

IACUC Office

Post Approval Monitoring Program

animalwelfare@drexel.edu

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Post Approval Monitoring Program

Guide for the Care and Use for Laboratory Animals: Eighth Edition (2011) - pg. 33-34

Continuing IACUC oversight of animal activities is required by federal laws, regulations, and policies. A variety of mechanisms can be used to facilitate ongoing protocol assessment and regulatory compliance...

... Methods include continuing protocol review; laboratory inspections (conducted either during regular facilities inspections or separately); veterinary or IACUC observation of selected procedures; observation of animals by animal care, veterinary, and IACUC staff and members; and external regulatory inspections and assessments.

National Academies of Sciences, Engineering, and Medicine. 2011. Guide for the Care and Use of Laboratory Animals: Eighth Edition. Washington, DC: The National Academies Press. <https://doi.org/10.17226/12910>.

Post Approval Monitoring Program

Drexel University's mechanisms to facilitate ongoing protocol assessment and regulatory compliance:

- Triennial Review of ongoing IACUC protocols
- IACUC semiannual inspections every six months of animal facilities, satellite facilities, and laboratories where animal activity occurs
- University Laboratory Animal Resources (ULAR) animal caretakers monitor the animals at least once per day (twice per day for larger animal species)
- The veterinary staff observes the care and use of animals during weekly rounds, clinical case monitoring, during follow-up checks, laboratory visits, and when assisting the investigators in their research.
- The Department of Environmental Health and Radiation Safety (EHRS) inspects all laboratories and animal facilities on a semiannual basis.
- **Drexel University employs a full time Animal Welfare Education Specialist to oversee post approval compliance. The Animal Welfare Education Specialist confirms compliance through the Post Approval Monitoring (PAM) program which consists of both observation and document review.**

Post Approval Monitoring Program

Post Approval Monitoring (PAM) is a continuation of Institutional Animal Care and Use Committee (IACUC) oversight of animal activities, providing an assurance to regulatory agencies and to the research institution, that animal activities supporting research and teaching are monitored for compliance with approved IACUC protocols.

Drexel's PAM Team validates compliance with approved protocols, regulations, and Drexel's animal care and use program policies, working collaboratively to build an educational partnership with researchers.

The CLARITY Project



DREXEL UNIVERSITY
Office of
**Research &
Innovation**

RATIONALE:

Ensure the continued growth of the University's research enterprise

GOAL:

Create/Refine policies, guidelines, processes, roles / responsibilities, and systems to streamline the functions of ALL ORI teams

Post Approval Monitoring Program

The CLARITY Project

Reviewed
Current
Documentation
and Process

- Policies and Procedures
- Reporting Forms
- Website
- Resources available to research community

Revised and
Developed
Procedures and
Resources

- Provide clarity
- Set expectations
- Foster collaborative culture focusing on the animals' well-being.

PAM Process - Broad Overview

Scheduled

- Protocols selected at random, usually dealing with higher pain categories
- PAM staff meeting with Laboratory staff to review the protocol and procedures, possibly observing surgeries
- Report generated with findings
 - Documenting any significant, minor or repeat findings

Unscheduled

- For cause, as brought to the attention of IACUC, ULAR, Veterinarian, etc.
 - Usually pertaining to animal welfare and must be immediately investigated/remedied
- Report generated with findings

Post Approval Monitoring Types as conducted by the Animal Education Welfare Specialist

Protocol Review

Highest priority is Category E (unalleviated pain or distress), USDA species, special requirements or expectations

Next priority is Category D (tumor models, aged animals, single minor surgeries, etc)

