Requirement for and Guidance on Post Approval Monitoring

Background:

Virginia Tech is committed to ensuring humane care and treatment of animals used in research and teaching by faculty, staff, and students. Virginia Tech is a Registered Research Facility with the United States Department of Agriculture Animal and Plant Health Inspection Service (USDA-APHIS), and has an approved Animal Welfare Assurance on file with the Public Health Service’s (PHS) Office of Laboratory Animal Welfare (OLAW). The Institutional Animal Care and Use Committee (IACUC) at Virginia Tech is mandated, through federal laws, regulations and guidelines, to act on behalf of the Government in the oversight of the program of animal care and use at our institution.

The IACUC has the authority and responsibility to initially approve research and teaching protocols, and subsequently monitor ongoing animal activities to verify compliance with the approved protocol, and by extension, with federal regulations. Non-compliance with federal regulations by PIs/Instructors and their staff can result in: suspension of research and teaching protocols; the suspension or loss of the privilege to use animals in research and teaching at Virginia Tech; the loss of federal research funding across the entire institution; or, the loss of permission to conduct animal research at the institution. Post approval monitoring (PAM) of animal activities provides assurance to the IACUC and to the institution that researchers, instructors, and research, teaching and testing support staff are conducting their activities in accordance with their respective IACUC approved protocols, and are thus complying with applicable local, state, and federal regulations. In a large, decentralized institution such as Virginia Tech, Post Approval Monitoring of randomly selected or specifically targeted protocols helps the IACUC assess protocol compliance by research and teaching staff.

Policy:

Virginia Tech has determined that Post Approval Monitoring of compliance in animal activities (e.g., in approved research and teaching protocols) is a mandatory requirement for researchers, instructors and personnel who participate in - Virginia Tech IACUC protocols.

A PAM Officer, employed within the Office of Research Compliance, serves as compliance liaison between the research, instruction and testing community, the IACUC, the Office of the University Attending Veterinarian, the Office of Research Compliance, compliance organizations, and state and federal agencies. The PAM Officer monitors/assesses compliance by conducting inspections including, but not limited to: research records, laboratories, animal handling, procedural techniques, animal facilities, and workplace occupational health and safety issues.

The findings of these inspections will be utilized by the IACUC to require correction of deficiencies in specific protocols, and to assess trends that may require program-wide policies and updated training. By identifying and rectifying deficiencies and non-compliance promptly, Virginia Tech is better able to continuously improve its program of animal care and use.
Periodic reports of inspections will be brought to the IACUC Chair. If the IACUC Chair determines non-compliance may have occurred, those issues will be presented at the next convened IACUC meeting, where a quorum is present, for discussion and action. During the convened meeting IACUC Members will make a determination of whether the non-compliance is deemed minor or serious, and will recommend corrective action or sanction. If the Attending Veterinarian determines that the issue presents an immediate animal welfare concern, the procedure may be halted, with an emergency IACUC meeting, with a quorum present, held to determine what additional action may be required. Potential animal welfare concerns will be reported to the Chair and Attending Veterinarian within one business day of receipt.

After determination of non-compliance by the IACUC, the PI will be notified in writing of the issue and any remediation actions required by the IACUC. The PAM officer or designee will monitor status of satisfactory completion of action items and updates will be reported to the IACUC.