SAU IACUC HANDBOOK

FALL 2023

Version 1.0

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Abbreviations and Acronyms

Abbreviations

Assurance	Animal Welfare Assurance letter with OLAW
Guide	Guide for the Care and Use of Laboratory Animals, 8th Edition (2011)
PHS Policy (2015)	Public Health Service Policy on Humane Care and Use of Laboratory Animals

Acronyms

APHIS	Animal and Plant Health Inspection Service (USDA)
AO	Authorizing Official
AWA	Animal Welfare Act
AWRs	Animal Welfare Regulations (USDA)
BOT	Board of Trustees
CEO	Chief Executive Officer
CFR	Code of Federal Regulations
DMR	Designated Member Review
FCR	Full Committee Review
SAU	Southern Arkansas University
IACUC	Institutional Animal Care and Use Committee
IO	Institutional Official
NIH	National Institutes of Health
OLAW	Office of Laboratory Animal Welfare (NIH)
PHS	Public Health Services
PI	Principal Investigator
USDA	United States Department of Agriculture

Section 1: IACUC Authority and Responsibilities

Policy 1.10: Ethical Standards and Practices for SAU Activities Involving the Care and Use of Animals

Policy

SAU recognizes the importance of animals in research and educational activities and the scientific and ethical responsibility for their humane care and use. All individuals involved with the care and use of animals in research and educational activities at SAU are responsible for ensuring the health and well-being of the animals.

The IACUC is responsible for overseeing the provisions for the care and well-being of vertebrate animals used for research and educational purposes at the University. The IACUC serves the public by ensuring compliance with all legal and ethical standards regarding the use of vertebrate animals in research and educational activities at SAU.

Certain categories of animals are exempt from IACUC oversight:

- invertebrate animals (i.e. eggs, insects, crustaceans, etc.) used in research
- service animals
- animals under the control of a law enforcement officer acting in the course of his or her duties
- animals used in agricultural research, where the goal of that research is solely for animal production and does not have biomedical applications
- animals kept in residence halls as approved by the SAU Department of Housing
- animals maintained on the SAU Farm or used in SAU Rodeo activities

The primary ethical principles applied to research and educational activities involving animals that are covered by the IACUC are those set forth in the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training (*Federal Register*, May 20, 1985, Vol. 50, No. 97 [FR Doc. 85-12059]).

Any researcher working with animals at SAU that are exempt from IACUC oversight may voluntarily work with IACUC and participate in oversight. IACUC approval and oversight may be required by some external granting agencies before funding is dispersed, even if the grant proposal uses animals that the SAU IACUC deems exempt. PI's are encouraged to check with both SAU IACUC and the granting agency prior to submitting any proposal that includes live animal research.

Additionally, all individuals involved in the care and use of animals for SAU research and/or educational activities, including those exempted from IACUC oversight are expected to adhere to the principles of *expertise* (competent to do the work) and *integrity* (uphold professional principles and standards). Additional ethical principles may be applied when appropriate. Training on the ethical principles and personnel responsibilities of individuals involved with the care and use of animals is provided by SAU through voluntary training programs found on the CITI Program website. This training is free of charge using the SAU portal.

Policy 1.20: Compliance with Applicable Laws and Regulations

Policy

The IACUC and all associated entities will comply with Federal and State law and regulations, and University policy. In the case of variances between federal, state, local, laws and University policy, the more protective standard typically takes precedent.

Procedures and Regulatory Guidance

1. Office of Laboratory Animal Welfare (OLAW)
    a. The OLAW implements Public Health Services (PHS) Policy. While OLAW (https://olaw.nih.gov/home.htm) is located organizationally at the National Institutes of Health (NIH) in Bethesda, Maryland, OLAW's responsibility for laboratory animal welfare extends beyond NIH to all PHS-supported activities involving animals. Periodically, OLAW issues policy guidance, interpretation, or general notices regarding PHS Policy, and co-sponsors animal welfare workshops that are held in different locations across the country.
    b. Specific OLAW responsibilities include:
        i. Implementation of the PHS Policy
        ii. Interpretation of the PHS Policy
        iii. Negotiation of Animal Welfare Assurances
        iv. Evaluation of compliance with the PHS Policy; and Education of institutions and investigators receiving PHS support

2. Animal Welfare Assurance
    a. Before the PHS may award a grant or contract that involves the use of animals, the recipient institution and all performance sites involving or using animals must have on file with OLAW an approved Animal Welfare Assurance (Assurance). The Assurance is the cornerstone of a trust relationship between the institution and the PHS. Included in the Assurance are:
        i. The designation of the Institutional Official (IO) responsible for compliance
        ii. A commitment that the institution will comply with the PHS Policy, with the *Guide*, and with the Animal Welfare Act and the Animal Welfare Regulations (AWRs)
        iii. A description of the institution's program for animal care and use
    b. The PHS Policy applies to the use of live, vertebrate animals in any activity supported or conducted by the PHS. PHS agencies include:
        i. Agency for Healthcare Research and Quality
        ii. Agency for Toxic Substances and Disease Registry
        iii. Centers for Disease Control and Prevention
        iv. Food and Drug Administration
        v. Health Resources and Services Administration
        vi. Indian Health Service
        vii. National Institutes of Health
        viii. Office of Public Health and Safety
        ix. Office of the Secretary

x. Program Support Center
xi. Substance Abuse and Mental Health Services Administration
xii. Office of the Assistant Secretary for Preparedness and Response

c. SAU has an Assurance on file with OLAW (**ASSURANCE APPLICATION PENDING**). The Assurance may be active or inactive depending on whether the University has any on-going PHS-funded animal research.

3. United States Department of Agriculture (USDA)

In 1966, Congress passed the Laboratory Animal Welfare Act (PL 89-544) and the USDA was named the responsible agency for the enforcement of the Animal Welfare Act (AWA) to protect certain animals from inhumane treatment and neglect. The USDA's Animal and Plant Health Inspection Service (APHIS) administers the AWA, its standards, and its regulations. SAU is a registered Class **(???????)** Research Facility with the USDA **NUMBER AND ACCOUNT PENDING**).

4. Animal Welfare Act

The AWA requires that minimum standards of care and treatment be provided for certain animals bred for commercial sale, used in research, transported commercially, or exhibited to the public. Individuals who operate facilities in these categories must provide their animals with adequate care and treatment in the areas of housing, handling, sanitation, nutrition, water, veterinary care, and protection from extreme weather and temperatures.

a. Inclusions:

The AWA (Title 7, Chapter 54, Section 2132(g)) defines the term "animal" to mean any living or dead dog, cat, monkey (nonhuman primate mammal), guinea pig, hamster, rabbit, or such other warm-blooded animal that is being used, or is intended for use, for research, testing, experimentation, or exhibition purposes, or as a pet. With respect to a dog, the term means all dogs including those used for hunting, security, or breeding purposes.

b. Exemptions:

The AWA (Title 7, Chapter 54, Section 2132(g)) excludes birds, rats of the genus *Rattus*, and mice of the genus *Mus*, bred for use in research, and horses not used for research purposes, While these animals are excluded from the AWA, they still fall under the purview of the IACUC if they will be used for research or educational activities at SAU.

c. Research Facilities

i. In addition to providing the required standards of veterinary care and animal husbandry, regulated research facilities must provide dogs with the opportunity for exercise and promote the psychological wellbeing of primates used in laboratories. Researchers must also give regulated animals anesthesia or pain-relieving medication to minimize the pain or distress caused by research if the experiment allows. The AWA also forbids the unnecessary duplication of a specific experiment using regulated animals.

ii. Research facilities must establish an IACUC to oversee the use of animals in experiments. The IACUC is responsible for ensuring that the facility remains in compliance with the AWA and for providing documentation of all areas of

compliance to the USDA/APHIS. The AWA also does not permit APHIS to interfere with research procedures or experimentation. To ensure that all licensed and registered facilities continue to comply with the AWA, APHIS inspectors make unannounced inspections at least once annually.

iii. If an inspection reveals deficiencies in meeting the AWA standards and regulations, the inspector instructs the facility to correct the problems within a given timeframe. If deficiencies remain uncorrected at the unannounced follow-up inspection, APHIS documents the facility's deficiencies and considers possible legal action.

iv. APHIS also conducts reviews and investigates alleged violations. Some cases are resolved with Official Notices of Warning or agency stipulation letters, which set civil penalties for the infractions. Civil penalties include cease-and-desist orders, fines, and license suspensions or revocations. If APHIS officials determine that an alleged AWA violation warrants additional action, APHIS submits all evidence to the USDA for further legal review.

v. In addition to conducting regular inspections, APHIS will perform inspections in response to public input about the conditions of regulated facilities. Concerned individuals also are encouraged to inform APHIS about facilities that should be licensed or registered.

Policy 1.30: Authority of the IACUC

Policy

1. The IACUC derives its authority and requirements from federal law.

2. The IACUC reports to the IO. The IO is given the administrative and operational authority to commit institutional resources to ensure compliance with the PHS Policy and other requirements.

3. The IACUC's authority to review, approve, withhold approval, or suspend protocols is independent of the IO, who may not overrule an IACUC decision to withhold approval of a protocol.

4. If the IACUC approves a protocol, SAU is not required or obligated to conduct the research activity. SAU may also subject protocols to additional institutional review (e.g., unit head, Lab Safety committee, etc.).

5. The IACUC shall maintain appropriate confidentiality of IACUC submission materials (including, but not limited to, protocols, annual reviews, amendments, etc.), decisions, and discussions both inside and outside of IACUC meetings.

Procedures and Regulatory Guidance

1. IACUCs derive their authority from the law. The Health Research Extension Act of 1985 and the AWA mandate the existence of IACUC's. The laws require the Chief Executive Officer (CEO) of an organization to appoint the IACUC, whose responsibilities are delineated in the law and federal policy and regulations. The OLAW considers the CEO to be the highest operating official of the organization. The President of SAU delegates authority through the IO to appoint the membership of the IACUC.

