



# Northwestern University Post-Approval Monitoring Checklist



## Performance Standard:

The goal of post-approval monitoring 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 of Animal Care and Use Committee (ACUC) protocols is performed to provide assurance to regulatory agencies and Northwestern University that animal experiments are monitored for compliance with approved ACUC protocols. The Compliance Liaison Team (CLT) confirms consistency with approved protocols and accuracy of practices.

## Roles:

- Investigators and research personnel will work in conjunction with the visiting CLT to facilitate observation of procedures and document compliance with approved protocols.
- CLT: Will work with the investigator and research personnel to observe activity, prepare accurate reports, and if necessary, provide training and recommendations for maintaining compliance.
- Compliance Liaison Associate (CLA): Will coordinate visits, correspondence, and documentation, maintain records, and correspond with the ACUC.
- Animal Care and Use Committee (ACUC): Shall provide operational oversight of the Compliance Liaison Team (CLT) and the post approval monitoring program, assure that the ACUC receives reports or updates on items of concern, and provide training support as required to assure compliance.

## Required Protective Measures:

The CLA, as well as other visitors, shall wear the PPE prescribed for the specific activity/procedure of the laboratory

## Policy Expectations:

- I. Selection of Protocols for Review:
  - A. Active protocols involving the use of USDA Category C, D, or E will be monitored on a random basis, or at the discretion of the ACUC and veterinary personnel.
  - B. Protocols involving less invasive procedures will be monitored at the discretion of the ACUC and veterinary personnel.

- C. In general, the Compliance Liaison Associate (CLA) 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 CLA shall make an appointment for visits (follow-up visits may also be scheduled).
- B. The CLT shall use the ACUC-approved “Post-Approval Monitoring Checklist” for the review (document attached to this policy).
- C. During each monitoring session, the CLT 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. Items that will be reviewed are listed on the attached “Post Approval Monitoring Checklist” and include the following sections:
  - Protocol and Personnel
  - Study Procedures
  - Anesthesia
  - Surgery
  - Post-Surgical Care
  - Euthanasia
  - Record Keeping
  - Laboratory
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- D. 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 ACUC in accordance with Public Health Service Policy. The ACUC staff, in conjunction with the ACUC Chair, will gather information to present to the ACUC for review and, if necessary, further investigation.

## E. Process of Sharing Information Concerning the Review:

- 1) The CLT 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.

- 2) The CLA shall send a written draft report of the monitoring results to the Principal Investigator and other research personnel. Investigators will have an opportunity to respond to the draft report before the final report is prepared.
- 3) The CLA shall send a final written report of the monitoring results to the Principal Investigator, research personnel, ACUC, and the Attending Veterinarian.

#### F. Process Follow-Up:

- 1) The CLA will follow up on any issues that require protocol modifications, orientation of new personnel, or training. The CLA will support the laboratory corrective action by providing required training and/or assistance with form preparation (addendum submission).
- 2) On occasion, additional monitoring sessions may be part of the follow-up to assist with proper corrective actions.

#### G. Recordkeeping:

- 1) A copy of the final compliance monitoring report shall be kept in the protocol file.
- 2) The non-compliant information shall be entered into the Compliance Database for use as institutional trending or follow-up and determination of general training or informational needs.



# Northwestern University Post-Approval Monitoring Checklist



Principal Investigator: \_\_\_\_\_

Protocol #: \_\_\_\_\_

Protocol Title: \_\_\_\_\_

Species: \_\_\_\_\_

Date of Monitoring: \_\_\_\_\_

CL Team Members: \_\_\_\_\_

CLA: \_\_\_\_\_

## The Protocol and Personnel

- Y N N/A 1. Do the PI and research personnel have the most recent version of the complete protocol, including amendments, in their lab space?
- Y N N/A 2. Have the investigators and research personnel read the protocol?
- Y N N/A 3. Are the people performing the study listed on the protocol?
- Y N N/A 4. Are all personnel currently enrolled in the Occupational Health Program?
- Y N N/A 5. Is each room where animals are taken listed on the protocol?

## Study Procedures

- Y N N/A 6. Does the protocol number on the animals' cage card match the ACUC 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?
- Y N N/A 9. Are investigators/research personnel wearing appropriate 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, ages, and number of animals consistent with those in the approved protocol?

## Anesthesia

- 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 ACUC?
- Y N N/A 18. Is the location and 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 ACUC) and is an identification method in place to indicate which animals have had a procedure performed on them?

## Post-Surgical Care

- Y N N/A 24. Is the post-surgical area in compliance with the approved protocol?
- Y N N/A 25. Are the methods of analgesia (dose, frequency, duration) consistent with the approved protocol?
- Y N N/A 26. Is post-surgical/post-procedural care adequately documented?
- Y N N/A 27. Are any post-operative problems reported to CCM veterinary staff?

## Record Keeping

- Y N N/A 30. Is there an up-to-date and complete surgical/procedure log?
- Y N N/A 31. Are individual animals appropriately identified (cage cards, ear tags, tattoos, etc.)?
- Y N N/A 32. Are medical and post-procedural care progress notes complete and accurate?
- Y N N/A 33. Is medication/anesthetic/analgesic administration accurately documented?
- Y N N/A 34. Are injections, blood collection, and fluid collection amounts dated and documented?

## Euthanasia

- Y N N/A 28. Does the method of euthanasia correspond with what is written 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 35. 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 ACUC?
- Y N N/A 36. Are drugs, suture material, and other items within the expiration date noted on the package?
- Y N N/A 37. Are controlled substances stored/logged appropriately?
- Y N N/A 38. If applicable, are sharps containers located within the lab?
- Y N N/A 39. Are there any safety issues or other concern that pose a threat to human or animal safety, or animal welfare?

## Comments/ Clarifications:

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