

INSTITUTIONAL ANIMAL CARE AND USE POLICY

Post-approval Monitoring Program – Approval Date: July 11, 2022

Post-approval Monitoring (PAM) allows SUNY Downstate’s Animal Program to regularly review animal care and use activities, confirm and document compliance with approved protocols and regulatory requirements, work with users to enhance animal well-being, identify and correct deficiencies, and prepare for external regulatory and accrediting site visits and reviews. The reviews performed are not intended to be negative or punitive but rather a collegial review of approved activities, and an opportunity for education and sharing program expectations. We will help to proactively maintain compliance with the approved protocol document while research projects evolve.

The PAM program aims to enhance the animal care and use program by:

- Providing a resource to the research community by disseminating information and answering questions.
- Monitoring of protocols after approval occurs through various indirect methods (e.g., conducting surgeries, planning major manipulations, protocol records review, daily care of animals, etc.).
- Creating an atmosphere for collegial dialogue and exchange of information between the individuals conducting the research and the IACUC.
- Establishing a relationship of advocacy between the laboratory, Office of the IACUC, Division of Comparative Medicine (DCM) and the IACUC.
- Acknowledging compliant laboratories on campus, resolving unintentional non-compliances, assisting laboratories with maintaining compliance with regulatory requirements and institutional policies, and assisting with protocol amendments as research projects evolve.
- Facilitating work done by investigators by helping balance good science and good animal welfare.
- Working to identify additional resources that may be needed to support investigator research needs.

The various methods of conducting PAM, detailed below, will aid in identifying and assisting with corrections and enhancements needed to ensure animal welfare and protect Downstate’s researchers and research program. The success of our animal research program is dependent upon a collaborative effort by all parties; PIs and research staff with the various groups within the Office of Research Administration – Sponsored Programs Administration, IACUC, DCM, Office of the IACUC, and IBC.

BACKGROUND

Downstate is regularly visited by external and internal oversight agencies. On-site visits occur as part of each entity’s requirements, usually within specified intervals in addition to any reason they may have to perform a visit ‘for cause’. The United States Department of Agriculture (USDA) is required to perform unannounced visits at least annually, the New York State Department of Health (NYSDOH) is also required to visit at least annually, the Drug Enforcement Agency (DEA) performs unannounced visits, the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALACi) visits triennially as part of Downstate’s reaccreditation

process, the Office of Laboratory Animal Welfare (OLAW) visits as their resources permit, and the Research Foundation (RF) performs annual internal financial audits.

Audits from these various groups includes a thorough review of research protocols and procedures, observation and assessment of individual animals and their care, aspects of the physical environment both within the animal facility and laboratories where animal procedures are performed, mechanisms and effectiveness of program oversight internally, and maintenance of institutional regulatory compliance with theirs and the other regulatory and accrediting bodies. These are the same areas of focus for PAM.

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. Downstate's PAM program has evolved and become more formalized based upon recommendations from multiple AAALACi site visits. Downstate has elected to involve dedicated staff as a part of the PAM program ([OLAW FAQ G6](#)).

Continuing IACUC oversight of animal activities is required by federal laws, regulations, and policies.

- “The IACUC shall conduct continuing reviews of activities covered by this subchapter at appropriate intervals as determined by the IACUC...” - *USDA. (9 CFR §2.31(d)(5))*
- “PAM helps ensure the well-being of the animals and may also provide opportunities to refine research procedures.” – *Guide p. 33.*
- “The IACUC shall conduct continuing review of activities covered by this Policy at appropriate intervals as determined by the IACUC...” – *PHS Policy, V.D.5.*
- “...there will be a system for ensuring animal procedures conform with the approved protocol or study plan.”- *AAALAC FAQ C5*

This policy will cover the following topics:

- PAM Frequency
- Regulatory Guidance
- Post-approval Monitor
- Types of PAM Visits
- Communications
- IACUC Review
- Reporting Requirements

PAM FREQUENCY

In addition to the required semi-annual site visits of all animal care and use areas (including DCM and satellite housing areas), the IACUC has determined the frequency of PAM visits based upon a risk assessment regarding the species involved and the level of procedure invasiveness. The IACUC may also request PAM visits as part of the approval of new procedures, to assess the appropriateness of post-procedural monitoring and care, or based upon the details of previous non-compliances.