2. Liability:
   Under PHS Policy, the primary responsibility for meeting applicable federal and state rules rests with the research facility or PHS awardee institution. The IO is the individual held responsible on behalf of the research facility for ensuring compliance. Failure to comply with PHS Policy could result in OLAW's withdrawal of approval of the SAU's Assurance, thereby making the institution ineligible to receive federal funds for activities involving animals. Failure to comply with the AWA could result in the USDA's assessment of monetary fines and withdrawal of SAU's Certificate of Registration.

3. Response to External Requests for Information:
   The IACUC will adhere to requirements for providing copies of documents to the public as specified in the Freedom of Information Act. Redaction of proprietary and private information is allowed but must be done so judiciously and consistently for all requested documents.

Policy 1.40: Responsibilities of the IACUC

Policy
The IACUC is responsible for performing the following functions:

1. Review the University's program for humane care and use of animals at least once every six months, using the *Guide* as a basis for evaluation.

2. Inspect all of SAU's facilities, including satellite facilities, used to house animals covered under IACUC protocols at least once every six months, using the *Guide* as a basis for evaluation.

3. Prepare reports of the IACUC evaluations as set forth in the PHS Policy IV.B.3 and submit reports to the IO.

4. Review concerns involving the care and use of animals at SAU.

5. Make written recommendations to the IO regarding any aspect of SAU's animal program, facilities, or personnel training.

6. In accord with PHS Policy IV.C.1-3, the IACUC shall review and approve, require modifications in (to secure approval), or withhold approval of activities related to the care and use of animals.

7. Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the use of animals in ongoing activities as set forth in PHS Policy IV.C.

8. Notify investigators and the University in writing of its decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications required to secure IACUC approval as set forth in the PHS Policy IV.C.4.

9. Conduct continuing review of each previously approved, ongoing activity covered by PHS Policy at appropriate intervals as determined by the IACUC, including a complete review in accordance with the PHS Policy IV.C.1-4 at least once every three years.

10. Be authorized to suspend an activity involving animals as set forth in the PHS Policy IV.C.6.

Policy 1.50: IACUC Document Retention and Recordkeeping Requirements

Policy

The IACUC will maintain all necessary documents for a minimum of three years with the exception of records related directly to protocols, which must be kept for the duration of the activity and for an additional three years after completion of the activity. These documents will be securely maintained on the University shared, with access being granted only to the IACUC committee and SAU administration. Reasonable requests for access to the shared drive or files contained within should be directed to the IACUC Chairperson. Their contact information is available on the SAU IACUC webpage. Documents shared among IACUC committee members (hard copy or digital) are to remain confidential and any identifying information and not to be shared with anyone outside the committee without written permission from researcher and IACUC

Procedures and Regulatory Guidance

1. IACUC-related documents may include, but are not limited to, the following:
    a. Animal Welfare Assurance on file with OLAW
    b. Minutes of IACUC meetings
    c. Records of IACUC activities and deliberations
    d. Minority IACUC views
    e. Documentation of protocols reviewed by the IACUC and proposed changes to protocols
    f. IACUC semiannual program evaluations and facility inspections, including deficiencies identified and plans for correction
    g. OLAW annual reports
    h. USDA-related documents (i.e., registration, Annual Report of Research Facility, Program of Veterinary Care, etc.)
    i. Accrediting body determinations
    j. Animal adoption forms

2. Records documenting such activities as the provision of adequate veterinary care, training, and occupational safety, are expected to conform with the recommendations of the *Guide* and with commonly accepted professional standards.

3. Meeting Minutes
    a. Review of proposals by the IACUC invokes a deliberative process, and the PHS Policy and AWRs require that GVSU maintain "minutes of IACUC meetings, including records of attendance, activities of the Committee, and Committee deliberations" (PHS Policy IV. E; 9 Code of Federal Regulations (CFR) Part 2 Subpart C 2.35 (a)(1)). The IACUC has some latitude in the degree of detail in these minutes.
    b. Recorded minutes from IACUC full committee reviews are intended to reflect the substantive discussion of protocols. Minutes are intended to contain sufficient information that a reasonable person could understand the nature of the discussion. Meeting minutes are not intended to provide a verbatim transcript of discussion nor to reiterate shared knowledge of the IACUC such as recent discussions about a protocol in previous minutes. Historical evidence of compliance or noncompliance would be

recorded in the minutes if it were germane to the discussion. Minutes may include reference to historical discussion by the IACUC from members who have served on the IACUC and observed the procedures being proposed, served as reviewers for protocols involving similar procedures (where their questions were answered), or participated in past IACUC discussions about the procedures.

c. Minutes of each full committee review are recorded in writing and include records of attendance, activities of the IACUC, and a summary of the issues discussed and the resolution of issues:

i. Records of Attendance:

Although members may arrive late or leave during a meeting, generally a member is marked as either present or absent. An exception would be when the IACUC member leaves the meeting room during discussion of a protocol on which that member is a participant. If the temporary absence of a member drops the number of members present below the quorum no official actions may take place and this will be noted in the minutes.

ii. Activities of the IACUC

Activities of the IACUC include, but are not limited to, corrections or approval of previous minutes; presentation of program, policy, facility and compliance reports; and decisions on policies, protocols, and amendments. The minutes must reflect the IACUC votes on protocols.

iii. Deliberations of the IACUC

A deliberation of the IACUC refers to the discussion and reasons leading to particular IACUC decisions. Minutes should include as a minimum a summary of the key points discussed prior to a committee decision. Completed minutes are distributed to all IACUC members. Minutes are discussed at a subsequent convened meeting of the IACUC and the IACUC votes on approval. A copy of the approved meeting minutes is then provided to the IO. This informs the IO of all actions taken by the IACUC.

4. Protocols

The PHS Policy and the AWRs require that animal applications and proposed significant changes be retained for the duration of the animal activity and for an additional three years after the end of the activity. Proposals submitted to the IACUC must be kept for three years even if approval was not granted or animals were not used. The records must show whether or not IACUC approval was given.

5. Other Records

a. Both the PHS Policy and the AWRs require that institutions retain the semiannual program review and facility inspections reports and any recommendations of the IACUC.

b. PHS Policy requires the OLAW Assurance and reports of accrediting agencies (e.g., Association for Assessment and Accreditation of Laboratory Animal Care) be kept on file.

c. Depending upon the species, USDA requires records documenting the number of animals acquired, transported, sold, or euthanized by the research facility.

d. Animal health records are not usually maintained by the IACUC but are kept in the animal facility or in research laboratories.
e. All of these records must be accessible to OLAW, USDA/APHIS, and funding agencies for inspection or copying.

Policy 1.60: Review and Approval of IACUC Policies

Policy

1. New policies and significant changes to existing policies must be reviewed and approved by the IACUC.

2. Existing policies must be reviewed not less than once every 3 years by the IACUC, but more frequent review may occur as necessary.

Procedures and Regulatory Guidance

1. Significant vs. Minor Policy Changes
    a. Significant policy changes are those considered by the IACUC or IO to fundamentally change the interpretation of the policy and/or that add additional conditions to the policy. Significant policy changes recommended by the IO and/or the IACUC must be re-reviewed by the IACUC
    b. Minor policy changes are those considered by the IACUC or IO to not change the fundamental interpretation of the policy. Such changes include, but are not limited to:
        i. Grammatical/typographical edits
        ii. Addition of clarifying statements to the policy that do not change the fundamental interpretation of the policy
        iii. Changes in the administrative procedures and/or regulatory references supporting the policy

2. New Policies or Significant Changes to Existing Policies
    a. IACUC Review and Approval
    Any new policies or significant changes to existing policies must be reviewed and approved by a majority vote of the IACUC.
    b. IO Review and Approval
    Following IACUC approval the IO may, at their discretion, review and approve the policy. The IO may approve as written or recommend changes to the policy.
        i. If the IO recommends major changes, the policy will be returned to the IACUC for further review and discussion, and the policy will require reapproval by the IACUC
        ii. If the IO approves the protocol with minor changes recommended, the policy will be updated to reflect the minor changes and forwarded to the IACUC for final review and approval.
        iii. If the IO approves the protocol as written without further recommendations, or chooses not to review it, the policy will be forwarded to the IACUC for final review and approval.

Section 2: IACUC Operations

Policy 2.10: IACUC Board Composition

Policy

1. The IACUC will meet the minimum compositional requirements set forth in PHS regulations and policy.
2. The IACUC is composed of regular voting members and may include, as conditions warrant, alternate voting members.
3. The IACUC may use consultants during review discussions as necessary. There is a specific one-to-one designation of IACUC members and alternates. An IACUC member and their alternate may not count toward a quorum at the same time or act in an official member capacity at the same time.
4. Some IACUC members fulfill specific regulatory requirements (e.g., veterinarian with program responsibility, an individual nonaffiliated with the University); others have unique roles by virtue of their position (e.g., Chairperson, Veterinarian, etc.)
5. All IACUC members will be classified as either affiliated or non-affiliated and as either scientist, nonscientist, or veterinarian.

Procedures and Regulatory Guidance

1. IACUC Minimal Composition Requirements

PHS Policy Policy IV.A.3.a., Policy IV.A.3.b

• A voting member is an individual appointed by the IO
• Minimum of five members:
  o One Doctor of Veterinary Medicine with training or expertise in laboratory animal science and medicine who has direct or delegated program authority and responsibility for activities involving animals at the institution.
  o One practicing scientist experience in research involving animals.
  o One member whose primary concerns are in a nonscientific area (e.g., ethicist, lawyer, clergy, etc.).
  o One member not affiliated in any way with the institution and not a member of immediate family of a person who is affiliated with the institution.
• The PHS Policy requires institutions to follow the Guide, which states that committee membership should include at least one public member to represent general community interests in proper care and use of animals, and that public members should note be laboratory animal users

2. Specific IACUC Roles

a. Veterinarian

PHS Policy and the AWRs mandate the appointment of a veterinarian with direct or delegated program responsibility to the IACUC. The IO may appoint more than one veterinarian to the IACUC, but the veterinarian with direct or delegated program responsibility must be designated as such. The veterinarian with program responsibility, e.g., Attending Veterinarian, must have training or experience in laboratory animal science and medicine or in the care of the species being used.

b. Chairperson

The Chairperson is appointed by the IO and is a faculty member of GVSU with research experience. In addition to serving as a member of the GVSU IACUC, the IACUC Chairperson shall:

i. Direct the proceedings of convened meetings of the IACUC.
ii. Hold regular meetings with the IACUC administrative support staff.
iii. Write letters from the IACUC regarding IACUC decisions and actions.
iv. Sign IACUC letters, as needed.
v. When directed by the IACUC, make decisions about researcher/instructor responses to IACUC conditions for protocol approval.
vi. Represents SAU in interactions with personnel of federal and state agencies regarding the humane care and use of laboratory animals at SAU.
vii. Represent the IACUC in discussions with researchers, instructors, and other SAU and community stakeholders.