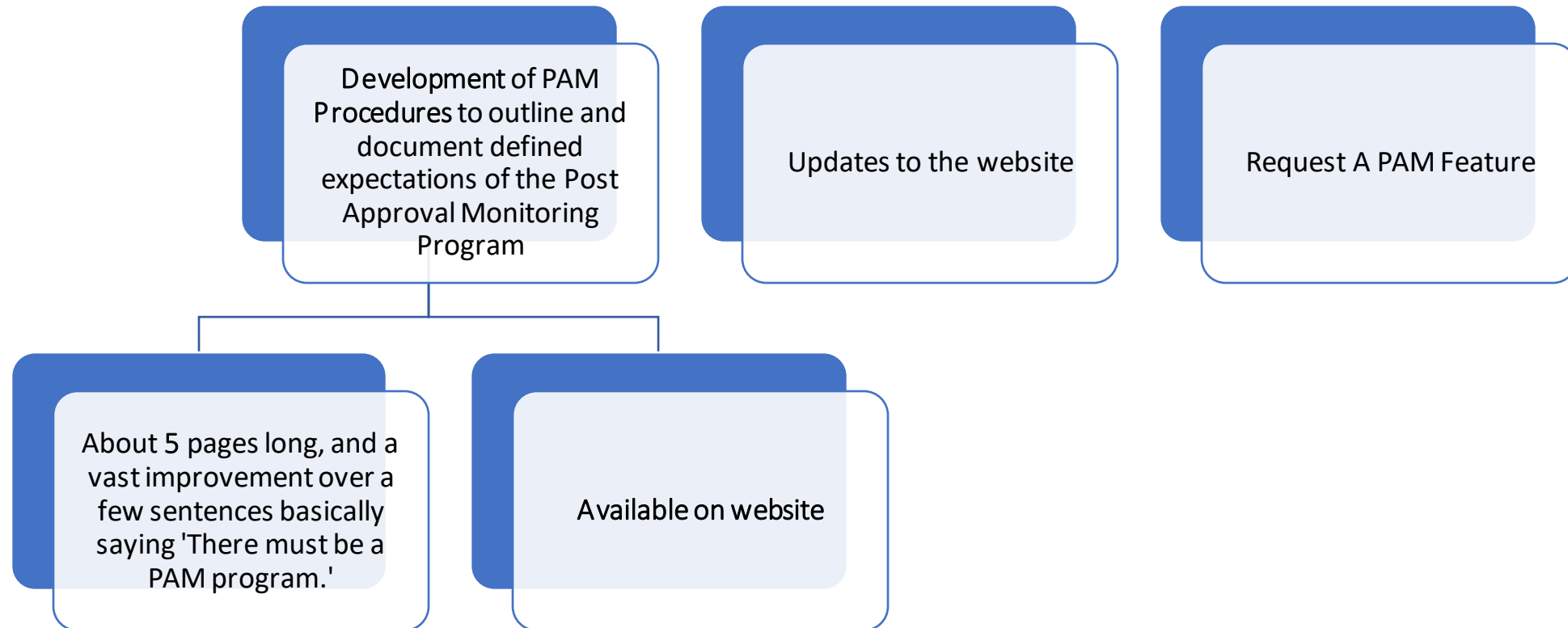
Lowest priority given to Category C (tissue collection)

All lab animal activity can be monitored:

Colony room inspections
Surgery/Procedure Observations
Records/Documentation Review

For Cause

Improvements to Current Program



Visit Expectations

Approximate visit length ~1 hour

- Procedure observations may take longer, depending on length of procedure being conducted

Use of a PAM checklists to
guide the discussion of
protocol/procedures

Tour of laboratory, clinical
space, surgery areas

Record Review

Everything does not have
to be conducted in 1 visit

- Can be broken up to best suit the time of the research staff

PAM Checklist - Protocol

Protocol, Personnel, Laboratory

7. Yes No NA Does the PI have the most recent version of the complete protocol, including amendments?
8. Yes No NA Are the people performing the study listed on the protocol and appropriately trained?
9. Yes No NA Do all personnel have an up to date Occupational Health Certificate?
10. Yes No NA Are lab personnel wearing PPE appropriate for the species and procedures being performed?
11. Yes No NA Are the condition of laboratories adequate and safe for personnel and animals?

Notes:

Animal Numbers, Housing, Justification

12. Yes No NA Are all animal use rooms listed on the protocol?
13. Yes No NA Is the species, age of animals, and weight consistent with what is listed on the protocol?
14. Yes No NA Do cage cards have required information?
15. Yes No NA Does the experiment follow the timeline stated in the protocol?

Notes:

Special Care, Satellite Housing, Animal Transport, Second Use, Prolonged Restraint

16. Yes No NA Is the special care listed in the protocol provided?
17. Yes No NA Is satellite housing/ animal transport consistent with the protocol?
18. Yes No NA Is animal restraint consistent with the protocol?

Notes:

PAM Checklist – Colony Room



QA Post Approval Monitoring (PAM) Checklist Drexel University, Philadelphia PA

Date:

Protocol #:

Title:

Species:

Principal Investigator:

PAM Staff Present:

Animal Room QA

Yes No NA Are all animal use rooms listed on the protocol?

Yes No NA Is the species, age of animals, and weight consistent with what is listed on the protocol?

Yes No NA Do cage cards have the required information?

Yes No NA Are cage card flags being utilized? Are they filled out with all necessary information?

