BACKGROUND

The University of Rhode Island (URI) is committed to observing 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, and provide assurance to regulatory agencies and the IACUC that animals are cared for according to Federal policies and guidelines. It is also important to ensure 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 avoid distractions and consumption of resources to resolve issues of non-compliance
- The Animals which receive better treatment during all phases of a research protocol, and
- The Science which will be more consistent and of a higher quality.

POLICY AND PROCEDURE

The PAM program consists of several inter-related activities:

1. Routine monitoring sessions by the IACUC Administrator or designee
2. Semi-annual site inspection by the IACUC
3. Protocol specific reviews

Routine Monitoring Sessions

Animal-related activities are subject to routine monitoring and evaluation by the attending veterinarian and the animal care staff. Additionally, the IACUC Administrator or designee will conduct PAM specific routine monitoring, which includes, but is not limited to: a) observations of animal health and welfare, b) periodically monitoring protocol adherence, and c) monitoring compliance with standard laboratory practices. During each PAM monitoring session, the IACUC Administrator or designee will record observations. Reports of visits conducted, including corrective actions, will be 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 aid protocol compliance review in the following manner: a) acts as a mechanism to monitor compliance with facility-related issues regarding equipment and processes, b) monitoring of drug storage and usage, c) monitoring of surgical and procedure logs, d) assessment of lab personnel general knowledge of protocol content, e) monitoring for potential red flags regarding animal health and welfare, and f) dissemination of information regarding new policies and reinforcement of “best practice.” Prior to the semi-annual site visits, the Office of Research Integrity requests that staff associated with each approved protocol be available to answer questions during the site visit. Additionally, the Office of Research Integrity will provide information to the site inspectors regarding approved protocols to aid in this process.

Protocol Specific Review

Selection of Protocols for Review:

1. All active protocols which include: exemptions to social housing of animals, Category E designation or USDA-covered species will be monitored at least once annually, or more frequently, at the discretion of IACUC and the Attending Veterinarian.
2. All protocols, including field research protocols, will be monitored at least once every three years, or more frequently, at the discretion of IACUC and Attending Veterinarian. Approximately one-third of the protocols involving less invasive procedures will be monitored annually.
3. In general, the IACUC Administrator or designee will schedule monitoring sessions with the Principal Investigator (PI) or laboratory personnel in advance. However, the PAM program reserves the right to perform monitoring without prior notice.

Process of Protocol Specific Reviews:

1. The IACUC Administrator or designee shall notify the PI that the protocol will be monitored and attempt to make an appointment for routine visit. If the PI is unresponsive, the Institutional Official will be notified and can determine if corrective action(s) need to be taken. Follow-up non-compliance visits may or may not be scheduled.
2. The IACUC Administrator or designee will provide the PI with the monitoring form prior to the visit (see Appendix A)
3. The IACUC Administrator or designee may bring the Attending Veterinarian, a member of the IACUC or an external consultant if the IACUC deems necessary.
4. The PI and/or laboratory personnel associated with the protocol will be expected to be present for the visit and to participate in providing information to the IACUC Administrator or designee as requested. The PI or IACUC Administrator or designee may invite the Attending Veterinarian or animal care staff to participate in providing information, if appropriate.
5. During each monitoring session, the IACUC Administrator or designee will compare 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 guidelines and federal regulations and guidelines. When possible, the IACUC Administrator or designee will discuss monitoring results, including any and all departures noted, with the PI and other laboratory personnel before leaving the laboratory. The discussion may include formulation of a corrective action plan (acceptable to the post-approval monitor) to be implemented by the PI, as needed.

Process of Follow-Up:

1. The IACUC Administrator or designee will send 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, IACUC Chair, Director of Research Integrity, and Attending Veterinarian. If no departures are noted, the PI will receive a congratulatory report.
2. The post-approval monitor will follow up on any issues that require corrective action and will attempt to support the laboratory corrective action by providing or scheduling required training and/or assistance with form preparation (e.g., amendment submission).
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, reverting to the procedures which are already listed in the approved protocol, or training/re-training

Reporting:

1. Issues of veterinary care that pose an immediate threat to animal welfare will be referred to the Attending Veterinarian for immediate resolution.
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 will be immediately reported to the IACUC Chair and
the Director of Research Integrity. Such departures will be reported to the IACUC for discussion by the Committee to determine which require specific IACUC corrective actions, and whether they are reportable to the Office of Laboratory Animal Welfare (OLAW), or United States Department of Agriculture (USDA).

3. Reports of visits conducted, including corrective actions, will be reviewed at convened IACUC meetings.

Process of Appealing Concerns:

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

Recordkeeping:

1. A copy of the final monitoring report, including a record of all corrective actions, will be retained in the electronic protocol file.
2. The information concerning departures from approved protocols or applicable regulations and guidelines will be recorded for use as institutional trending or follow-up.

RESPONSIBLE PARTIES

1. The URI IACUC is responsible for ensuring the implementation of this policy. The PAM program should be considered an extension of the oversight and educational functions of the IACUC.
2. Principal Investigators are responsible for ensuring they and their laboratory staff strive to maintain compliance and work with the post-approval monitor to observe and confirm monitoring procedures with the approved protocol.
3. Attending Veterinarian and animal care staff: Provide medical and day-to-day care for animals and special veterinary services in support of the approved protocols in collaboration with the researchers and IACUC.
4. IACUC Administrator: Works with the PI and laboratory staff to observe activity, prepare accurate reports, and provide recommendations for maintaining compliance, and endeavors to provide training and assistance if needed.
5. Director of Research Integrity: Provides operational oversight and management of the post-approval monitor and the post-approval monitoring program, assures the IACUC receives reports or updates on items of concern, and provides support as required to assure compliance.

REFERENCES