

1. PERFORMANCE STANDARD

The goal of post-approval monitoring is to work with, and in support of, research staff members and to confirm accurate and consistent protocol performance in a collegial and unobtrusive manner.

2. BACKGROUND

Post approval monitoring of Animal Use Protocols (AUPs) is performed to provide assurance to regulatory agencies and SHSU that animal experiments are monitored for compliance with approved IACUC protocols. The Committee confirms consistency with approved protocols and accuracy of practices.

3. ROLES

3.01 Investigators and research personnel will work in conjunction with the IACUC to facilitate observation of procedures and document compliance with approved protocols.

3.02 The IACUC will do the following:

- a. Work with the investigator and research personnel to observe activity, prepare accurate reports, and if necessary, provide training and recommendations for maintaining compliance.
- b. Provide operational oversight of the post approval monitoring program, assure that the IACUC receives reports or updates on items of concern, and provide training support as required to assure compliance.

3.03 The IACUC Coordinator will coordinate visits, correspondence, and documentation, maintain records, and correspond with the IACUC.

4. REQUIRED PROTECTIVE MEASURES

The IACUC, as well as other visitors, shall wear the Personal Protective Equipment (PPE) prescribed for the specific activity/procedure of the laboratory.

5. POLICY EXPECTATIONS

5.01 Selection of Protocols for Review

- a. Active protocols involving the use of USDA Category C, D, or E will be monitored on a random basis, or at the discretion of the IACUC and the Attending Veterinarian.
- b. Protocols involving less invasive procedures will be monitored at the discretion of the IACUC and the Attending Veterinarian.
- c. In general, the IACUC Coordinator will schedule monitoring sessions with the Principal Investigator or other research personnel in advance.
- d. “For cause” monitoring may be conducted at any time, with or without advance notice to the Principal Investigator or research personnel

5.02 Process of Monitoring

- a. The IACUC Coordinator shall make an appointment for visits (follow-up visits may also be scheduled).
- b. The Committee shall use the IACUC-approved “Post-Approval Monitoring Checklist” for the review (document found on IACUC website under Applications).
- c. During each monitoring session, the Committee will compare procedures conducted in the laboratory with those listed in the approved protocol.

Documented discrepancies between procedures performed in the lab and those listed in the protocol will be brought to the attention of the Principal Investigator. Items that will be reviewed are listed on the attached “Post Approval Monitoring Checklist” and include the following sections

- (1) Protocol and Personnel
- (2) Study Procedures
- (3) Anesthesia
- (4) Surgery
- (5) Post-Surgical Care

- (6) Euthanasia
- (7) Record Keeping
- (8) Laboratory

6. ANIMAL MISUSE, MISTREATMENT OR NEGLECT

Welfare issues and discrepancies, which result in animal welfare concerns (deliberate animal misuse, mistreatment or neglect, or those that involve willful disregard for appropriate animal care) will be immediately reported to the IACUC in accordance with Public Health Service Policy. The IACUC staff, in conjunction with the IACUC Chair, will gather information to present to the IACUC for review and, if necessary, further investigation.

7. PROCESS OF SHARING INFORMATION CONCERNING THE REVIEW

- 7.01 The IACUC shall discuss monitoring results with the Principal Investigator and other research personnel before leaving the laboratory. Issues that pose an immediate threat to animal welfare shall be referred to the Attending Veterinarian or other veterinarian for immediate resolution.
- 7.02 The IACUC Coordinator shall send a written draft report of the monitoring results to the Principal Investigator and other research personnel. Investigators will have an opportunity to respond to the draft report before the final report is prepared.
- 7.03 The IACUC Coordinator shall send a final written report of the monitoring results to the Principal Investigator, research personnel, IACUC, and the Attending Veterinarian.

8. PROCESS FOLLOW-UP

- 8.01 The IACUC Coordinator will follow up on any issues that require protocol modifications, orientation of new personnel, or training. The IACUC Coordinator will support the laboratory corrective action by providing required training and/or assistance with form preparation (addendum submission).
- 8.02 On occasion, additional monitoring sessions may be part of the follow-up to assist with proper corrective actions.

9. RECORD KEEPING

- 9.01 A copy of the final compliance monitoring report shall be kept in the protocol file.
- 9.02 The non-compliant information shall be entered into the investigator's protocol file for continual monitoring.

APPROVED: <signed>
Dana L. Hoyt, President

DATE: 7/9/14

CERTIFICATION STATEMENT

This academic policy statement (APS) has been approved by the reviewer(s) listed below and represents SHSU's Division of Academic Affairs' policy from the date of this document until superseded.

Original: February 12, 2014
Reviewer(s): Council of Academic Deans
Academic Affairs Council

Review Cycle: February 1, ENY*
Review Date: February 1, 2016

Approved: <signed>
Jaimie L. Hebert
Provost and Vice President
for Academic Affairs

Date: 7/17/14

***ENY = Even Numbered Year**