Protocol post-approval monitoring policy

An important part of Purdue University’s program for the care and use of animals used in research, teaching, or testing, is the meaningful monitoring of the protocols that have been approved by the PACUC. The protocol post-approval monitoring policy has been developed to contribute to this important oversight requirement. The protocol post-approval monitoring process could involve laboratory/site visits to observe animal procedures being performed, evaluate record keeping, and discuss approved activities.

Protocol post-approval monitoring process and procedures

Protocol post-approval monitoring visits may be announced or unannounced. Post-approval monitoring visits will be conducted by at least one of the laboratory animal veterinarians (LAV) and the PACUC Administrator/Senior Compliance Officer. The PACUC chair and the Industrial Hygienist – Occupational Health may attend whenever possible.

The approved protocols will be prioritized to determine the frequency and order of monitoring, based on the potential for pain and distress, significant personnel changes, and current activity of protocols. Problems or deficiencies noted on these visits will be corrected at the time the deficiency is noted and further training/education provided, if needed. A summary of these visits, and actions taken to correct the deficiency, will be reported to the PACUC by the PACUC Administrator/Senior Compliance Officer or LAV at the next monthly meeting.

Post-approval monitoring will be conducted using the Protocol Post-Approval Monitoring Form and a database will be utilized to aid in the prioritizing of protocols.
Purdue Animal Care and Use Committee (PACUC)

Protocol Post-Approval Monitoring Form

Principal Investigator:__________________________  Protocol #:__________________________

Protocol Title:________________________________________

Species:__________________________  Site Visited:__________________________

Personnel Present:________________________________________

Monitoring Team:________________________________________

Monitoring Date:__________________________  Monitoring Time:__________

PROTOCOL AND PERSONNEL SECTION

__ Y __ N 1. A current copy of the approved protocol (and subsequently approved amendments) is available in, or near, the site visited.

__ Y __ N 2. All personnel involved in the project are listed on the protocol and have completed the PACUC orientation program and the occupational health program participation/declination form.

__ Y __ N 3. The principal investigator and all project personnel have accurate knowledge of the procedures approved on the protocol and have received training relevant to the project.

__ Y __ N 4. The principal investigator and other project personnel (working without direct supervision) have accurate qualifications documented in the PACUC office via Animal Care and Use Qualification Forms.

NOTES:________________________________________

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02/2012
Re-approved 03/20/2019
STUDY PROCEDURES SECTION

__ Y __ N 5. The procedures being conducted are approved in the protocol or amendments.

__ Y __ N 6. The site visited has a dedicated workspace for the animal procedures being conducted.

NOTES:


ANESTHESIA SECTION

__ Y __ N 7. The methods of anesthesia used are approved in the protocol.

__ Y __ N 8. The anesthetized animals are appropriately monitored according to the protocol.

__ Y __ N 9. The inhalant anesthetics are properly scavenged or exhausted.

__ Y __ N 10. The anesthesia dosages, frequency, and routes of administration are recorded.

NOTES:


02/2012
Re-approved 03/20/2019
SURGERY SECTION

___ Y ___ N  11. The surgeries are appropriately recorded.
___ Y ___ N  12. The surgical procedures are performed in an approved area.
___ Y ___ N  13. The facilities are clean and organized.
___ Y ___ N  14. The use of sterile gloves and instruments are utilized when performing recovery surgery.
___ Y ___ N  15. The animals are aseptically prepped when performing recovery surgery.

NOTES:________________________________________________________________________
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POST-SURGICAL/PROCEDURAL CARE SECTION

___ Y ___ N  16. The post-surgical/procedural monitoring and care being performed are as approved in the protocol.
___ Y ___ N  17. The analgesics used are as approved in the protocol and available.
___ Y ___ N  18. The analgesic dosages, frequency, and routes of administration are recorded.
___ Y ___ N  19. The post-surgical/procedural care is recorded.
___ Y ___ N  20. The recovery area is appropriate.

NOTES:________________________________________________________________________
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02/2012
Re-approved 03/20/2019
EUTHANASIA SECTION

__ Y ___ N 21. The methods of euthanasia are as approved in the protocol.

__ Y ___ N 22. The euthanasia dose and route of administration are recorded, if applicable.

NOTES:______________________________________________________________
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GENERAL INFORMATION SECTION

__ Y ___ N 24. The number of animals used is recorded and kept current.

__ Y ___ N 25. The injections, blood collection, and fluid collection are as described in the protocol.

__ Y ___ N 26. The drugs, fluids, sutures, etc., are within the expiration date.

__ Y ___ N 27. The principal investigator has live animals outside of the approved housing facility for more than 12 hours.

__ Y ___ N 28. Occupational health and safety issues are properly addressed, posted, and/or documented (e.g., hazard assessment posted to include appropriate PPE, emergency contact list posted, N-95 mask, gloves, eye protection, other PPE).

NOTES:______________________________________________________________
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02/2012
Re-approved 03/20/2019