3. Determination of Affiliated vs. Unaffiliated

a. Nonaffiliated Members

i. The nonaffiliated member(s) represent general community interests. Neither they, nor their immediate family, have a current affiliation with SAU.
ii. These members have equal status (e.g., voting) to every other committee member and are provided the opportunity to participate in all aspects of IACUC functions.
iii. An individual who has no affiliation with the organization, other than as a member of the IACUC, is considered to be unaffiliated. An individual whose only association with SAU is that of health care patient, research participant, or former student may be considered unaffiliated.
iv. Paying an unaffiliated member reasonable market value for the costs associated with participation as a member of the IACUC (e.g., transportation and parking costs) does not cause a member to become “otherwise affiliated” or cause a member to have a conflicting interest.
v. An individual must be able to answer “No” to all of the following questions to be considered unaffiliated with SAU:

1. Are you (or any dependent member of your immediate family) a full or part-time employee, paid entity, or agent of any SAU institution?
2. Are you (or any dependent member of your immediate family) a

healthcare provider holding credentials to practice at a SAU institution?

3. Are you a former employee of a GVSU institution who worked for the SAU institution within the past 5 years?
4. Do you receive any funding or perquisites under the control of SAU, except as compensation for IACUC?
5. Are you (or any dependent member of your immediate family) a current student at SAU?
6. Do you serve SAU in any other capacity (e.g. serving on other committees)?

b. Affiliated Member

A member is considered an affiliated member when they do not meet the conditions of a nonaffiliated member.

4. Determination of Scientist vs. Nonscientist

a. Scientist

For the purposes of determining IACUC member status, a scientist is a person who routinely utilizes the scientific method in the conduct of their discipline-related scholarship. Scientists may or may not have previous animal research experience; however, PHS Policy requires that the IACUC include at least one practicing scientist experienced in research involving animals.

b. Nonscientist

For the purposes of determining IACUC member status, a nonscientist is a person who does not routinely utilize the scientific method in the conduct of their discipline-related scholarship. Examples include, but are not limited to, ethicist, lawyer, member of the clergy, librarian, etc. PHS Policy requires that the IACUC include a member whose primary concerns are in a nonscientific area.

5. There are no specific prohibitions regarding individuals filling more than one role on the IACUC but OLAW strongly recommends against the same person serving multiple roles, because the responsibilities and authorities vested in each of the positions are distinct and often require different skills. Appointing one individual to more than one of these roles may circumvent intended checks and balances. The perception of conflict of interest is also of importance, as such perceptions can lead to allegations of improprieties from various sources.

6. SAU considers persons with expertise in the disciplines involved in institutional research and teaching programs for service on the IACUC. In addition to the required categories of membership, it is suggested that individuals with expertise in specific areas pertinent to protocol review and program oversight be considered (e.g. statisticians, occupational health experts, information resource specialists, animal health technicians, and scientific research staff).

Policy 2.20: IACUC Member Training and Continuing Education

Policy:

1. New IACUC members must participate in a new member CITI training prior to voting at an IACUC meeting.

2. IACUC Chairperson will provide IACUC members with continuing education opportunities related to their responsibilities as a committee member.

Procedures

1. New Member Training
    a. The objectives of New Member Training include the following:
        i. Introduce members of the role of the IACUC and its evolution
        ii. Provide the basic information necessary for IACUC members to perform their responsibilities.
        iii. Provide a forum for response to, and discussion of, members' concerns and questions.
    b. New IACUC member training consists of the following:
        i. Description of the IACUC and its responsibilities and authority
        ii. Overview of U.S. government principles and federal regulations
        iii. Criteria for membership
        iv. Individual roles and responsibilities
        v. Overview of the protocol review process, including monitoring of approved protocols, periodic review, protocol modifications
        vi. Overview of semi-annual program reviews and lab inspections

2. Training on the ethical principles and personnel responsibilities of individuals involved with the IACUC is provided by SAU through training programs found on the CITI Program website. This training is free of charge using the SAU portal.

3. It is the responsibility of the IO notifies the chair of the new member. It will then be the responsibility of the chair to make sure that the new member completes all CITI training that pertains to that persons affiliation.

4. Essential documents are made available to each IACUC member. These include, but are not limited to, the following:
    a. SAU Assurance Letter with OLAW
    b. SAU IACUC Handbook of Policies and Procedures
    c. Animal Welfare Act Regulations
    d. Public Health Service Policy on Humane Care and Use of Laboratory Animals
    e. Guide to the Care and Use of Laboratory Animals
    f. Euthanasia of Research Animals: American Veterinary Medicine Association Guidelines
    g. OLAW/Applied Research Ethics National Association IACUC Guidebook

5. Continuing Education

a. The objective of providing ongoing training for IACUC members is to increase their knowledge, understanding, and awareness of current laws and regulations, new directives, best practice guidelines and institutional policies. It also provides a regular forum for the IACUC to discuss concerns or questions brought forth by the faculty, staff, or members of the community.

b. Continuing education for IACUC members may occur at IACUC meetings. Information provided for these sessions will include questions and concerns brought to the attention of the IACUC official directives, relevant publications, conference announcements, seminar proceedings, animal facility staff and/or veterinarian's observations/recommendations, issues involving facility inspections and program evaluations, and compliance issues. Additional refresher training courses are also available through the CITI Program website free of charge using the SAU Portal

6. The IACUC will maintain documentation of training, in the form of completed certificate from the CITI Program website. These documents will be securely maintained on the University shared drive.

Policy 2.30: IACUC Member Conflict of Interest

Policy

1. IACUC member(s) may participate in the IACUC review, but will not have any action when it comes to the approval of an activity in which that member(s) has a conflicting interest, except to provide information requested by the IACUC.

2. IACUC members and consultant are required to disclose any conflicts of interest according to the applicable SAU Policies.

3. Any IACUC member is said to have a conflict of interest whenever that person, their spouse, domestic partner, or depend child falls under any of the following conditions:
    a. Is an investigator or sub-investigator on the protocol.
    b. Has entered into a financial arrangement with the sponsor or agent of the sponsor, hereby the outcome of the study could influence the value of the economic interest.
    c. Acts as an officer or a director of the sponsor or an agent of the sponsor.
    d. Has an equity interest in the sponsor.
    e. Has received payments of other incentives from the sponsor that when aggregated for the member and spouse/domestic partner/dependent children exceeds $5000.
    f. Is involved in a potentially competing research program.
    g. Has a philosophical or moral-objection to the study itself.
    h. Has identified themselves for any other reason as having a conflict of interest.

Procedures

1. University policies governing conflict of interest include:……..

2. Members holding a financial or non-financial conflict of interest(s) with the study or investigators shall:
    a. Announce the presence of a conflict and disqualify themselves from accepting a protocol review or participating in a convened committee review, except to provide information on request.
    b. Leave the meeting during the discussion and the vote on any motion to approve, require changes, or disapprove the research in questions. (Note: When a person with a conflict of interest leaves the room, they cannot be counted towards a quorum. If quorum is lost, the protocol will be tabled. Those dismiss or absent themselves during a meeting will be identified as doing so in the minutes.)

3. If an IACUC member is unsure if they have an actual or perceived conflict of interest with the research under review, the member shall inform the IACUC Chairperson of the potential conflict prior to engaging in the review of the research. The Chairperson will review the potential conflict, consulting with ORCI as needed, and determine if the member should recuse themselves from protocol review. In cases where the presence or appearance of conflict remains unclear following Chairperson/ORCI review, the member with the perceived or actual conflict of interest shall recuse themselves from protocol review.

Policy 2.40: IACUC Recommendations to the Institutional Official

Policy

The IACUC will make written recommendations to the IO regarding any aspect of the Institution's animal program, facilities, or personnel training, as needed.

Procedures

1. Recommendations regarding any aspect of SAU's animal program, facilities, or personnel training are formulated at convened meetings of the IACUC.

2. Recommendations are prepared in writing by the Attending Veterinarian, the IACUC Chairperson, and/or any IACUC member. A copy of these recommendations is reviewed approved at a convened meeting of the IACUC. Any minority views are noted and included in the final report.

3. The IACUC Chairperson or their designee submits recommendations, including minority views that are approved by IACUC to the IO.

Policy 2.50: Conducting IACUC Meetings

Policy

1. There is no requirement that any particular member or category of members be present at all IACUC meetings. SAU, however, must have a properly constituted IACUC in order for the IACUC to conduct valid official business and vote.

2. Quorum
    a. The following IACUC actions require a quorum: full committee review of a research or animal use project, disapproval of an IACUC application, and suspension of an activity.
    b. A "quorum" is defined as a majority of the regular IACUC voting members.
    c. A protocol is approved only if a quorum is present, and if more than 50% of the quorum votes in favor of protocol approval. For reasons other than conflict of interest, abstentions from voting do not alter the quorum or change the number of votes required.
        i. Example: If the IACUC has 7 voting members, at least 4 members must be present at a convened meeting to constitute a quorum.
        ii. Example: An IACUC has 9 voting members and 6 are present at a convened meeting, thus constituting a quorum. Approval of a protocol at the meeting would require a minimum of 4 votes whether or not there were abstentions.

    d. If "quorum" is officially met, then as a committee we can officially make decisions and vote.