Yes No NA Is breeding being performed? Are the breeding schemes/ages of animals being adhered to?

Yes No NA

Notes:

What To Expect After A Visit

- The PAM Team shall send a written draft report of the monitoring results and recommended action plans, where applicable, within 10 days to the Principal Investigator and participating research personnel following the monitoring event via email. The Principal Investigator will have an opportunity to respond to the draft report with a plan, timeline, and responsible roles to address improvement report within 10 days before the final report is prepared.
 - IACUC leadership will be notified of significant and/or repeat findings.
- The PAM Team shall send a final written report of the monitoring results and improvement action plans to the Principal Investigator after improvements are completed or with a timeframe for completion.
 - Department Chairs will be included in the communication of final reports involving significant and/or repeat findings.
- The PAM Team presents a monthly summary of PAM visits to the IACUC at each scheduled IACUC Meetings.

Metrics



We plan on using metrics to identify areas that may show up repeatedly during PAMs



To also be able to offer more training opportunities

<https://drexel.edu/research/compliance/animal-care-use/post-approval-monitoring/>

POST APPROVAL MONITORING

Drexel University's **Office of Research and Innovation** (ORI) is committed to the health and safety of both personnel and animals. Once an animal use protocol has been approved by the **Institutional Animal Care and Use Committee** (IACUC), it is routinely monitored by several University entities. The routine monitoring of animal activities is to ensure compliance with the protocol and to provide the highest standard of animal welfare.

Post Approval Monitoring is a one of these compliance entities, and is a highly regarded, quality customer service offered to all laboratory animal users of Drexel University. The ORI has the responsibility of ensuring that all laboratory animal research practices are consistent with the recommendations of the **Guide for the Care and Use of Laboratory Animals [PDF]**, the regulations of the **Animal Welfare Act**, and the **Public Health Service Policy on Humane Care and Use of Laboratory Animals**. The Animal Welfare Analyst of the ORI works with each animal user on an individual basis to cater the review of each animal use IACUC approved protocol according to its specific complexities and goals. All lab animal research at Drexel including field studies are monitored as a service to support and protect research staff and animals, in keeping their protocols and animal activities compliant with the latest federal and institutional standards. Assistance is also provided to navigate best practices for the most efficient and humanely productive science possible.

> [VIEW THE POST APPROVAL MONITORING FAQs](#)

POST APPROVAL MONITORING RESOURCES

[Post Approval Monitoring Checklist \[PDF\]](#)

[Post Approval Monitoring Animal Facility Checklist \[PDF\]](#)

[ACU-502 Post Approval Monitoring Procedures \[PDF\]](#)

Please do not hesitate to reach out to the Animal Welfare Analyst for all animal welfare related questions, comments or concerns at animalwelfare@drexel.edu. Your thoughts, opinions and feelings matter to us.

> [POST APPROVAL MONITORING REQUEST FORM](#)

UPDATES

> [CLICK HERE TO READ THE LATEST](#)

CONTACT



**Animal Welfare Analyst and
Post Approval Monitor**
animalwelfare@drexel.edu

Request A PAM Feature

- Having an electronic form on the website that investigators can fill out to request a PAM visit
- This will facilitate communication, instead of just a 'luck of the draw' mentality

Post Approval Monitoring Request Form

The primary goal of the Post Approval Monitoring (PAM) program is to ensure animal well-being and to maintain regulatory compliance while working collaboratively with Principal Investigators (PI) and research personnel. Associated with this, the process will facilitate the science by serving as a resource to the researchers. The PAM process is positioned to convey IACUC policies of animal care and use, identify opportunities for improvement and make recommendations on how to achieve improvement. Ultimately, the PAM process will confirm that animal procedures are performed and conducted under an approved protocol is consistent with what the IACUC approved.

Some benefits that may be gained from a PAM review, but are not limited to, are:

- Increased understanding of the regulations that guide our research projects.
- Increased communication concerning Federal regulations and University policies.
- Access to an individual to clarify the Federal regulations and University policies.

If you have any questions, please contact animalwelfare@drexel.edu.

If you would like to request a Post Approval Monitoring (PAM) visit, please fill out the information below as completely as possible:

Requester:

Email Address:

PI Name, if not requested
by PI:

PAM review type, select all that apply:

- Full Protocol(s) Review
- Surgery/Procedure Observation
- Laboratory Space Inspection
- Animal Colony Room Inspection
- Records Inspection
- Other: Please Specify:

Optional: Please provide a few available dates to help facilitate the scheduling of the PAM visit.



Thank You!

Any Questions?

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