

Post-Approval Monitoring

- i. Purpose: The purpose of the Post-Approval Monitoring (PAM) Program is to ensure research and teaching activities involving live, vertebrate animals are conducted in accordance with all applicable federal and state laws, accrediting body regulations, University policies, and are following Institutional Animal Care and Use Committee (IACUC) approved research and teaching protocols and amendments. In addition to ensuring compliance, PAM review serves as a valuable educational and training tool.
- ii. Policy:
IACUC oversight of animal research and teaching activities is required by federal laws, regulations, and policies. PAM is one method that is used by UC Merced to ensure ongoing protocol monitoring, regulatory compliance, and animal welfare. Any approved animal care and use research or teaching protocol may be subjected to PAM reviews.
- iii. Definitions:
 - A. Post-approval monitoring (PAM): Oversight methods to ensure ongoing regulatory compliance within research facilities, approved protocols, and the well-being and protection of animals used in research.
- iv. Responsibilities:
 - A. IACUC:(*The guide pg. 25*) The committee is responsible for oversight and evaluation of the entire Program and its components as described in other sections of the Guide. Its oversight functions include review and approval of proposed animal use (protocol review) and of proposed significant changes to animal use; regular inspection of facilities and animal use areas; regular review of the Program; ongoing assessment of animal care and use; and establishment of a mechanism for receipt and review of concerns involving the care and use of animals at the institution.
 - B. Research Compliance Integrity (RCI): RCI staff as delegated by the IACUC, identifies, plans, and conducts PAM activity with PI and/or lab staff.
 - C. Department of Animal Research Services (DARS): Assist as needed with PAM. Provide training and verifies lab personnel in conducting approved surgical and/or specialized procedures.
 - D. Environmental Health & Safety (EH&S): Provides guidance on protocols and inspections that involve any chemical, biological or other hazards under EH&S purview.
- v. Selection of Protocols:
 - A. Protocols are selected for PAM evaluation at the discretion of the IACUC. Any IACUC approved protocol is subject to random selection as part of PAM.
- vi. Notification of/ PAM request
 - A. PAM activities will be scheduled in consultation with PI.
 - B. Any PI with approved protocol(s) can request PAM activities.
- vii. Assessment/Process of monitoring: PAM activities will be assessed by a team including at least one IACUC member and may include one or more of the following:

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- A. Lab inspection: Assessment includes facility and lab inspection, documentation of equipment maintenance, calibration, controlled substance logs, hazardous disposal, and proper use of space.
 - B. Record review: Assessment includes reviewing research related documents for completeness.
 - C. Preparedness of personnel and/or skills to perform animal research: Assessment includes understanding the Animal Use Protocol (AUP), awareness of IACUC policy and guidelines applicable to the approved procedures and knowledge of appropriate contacts for various potential problems.
 - D. Education: Updates regarding new policies and procedures will be discussed with research personnel.
- Other activities that are considered a part of PAM are: Annual Renewals, De-Novo Renewals, Amendments and Semi-Annual Facility inspections.
- viii. Process of Sharing Information Concerning the Review:
 - A. Sharing with Principal Investigator (PI): PI will be notified in writing of PAM activities including scheduling of PAM (prior to the review), any minor or significant finding(s) identified in their laboratory, facility, or designated area (post-review). If applicable, the PI may be required to provide a response to findings along with a written plan with a timeline outlining how findings will be corrected.
 - B. Sharing with IACUC: PAM activities and findings will be notified to the IACUC, and related documents will be kept on a shared file on box which will be accessible to all IACUC members. Any findings considered to be significant will be urgently brought to the attention of the IACUC.
 - ix. Follow-up Process (one or more of the following as applicable)
 - A. IACUC administrative staff will follow up with PI and/or research personnel regarding any findings upon completion of PAM.
 - B. Meeting with the PI to discuss inspection any findings, provide education, and additional resources the PI may need..
 - C. Any non-compliance identified upon completion of PAM activity will be addressed according to IACUC Policy 104 "Investigating Allegations of Mistreatment or Other Noncompliance Issues".
 - D. IACUC admin staff will follow up with PI and/or research personnel regarding any findings upon completion of PAM.
 - X. Record Keeping.
 - A. PAM activities and findings will be kept on a shared file on box which is accessible to all IACUC members.
 - B. PAM activities and findings will be shared with Vice Chancellor for Research as an attachment in the semi-annual report.

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Post-Approval Monitoring Checklist

PAM visitation date: _____

PAM visitation site: _____

IACUC protocol(s) under review (# and expiration date):

Investigator: _____

If student, faculty supervisor: _____

Protocol personnel present:

PAM Liaison present: _____

The Protocol and Personnel:	Yes	No	Not observed	Not applicable	Notes:
Most recent version of IACUC approved protocol available for reference (including modifications)	☐	☐	☐	☐	
Most recent annual renewal of this protocol completed	☐	☐	☐	☐	
All investigators and research personnel have read the protocol	☐	☐	☐	☐	
Room(s) where animals are taken listed on the protocol	☐	☐	☐	☐	
All personnel involved listed in the protocol	☐	☐	☐	☐	
Personnel training documented and CITI training current	☐	☐	☐	☐	
Personnel trained to handle toxic or dangerous materials or animals and trained in potential transmission of zoonotic agents between researchers and study subjects (must have a BUA on file)	☐	☐	☐	☐	

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Appropriate personal protective equipment (PPE) used	☐	☐	☐	☐	
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Personnel current with Occupational Health requirements	☐	☐	☐	☐	
Report a Concern sheet present (whistleblower)	☐	☐	☐	☐	
Emergency plan and telephone numbers available	☐	☐	☐	☐	
Animal Laboratory:	Yes	No	Not observed	Not applicable	Notes:
Cleanliness/sanitation/density acceptable	☐	☐	☐	☐	
Animal species, strains, ages and number as approved	☐	☐	☐	☐	
Protocol number on the animals' cage cards match approved IACUC protocol number	☐	☐	☐	☐	
Individual animals appropriately identified (cage cards, ear tags, tattoos, etc.)	☐	☐	☐	☐	
Drugs/medications/anesthetics as approved and accurately documented	☐	☐	☐	☐	
Storage/documented use of controlled substances	☐	☐	☐	☐	
Non-surgical animal procedures as approved	☐	☐	☐	☐	
Injections, blood collection and fluid collection amounts dated and documented	☐	☐	☐	☐	

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Lab is approved by the IACUC if housing USDA species for greater than 12 hours.	☐	☐	☐	☐	
Drugs, suture materials, and other items within expiration dates	☐	☐	☐	☐	
Sharps containers located within the lab per EH&S Guidelines.	☐	☐	☐	☐	
Safety issues or other concerns that pose a threat to human or animal safety or animal welfare?	☐	☐	☐	☐	
Anesthesia:	Yes	No	Not observed	Not applicable	Notes:
Methods of anesthesia in compliance with protocol and accurately documented	☐	☐	☐	☐	
Personnel properly trained to perform anesthesia	☐	☐	☐	☐	
Anesthetized animals monitored according to the approved methods in the protocol	☐	☐	☐	☐	
Animals maintained at an appropriate depth of anesthesia for the procedure performed	☐	☐	☐	☐	
Inhalant anesthetics scavenged appropriately	☐	☐	☐	☐	
Pharmaceutical-grade compounds used for anesthesia (where applicable)	☐	☐	☐	☐	
Anesthetic machines serviced and calibrated every 2 years	☐	☐	☐	☐	
Surgical Procedures and PostSurgical Care:	Yes	No	Not observed	Not applicable	Notes:

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Surgical location and techniques consistent with protocol (including animal preparation and post-surgical areas and techniques)	☐	☐	☐	☐	
Up-to-date and complete surgical/procedural log (i.e. USDA medical record)	☐	☐	☐	☐	
Personnel performing surgical procedures trained to do so	☐	☐	☐	☐	
Aseptic technique used for survival surgery	☐	☐	☐	☐	
Surgical materials sterilized	☐	☐	☐	☐	
Surgical materials not expired	☐	☐	☐	☐	
Analgesics used for painful procedures and/or surgery (unless scientific justification for not using analgesia approved by IACUC)	☐	☐	☐	☐	
Post-surgical analgesia consistent with protocol	☐	☐	☐	☐	
Analgesic dosages, frequency and routes of administration accurately recorded	☐	☐	☐	☐	
Intra-operatively and post-surgical monitoring and care performed and progress documented (appropriate heat source such as water recirculating heating pad used for recovery)	☐	☐	☐	☐	
Post-operative problems reported to Veterinarian.	☐	☐	☐	☐	
Identification method in place to indicate which animals have had a procedure performed on them	☐	☐	☐	☐	

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Euthanasia:	Yes	No	Not observed	Not applicable	Notes:
Animals euthanized at humane endpoints	☐	☐	☐	☐	
Euthanasia performed per protocol	☐	☐	☐	☐	
All euthanasia methods comply with 2020 AVMA Guidelines for Euthanasia of Animals	☐	☐	☐	☐	
Euthanasia performed away from the presence of other live animals	☐	☐	☐	☐	
Death assured by performing an approved physical/secondary method of euthanasia	☐	☐	☐	☐	
Carcass disposition appropriate	☐	☐	☐	☐	

Are there any resources you feel could help improve your research process?

☐Yes (please explain below) ☐No

Notes:

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IACUC PAM Liaison signature

Please print name CLEARLY.