3. Conflict of Interest
    If the investigator submitting a protocol believes that an IACUC member has a potential conflict, the investigator may request that the member be excluded from reviewing and voting on a protocol. The Chairperson will present the declared conflict and the IACUC will determine whether a conflict exists. Should an IACUC member declare involvement in any way in a research protocol under review by the IACUC, or state a conflict of interest with the research protocol, then the member:
    a. May remain in the meeting room to provide information requested by the IACUC and during discussions.
    b. Must leave the meeting room during the voting process and will not be counted into the means of "quorum".

Procedures and Regulatory Guidance

1. University policies governing conflict of interest include:……..

2. Both the PHS Policy (IV.B.6; IV.B.7; IV.C.2; IV.C.6) and the AWRs (§2.31(c)(8); §2.31(d)(2)); §2.31(d)(4); §2.31(d)(6)) allow the IACUC to conduct a full committee review of protocols, withhold approval of IACUC applications, and suspend a previously approved IACUC protocol.

3. In addition to the IACUC having the authority to suspend an active IACUC protocol, the IACUC Chairperson, the IACUC veterinarian, and the IO, may suspend an animal activity when animal welfare concerns are identified, until such time that the IACUC can convene and consider the matter formally. See IACUC Policy 5.10: Animal Welfare Concerns and Noncompliance.

Policy 2.60: Ethical Cost-Benefit Analysis

Policy

The IACUC will critically evaluate protocols to ensure that the objectives and potential benefits of the proposed activity are acceptable when compared to the potential animal welfare concerns of the animals to be involved in the activity (i.e, a cost-benefit analysis).

Procedures and Regulatory Guidance

1. Animal activities are most frequently justified from an ethical cost-benefit perspective. This means that any animal pain, morbidity, and mortality must be outweighed or at least balanced, by the potential benefits of the project in terms of its relevance to human or animal health, advancement of knowledge or the good of society. Ethical cost-benefit assessment should be a major focus during initial and continuing review by the IACUC. This assessment should not, however, be misconstrued as the equivalent of an NIH study section review of scientific merit. Instead, it represents a threshold level of review that documents that the use of animals continues to be justified. Without such assessment, there is lack of accountability, which negates the purpose of review, particularly for projects not funded by the PHS or other funding agencies with rigorous peer review.

2. The obvious question that arises is why an ethical cost-benefit relationship would change over time. After a protocol is initially approved by the IACUC it is possible that new information may have become available, which allows application of one of the "three R's" (reduction, refinement, replacement). For example, new in vitro techniques or statistical methods may be discovered that could reduce the number of animals required. Also, an investigator may find that a lesser degree of morbidity can be used as an experimental end point. Conversely, in some situations, it may be necessary for scientific reasons to increase the number of animals or to allow animals to reach a more advanced stage of morbidity than originally specified in the protocol. In either case, the ethical cost-benefit ratio will be altered and the IACUC should, therefore, re-evaluate this new relationship. Proposed changes in the protocol can be considered during continuing review and approved as warranted. Admittedly, there are considerations related to scientific continuity and grant requirements that may dictate whether changes in a protocol are possible. Nonetheless, it is incumbent on investigators and the IACUC alike to determine during continuing review whether the 3Rs can be applied further to the protocol.

3. Investigators may seek training in research and testing methods that minimize the number of animals required to obtain valid results and minimize animal distress. Topics must be covered as a means to how many subjects will be utilized in the protocol, but the P.I. does not need a direct p-value or power analysis in the protocol.

2.70: Comparison of IACUC Protocols to Grants

Policy
The IACUC, in conjunction with the ORCI, will evaluate protocols to ensure consistency with grant submissions, if applicable.

Procedures and Regulatory Guidance
1. PHS agencies will not make an award for research involving live vertebrate animals unless the applicant organization and all performance sites are operating in accordance with an approved Assurance and have provided verification that the IACUC has reviewed and approved those sections of the application that involve use of vertebrate animals, in accordance with the requirements of the PHS Policy. Additionally, PHS agencies will not make an award for research involving live vertebrate animals to an individual unless that individual is affiliated with an organization that accepts responsibility for compliance with PHS Policy and has filed the necessary Assurance with OLAW. Regardless of when the review occurs, the PI should ensure that the research described in the grant proposal application is consistent with any corresponding protocol(s) reviewed and approved by the IACUC. Therefore, a copy of the funded or unfunded grant proposal application may be requested by the IACUC and reviewed by a designated member(s) to confirm that all research outlined in the grant is included in the approved IACUC protocol.

2. Verification of Protocol and Proposal Consistency
    a. The extents of the verification of consistency between grant proposals and IACUC protocols will be a confirmation that the species and procedures relating to use of animals described in the proposal are included in the protocol. This will be a unidirectional comparison of the procedures described in the grants. In conducting the verification, the IACUC focuses on the following two (2) questions:
        i. Are the species used in the grant proposal included in the IACUC protocol?
        ii. Are animal care and use procedures described in the grant proposal included in the IACUC protocol?
    b. Verification of grant and protocol consistency concentrates on animal care and use and **will not** include a judgement of scientific merit.

3.Timing of Verification
The IACUC will compare the grant to the protocol during the review of the protocol. In addition, the IACUC will compare the grant to the protocol when a new funding source for a protocol is proposed.

4. Protocol Amendments
    a. There are two types of amendments to animal research protocols that have specific relevance to this policy: 1) a change in funding source and 2) a change in animal use procedures. Submission of an administrative amendment requesting a change in funding source will include a verification of consistency between the new grant and the current protocol to which it is being linked. The verification will include a confirmation that the species and procedures relating to use of animals described in the proposal are included in the protocol.

b. The IACUC understands that research projects evolve over time and therefore the specific direction of a protocol may change from the original description of animal use procedures. These changes should be submitted as a significant amendment to the protocol and should be consistent with the objectives, purpose, or aims stated in the original protocol. It is the PI's responsibility to explain how the changes relate to the original protocol. Because the determination of consistency between the grant and original protocol has already been established, there will generally be no need to "re-verify" grant-to-protocol consistency for amendments.

c. For PHS-supported grants (e.g., NIH, Centers for Disease Control, etc.) it is the responsibility of the PI to indicate any significant changes in the use of vertebrate animals in the Progress Report Summary section of their Non-Competing Continuation Progress Report (PHS 2590).

5. Managing Grant-Proposed Inconsistencies

The PI, through the IACUC, will be consulted regarding any apparent inconsistency. As noted above, significant changes require that the IO notify the extramural Program Official. Verification of this request and subsequent approval must be shared with the IACUC.

Policy 2.80: Occupational Health and Safety

Policy
The IACUC is responsible for ensuring a safe working environment for personnel involved in the animal care and use program.

Procedures and Regulatory Guidance
1. At SAU, the Laboratory Safety Program (INPUT WEBLINK) has been developed to protect the health and safety of faculty, students, and staff, including those who work with vertebrate animal species in the course of their research or educational activities. The program is designed to customize the participation requirements based on the type and degree of exposure to animals.

2. There are ethical and legal requirements to inform individuals of workplace health risks that could potentially affect them and appropriate precautions to mitigate those risks. The objectives of SAU's Occupational Health and Safety Program can be achieved only if employees are appropriately trained and understand the hazards associated with their work area and job duties, and how those risks are mitigated through institutional policies, engineering controls, work practices, and personal protective equipment.

3. The IACUC will consult with the SAU Laboratory Safety Officer when necessary and, when detected, report violations of SAU Occupational Health and Safety Program rules to the SAU Laboratory Safety Officer.

4. The IACUC and SAU Laboratory Safety Office will provide all IACUC protocol personnel and animal care staff with the following:
    a. Access to SAU occupational health and safety training programs
    b. Appropriate guidelines and training that outline general health and safety issues associated with working with animals, including the following as applicable:
        i. Zoonoses
        ii. Chemical safety
        iii. Microbiologic and physical hazards (e.g., allergens and radiation)
        iv. Hazards associated with experimental procedures
        v. Handling of waste materials
        vi. Personal hygiene
        vii. Precautions taken during pregnancy, illness, and immune suppression
    c. Risk Assessment

5. In general, the guidelines outlined by the Guide, and in the text, Occupational Health and Safety in the Care and Use of Research Animals (National Research Council, 1997) will be followed.

6. All animal caretakers, employees, and students working with animals are likely to be either SAU employees or students. Prior to commencing work with animals, a medical evaluation or health history will be taken from all those who will come into contact with animals. This information will be reviewed and approved by qualified medical personnel prior to their

commencing work with animals. Employees working with laboratory animals will be required to present evidence of having passed a medical evaluation and, when appropriate, evidence that they have been adequately immunized against diphtheria, Haemophilus influenzae type B, pertussis, polio, rabies, rubella, and tetanus.

7. Information on epizootic diseases and zoonoses frequently associated with species used in the facility will be kept on file, and the animal caretakers will be made familiar with these files. Animal caretakers will be made aware of the Animal Welfare Act and the PHS policies on the humane care and use of animals in research. This involves an appropriate understanding of federal regulations and university policies and procedures on animal care and use by faculty and staff.

8. In the event of an animal bite, scratch, or other injury that requires medical attention, the affected individual must complete the SAU Workers' Compensation Injury Report Form (INPUT WEBLINK). In addition, Injury Report forms are available in all laboratories.

9. Safety with regards to chemical and biological hazards will be governed by the SAU Lab Safety and Chemical Hygiene Plan. In addition, all investigators, employees, students, or animal caretakers who could come in contact with chemicals while at work, will be required to take a course in laboratory safety administered by the SAU Laboratory Safety Officer.

10. Protective clothing and gear will be made available to personnel working with animals and working in the animal facilities.

