping

- Y N N/A 24. Is the animal's weight recorded at appropriate intervals?
- Y N N/A 25. Are animals appropriately identified (e.g., cage cards, ear tags, tattoos)?
- Y N N/A 26. Are medical and post-procedural care progress notes complete and accurate?
- Y N N/A 27. Is medication/anesthetic/analgesic administration accurately documented?

Euthanasia

- Y N N/A 28. Are the agents/methods of euthanasia approved in the protocol??
- Y N N/A 29. Is death assured by performing an appropriate physical/secondary method of euthanasia when required?

Laboratory

- Y N N/A 30. If USDA-covered species are housed in the lab for greater than 12 hours (or 24 hours for non USDA-covered species), has the lab been approved for this activity by the IACUC?
- Y N N/A 31. Are drugs, suture materials, and other items within their expiration date?
- Y N N/A 32. Are controlled substances stored/logged appropriately?
- Y N N/A 33. Is a sharps container located within the laboratory/procedure room?

Y N N/A 34. Are there any safety issues or other concerns that pose a threat to human or animal safety, or animal welfare?

Y N N/A 35. Were unanticipated post-procedure health issues reported to CCM veterinary staff?

Comments/ Clarifications:

Northwestern University PAM Checklist for Protocol Audits

Principal Investigator: _____

Protocol Reviews: _____

Protocol Number: _____

Protocol Title: _____

Species: _____

Date of Monitoring: _____

PAM Team Member(s): _____

General Questions

- | | | | |
|---|---|-----|---|
| Y | N | N/A | 1. Do all protocol approved personnel working with animals have an up-to-date enrollment in the Occupational Health Program? |
| Y | N | N/A | 2. Does the laboratory maintain the required in-lab training documentation for personnel working with live animals? |
| Y | N | N/A | 3. Have the PI and research personnel read the protocol(s), including amendments, and do they have access to them in their lab space? |
| Y | N | N/A | 4. Are drugs, suture materials, and other items within their expiration date? |
| Y | N | N/A | 5. Are controlled substances stored/logged appropriately? |

Study Identification & Funding

- | | | | |
|---|---|-----|--|
| Y | N | N/A | 6. Does the title match the grant, if federally funded? |
| Y | N | N/A | 7. Does the chart string in AOPS match the funding type described on the protocol? |
| Y | N | N/A | 8. Was congruency confirmed prior to grant award? |

Experimental Design

- | | | | |
|---|---|-----|---|
| Y | N | N/A | 9. Are there any inconsistencies between the laboratory's In-Lab Training Records and the Define Procedure Personnel page of the ASP?? |
| Y | N | N/A | 10. Are the species approved on the ASP provided an acclimation/stabilization period in line with IACUC policy? |
| Y | N | N/A | 11. Are animals transported to/from the necessary animal housing and use areas via the appropriate route and acceptable means (e.g., cart)? |
| Y | N | N/A | 12. Are investigators/research personnel utilizing appropriate Personal Protective Equipment (PPE) and/or other equipment for the species and procedures performed? |
| Y | N | N/A | 13. Does the laboratory adhere to breeding and housing density? |
| Y | N | N/A | 14. Is the breeding colony appropriately monitored and managed? |
| Y | N | N/A | 15. Are laboratory personnel able to identify signs of pain and/or distress in animals? |
| Y | N | N/A | 16. Are restraint devices used appropriately and as approved in the ASP? |
| Y | N | N/A | 17. Are injection routes (e.g., ID, IM, SQ, IV, IP) in accordance with the protocol? |
| Y | N | N/A | 18. Are laboratory personnel knowledgeable regarding maximum blood collection volumes? |
| Y | N | N/A | 19. Are animals anesthetized as approved in the ASP, and are they appropriately monitored? |
| Y | N | N/A | 20. Is acceptable heat support provided while animals are anesthetized? |
| Y | N | N/A | 21. Are pre-, peri-, and post-operative drugs properly administered in accordance with the protocol? |
| Y | N | N/A | 22. Does the laboratory ensure that aseptic technique is observed during survival surgery? |
| Y | N | N/A | 23. Is post-operative monitoring and analgesia documented per IACUC policy? |

Y N N/A 24. Can staff describe surgical preparation, procedures/surgeries in step-by-step fashion, including post-op procedures and monitoring?

Animal Housing & Use

Y N N/A 25. Are approved animal housing and use locations consistent with AOPS?

Y N N/A 26. If needed, does the lab have an SOP describing their sanitation process for lab equipment that cannot be cleaned via cage wash?

Y N N/A 27. If needed, is there an up-to-date Satellite Request Form attached to the ASP?

Y N N/A 28. Are any animal care exceptions described consistently within the protocol?

Protocol Attachments

Y N N/A 29. If one or more attachments are required (e.g., federal funding information), are they complete and up-to-date?

Endpoints & Recordkeeping

Y N N/A 30. Can staff describe their animal endpoints? Is there a primary and secondary method of euthanasia approved on the ASP, and are those the methods used by the laboratory?

Y N N/A 31. Can staff describe what labelling should be present on a carcass bag?

Y N N/A 32. Is proper care taken when disposing of hazardous substances?

Y N N/A 33. Is the laboratory aware that documents relevant to the study must be maintained for the duration of the study and at least three years after its completion?

Y N N/A 34. Are personnel familiar with the procedures in place for reporting animal welfare concerns?

Comments/ Clarifications:
