

Institutional Animal Care and Use Committee (IACUC)
Directive 17.0: Post-Approval Monitoring (PAM) for the
Animal Research Program

1.0 Directive Purpose

The purpose of this document is to describe the nature in which the PAM program will be conducted at Brown University.

2.0 Statement

Post-approval monitoring of animal research programs is required by federal law though the formality of how the PAM program is to be administered is left to organizations to determine. Regulators and AAALACi encourage institutions to develop formal PAM programs to ensure programmatic compliance is maintained and the animals in the program continue to receive the highest level of animal welfare.

Ongoing PAM program elements at Brown include the following:

- Animal research personnel training compliance audit conducted by Office of Research Integrity (ORI) staff,
- Ongoing monitoring of animal and laboratory activities by the Center for Animal Resources and Education (CARE) Staff,
- IACUC review and continuing review of animal use protocols,
- Semiannual program review and facilities inspections by the IACUC,
- Administrative audits of IACUC-approved animal use protocols to assess regulatory and IACUC policy compliance,
- Animal Care Technician (ACT) and Veterinary Technician (VT) ongoing monitoring of animal health concerns with reporting responsibilities to veterinarians,
- Veterinarian and VT ongoing and frequent interactions with laboratory personnel.

Additionally, the PAM program at Brown encompasses three separate and distinct processes that also promote continuous monitoring of the animal research program. These three paths include:

1. Research Engagement Visits (REVs),
2. ORI and CARE Quality Assurance (QA)/ Quality Improvement (QI) Visits.
3. IACUC Requested PAM visits.

2.1 REV Visits

REV visits are facilitated by ORI and are service oriented focusing on collaboration, education, and support. The purpose of these visits is to build relationships, meet researchers in an informal capacity, learn about challenges, and provide education where needed. The information obtained from these visits may be used for program improvement initiatives.

2.2 ORI and CARE QA/QI Visits

These visits will be targeted based on programmatic need and or trends with respect to compliance in the animal program. ORI will partner with CARE to coordinate the visits with the labs. The goal of these visits is to engage the community with proactive education in a way that leads to improved compliance and animal welfare outcomes. For example, if CARE is seeing widespread hazardous agent cage labeling issues within the animal facilities, visits and or training may be coordinated with respective researchers to re-educate on the proper practice and expectations when using hazardous agents within animals.

2.3 IACUC Requested PAM Visits

These visits are designed to address specific concerns as identified by the IACUC during convened meetings. Through enhanced oversight, the visits provide opportunity for both the IACUC and the researchers to work together to ensure compliance matters are addressed sufficiently and any additional education is provided that may be warranted. These visits may be scheduled at a mutually convenient time or unannounced as determined by the committee and may be conducted at regular intervals if necessary.

2.4 If Concerns Are Identified During Any Visit

In all cases, if a concern is uncovered, education will be provided in real-time. Further investigation may be needed depending on the nature of the concern and its impact to animal welfare. CARE and ORI will communicate the next steps to the lab as it relates to any concern identified at the time of the visit. Such steps could include submission of an animal event report to the IACUC, further investigation, suspension of an animal activity, or other requirements as deemed necessary by the IACUC.

Any issues that pose an immediate threat to animal welfare will be addressed with the PI and reported promptly to the Attending Veterinarian for immediate resolution. Incidents of this nature will also be brought to the IACUC for review. (Examples: *Animal abuse, mistreatment, or neglect; significant deviation from the approved protocol or SOP; unauthorized animal research activity, etc.*).

3.0 Definitions: N/A

4.0 Responsibilities

All individuals to whom this document applies are responsible for compliance therewith.

5.0 Related Information

Brown University is a community in which employees are encouraged to share workplace concerns with University leadership. Additionally, [Brown's Anonymous Reporting Hotline](#) allows anonymous and confidential reporting on matters of concern online or by phone (877-318-9184).

The following information complements and supplements this document. The information is intended to help explain this guideline and is not an all-inclusive list of policies, procedures, laws and requirements.

5.1 Related Directives/Policies/SOPs: N/A

5.2 Related Procedures: N/A



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5.3 Related Forms: N/A

5.4 Frequently Asked Questions (FAQs): N/A

5.5 Other Related Information: References

- Institute for Laboratory Animal Research, National Research Council. 2011. [The Guide for the Care and Use of Laboratory Animals, 8th edition.](#) Washington, DC: National Academies Press.
- [Animal Welfare Act.](#) United States Department of Agriculture Animal and Plant Health Inspection Service. March 2023. USDA-APHIS
- United States Department of Health and Human Services, National Institutes of Health, Office of Laboratory Animal Welfare. October 2015. [Public Health Service \(PHS\) Policy on Humane Care and Use of Laboratory Animals \(Policy\)](#)

6.0 Directive Owner and Contact

6.1 Owner: Animal Research Compliance

6.2 Approved by: Animal Research Compliance

6.3 Subject Matter Contact: Animal Research Compliance

- IACUC@brown.edu

7.0 Document History

7.1 Effective Date: September 8, 2023

7.2 Last Reviewed: N/A

7.3 Update/Review Summary: N/A