11. Nonhuman primates will not be housed at SAU animal facilities.

Policy 2.90: Semiannual Program Review and Facility Inspections

Policy

1. The IACUC will review SAU's program for human care and use of animals at least once every six months.

2. The IACUC will inspect animal facilities housing IACUC-approved animals at least once every six months.

Procedures and Regulatory Guidance

1. Semiannual Program Review
    a. Semiannual program reviews are conducted in accordance with the *Guide*. The animal care and use program review includes an evaluation of institutional policies and responsibilities (lines of authority and reporting channels), IACUC membership and functions, and IACUC recordkeeping and reporting procedures. It also includes a review of the adequacy and appropriateness of the veterinary medical care program, the training program for personnel, and the occupational health and safety program.
    b. The IACUC's mandate to perform semiannual program evaluations as a means of overseeing the animal care and use program puts the IACUC in an advisory role to the IO. In its semiannual reports, the IACUC advises the IO of the status of SAU's compliance, establishes plans and schedules for correcting deficiencies necessary to either maintain or achieve compliance, and makes recommendation to the IO regarding any aspect of the Institution's animal program, facilities, or personnel training.
    c. Performing Semiannual Review
        i. During the regular convened meetings of SAU's IACUC in January and July of each year, the IACUC reviews SAU's animal care and use program using a Semiannual Program Review Checklist provided by OLAW. The checklist is designed to evaluate:
            1. Occupational health and safety
            2. Training for IACUC members, research and instructional staff, and husbandry staff
            3. The institutional disaster plans
            4. Sanitation and cleaning practices
            5. Surgical support and post-operative analgesia
            6. Compliance with approved protocols
            7. Procedures for reporting allegations of inappropriate animal care or use
            8. Accessibility to veterinary care during and after typical working hours
        ii. Each area is evaluated and any deficiencies are categorized as minor or significant. No IACUC member is involuntarily excluded from participating in any portion of the program review.
        iii. A quorum of the IACUC members must be present during the semiannual program review. The IACUC Chairperson requests additional comments and minority views from all members present.
        iv. Semiannual Program Review Final Report

1. Findings from the semiannual program review, including a deficiency correction schedule if needed, are compiled into a final report that includes the following items:
    a. Description of the institution's adherence to the applicable regulations (AWRs, PHS Policy, the Guide) and identification of any deviations from these documents
    b. Review of IACUC actions
    c. Review of SAU's Program for Animal Care
    d. Recent animal facility inspection report(s)
    e. Veterinarian's report summarizing veterinary care provided during the reporting period
    f. Minority views, if any
2. The AWRs require the report to be signed by a majority of the IACUC members
3. The final report is distributed to the Vice Provost for Administration, the IO, and the President.

2. Facility Inspections
    a. Facility inspections are conducted in accordance with the Guide, AWRs, and PHS Policy. The AWRs do not include a clear definition of "animal facility;" however, housing is described in other terms throughout the AWRs. The Guide states than an animal facility consists of functional areas for animal housing, care, and sanitation; receipt, quarantine, and separation of animals, separation of species, or isolation of individual projects; and storage. The PHS Policy defines "animal facility" as "any and all buildings, rooms, areas, enclosures, or vehicles, including satellite facilities, used for animal confinement, transport, maintenance, breeding, or experiments inclusive of surgical manipulation."
    b. The *Guide* requires inspection of animal facilities in which animals are housed for at least 24 hours. The AWRs apply to animal study areas where animals are maintained for more than 12 hours (applicable only to USDA-covered species).
    c. Laboratories in which routine procedures, such as immunization, dosing, and weighing, are conducted may be evaluated by other means such as random inspections. The institution, however, through the IACUC, is responsible for all animal-related activities regardless of where animals are maintained or the duration of the housing. The IACUC must have reasonable access to these areas for the purpose of verifying that activities involving animals are being conducted in accordance with the proposal approved by the IACUC.
    d. All IACUC members are invited, and encouraged, to attend the facility inspections. This may be accomplished by assigning specific facilities to subcommittees, which must consist of at least two IACUC members. No member is involuntarily excluded from participating in any portion of the facility inspections.
    e. Ad hoc consultants may be used although the IACUC remains responsible for the evaluations and reports; ad hoc consultants must not be used as substitutes or replacements for IACUC members. The inspection team should have a working knowledge of the *Guide* and AWRs in order to fully evaluate the facilities that are being inspected.

f. The IACUC may determine whether the supervisory personnel of various facilities should be notified of the date and time of an inspection. Advance notification allows individuals to be available to answer questions; an unexpected visit may show the facility during usual operations but also may result in a visit having to be rescheduled if key individuals are not available. Although advance notification is not required, the IACUC may provide, as circumstances warrant, reasonable notice to investigators of the dates, times, and locations of inspections.

g. Performing Inspections

i. Every six (6) months, the IACUC Chairperson organizes the inspection schedule of the animal facilities located on campus and any satellite facilities. All facilities currently housing animals on SAU IACUC-approved protocols will be inspected. If no animals are currently housed in a given facility on the date of the inspection, the facility will still be inspected if it is anticipated that animals will be housed in the facility before the next facility inspection date. Inspections are conducted during April and October each year.

ii. Adherence to the following recommendations will assist the IACUC in performing inspections:

1. An updated list of all facilities to be inspected shall be maintained by the IACUC.
2. All proposals submitted to the IACUC should specify locations where animal procedures will be performed.
3. It is helpful to maintain a list of all facilities including room number, function of the room, species and deficiencies identified during the previous inspection.
4. For satellite areas, a contact person is useful.
5. For facilities with multiple rooms, a floor plan can assist the inspectors.
6. If a subcommittee is performing the inspection, a blend of IACUC members who last inspected the area with members who did not participate in the last review, can improve the process.
7. Apparent deficiencies should be discussed with the person in charge of the facility to ensure that the team's perception of the situation is accurate. In some cases an apparent deviation will be due to the experiment in progress, e.g., withholding of food prior to surgery.
8. The IACUC will use a Facilities Inspection checklist supplied by OLAW during inspections to provide consistency and help document that all categories were assessed.

iii. Categories of items to be inspected may include, but are not limited to, the following:

1. Sanitation
2. Food and water provisions
3. Animal identification
4. Waste disposal
5. Animal health records
6. Controlled and/or expired drugs
7. Environmental control

8. Occupational health and safety concerns
9. Staff training
10. Knowledge of animal care procedures
11. Knowledge of applicable rules and regulations, and security

iv. Deficiencies detected during facility inspections are categorized as minor or significant and discussed by the IACUC as necessary. If the IACUC recognizes the matter as one of concern, the PI is promptly notified of the deficiency in their animal facility and a plan to rectify the issue is developed and included in the report. The PI is required to promptly provide a response to the deficiency notification with a description of how the deficiency has been corrected or to submit a written plan with a timeline outlining how the deficiency will be corrected. Facility deficiencies raised by individuals who are not members of the IACUC will be brought to the attention of the IACUC Chairperson and addressed in this same manner.

v. Facility deficiencies may also be discussion at a regular, convened IACUC meeting following the inspections. The IACUC Chairperson requests additional comments and minority views from all members present.

vi. Facility Inspection Final Report

1. After the inspection, the IACUC Chairperson prepares a report that summarizes the inspection's findings, including a deficiency correction schedule if necessary.
2. The Chairperson's report is distributed to the Vice Provost for Administration, the IO, and the President.
3. The facility inspection report is also included in the next semiannual program review report prepared by the IACUC.

h. Deficiency Correction Schedule

i. All deficiencies identified during the facility inspections and/or semiannual program review are designated by the IACUC as minor or significant. A significant deficiency is defined as a situation that is or may be a threat to animal health or safety.

ii. For both categories of deficiencies, a reasonable and specific plan and schedule with dates for correction must be included in the final report. All individuals to be involved in the corrections should be consulted to ensure that the plan is realistic.

iii. If applicable, the IACUC, through the IO, must promptly report to OLAW and USDA any serious or continuing noncompliance with the PHS Policy or any serious deviation from the provisions of the Guide in accordance with SAU's Assurance, and federally funded projects will have their relevant funding agency informed. If major deficiencies are not corrected by the deadline set by the IACUC, then the project will be suspended.

Section 3: IACUC Protocol Personnel Responsibilities

Policy 3.10: IACUC Principal Investigator Responsibilities and Qualifications

Policy

1. All animals used for on campus research, field-research, teaching or testing purposes that is conducted by or under the direction of any employee, faculty, staff, student or agent of SAU in connection with his or her responsibilities must be under the direct supervision of a SAU faculty or staff member who shall serve as the Principal Investigator (PI) of the IACUC protocol. The PI shall ensure that the project meets/maintains IACUC approval and protocols. Only full-time faculty members qualify to serve as PI on a project. The faculty member's appointment must be as a Full Professor, Associate Professor, or Assistant Professor. Exceptions may be made for Full time (FT) Instructors or other FT faculty members. A student may submit a protocol for approval by the IACUC chair and IO only with a faculty member serving as the PI/advisor/sponsor.

2. Generally, faculty and staff are considered to be sufficiently knowledgeable to supervise and/or conduct research as determined by their appointment. The IACUC, however, may at its discretion, determine that a faculty member lacks sufficient expertise to carry out any particular research project based on their relevant training and experience. PI shall complete all CITI Program training required by IACUC prior to submission of a protocol. See Policy 1.10 and 2.20 for details on CITI Program training modules provided by SAU

3. The PI may delegate the performance of any or all components of the research to project personnel if they certify to the IACUC that the individuals are sufficiently trained to perform the functions assigned.

4. Individuals who do not meet any of the above criteria may, by demonstrating sufficient cause and necessary expertise, petition the IACUC Chairperson and IO for permission to submit an IACUC protocol. IACUC may require additional training or consultation for protocol approval.

Procedures

In order for work to begin on an approved animal use protocol the PI must certify that all of the following conditions are true, and that all personnel on the protocol will abide by the following conditions:

1. All students, staff, and faculty on this project are familiar with the AWA and the PHS Policy, the *Guide*, and recognize their responsibility in strictly adhering to approved protocols.

2. All individuals listed on this project are qualified or will be trained to conduct procedures involving animals under this proposal, and that they have completed approved SAU Animal Care and Use training, and received training in the biology, handling, and care of this species; aseptic surgical methods and techniques (if necessary); the concept availability and use of research or testing methods that limit the use of animals or minimize distress; the proper use of anesthetics, analgesics, and tranquilizers (if necessary), and procedures for reporting animal

welfare concerns. All individuals involved have completed any required CITI Program Training involved with the PI approved protocol.

3. All procedures will be conducted in accordance with SAU Occupational Health and Safety procedures, including those pertaining to personal protective equipment.

