

Title: **Post Approval Monitoring**

Effective Date: **December 10, 2009**

Revision # **03**

Standard Operation Procedure Number: **IACUC-RVW-023** **Last Committee Review: September 21, 2018**

Purpose and Scope

The purpose of this Standard Operating Procedure (SOP) is to outline the procedures used to meet the expectation for conducting Post Approval Monitoring (PAM) of IACUC protocols.

Monitoring of protocols after approval occurs through various indirect methods (e.g., conducting surgeries, planning major manipulations, daily care of animals, etc.). These procedures provide for a structured methodology to assist with meeting this expectation.

Reference

IACUC-RVW-011 Investigation of Possible Non-Compliance

Policy/Procedure

At least once (and not more than twice) annually, a PAM sub-committee will be organized (this may be in conjunction with semi-annual review). This sub-committee will consist of at least 2 voting IACUC members, but no IACUC member will be excluded who wishes to participate.

The PAM sub-committee will:

1. Randomly select or target up to 5 IACUC protocol forms from all of the active protocols to be reviewed. Protocols may also be requested by the Vice President for Research and Economic Development. Reasons for targeting a protocol include but are not limited to the following:
 - a. Studies using pain category E animals
 - b. Studies or groups which have previous compliance issues
 - c. Studies which house regulated animals in facilities not routinely inspected
2. Thoroughly review the protocol(s) selected as well as research records and progress reports.
3. Conduct an interview with the PI(s) of each protocol selected. This interview can be via phone conversation, email or personal visit. The interview will primarily consist of:
 - a. Questions regarding how procedures already conducted were accomplished
 - b. Questions regarding plans for procedures not yet completed
 - c. Inventory of animals acquired and animals used
 - d. Questions regarding any changes, challenges, or issues during implementation of procedures already conducted
4. Verify from sources other than the PI(s) that no material changes in the study have occurred since previous IACUC review. Note: This step is not a requirement.
5. Visit specific laboratories and animal facilities if warranted based upon the findings of the interview. Note: This step is not a requirement.
6. Write a report for each protocol identifying:
 - a. the overall impression of the PAM sub-committee based upon the interview and(or) inspection
 - b. any deviations from the protocol
 - c. any recommendations made by the sub-committee to the PI(s) during the interview and(or) inspection
 - d. any actions the PAM sub-committee requests from the IACUC

Reviewed:

IACUC Chairperson

Date

Research Compliance Director

Date