MONTCLAIR
STATE UNIVERSITY

Office of Research Compliance and Regulatory Programs

Institutional Animal Care and Use Committee

Post-Approval Monitoring (PAM)

FINAL 1.0
October, 2024

Table Of Contents

I. Purpose and Benefits

The Guide for the Care and Use of Laboratory Animals 8th Edition: "Continuing IACUC oversight of animal activities is required by federal laws, regulations, and policies." "PAM helps ensure the well-being of the animals and may also provide opportunities to refine research procedures."

Post Approval Monitoring (PAM) is a program that monitors laboratory research related activities to confirm congruence of research activities to the approved IACUC protocol and to ensure continued compliance with the federal regulations and guidelines that govern research. The program is designed to establish collaborative partnerships between the IACUC and investigators to promote animal welfare, quality research and improve the overall research animal program. PAM will ensure that researchers are following current best practices and adhering to regulations regarding animal research, namely:

- Montclair IACUC Policies and Procedures
- Montclair Vivarium / LAR Guidance and SOP's
- Public Health Service (PHS) Policy
- Animal Welfare Act (AWA)
- Funding agencies, if applicable

By providing feedback and education to investigators, PAM also provides an opportunity for in-depth direct observation of research procedures and activities on approved protocols. It can also open the dialogue for research practice improvement and helps build collaborative relationships between researchers and the IACUC. PAM can also serve to assess the effectiveness of training programs and identify possible training flaws. The PAM program is administered by the Research Compliance and Regulatory Programs in the Office of Research.

II. PAM Methods and Procedures

A. PAM methods include, but are not limited to:

- Protocol review
- Semiannual Inspection
- Self-Assessment Questionnaire
- Laboratory Visitation
    - Utilization of PAM Checklist
    - Observation of procedures

    - Observation of animal handling & husbandry practices
- Review of sanitation practices
- Animal number tracking and congruence
- Follow-ups to reported concerns
    - Follow-ups to reported concerns may occur at any time.

B. Protocol Selection Process:

- All approved and active IACUC protocols will be considered for PAM at least once every three years.
- The PAM Reviewer will review a protocol with an approval from the year prior (i.e. if approved in 2024, will be reviewed in 2025).
- Though all IACUC approved protocols may be scheduled for PAM, considerations that prompt unplanned PAM are protocols that include:
    - USDA Pain Categories E or D
    - Surgical procedures
    - Recent modifications adding new species or activities

C. PI Notification and Scheduling Procedures:

- The PAM Reviewer will be a member of the RCRP staff.
- The will notify the Principal Investigator by email at least two weeks prior to the proposed PAM visitation date.
- The IACUC requests that the PI respond within five business days of receiving the PAM notification.
- If a PI has not responded after ten days, a second notification letter will be sent to the PI.
    - The PI may, at his or her discretion, designate another person to serve as a point of contact with the IACUC to schedule the PAM visit.
- The review should be within three weeks from the time the PAM notice is sent.
    - The IACUC will make every effort to work with investigators to schedule reviews at a time least disruptive for them and their staff.
- When a mutually convenient date and time is confirmed, the Liaison will send the PAM Checklist and a copy of the approved IACUC protocol to the PI, for reference.
- The PI is required to attend the initial discussion with the PAM Liaison.
    - The PI will be informed that all and any staff that are involved in the approved research activities should be present during the PAM visit.

- The PAM Liaison will notify the investigator if any specific research records will be requested for review.

D. Laboratory Visit Procedures:

- The PAM Liaison will review the approved protocol and related documents prior to the PAM visit.
- Utilizing the PAM Checklist, at the time of the scheduled visit the Liaison will review the protocol and the research activities for congruency.
- Suggestions or on-the-spot training may occur (if LAR staff is available).
- A PAM report will be disclosed to the IACUC Committee at the subsequent meeting or sent via a CANVAS announcement if no meeting will be held in a given month.
    - Any animal welfare concerns are reported promptly to the IACUC.
- A follow-up email from the PAM Liaison will be sent to the Principle Investigator within 2 weeks following the PAM.

E. PAM Visit Preparation for PI and Staff:

- PI or designee should plan for adequate space within the lab for review of research records on-site. This includes but is not limited to:
    - Protocol documents
    - Training records
    - Husbandry logs
    - Procedural logs
    - Surgical records
    - Euthanasia records
- Laboratory should be cleaned and organized.
    - Check for expired materials.
    - Proper signage posted
- If conducting a specific procedure during the PAM visit for observation, the PI and research staff should be prepared to demonstrate and explain the activities being performed and record-keeping processes.
- Access to a photocopier is also requested as available.
- Have any questions or concerns ready to discuss with the PAM Liaison.