4. Any change in the care and use of animals involved in the protocol, including any change in the personnel listed on the protocol, that would affect animal welfare will be promptly forwarded to the IACUC for review. Such changes will not be implemented until approval is obtained from the IACUC. Animals will not be transferred between investigators without prior approval.

5. The PI has reviewed the pertinent scientific literature and the sources and/or databases and have found no valid alternative to any procedures described herein which may cause more than momentary or slight pain, distress, or generalized discomfort to animals, whether it is relieved or not.

6. The PI has made every reasonable effort to minimize the number of animals used and reduce the amount of pain, distress, and/or discomfort these animals must experience.

7. That the activities described within the protocol submitted for IACUC review are consistent with those described in any related grant, contract, or subcontract.

8. That, to the best knowledge of the PI, the information contained in the animal use protocol is accurate.

9. That animal use approval and/or any other animal use privileges may be revoked by the IACUC if any of the aforementioned assurance statements are violated.

10. It is implicit upon submission of a protocol that the PI has read and agrees to abide by the above obligations.

Policy 3.20: Required Training for IACUC Protocol Personnel and SAU Animal Users

Policy

1. All personnel on approved IACUC protocols and other personnel who work directly with animals on IACUC protocols must be appropriately qualified and trained to perform their specific assigned activities of the protocol. PI shall complete all CITI Program training required by IACUC prior to submission and/or approval of a protocol. Training on the ethical principles and personnel responsibilities of individuals involved with the care and use of animals is provided by SAU through voluntary training programs found on the CITI Program website. This training is free of charge using the SAU portal.

2. PIs are responsible for ensuring that appropriate training is accomplished and documented for all protocol personnel. IACUC may require additional specific training for protocol personnel.

Procedures and Regulatory Guidance

1. Although the PHS Policy and AWRs do not specify a particular training program or the frequency with which a training program should be offered, the requirement for competence is mandatory.
    a. The AWRs, in Sec. 2.32 (a) and (b), specify: It shall be the responsibility of the research facility to ensure that all scientists, research technicians, animal technicians, and other personnel involved in animal care, treatment, and use are qualified to perform their duties. This responsibility shall be fulfilled in part through the provision of training and instruction to those personnel. Training and instruction shall be made available, and the qualifications of personnel reviewed, with sufficient frequency to fulfill the research facility's responsibilities.
    b. The PHS Policy, Section IV.C.1.f. places responsibility specifically with the IACUC to ensure that personnel conducting procedures on research animals are appropriately qualified and trained in those procedures.

2. Training in the care and use of research animals is also an important aspect of the alternatives concept (replacement, reduction and refinement). Training in the recognition and alleviation of animal pain, distress, and abnormalities addresses refinement. Similarly, training in the conduct of animal procedures prepares staff to work without causing unnecessary harm to the animal. Technical proficiency also invokes reduction by avoiding wasted animal lives through failed procedures.

3. Training made available for each type of staff should be specific to the animal species involved and to the kind of procedures to be performed or animal-related interactions.
    a. For training purposes, staff can be grouped as:
        i. Researchers (including PIs and their research assistants)
        ii. Students
        iii. IACUC committee members
    b. Training should also be made available to temporary staff, such as students and temporary faculty

4. Training requirements for IACUC protocol personnel and SAU animal users
    a. All IACUC protocol personnel must complete the following requirements:
        i. CITI Animal Care and Use course
        ii. CITI Responsible Conduct of Research course
        iii. SAU Laboratory Safety Course
        iv. Medical evaluation form ?
    b. Expiration of Training Requirements
        i. Completion of the Animal Care and Use course and Responsible Conduct of Research course are valid for three years.
        ii. At this time, the Laboratory Safety course has no expiration date.
        iii. A new medical evaluation form must be completed every five years and at any time when the individual will be working with a new category of animals (e.g., rodents, amphibians, reptiles, etc.) that was not previously disclosed on a medical form submitted by the individual within the past five years.
        iv. A lapse occurring in any of the above training requirements during an active protocol will be treated as noncompliance according to Policy 5.10: Animal Welfare Concerns and Noncompliance.
    c. Courses Involving Students Who Will Be Handling Animals
        i. Some SAU courses (usually laboratory courses) involve activities in which students handle live vertebrate animals as part of the course instruction. Such activities require IACUC approval prior to performing the activity in the course. Course instructors must be included as protocol personnel on the IACUC protocol covering this activity.
        ii. Students who only handle live vertebrate animals as part of receiving course instruction are not required to complete the IACUC training requirements above in order to participate in the course activity. However, the course instructor is responsible for providing sufficient training to prepare the students for their involvement in the activity (e.g., handling techniques to be used, etc.). The course instructor is also responsible for informing the students of any risk involved in the activity (e.g., allergies, specific risks related to handling of the specific animals, etc.). Students may be required by IACUC to take CITI Program courses pertaining to specific activities involving animals, to be determined in protocol approval.
    d. Externally-Affiliated Protocol Personnel
    IACUC protocol personnel who are collaborating with an SAU PI and who are otherwise unaffiliated with SAU must either complete the same IACUC training requirements as SAU personnel, or provide evidence they are appropriately qualified by training and experience for their designated protocol roles. This evidence includes knowledge of applicable laws, regulations, codes and guidance; relevant ethical and professional standards; and competency to conduct protocol activities such that interactions with the animals will minimize risks and ensure the well-being of the animals.
    e. The IACUC may, at its discretion, require additional training be completed for any protocol member prior to approving that individual to work on a protocol and/or to perform certain procedures on a protocol.

Policy 3.30 IACUC Protocol Personnel Conflict of Interest

Policy

1. IACUC protocol personnel are required to disclose any conflicts of interest. Personnel must adhere to SAU conflict of interest policy.
2. Any IACUC researcher is said to have a conflict of interest whenever that person, their spouse, domestic partner, or dependents child falls under an of the following conditions:
    a. Has financial arrangements with the sponsor or agent of the sponsor, whereby the outcome of the study could influence the value of the economic interest.
    b. Acts as an officer or a director of the sponsor or an agent of the sponsor.
    c. Has an equity interest in the sponsor.
    d. Has received payments or other incentives from the sponsor that when aggregated for the member and spouse/domestic partner /dependent child.
    e. Has identified themselves for any other reason as having a conflict of interest.

Procedure

1. University policies governing conflict of interest include: NEED TO ADD FROM HANDBOOK

2. A conflict of interest affecting a protocol must be indicated in the protocol submission.

Policy 3.40 Minimizing Pain and Distress

Policy

1. The IACUC protocol PI is responsible for ensuring the health and well-being of all animals used on an IACUC protocol meet and follow the standards of the USDA Pain and Distress categories. The IACUC will critically evaluate protocols to ensure that pain and distress are minimized in animals and assure that appropriate steps will be taken to enhance animal well-being.

2. Animals experiencing more than momentary or slight pain or distress require appropriate sedation, analgesia, or anesthesia unless suitable, scientific justification is provided by the PI and approved by the IACUC. Researchers must follow the appropriate requirements related to the acquisition, storage, use, disposal, and recordkeeping of sedative, analgesic, and anesthesia agents.

Procedures and Regulatory Guidance

1. In design of the research, training, or educational activities, it is the responsibility of the PI to consider and include procedures that minimize animal pain or distress.

2. If a proposed activity may cause more than momentary or slight pain or distress to animals, the AWRs specifically require investigators to consult with the Attending Veterinarian or their designee during protocol development.

3. The PHS Policy and AWRs stipulate that the PI has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animal and has provided a written narrative description of the methods and sources used to determine that alternatives were not available.

4. The IACUC will ensure that the protocol addresses:
    a. Appropriate sedation, analgesia, and anesthesia;
    b. Criteria for timely intervention, removal of animals from study, or euthanasia if painful or stressful outcomes are anticipated
    c. Details of post-procedural care.

5. The protocol must provide adequate information for the IACUC to assess the potential animal pain and/or distress resulting from the activity and the effectiveness of the pain- and distress-relieving agents proposed for use. If necessary, criteria for re-dosing the animals should also be established.

6. Examples of procedures which the Guide suggests may have the potential to cause pain or distress, include the following:
    a. Physical restraint
    b. Survival surgeries
    c. Food or water restriction
    d. Death as an endpoint
    e. Noxious stimuli

f. Skin or corneal irritancy testing
g. Tumor burdens
h. Intra-cardiac or orbital sinus blood sampling
i. Abnormal environmental conditions

7. Assessing Pain and Distress
    a. Numerous references indicate that animals and humans receive and process noxious stimuli using similar mechanisms. An animal's response to pain is often adaptive to reduce movement to minimize re-injury and aid recuperation. This response, however, may lead to physiological and behavioral changes which impact negatively on both the animal's well-being and the research results.

    b. Fundamental to the relief of pain is the ability to recognize its clinical signs in various species of animals. Due to the inability of animals to verbalize, it is essential that personnel working with animals receive adequate training on how to recognize clinical signs of pain and distress. It is often useful to start with a general set of observations for assessing pain and distress such as change in body weight, physical appearance/posture or changes in unprovoked and provoked behavior. The assessment system should then be modified on a case-by-case basis using specific changes that may be anticipated in a particular study.

8. Alleviation of Pain and Distress
    a. Accepted best practices for dealing with the possibility of unrelieved pain and distress should be considered and incorporated into protocols unless there is a sound scientific rationale for deviation from those practices. The PI must also provide an assurance that unrelieved pain will continue for only the minimum period of time necessary to attain the study objectives.
    b. Protocol methodology should be considered that decreases the potential for pain or distress. In addition to thorough searches of the literature, this can be done through the careful use of pilot studies to determine earlier endpoints or less invasive alternatives.
    c. Pharmacologic treatment of pain or distress should be given as consistent with the type of pain/distress and the needs of the research question. The Attending Veterinarian must be consulted for all such protocols and should provide guidance to investigators and the IACUC. Nonpharmacologic treatments should also be employed. This may include special housing considerations, dietary and other environmental enrichments, adjustments and careful supportive care.
    d. It is the responsibility of the PI to show that they have considered all the options for minimizing pain and distress that do not compromise the scientific validity of the activity.
    e. The IACUC's deliberations regarding the management of potential pain and distress in a protocol will be documented in the meeting minutes.
    f. Personnel should be trained in pain and distress management.
    g. The IACUC should ensure that there is a mechanism in place for prompt reporting of sick or injured animals to the following individuals as appropriate: PI, Attending Veterinarian, other SAU personnel.