Once every 3 years

- Non-USDA species, pain category C protocols
- USDA species, pain category C protocols

Once annually

- USDA species, pain category D protocols
- Non-USDA species, pain category D protocols
- Non-USDA species, pain category E protocols (including pain category E procedures, if active)

Twice annually

- USDA species, pain category E protocols

REGULATORY GUIDANCE

The PAM program uses the following documents as standards, references, and guidance:

- [Guide for Care and Use of Laboratory Animals](#)
- [Animal Welfare Act & Regulations](#)
- [PHS Policy on Humane Care and Use of Laboratory Animals](#)
- [USDA Animal Care Policy Manual](#)
- [AVMA Guidelines for the Euthanasia of Animals: 2020 Edition](#)
- [AAALACi Policies, Position Statements, and FAQs](#)

Financial Compliance policies and regulations:

- [Service Center Policy \(12/26/14\) of the Research Foundation for The State University of New York](#)
- [NIH National Center for Research Resources' \(NCRR\) Cost Analysis and Rate setting Manual for Animal Research Facilities \(CARS\)](#)
- [FAQs for Costing of NIH-Funded Core Facilities](#)

POST-APPROVAL MONITOR

PAM can be performed by the Director or Sr. Research Support Specialist of the Office of the IACUC, the Attending Veterinarian (AV) or their designee, DCM Veterinary Technicians, IACUC members, or individuals with special skills or expertise at the request of the IACUC.

TYPES OF PAM VISITS

Formal PAM

During regularly scheduled procedures, the post-approval monitor compares procedures conducted in the laboratory with those listed in the approved protocol. The post-approval monitor will offer to coordinate a pre-PAM meeting with the PI and laboratory members to explain the PAM program in greater detail and discuss any measures that need to be taken so that there is no negative effect on the studies or data (e.g., the presence of the post-approval monitor impacting behavioral experiments). A visit to observe planned protocol procedures is scheduled with the laboratory in advance.

Informal PAM

Informal PAM may be conducted by impromptu lab and DCM housing and procedure site visits. Downstate is subject to unannounced external visits, and as such works to maintain our facilities and program to be ready each day. Informal PAM visits will help to identify areas that may require additional attention between semi-annual site visits and formal PAM visits as part of this preparation. The IACUC acknowledges that not all items can be quickly or easily resolved, but our oversight bodies are generally more understanding if we have identified concerns and are actively and effectively working to resolve them.

IACUC Semiannual Site Visit Follow-up

During a site visit follow-up, specific items noted during IACUC or other external agency site visits may be discussed and resolution plans may be established or reviewed. The Post-approval Monitor will follow-up on behalf of the IACUC to confirm completion of the resolution plan and provide assistance to the laboratory in resolving the item if needed.

COMMUNICATIONS

A synopsis of the overall laboratory performance and any potential concerns will be openly discussed to confirm the accuracy of the observations made during the review with all personnel in attendance. Following the visit, the post-approval monitor will communicate promptly with the PI and personnel involved with written post-visit correspondence. If there were no concerns identified during the visit, the PI and personnel involved will be commended for their attention to detail, professional manner in which the animal activities were conducted, and the humane manner in which the animals were handled.

If there are concerns to be addressed, the post-approval monitor will work with the PI and laboratory personnel to develop and implement a resolution plan (e.g., protocol amendment submissions, retraining). Any issues and resolution plans will be summarized in a post-visit correspondence email. Collaboration to correct non-compliant items or any suggestions for improvement will be ongoing between the PI, his/her staff and the Office of the IACUC and/or DCM to assist with implementing necessary changes.

During the semiannual site visit, any deficiencies noted will be discussed at the time and the PI will be notified by email. A plan and date for correction will be agreed upon in an email response back to the post-approval monitor and reviewed by the IACUC. Any questions or concerns in resolving items should be communicated to the post-approval monitor in order to assist with any issues.

IACUC REVIEW

The IACUC is ultimately responsible for oversight of all PAM activities. The IACUC will be updated on a monthly basis of all activities. They will receive a summary of the visits performed, their outcome, and the status of any corrective action plans. Members will provide feedback and modifications to any corrective action plans, which will be communicated with the PI. PAM communications shall be maintained by the Office of the IACUC on a secure server.

REPORTING REQUIREMENTS

The IACUC has certain reporting requirements to regulatory, accrediting and funding agencies. The details of specific events will be reviewed and communicated to the appropriate agencies by the IACUC, through the Institutional Official.

The following guidance will be used when determining what events are reported.

- [NOT-OD-05-034: Guidance on Prompt Reporting to OLAW under the PHS Policy](#)
- [Animal Welfare Act & Regulations](#)
- [AAALACi Reporting Requirements - FAQ](#)
- The Sponsored Programs Administration will review the requirements for reporting to individual funding agencies.

