Policy # BP-13-2012

Policy Title: Post Approval Monitoring of Protocols

Policy: Post-approval monitoring ("PAM") of animal activities is required by federal laws, regulations and policies. In the broadest sense, PAM consists of all the continuing oversight activities undertaken by both internal and external groups, including the Institutional Animal Care and Use Committee ("IACUC"), Environmental Health and Safety ("EHS"), Animal Care Services ("ACS"), United States Department of Agriculture/Animal Plant Health Inspection Service ("USDA/APHIS") and the Association for the Assessment and Accreditation of Laboratory Animal Care, International ("AAALACi").

PAM as conducted by the IACUC consists of semi-annual inspections (as covered in Policy BP-14-2012), spot/follow up inspections, continuation emails and PAM sessions near the time of annual continuation.

- **Spot/Follow up inspections**: As necessary in order to follow up on deficiencies, incidents of non-compliance, or as a part of ongoing animal program monitoring.
- **Continuation email**: Sent three months prior to lapse date, this email is a request for information from the PI. It queries the PI on the number of animals used within the previous year, any unexpected events and the need for modification. The email also asks for confirmation that the PI would like to continue the protocol and asks the PI to confirm the list of personnel.
- **PAM session near the time of annual continuation**: These PAM sessions are conducted by IACUC staff or IACUC members. The PAM session is structured as an interview with questions designed to prompt discussion on topics including unexpected outcomes, need for modifications, pain and distress classification and risk/hazard assessment. PAM also provides a venue in which the IACUC can communicate new policies or changes to existing IACUC administrative practices and promote collegial communication between the IACUC office and Principal Investigators.

PAM as conducted by EHS: Environmental Health and Safety personnel typically inspect all animal use laboratories at least once a year. These audits focus on biosafety, chemical safety and occupational health and safety. Audit reports are available for review as a part of PAM of the animal care and use program.

PAM as conducted by ACS veterinary staff: Animal rooms are checked by ACS animal care staff daily and issues of concern are brought to the attention of the ACS veterinary staff immediately. ACS veterinary staff will follow up with the Principal Investigator and the IACUC when there are incidents of non-compliance. Additionally, ACS veterinary staff may conduct
PAM by observing invasive procedures, animal handling and techniques as warranted. ACS uses the Guidance document: “Guidelines for Reporting Protocol Deviations, Adverse Events or Unexpected Outcomes” to direct the review and reporting of findings during these PAM activities.

**PAM as conducted by outside agencies:** Aspects of the University’s animal care and use program are subject to inspection by outside agencies, including, but not limited to USDA/APHIS, Department of Defense (“DOD”), Office of Laboratory Animal Welfare (“OLAW”), Occupational Safety and Health Administration (“OSHA”) and AAALAC as dictated by regulations and policies. Compliance with protocols, policies, regulations and procedures may be a focus of these inspections.