9. Use of Sedatives, Analgesics, and Anesthesia
    a. Under no circumstances may drugs used for sedation, analgesia, or anesthesia be expired.
        i. The expiration date is the date printed on the label/package for materials with a manufacturer's expiration.
        ii. Dilutions and compounding of sedatives, analgesia, and anesthesia may be permitted if commercial options are not available. The attending veterinarian must be consulted. For dilutions, preparations, reconstitutions, or mixtures of drugs of fluids prepared using aseptic technique and under proper storage conditions, the expiration date is no more than 30 days from the date of preparation. Such materials must be labeled by name, drug concentration, and include the new expiration date as soon as they are prepared.
        iii. An item is considered expired the day after the month or date indicated on the label. For example, an item labeled February 2021 would be considered expired on March 1, 2021.
    b. Off-label use of any drug whether sedative, analgesia, anti-microbial, parasiticide, or anesthesia may be permitted by the attending veterinarian. The PI must provide a valid explanation for off-label usage in protocol submission.
    c. Items are to be stored only according to acceptable storage methods, in consultation with SAU Laboratory Safety.
    d. Items are to be discarded only via accepted disposal methods in consultation with SAU Laboratory Safety. Whenever possible, disposal should occur immediately after use.
    e. Recordkeeping related to the use of sedatives, analgesics, and anesthetics should include, at a minimum, the following information: animal or group identification and the date of procedure; agent used, including dosage, route, and time of any drugs administered; on-going monitoring, including periodic assessment of anesthetic depth, activity of the animals, incision site observations, and any pain- or procedure-related complications and response to these actions; and identification of the person performing monitoring. Records must be maintained for at least one year beyond the end of the approved protocol.
    f. Several analgesics and anesthetics are controlled substances and may require certain authorizations and procedures prior to use in animals. Controlled substances must be properly stored with appropriate recordkeeping. The PI is responsible for determining if the agent to be used is a controlled substance; acquiring any authorizations, if needed; and ensuring appropriate acquisition, storage, use, disposal, and recordkeeping. When controlled substances are to be used, consultation with the Attending Veterinarian is required. Note that records related to controlled substances may need to be retained longer than one year beyond the end of the protocol.
    g. When controlled substances are to be used, the current Attending Veterinarian will be responsible for holding and maintaining a DEA license. The AV will purchase, store, and administer any controlled drug in accordance with DEA/controlled drug regulations.

Policy 3.5: Animal Procurement

Policy

1. The source of animal procurement must be approved by the IACUC.

2. With the exception of PI's new to SAU, who are transferring animals from another institution (see Policy 5.30: Animal Holding Policy), PIs must have an active, approved IACUC protocol or a protocol under Policy 5.30 before ordering/acquiring/housing animals. The protocol must allow for the acquisition of the requested species, strain, and number of animals, and the number of animals to be received must not cause the number of approved animals on the protocol to be exceeded.

3. The PI is responsible for maintaining thorough and accurate record keeping regarding the procurement of animals.

Procedures and Regulatory Guidance

1. The approved protocol must indicate the source of the animals. Typical animal sources include commercial vendors, other institutions, or animals captured in the field; however, the IACUC may approve an alternate procurement source, if sufficient justification is provided. Animals captured/sourced from the field must be approved/justified by IACUC in submitted protocols

2. Record keeping related to animal procurement should include, at minimum, the following information: source of animals, number of animals, date of acquisition, and assessment of animal condition upon receipt, including a description of any abnormalities. Records must be maintained for one year following the submission of the protocol closure report.

Policy 3.60: Transportation of Animals

Policy

1. The interfacility and interfacility transportation of regulated species in the possession of SAU personnel and personnel approved on a SAU IACUC protocol must follow AWA and USDA standards. Transportation of animals must follow state and federal laws.

2. SAU personnel and personnel approved on a SAU IACUC protocol are considered in possession of an animal from the time they initially receive the animal from a procurement/collection source tot the time the animal is removed from a protocol (e.g., transferred directly to another non-SAU investigator, released to a third-party courier to transport the animal to another researcher, released for adoption, released into nature, disposed of properly following euthanasia, etc.)

3. Risks to both the animals and the personnel transporting the animals must be minimized during transport. This includes maintaining the health and well-being of the animals, avoiding pathogen exposure, preventing injury, reducing the animal's exposure to stressors, and preventing escape of the animals.

4. Transportation/possible transportation of wildlife must be mentioned/approved in IACUC protocols.

5. Transportation of the animals through general public spaces should be minimized to the extent possible. When such transport must occur, the safety of the general public must be considered, and risks to the general public must be minimized to the extent possible.

Procedures and Regulatory Guidance

1. Never leave an animal alone or unattended outside of a secured animal housing facility or laboratory.

2. Animals and animal caging must be appropriately contained within the vehicle during transport to protect the animals, minimize risk of escape, and to protect personnel from potential exposure to hazards.

3. Transportation methods must minimize stress to the animals through maintaining appropriate ventilation, avoiding extremes in temperature and humidity, minimizing noise and odors, preventing exposure to pathogens, and minimizing interactions with other animals or people. Animal enclosures must have locking mechanisms or latches that cannot be dislodged by movement. Cages should be kept level at all times, and each cage must be secured appropriately. If possible, stacking of cages should be avoided; if stacking is necessary, care just be taken to ensure the cages are stacked safely and each cage is secured properly.

4. Animal enclosures must be appropriately cleaned and sanitized to prevent the spread of pathogens. Reusable enclosures must be sanitized between use to prevent the spread of pathogens

5. When transporting animals through public spaces, the animals should be obscured from view as much as possible.

6. Transportation of rodents out of the animal facility requires a secondary enclosure, and cages must be covered during transport to minimize the release of the animal allergens and bedding into the environment

7. Whenever possible, University-owned vehicles should be used for animal transport. See current SAU protocols for information about the use of University-owned vehicles

8. If the animal is released to a third-party courier, the SAU researcher/PI is responsible for selecting a trusted courier and ensuring the animal is packaged appropriately safely to the fullest extent possible.

Section 4: IACUC Protocol Review

Policy 4.10: Activities Requiring IACUC Review

Policy

1. All research and educational activities conducted by SAU faculty, staff and/or students and that involve the use of vertebrate animals are subject to review by the IACUC prior to initiation, except the following:
    a. Activities involving animals that perform tasks, participate in club activities, or appear in exhibits or demonstrations
    b. Use of tissues, organs or other parts of dead animals if received as such
    c. Noninvasive observations of wild animals in their natural habitat

2. All individuals performing animal husbandry activities and/or any procedures associated with the protocol must be listed and approved as personnel on the protocol.

Procedures and Guidance

1. Examples of activities performed by SAU faculty, staff, and students that require IACUC review include, but are not limited to:
    a. Activities performed on the premises of SAU
    b. Activities performed involving the use of facilities or with equipment belonging to SAU
    c. Activities satisfying a requirement imposed by SAU for a degree program or completion of a course of study
    d. Activities certified by a dean or department head to satisfy an obligation of a faculty appointment at SAU, including requirements for clinical or adjunct appointments
    e. Field studies that involve killing, trapping, banding, darting, implantation of telemetry devices, or any other invasive manipulation

2. IACUC review may be required even if the activity does not seem to qualify as "true research" (e.g., when the results are not intended for publication, will not advance work in another area, or will not contribute to generalizable knowledge), but is carried out for an educational purpose. For example, IACUC review is required for the following activities:
    a. Student educational activities involving live animals when that activity involves any change in the activities associated with the care of the animals
    b. Student educational activities when the student is not supervised by a person with appropriate expertise who has overall responsibility for the care and husbandry of the animals
    c. Student research conducted in collaboration with another institution or organization, including commercial entities

3. When a protocol has been reviewed and approved by another institution's IACUC, the SAU IACUC may not require additional review and approval. However, the PI must inform the SAU IACUC of the activity, and the SAU IACUC must have documentation from the collaborating institution before the SAU IACUC will approve of the activity.

4. Consulting Activities

Activities involving animals in which the faculty/staff/student acts in a consultant role require IACUC review and approval unless all of the following conditions are met:

a. The investigator is hired on his or her own time
b. The investigator holds no rights in the work
c. Neither the investigator nor SAU retains any data

5. Research in Foreign Countries

a. The standards for ethical and responsible use of animals in research will not be relaxed even if different customs prevail. This includes the use of animals in foreign research institutions, and fieldwork involving either domestic or wild animals.
b. Research projects must also be approved by the local equivalent of an IACUC before they are initiated. Where there is no equivalent board or group, investigators must rely on local experts or community leaders to provide approval. The IACUC requires documentation of this local approval, as well as documentation of any necessary permits, before granting final approval for the project.
c. With regard to activities supported by PHS funds, foreign institutions that serve as performance sites must also have Assurances on file with OLAW.

6. Student Internships Off-Campus

Students working with vertebrate animals as a part of an off-campus internship may be exempt from IACUC approval if the following conditions are met:

a. The internship or research is not funded by SAU
b. The organization that is hosting the student internship has authorization to perform the vertebrate work from the necessary regulatory agencies
c. The student has notified and documented their work with their academic advisor at SAU

7. Use of Dead Animals or Animal Tissues

a. IACUC review is not required prior to using dead animals or animal tissues, provided the material is obtained in one of the following ways:
    i. Acquired from a commercial source
    ii. Obtained from animals sacrificed following an IACUC-approved project at SAU or another institution, or a governmental agency
    iii. Samples remaining from diagnostic tests performed by private laboratory facilities
    iv. Found in nature, if animal is already dead at time of collection (i.e., roadkill, a dead animal found on campus, etc.)
b. IACUC approval is required if an animal is both procured and sacrificed solely and specifically for a research or educational purpose.

