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I. Purpose

This SOP outlines the Post-Approval Monitoring (PAM) procedures. The intent of the post-approval monitoring will be to work with Investigators to support their research to guarantee accurate protocol performance while maintaining IACUC and institutional standards. Post-approval monitoring serves to confirm that the care and use of animals for research or educational purposes abides by the practices and procedures approved by IACUC.

II. Scope/Responsibility

Post-approval monitoring applies to all IACUC approved protocols.

It is the responsibility of all Investigators with IACUC approved protocols to maintain documentation that will enable post-approval monitoring and work with the IACUC to schedule post-approval monitoring for procedures described in the protocol.

The IACUC has the responsibility to schedule post-approval monitoring of any protocols and report findings to the Investigator and IO. The IACUC can delegate post-approval monitoring to a qualified monitor or quality assurance auditor.

The IACUC and the Investigator have the responsibility to work together to ensure that when non-compliance is documented during post-approval monitoring, corrections to the procedures are implemented or an amendment is submitted for approval within one week.

III. Procedure

1. Selection and scheduling

Protocols can be monitored at any given time either by being randomly chosen, suggested by RUSVM students or colleagues, or as a means to a follow up of past non-compliance issues. At least 10% of all active protocols will be monitored annually.

The Investigator(s) will be contacted to schedule post-approval monitoring. Prior to the PAM, the committee will receive a notice of scheduling and given access to the relevant protocol documents. The personnel conducting the PAM will ensure they are familiar with the protocol and procedures described by thoroughly reviewing the protocol documentation available to them.

2. PAM visit

The approved protocol will be compared with the practices and procedures that are being performed on the animals and any non-compliance documented and discussed with the Investigator(s) to identify solutions to any non-compliance issues identified. All non-compliance issues will be documented and a plan to prevent non-compliance in the future agreed upon.



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Major non-compliance issues also will be reported to the IACUC Chair immediately. If any non-compliance issues are believed to result in undue pain for the animal(s) involved in the procedure or could result in death (unplanned) of the animal, the procedures can be stopped until guidance can be obtained from the IACUC Chair and/or AV.

3. Post-PAM visit

All findings during the PAM visit and proposed solutions to ensure future compliance will be documented and signed by the personnel conducting the PAM visit and the Investigator(s). If there is disagreement in findings, the Investigator can respond with a report added to the PAM report. The report(s) will be submitted to the IACUC within 1 week of the PAM visit and discussed with the IACUC members.

Any amendments required to ensure compliance will be submitted to IACUC within 2 weeks of the PAM visit.

V. Review

This SOP is subject to annual review.

Policy Approval:

03 November 2023

Signed

Dr. Jennifer Ketzis, IACUC Chair

Date