IACUC POLICY
Post-Approval Monitoring

Background

The University of Rhode Island (URI) is committed to adhering to Federal policies and regulations for the humane care and use of animals. This policy provides guidelines for monitoring protocols and procedures following approval by the Institutional Animal Care and Use Committee (IACUC).

Post-approval monitoring (PAM) is performed to confirm the consistency and accuracy of approved protocols and practices. PAM provides assurance to regulatory agencies and the IACUC that animals are cared for according to federal policies and guidelines. PAM ensures that experiments are performed in accordance with approved IACUC protocols.

The goal of PAM is to work with, and in support of, research faculty, staff, and students to confirm accurate and consistent protocol performance in a collegial and unobtrusive manner. The intent of the PAM program is to benefit the research process by supporting:

- the INSTITUTION by reducing non-compliance;
- the RESEARCHERS by helping them to identify and resolve issues of non-compliance;
- the ANIMALS which receive the best possible treatment during all phases of a research protocol; and
- the SCIENCE which will be more consistent and of higher quality.

Responsible Parties

1. The URI IACUC is responsible for ensuring the implementation of this policy. The PAM program is considered an extension of the oversight and educational functions of the IACUC.
2. PIs are responsible for ensuring they and their laboratory staff maintain compliance and work with the IACUC-appointed monitor to observe and confirm monitoring procedures with the approved protocol.
3. The AV, CVT, and animal care staff provide medical and day-to-day care for animals and special veterinary services in support of the approved protocols and in collaboration with the researchers and IACUC.
4. IACUC Administrator fosters communication between all parties, reviews and maintains records, and provides training and assistance if needed.

Policy and Procedure

The PAM program consists of several inter-related activities conducted by delegates of the IACUC, including the Attending Veterinarian (AV), Certified Veterinary Technician (CVT), and IACUC Administrator.

Routine Monitoring Sessions

Animal-related activities are subject to routine monitoring and evaluation by IACUC-appointed monitors, which includes, but is not limited to a) observations of animal health and welfare, b) periodic monitoring of protocol adherence, and c) periodic monitoring of compliance with institutional guidance and standard laboratory practices. During each PAM monitoring activity, the monitor records observations. Reports of visits conducted, including corrective actions, are reviewed at convened IACUC meetings.

Semi-Annual Site Visits

Semi-annual site visits are performed according to the URI IACUC Governance and Operating Policies. Although aimed mainly at facilities, these inspections also promote protocol compliance by reviewing and assessing facility-related issues regarding equipment and processes, drug storage and usage, surgical and procedure logs, lab personnel general knowledge of protocol content, and potential red flags regarding animal health and welfare. In addition, semi-annual site visits present an opportunity for the IACUC to disseminate information regarding new policies and reinforce best practices.

Prior to the semi-annual site visits, an IACUC representative requests that staff associated with each approved protocol be available to answer questions during the site visit. Additionally, the IACUC representative provides information to the site inspectors regarding approved protocols to aid in this process.

Protocol-Specific Review

Selection of Protocols for Review and Review Frequency:

1. All active protocols which include IACUC-approved departures from the Guide, Category E designation, survival surgeries, or USDA-covered species are subject to monitoring at least once every other year, or more frequently, at the discretion of IACUC and the AV.
2. Protocols with Category D designation are subject to monitoring at least once every three years, or more frequently, at the discretion of IACUC and AV.
3. All animal use protocols, including those not included in the categories listed above, are subject to protocol-specific review at the discretion of the IACUC and the AV.
4. Research conducted off-site (e.g., field research) is subject to monitoring via record review and interview of PI and/or laboratory staff.

Process of Protocol-Specific Reviews:

1. In general, the IACUC-appointed monitor schedules monitoring sessions with the Principal Investigator (PI) or laboratory personnel in advance. However, the IACUC reserves the right to perform monitoring without prior notice.
2. The IACUC-appointed monitor notifies the PI that the protocol will be monitored and attempts to make an appointment for a visit. If the PI is unresponsive, the IACUC Chair is notified and determines if corrective action needs to be taken. Follow-up non-compliance visits may or may not be scheduled.
3. The IACUC-appointed monitor may bring an external consultant to the monitoring visit if the IACUC deems necessary.
4. The PI and/or laboratory personnel associated with the protocol are expected to be present for the visit and provide information to the IACUC-appointed monitor as requested. Information may be solicited from other relevant personnel, such as the AV, IACUC Administrator, or animal care staff, if appropriate.
5. During each monitoring session, the IACUC-appointed monitor compares procedures conducted in the laboratory with those described in the approved protocol. All procedures described in the approved protocol must be carried out in accordance with applicable IACUC policies and guidelines in addition to the federal regulations and guidelines. When possible, the IACUC-appointed monitor discusses monitoring results, including any departures noted, with the PI and other laboratory personnel before leaving the laboratory. The discussion may include the formulation of a corrective action plan acceptable to the monitor to be implemented by the PI, as needed.

Process of Follow-Up:

1. The IACUC-appointed monitor sends a written report of the monitoring results, including any and all departures from the protocol or applicable guidelines or regulations and any corrective action plan with deadlines, to the PI, laboratory personnel, and the IACUC.
2. The IACUC-appointed monitor follows up on any issues that require corrective action and attempts to support the laboratory corrective action by providing or scheduling required training.
3. On occasion, additional monitoring sessions may be part of the follow-up to assist with and ensure proper corrective actions. Corrective actions may include, for example, modifying an existing protocol or training/re-training.

Reporting:

1. Issues of veterinary care that pose an immediate threat to animal welfare are referred to the AV for immediate resolution. The IACUC is notified at this time.
2. Per the URI IACUC Governance and Operating Policies, any departures from the approved protocol, the Guide, or AWA regulations that may constitute significant, serious, or continuing violations are immediately reported to the IACUC Chair and the Director of Research Integrity. Such departures are reported to the IACUC for review and discussion by the Committee to determine specific IACUC corrective actions if required, and whether the departures or issues are reportable to the Office of Laboratory Animal Welfare (OLAW), United States Department of Agriculture (USDA), or AAALAC.
3. Reports of visits conducted, including corrective actions, are reviewed at convened IACUC meetings.

Appealing Concerns:

Investigators who disagree with monitoring results, corrective action plans, and/or recommendations may appeal to the IACUC.

Recordkeeping

A copy of the final monitoring report, including a record of corrective actions, is retained in the electronic protocol file.

References

National Research Council. (2011). *Guide for the Care and Use of Laboratory Animals: Eighth Edition*. https://grants.nih.gov/grants/olaw/guide-for-the-care-and-use-of-laboratory-animals.pdf