F. PAM Findings and Written Report

- The IACUC Coordinator will provide a draft report of factual observations noted during the review. This draft is vetted with the Director and other members of the IACUC as needed.
- The PI will be given the opportunity to review and comment on the draft report as per the timeline provided. If the Investigator fails to provide feedback as per the timeline, the report will be considered Final.
- The final PAM Report, i.e., the completed PAM Visit Checklist, is prepared and disseminated to the PI, Director, IACUC Chair, Attending Veterinarian, and the Vice Provost for Research.
- The IACUC Coordinator will maintain a copy of the PAM Report in the CANVAS protocol file and in the PAM folder of the IACUC Google Shared Drive.

G. Follow-Up Procedures:

- When there are corrective and/or preventive actions that need to be addressed, the PAM Liaison will monitor progress of completion of the actions. Generally, corrective actions are expected to be completed within 30 days of issuing the final report.
- A repeat PAM visit will be scheduled and conducted, as needed.

H. PAM Close-Out

- After IACUC approval, the IACUC Coordinator will send a PAM Close-Out notification* by email to the PI when all corrective actions have been completed. *It is important to note that this is a collaborative process, and the IACUC will recognize positive effort and cooperation on the part of Principal Investigators and their research staff. “Kudos” for such efforts will be designated in PAM Close-Out Letters as appropriate.

III. Appendices

1. PAM Notification Email
2. Follow-Up Communications
3. PAM Close-Out Letter
4. PAM Visit Blank Checklist

Appendix 1

PAM Notification Email

Dear Dr. _____,

You are receiving this email because you have an approved IACUC protocol, [####-###], "[TITLE]."

The IACUC Office will be conducting a Post-Approval Monitoring (PAM) visit to your laboratory regarding the above-mentioned protocol.

The requested time-frame for this visit is [RANGE OF DATES 2-3 WEEKS FROM NOW].

Please respond by [DATE, within 5 business days] with the time(s) during which you are available. If desired, you may designate another person to serve as a point of contact with the IACUC to schedule the PAM visit; however, the PI is required to be present at a mutually convenient time in order to answer any questions. Staff that are involved in the approved research activities should be present during the PAM visit when possible.

Once a date has been finalized, the PAM Liaison will send you a copy of the PAM Visit Checklist for reference and preparation purposes. The Liaison will also notify you in advance if any specific research records will be requested for review.

The Research Compliance
Best regards,

NAME
IACUC Coordinator

[SEND THIS EMAIL AGAIN AS A REMINDER IF PI HAS NOT RESPONDED WITHIN 10 DAYS FROM ORIGINAL EMAIL]

Appendix 2

Follow-Up Communications

Dear Dr. _____,

Thank you for your time and cooperation during the PAM Visit to your laboratory on [DATE] regarding approved IACUC protocol, [####-###], “[TITLE].”

I hope that you found the visit beneficial and productive. Attached please find the draft report of factual observations noted during the PAM Visit. Please read through the report carefully, and respond to this email with any comments, questions or concerns that you may have regarding the report.

Please provide feedback by [DATE, within 2 weeks of email]. After that time, the report will be considered Final.

Please note that, when there are corrective and/or preventive actions that need to be addressed, the PAM Liaison will monitor progress of completion of the actions following an agreed-upon timeline with you and your research team. A repeat PAM visit will be scheduled and conducted, as needed.

Best regards,

NAME
IACUC Coordinator

Appendix 3

PAM Close-Out Letter

Dear Dr. _____,

Thank you for your recent participation in the Post-Approval Monitoring (PAM) process for your approved IACUC protocol, [####-###], "[TITLE]."

This letter is to inform you that all corrective actions have been completed. The IACUC has approved the Final PAM Report, a copy of which is attached to this email. The Report has also been disseminated to the Director of Research Compliance, IACUC Chair, Attending Veterinarian, and the Vice Provost for Research.

[ADD "KUDOS" HERE AS APPROPRIATE]

If you have any questions or concerns regarding the PAM Report, please do not hesitate to contact iacuc@montclair.edu.

Best regards,

NAME
IACUC Coordinator

Appendix 4

PAM Visit Blank Checklist

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	☐	☐	☐	☐	
Appropriate personal protective equipment (PPE) used	☐	☐	☐	☐	

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	☐	☐	☐	☐	
Lab is approved by the IACUC if housing USDA species for greater than 12 hours (24 hours for rats and mice)	☐	☐	☐	☐	
Drugs, suture materials, and other items within expiration dates	☐	☐	☐	☐	
Sharps containers located within the lab	☐	☐	☐	☐	

Experimental diet(s) used	☐	☐	☐	☐	
Special housing used	☐	☐	☐	☐	
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	☐	☐	☐	☐	
Anesthetic machines serviced and calibrated annually	☐	☐	☐	☐	

Surgical Procedures and Post-Surgical Care:	**Yes**	**No**	**Not observed**	**Not applicable**	**Notes:**
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	☐	☐	☐	☐	
Post-surgical monitoring and care performed and progress documented (appropriate heat source used for recovery)	☐	☐	☐	☐	
Post-operative problems reported to Veterinary/Vivarium staff	☐	☐	☐	☐	
Identification method in place to indicate which animals have had a procedure performed on them	☐	☐	☐	☐	

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: