UNIVERSITY OF NOTRE DAME | RESEARCH Administration and Compliance

University of Notre Dame Institutional Animal Care and Use Committee (IACUC) Policy	
Title: Post-Approval Monitoring	
Effective Date: 7/20/24	**Last Revised Date: 7/20/24**

I. Purpose

Federal regulations require monitoring of all research activities related to animal use, including continued IACUC oversight of approved animal activities through ongoing protocol assessment and compliance review. Post-approval monitoring (PAM) involves a protocol-specific review of activities in cooperation with investigators outside of the IACUC protocol review process.

II. Definitions

Not for-cause review: Reviews conducted through routine random selection.

For-cause review: Reviews conducted at the direction of IACUC.

III. Policy

1. Responsibilities
    a. Principal Investigators (PI) will:
        i. Respond to PAM requests promptly
        ii. Be present during PAM visits (or assign a designee)
        iii. Verify protocol-specific procedures and support review by providing access to study records
        iv. Participate in the development and implementation of corrective actions when necessary
        v. Facilitate the cooperation of their research personnel with PAM representatives
    b. IACUC PAM Staff will:
        i. Provide management of the PAM process
        ii. Schedule and conduct PAM review visits
        iii. Provide recommendations for maintaining compliance

iv. Provide accurate documentation to the PI
v. Communicate findings from PAM visits to the IACUC

c. IACUC will:
i. Receive and evaluate reports of PAM visits
ii. Identify corrective actions
iii. Determine outcomes
iv. Communicate PAM actions taken with the Institutional Official as appropriate

d. Veterinary staff may:
i. Participate in PAM visits
ii. Provide verbal verification of facility operations, policies, and procedures

e. Institutional Official (IO) will:
i. Receive and evaluate reports of PAM activity if the IACUC deems it necessary based on the severity of noncompliance found.
ii. Provide guidance, resources, and support for systemic and policy changes, updates, and improvements to address issues identified through PAM activity

f. Failure to cooperate with PAM review will be considered noncompliance with IACUC policy, including (but not limited to):
i. Failure to respond to PAM communications
ii. Refusing to make records available
iii. Denying access to laboratory spaces without cause
iv. Failure to respond to the PAM review report and implement necessary changes and
v. Other actions that delay or prevent review of research activities.

g. The IACUC may take action when noncompliance described in (1)(f) is referred for review. PAM representatives may also notify the Department Chair or the IO of noncompliance with the PAM review process.

2. Protocol selection
a. Not-for-cause reviews may be conducted randomly or due to higher-risk activities identified in the protocol. These include, but are not limited to activities involving:
i. Survival surgery
ii. Food/water restriction
iii. Prolonged physical restraint
iv. Animals in specific USDA pain categories (C, D, E), especially protocols with animals in pain categories D and E
v. Significant increase in protocol activity
vi. Use of biohazards and/or hazardous chemicals
vii. Housing animals in satellite animal facilities

b. Protocols may be selected based on previous reports and recommendations from veterinary care staff.

3. Post-approval Monitoring Visits

a. Notre Dame Research Administration and Compliance (NDRAC) staff hold primary responsibility for conducting PAM review visits as designees of the IACUC.
b. Staff will notify the PI in writing at least 30 days before a not-for-cause PAM review. The review will be scheduled at a mutually agreeable time. The review may be scheduled with research personnel designated by the PI.
c. For-cause PAM review may be conducted at any time, with or without advance notice to the PI or research personnel.
d. The PI (and designee, if applicable) will be provided with an overview of the scope and process of the review and the checklist used to guide the review. The PI should use this list to gather any necessary information during the visit.
e. Before the PAM visit, the designated PAM reviewers will review the selected protocol. The PAM representative will complete the pre-review section of the PAM review checklist.
f. The PAM review session is centered on a dialogue between the investigators and PAM representatives. During the session, the PAM representatives will ask the PI and other laboratory staff present to verbally describe their animal procedures.
g. PAM representatives may inform the PI and other personnel of any IACUC or FLSC SOPs that apply to their research activities, including new or recently revised policies for education.
h. Any housing, breeding, or other laboratory rooms in which animals are housed or used in procedures will be inspected by PAM representatives.
i. PAM representatives will compare procedures conducted in the laboratory with the approved protocol. Discrepancies will be noted during the review and may require procedure changes or amendments to the IACUC protocol.
j. Animal misuse, mistreatment, or neglect, and discrepancies that result in animal welfare concerns will be immediately reported to the IACUC and the Attending Veterinarian in accordance with institutional policy and the PHS Policy.

4. Findings
    a. Preliminary results of the PAM visit will be communicated to research personnel present for review.
    b. If any findings are corrected during the visit, PAM representatives will record the correction before the visit is concluded.
    c. PAM representatives will draft a complete report summarizing the findings of the PAM visit.
        i. Major findings are identified when activities could adversely affect the safety and welfare of the animals or personnel or the scientific integrity of the research.
        ii. Minor findings are identified when activities do not directly impact animal welfare, personnel safety, or scientific integrity.
    d. A copy of the complete report will be sent to the PI, who will be asked to respond and submit any necessary amendments. PAM representatives may require that certain research activities cease until required amendments are approved.

e. Responses and correspondence will be included with the final report provided to the IACUC.
f. PAM representatives will follow up on any issues that require protocol modifications or additional personnel training. If necessary, an additional meeting may be scheduled.
g. At each monthly IACUC meeting, the PAM representative will report a summary of PAM reviews completed since the last meeting. The IACUC will be given the opportunity to provide feedback on the reviews and offer recommendations to the PAM representative. The IACUC has the authority to require additional corrective action and determine if there is a need for a noncompliance review.
h. Once the review is complete, a letter indicating the resolution of the PAM process will be forwarded to the PI. Any requirements identified by the IACUC after the PAM review will be communicated to the PI.
i. All formal PAM documentation is maintained in the NDRAC office. Official reports of findings are generated and reviewed with the Director of Research Compliance.

IV. References

1. Public Health Service (PHS) Policy.
2. The Guide for the Care and Use of Laboratory Animals, 8th ed.