

To ensure receipt and to expedite the review process, Animal Use Protocols (AUPs) should be hand-delivered to the IACUC Coordinator in the Office of Research and Sponsored Programs. The AUP must be fully completed, signed by the faculty/staff member in charge and the Chair of the Department in which the faculty/staff member works, and any supporting materials must be attached. The IACUC Coordinator records the receipt of each new AUP and creates a file for the application. If an AUP is sent through the mail, it is the responsibility of the faculty/staff member in charge to ensure that the application is complete and can be submitted for review.

Public Health Service (PHS) Policy stipulates that there are two valid methods of review of AUPs: (1) Full Committee Review and (2) Designated Member Review. The USDA concurs with the latter alternative practice of reviewing AUPs with minimally invasive procedures.

1. DEFINITIONS

- a. Full Committee Review: also referred to as FCR, this review method may only be conducted at a convened meeting with a simple majority (also referred to as a quorum) of members present. A majority vote of the quorum present is needed to approve, require modifications in (to secure approval), or withhold approval of a protocol. A quorum is defined by the regulations as one more than 50% of the Regular IACUC members present at a convened meeting. If a Regular member is unable to attend, his/her Alternate may attend so that quorum is maintained. When substantive modifications are required in a protocol to secure approval, the resubmitted protocol must be reviewed using the FCR review method. All Category E research involving animals will ALWAYS be assigned to FCR.
- b. Designated Member Review: also referred to as DMR, this review method may occur only after all members of the IACUC have received copies of the AUPs to be reviewed and have had the opportunity to call for FCR. If FCR is not requested, at least one member of the IACUC qualified to conduct the review is designated by the Chair. DMR may result in approval, require modifications (to secure approval), or request FCR. DMR may not result in disapproval.

2. FULL COMMITTEE REVIEW (FCR)

When an AUP is assigned to the IACUC for review, it is distributed to all IACUC members (Note: All Category E research involving animals will ALWAYS be assigned to FCR.) Topics that are considered by IACUC members during review are

specifically described in the Animal Welfare Act and the PHS Policy. They include, but are not limited to:

- a. Rationale and purpose of the proposed use of animals
 - b. Justification of the species and number of animals requested
 - c. Availability or appropriateness of the use of less-invasive procedures, other species, isolated organ preparation, cell or tissue culture, or computer simulation
 - d. Adequacy of training and experience of personnel in the procedures used
 - e. Unusual housing and husbandry requirements
 - f. Appropriate sedation, analgesia, and anesthesia
 - g. Unnecessary duplication of experiments
 - h. Multiple major operative procedures on single individuals
 - i. Appropriateness of USDA pain/distress category
 - j. Criteria and process for timely intervention, removal of animals from a study, or euthanasia if painful or stressful outcomes are anticipated
 - k. Post-procedure care
 - l. Method of euthanasia and/or disposition of animals
 - m. Safety of the working environment for personnel
 - n. Copies of appropriate licenses, certificates, and/or permits attached
3. DESIGNATED MEMBER REVIEW (DMR)

Committee members are given five (5) days to review an AUP and respond with comments or a request to have the AUP reviewed at a convened meeting of the Committee. If a full Committee review at a convened meeting is not requested, comments and questions about the AUP returned by Committee members to the IACUC Chair are communicated to the faculty/staff member in charge. Additional

information or further clarification may be requested from the faculty/staff member in charge prior to further review. The AUP may then be approved following satisfactory resolution of any questions. As mentioned above, DMR may not result in disapproval.

4. IACUC MEETINGS

Complex issues and complicated concerns may require discussion at a convened IACUC meeting. Convened IACUC meetings are held once each month or when needed. Following discussion at a convened IACUC meeting, the Committee votes to approve, disapprove, or table the AUP. As with the 5-day review, comments and questions about the AUP are communicated to the faculty/staff member in charge. The AUP may be approved following resolution of these questions.

5. SCHEDULE OF IACUC REVIEW

Completion of the AUP review process can take as long as 60 days depending on the review method used for a particular AUP. The length of time for review is variable and is dependent upon how thoroughly the AUP was prepared, how concerns were addressed, and how quickly responses are received. AUPs that include hazardous materials will require additional approval from the Biosafety Committee.

6. DURATION OF ACTIVE AUPs

AUPS are approved for the duration of the applied research project only, but they are subject to an Annual Review (Form F). Under PHS Policy, the maximum interval between IACUC review and approval is three years, i.e., a complete *de novo* review is required at least every three (3) years. The IACUC fulfills this obligation by requiring faculty/staff members in charge to submit a new AUP after three (3) years for continuing projects using animals. Applicable, current licenses, certificates and/or permits are required for the duration of the project.