Regulatory Communications: Regulatory communications concerning adverse event reports or non-compliance items determined to be reportable to regulatory agencies (e.g., OLAW, USDA, AAALACi, DOD) will be maintained on the OAW secure server. The investigator will be informed that such notifications are being made, the reason for notification, and if any additional action is needed on their part.

Any questions or concerns regarding the PAM Program should be addressed to: IACUC@Downstate.edu or to the IACUC Chair – IACUC.Chair@Downstate.edu

IACUC Policy Post Approval Monitoring Program – Appendix A Compliance Checklist for Post-Approval Monitoring Visits

The Protocol and Personnel

- Does the PI have the most recent version of the complete protocol, including amendments?
- Do the laboratory personnel have easy access to the most recent version of the complete protocol, including amendments?
- Have the laboratory personnel read and understood the protocol and any associated amendments?
- Are the people performing the study approved to perform the IACUC approved procedures?
- Are the people performing the study appropriately trained to work with animals?
- Are the people involved in the study proficient in recognizing pain or distress in animals?
- In the event of a veterinary medical emergency, do laboratory personnel know how to contact the DCM veterinary staff? If after hours, do laboratory personnel know how to contact the DCM veterinarian?

Study Procedures

- Are the animals being studied linked to a specific protocol? In other words, does the protocol number on the animal's cage card match the protocol being used?
- Are all procedures that the laboratory is performing described in the protocol?
- Are the procedures performed consistent with those in the approved protocol?
- Are laboratory personnel appropriately trained to perform these procedures? Is there documentation of this training?
- Are laboratory personnel wearing PPE and/or other attire (e.g., masks and gloves) appropriate for the species and procedures performed (e.g., surgery, use of hazards)?
- Are any expired materials or drugs properly labelled and segregated?

Anesthesia

- Are the methods of anesthesia consistent with the approved protocol?
- Are anesthetized animals monitored according to the approved method in the protocol?
- Are the animals maintained at an appropriate depth of anesthesia for the procedure performed?
- If inhalant anesthetics are used, are they scavenged properly?
- Are anesthetic machines routinely serviced and calibrated?
- Are all drugs in-date?

Surgery or other painful procedures

- Is surgery or any other painful procedure performed in a location that has been approved by the IACUC?
- Is the location and method of animal preparation appropriate and in accordance with the approved protocol?

- Is survival surgery performed using sterile instruments, sterile gloves, a surgery mask, and aseptic technique?
- Is an appropriate heat source used to keep the animal warm throughout the procedure?
- Are incisions closed appropriately and in accordance with the approved protocol (sutures, staples, and/or tissue glue)?
- Is there an appropriate recovery area for the animals?
- Is terminal surgery performed in a clean, organized area?

Post-Surgical Care

- Is post-surgical care consistent with the approved protocol?
- Are the methods of analgesia (dose, frequency, duration) consistent with the approved protocol?
- Are analgesics in-date and not expired?
- Are post-surgical (post-procedural) monitoring parameters and care adequately documented?

Euthanasia

- Does the method of euthanasia correspond with what is approved written in the protocol?
- Is death assured by performing an appropriate physical method of euthanasia when required?
- Are proper methods of carcass/tissue disposal in place?
- If performing CO₂ euthanasia in the laboratory, are the procedures consistent with the 2020 AVMA Guidelines (e.g., flow meter and 30-70% fill rate per minute)?

General Record Keeping

- Is there an up-to-date and complete surgical log?
- Are animals identified by protocol number and individual numbers or cage cards?
- Are medical and post-procedure care progress notes complete and accurate, as described in the protocol?
- Is medication administration accurately documented?
- Are injections, blood collection, and fluid collection amounts dated and documented?
- Are controlled substance records maintained and accurate?
- Is personnel training on protocol-specific procedures documented in some manner?

Laboratory

- Are animal procedural areas and equipment sanitized appropriately?
- Are fume hoods uncluttered and currently certified?
- If animals are housed in the laboratory for greater than 12 hours, has the laboratory been approved by the IACUC as a satellite housing area?
- Are drugs, suture material, and other items used for survival procedure within the noted package expiration dates?
- Are expired drugs/materials appropriately labeled and stored?
- Are drugs, food, or other items stored appropriately (away from detergents or other laboratory chemicals)?

- Are drugs used formulated as pharmaceutical grade? If not, is the use of non-pharmaceutical grade drugs listed and justified in the IACUC protocol?
- Are controlled substances stored appropriately? (e.g., double locked, secured, limited access).
- Are there any safety issues or other concerns that pose a threat to human or animal safety, or animal welfare?