<table>
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<th>IACUC GUIDELINE:</th>
<th>Post Approval Monitoring of IACUC Approved Protocols</th>
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<td>ACUP #</td>
<td>305</td>
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<td>IACUC Approval:</td>
<td>July 29, 2016</td>
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**Rationale**

The IACUC’s role of monitoring animal care and use is a requirement of the Animal Welfare Act Regulations (AWRs), Public Health Service (PHS) policy, the *Guide for the Care and Use of Laboratory Animals*, and the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC). The IACUC is responsible for upholding these standards in the care and use of animals in research. Monitoring is achieved by several mechanisms including, but not limited to, continuing protocol review, semi-annual facility inspections, and veterinary consultation and oversight. The IACUC’s post-approval monitoring (PAM) program is intended to augment these activities and assist investigators to effectively and efficiently achieve their scientific objectives in an ethical, compliant manner.

**Policy**

The PAM program is intended to have a proactive focus on education and training so as to identify and correct potential areas of non-compliance before they occur; provide an opportunity for open and collegial dialogue between the research team and the IACUC and veterinary staff, be flexible and scalable to meet and respond to the needs of the investigators and the institution; and to promptly identify, correct, document and report incidents of non-compliance. The PAM program is risk based and a risk based assessment will be used to determine the frequency and depth of PAM visits for procedures performed as part of approved IACUC protocols.

**Procedures**

All animal use activities conducted under the jurisdiction of the Texas A&M University - Commerce IACUC will be subject to PAM visits. PAM visits may be scheduled or unannounced; routine or for cause. In accordance with identified or potential risks, past compliance issues or program needs, PAM visits may be comprehensive or targeted in scope. The PAM program includes follow-up visits to selected research groups to verify corrective actions were implemented, validate further training has occurred and evaluate the effectiveness of the program.

An additional component of post-approval monitoring includes retrospective record reviews. Such reviews, when performed by ACF veterinary staff, will be communicated to the Office of Research & Sponsored Program’s office for documentation.
Risk Determination
Non-biased risk factors, prior laboratory performance and professional judgment will be used to assign individual PIs, research groups, or laboratories to high, medium or low risk categories.

High Risk categories may include, but are not limited to:

- Chronic disease models that require model specific monitoring/scoring or those that involve rapid disease progression
- USDA Pain Category E procedures
- Survival surgeries with increased potential for complications, are novel or complex, or with other factors that increase the need for monitoring
- Investigators new to animal research or the introduction of a new species or disease model
- Prior non-compliance concerns
- Requests from animal facility or veterinary staff
- Satellite housing locations (also known as lab housing)
- Exceptions to the Guide for the Care and Use of Animals that are deemed high risk
- Approved exceptions to IACUC policies

High risk areas will be visited at least once per year depending on activity level. Medium Risk categories may include, but are not limited to:

- Non-survival surgeries
- Routine and minimal risk survival surgeries
- Work with biohazards with a potential for transmission to other animals or to humans
- USDA Pain Category D procedures
- Large laboratories or laboratories with high rates of laboratory personnel turnover
- PI-maintained colonies

Low Risk categories may include, but are not limited to:

- Euthanasia and tissue collection
- Non-surgical procedures such as injections, blood collection
- Experienced laboratories with demonstrated positive findings from past monitoring visits and semi-annual inspections
Monitoring Process

Once the risk assessment had been done and the activity has been selected the Research Compliance Specialist will prepare for the PAM visits using the following steps:

Advance Activities:

- Prior to the PAM visit the Research Compliance Specialist will review the protocol(s) and other documents such as past monitoring results, relevant policies and standard operating procedures.
- PAM visits will typically be scheduled in advance to ensure that the PI and/or appropriate research staff are available and to avoid an unplanned disruption of scheduled laboratory activities.
- The Principal Investigator (PI) will be informed of the purpose and scope of the PAM visit.
- For cause visits may be conducted at any time, with or without advance notice to the PI or research personnel.

Post Visit Activities:

- The Research Compliance Specialist will provide any educational materials, policies, standard operating procedures (SOPs), sample forms or any additional assistance to the PI or research staff to address questions or issues discussed during the visit.
  - The Research Compliance Specialist will prepare a written report of the PAM visit to the PI and staff within a reasonable amount of time (e.g. 2-3 days). Input from the Research Compliance Administrator or others with specific expertise will be sought as needed to prepare the report. Further communication with the PI may be necessary to substantiate observations; gather additional information, or obtain initial PI input on recommended resolutions for issues not addressed during the monitoring visit.
  - The final report to be send to the PI and staff will contain a description of the findings, and as applicable, either a specific resolution plan or a request for the PI to develop and respond with a corrective action plan.

Follow-up Activities:

- The Research Compliance Specialist will follow-up to ensure all resolutions are completed within reasonable time frames.
- If necessary, the Research Compliance Specialist will re-visit the laboratory to verify that resolutions have been successfully implemented. Any observed instances of repeated or continued non-compliance will be reported to the Research Compliance Coordinator, IACUC Chair and Attending Veterinarian for further action.
Reporting:

- The IACUC will receive reports of the previous month’s PAM activities at scheduled full committee meetings.

Applicability

This policy applies to all IACUC approved protocols.

Exceptions

None

Contact Information

For any additional questions concerning this policy, please contact the Office of Research and Sponsored Program’s Office.

Approved:
Revised: Sylvia Rothenburg, Glenda Denton