7. APPROVAL OF AUPs

Once the AUP has met all requirements and is approved, a formal statement of approval will be sent to the faculty/staff member in charge of the research project. The IACUC approval notification will bear the signature of the IACUC Chair, a number that identifies the research project (assigned by the Research Compliance Coordinator), the faculty/staff member in charge, and the start and end dates of the project.

8. PROPOSED SIGNIFICANT CHANGES TO AUPs

All significant changes that the faculty/staff member in charge wishes to make to the research study **MUST** be reviewed and approved by the IACUC. This requires submission of the IACUC Amendment (Form G). Examples of changes generally considered significant are changes:

- a. in the Objectives of a Study;
- b. from Nonsurvival to Survival Surgery;
- c. in the Invasiveness of a Procedure or Discomfort to an Animal;
- d. in Animal Species;
- e. in Animal Numbers;
- f. in the Principal Investigator;
- g. in Research Personnel (additions/deletions);
- h. in Veterinary Care;
- i. in Pain Relieving Procedures;
- j. in the Method of Euthanasia;
- k. in Hazardous Agent Use;
- l. in Funding Source;
- m. in Animal Husbandry; or
- n. in Anesthetic Agent(s), or the Use or Withholding of Analgesics (not intended to limit the clinical judgment of the veterinarian in treating individual animals).

9. POST-APPROVAL MONITORING (PAM)

PHS Policy requires the monitoring of animal care and use once the AUP has received approval from the IACUC. PAM can include but is not limited to: (1) continuing protocol review; (2) laboratory inspections (conducted either during regular facilities inspections or separately); (3) veterinary or IACUC observation of selected procedures; (4) observation of animals by animal care, veterinary, and IACUC staff and members, and (5) external regulatory inspections and assessments.

10. ANNUAL REVIEW

For purposes of SHSU's IACUC, continuing protocol review will consist of an annual update from the faculty/staff member in charge of the research. This will require the submission of the Annual Review Form F. This will allow the investigator to submit proposed amendments for future procedures, to provide a description of any adverse or unanticipated events, and to provide updates on work progress.

The deadline for all Annual Review Forms will be **September 30** of each year the Animal Use Protocol (AUP-Form C) is active. **NOTE:** there is one caveat: once a PI receives his/her initial approval, s/he will be required to submit the Annual Review Form **TWICE**; in **YEAR 3 after the initial approval and 2 Annual Reviews**, PIs are then required to submit a brand new protocol. **For example**, if a PI's initial approval to his/her IACUC research protocol was granted March 31, 2014, his/her 2 Annual Review forms would need to be submitted by September 30, 2014, & September 30, 2015; a new Animal Use Protocol (IACUC Form C AUP) would be required by March 31, 2016, (**the initial approval is good for three (3) years**—thus, in the aforementioned example, that initial approval period would be March 31, 2014 – March 31, 2017).

11. ADDRESSING ANIMAL WELFARE CONCERNS

The SHSU IACUC has a mandate to evaluate concerns regarding the care and use of animals. Concerns may be raised by SHSU staff or employees, individuals in the community, or even members of the IACUC. Any person concerned about the manner of housing of animals, or the use of animals in teaching, research, and demonstrational/display activities has the opportunity to file a grievance with the IACUC. Grievances can be filed either through written response to IACUC Chair, Box 2448, SHSU, Huntsville, TX, 77341 or via telephone (936/294-4875). When filing a grievance, include the following information:

- a. A person(s) name and a method of contact (they will be informed of the outcome of the investigation).
- b. Time, date, and location of the alleged incidence you are reporting.
- c. If known, the name(s) of people involved with the alleged incident.
- d. A brief description of the alleged incident.

Note: Any alleged incident must be referred to this Committee within three (3) working days of the incident.

The identity of a person or persons making a grievance is kept strictly confidential within the IACUC.

12. SUSPENSION OF ANIMAL ACTIVITIES

SHSU’s IACUC is empowered to suspend a project if it finds noncompliance with the PHS Policy, [*Guide for the Care and Use of Laboratory Animals*](#) (aka *The Guide*), or violations of the Animal Welfare Act Regulations. Suspension may occur only after review of the matter at a convened meeting of a quorum of the IACUC and with the suspension vote of a majority of the quorum present. Further, the Committee must consult with SHSU’s AVP of Research regarding the reasons for the suspension. The AVP is required to take appropriate corrective action and report the action and the circumstances surrounding the suspension to the investigator’s faculty sponsor (if a student), the Department Chair, and the College Dean. If the suspended research is funded by the PHS, the AVP must promptly report the suspension to the Office of Laboratory Animal Welfare (OLAW).

APPROVED: _____ <signed>
Dana L. Gibson, 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	Review Cycle:	February 1, ENY*
Reviewer(s):	Council of Academic Deans Academic Affairs Council	Review Date:	February 1, 2016

Approved:	_____ <signed> Jaimie L. Hebert Provost and Vice President for Academic Affairs	Date:	_____ 7/17/14
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*ENY = Even Numbered Year