8. If it is unclear if an activity requires IACUC review, contact the IACUC Chairperson for an official determination. IACUC Chairperson's contact information can be found on the SAU IACUC website

Policy 4.20: IACUC Protocol Submission and Review

Policy

1. Protocol Submission

   An IACUC application is required for all research and educational activities involving the care and use of animals, except under those conditions in Section 1.

2. Protocol Review

   a. The IACUC shall conduct a review of those components related to the care and use of animals and determine that the proposed protocol is in accordance with PHS Policy, the AWRs, and the applicable U.S. Government Principles.

   b. If the IACUC does not have the scientific and technical expertise to evaluate all aspects of a proposal it may bring in outside expert consultants to provide information. Such consultants must not have a conflict of interest with the research activity and may not vote on any matters pertaining to the protocol.

   c. In all cases, it is the investigator's responsibility to justify and explain their proposed protocol to the satisfaction of the IACUC.

   d. Initial IACUC submissions are reviewed by either Full Committee Review (FCR), or Designated Member Review (DMR). Procedures for each level of review are described below.

   e. Under no circumstances will a protocol be permitted to begin (or resume) until IACUC approval is granted.

Procedures and Regulatory Guidance

1. Protocol Submission

   a. PI's must complete the appropriate protocol application, all of which can be found on the SAU IACUC website. Each initial application is assigned a protocol number. Protocol types fall into 3 following categories:

      i. Use of Vertebrate Animals in Teaching
      ii. Use of Vertebrate Animals in Biomedical Research
      iii. Use of Vertebrate Animals in Agricultural Research

   b. A digital copy of the completed proposal application form can be emailed to the IACUC chairperson.

2. Protocol Review

   a. Upon receipt of a new protocol submission, the IACUC chairperson will send the protocol submission form and all supporting documents to all IACUC members. The IACUC members are allowed **eight** business days to review the submission and request either FCR or DMR, and to enter any comments related to the protocol into IACUC electronic database on the SAU shared drive. Any IACUC member may call for FCR for a new protocol application. If no members request FCR, the protocol is sent to DMR. Failure on behalf of the IACUC member to respond within the eight-business day initial review period will be interpreted as a request to use DMR for review. If all members select DMR prior to the end of the eight-business day review period, the IACUC chairperson does not need to wait until the end of the eight-business day period to send the protocol to DMR for review. Procedures for FCR and DMR are described in further detail below.

b. Protocol or amendment proposals that include any of the following activities are required to be reviewed via FCR:

i. Major survival surgery
ii. Death as an endpoint
iii. Radiation sickness
iv. Tumor inducement
v. Toxicology
vi. Infectious disease
vii. Blunt force trauma
viii. Use of conditionally acceptable methods of euthanasia

c. IACUC Protocol Actions

Upon review of protocols, the IACUC may take one of the following actions:

i. Approval

When the IACUC has determined that all review criteria, based on the PHS Policy and AWRs, have been adequately addressed by the PI, the IACUC may approve the protocol, thus granting the PI permission to perform the activities described in the protocol. The IACUC-approved protocol may be subject to further appropriate review and approval by institutional officials due to financial, policy, facility, or other institutional or administrative considerations. Those officials, however, may not approve an activity if it has not been approved by the IACUC.

ii. Modifications Required to Secure Approval

The IACUC may require modifications to the protocol before granting approval. If the IACUC determines that a protocol is approvable contingent upon receipt of a very specific modification, or clarification of a specific point, the IACUC may handle these modifications or clarifications as administrative details that any member, such as the Chairperson, could verify prior to granting approval. If a protocol is unusually complex or involves untried or controversial procedures the IACUC may impose restrictions (e.g., approval for the use of a limited number of animals as a pilot study with a written report of interim results, or close monitoring by veterinary or other qualified personnel). If such modifications represent significant departures from standard/acceptable procedures, the IACUC can ask the investigator to modify the protocol to reflect the modifications imposed by the IACUC. If the protocol is missing substantive information necessary for the IACUC to approve the protocol, or the IACUC requires extensive or multiple modifications, then the IACUC can require that the protocol be modified and resubmitted. If the IACUC wishes to shift to the DMR mode for the approval of the modified protocol, that shift will be explicitly noted in the meeting minutes and the requirements for DMR must be met.

iii. Defer (Table Review)

The IACUC may defer or table a review if the protocol requires any of the following: significant clarification in order for the IACUC to make a decision, IACUC members with certain expertise are not present, the IACUC wishes to seek external consultation, or any other reason that prevents the IACUC from conducting its review. Subsequent review would happen within 30 days.

iv. Disapproval

When the IACUC determines that a protocol has not adequately addressed all of the requirements of the PHS Policy and AWRs, as applicable, or the described activities represent inappropriate or unethical use of animals, the IACUC may withhold approval. If approval is withheld the IACUC must provide the reasons for its decision and give the PI an opportunity to respond. The PI may choose to meet with the full IACUC or IACUC chairperson to discuss these reasons

d. Full Committee Review

i. FCR of protocols requires a convened meeting with a quorum of the IACUC members. A quorum of the committee is reached when a majority of the IACUC members are present.

ii. After a committee discussion, IACUC members vote to approve without modification, approve pending receipt of modifications, table the protocol until the next meeting, or disapprove the protocol. A majority vote of the quorum present is required to approve an action on a protocol submission. If quorum is not reached, or a majority vote is not obtained, no official action can be taken regarding the protocol, and the protocol will be reviewed at the next convened meeting.

iii. If the IACUC votes to approve pending receipt of modifications:

1. If the required modifications are all administrative in nature, the IACUC can vote to have the modified protocol reviewed by the IACUC Chairperson via Administrative Review.
2. If the modifications are not administrative in nature, and all members of the IACUC are present at a meeting, the committee may vote to have the modified protocol reviewed and approved by DMR, or returned for FCR at a convened meeting.
3. If the modifications are not administrative in nature, and all members of the IACUC are not present at a meeting, the committee may use DMR subsequent to FCR according to the following stipulations, per NIH Notice NOT-OD-09-035:
    a. All IACUC members agree in advance in writing that the quorum of members present at the convened meeting may decide by unanimous vote to use DMR subsequent to FCR. However, any member of the IACUC may, at any time, request to see the modified protocol and/or request FCR of the protocol.
    b. If an active Assurance is on file with OLAW, SAU has stipulated its intention to conduct reviews in this manner in the Assurance, or will provide information about this program change to OLAW in the next Annual Report.
    c. If all IACUC members do not agree in advance in writing that DMR subsequent to FCR can be used, the modified protocol will be subjected to the eight-business day review period outlined in Procedures 2a above.

4. If the IACUC votes to approve the application pending receipt of modifications, the Chairperson sends a request to the PI detailing the modifications needed to secure protocol approval and requests that the PI modify and resubmit the protocol. If the PI does not resubmit the modified protocol within 90 calendar days, or makes other arrangements with the ORCI or IACUC Chairperson to extend this 90-day time period, the submission will be considered withdrawn, and a new submission will be required if the PI still seeks to conduct the work.

iv. Investigators of protocols for which approval has been withheld may meet with the IACUC Chairperson to discuss the protocol.

e. Designated Member Review

i. The IACUC Chairperson designates one or more qualified members to review the proposal (or proposed amendment or annual renewal). All IACUC members will be able to send their comments to the DMR reviewer. It is at the discretion of the DMR reviewer to include comments from the other IACUC members when requesting modifications and/or further information from the PI.

ii. The DMR reviewer(s) can either approve, request modifications on the protocol, or refer the protocol to FCR. The DMR reviewer(s) may not withhold approval.

iii. If the protocol is assigned to more than one DMR reviewer, the reviewers must be unanimous in any decision. They will all review identical versions of the protocol and if modifications are requested by any one of the DMR then other DMR reviewer(s) must be aware of and agree to the modifications. If the DMR reviewers cannot reach an agreement on a decision, the protocol will be reviewed via FCR.

iv. If the DMR reviewer(s) approve(s) the protocol as written, it is sent to the Chairperson for final review. The Chairperson may confirm the approval or request additional information and/or modifications from the PI before approval. If the Chairperson wishes to request additional information and/or modifications from the PI, the Chairperson must notify the DMR reviewer(s) of this request and the DMR reviewer(s) must agree to the request. If the DMR reviewer(s) and Chairperson cannot reach an agreement on the request, the protocol will be reviewed via FCR.

v. If the DMR reviewer(s) request(s) additional information and/or protocol modifications

1. The DMR reviewer(s) enter(s) the required additional information and/or modifications in the IACUC electronic database on the SAU shared drive and send(s) them to the chairperson for review. The DMR reviewer(s) may choose to either review the protocol again when the modified application is resubmitted by the PI, or have the chairperson conduct the review of the resubmission. Selection of the chairperson review should only be made if the requested information and modifications are minor and/or administrative in nature.
2. The chairperson reviews the requested information and/or modifications, and if they wish to modify the information requested

by the DMR reviewer, the chairperson must communicate the proposed changes to the DMR reviewer(s), and the DMR reviewer(s) must agree to the changes before responding to the PI. If the DMR reviewer(s) and chairperson cannot agree on the information to be requested, the protocol will be reviewed via FCR.

3. The chairperson contacts the PI in writing or by email detailing the application's deficiencies and requests that the investigator modify and resubmit their application. If the PI does not resubmit the modified protocol within 90 calendar days, or makes other arrangements with the IACUC chairperson to extend this 90-day time period, the submission will be considered withdrawn, and a new submission will be required if the PI still seeks to conduct the work.
4. Modified applications from PIs are reviewed by the DMR reviewer(s), or chairperson if designated by the DMR reviewer(s), to approve or request further modifications. If the DMR reviewer(s) selected the chairperson to conduct the review of the modified submission, and the chairperson determines the modifications are more than minor in nature, the chairperson may send the protocol back to the DMR reviewer(s) for further review.

f. At any point during the review process, reviewers may contact the PI for clarifications, additional information, or in anticipation of questions the IACUC may raise.
g. The decision about a protocol will be sent to the PI, the AO, and any other relevant SAU officials.

Policy 4.30: Amendments to Approved IACUC Protocols

Policy

1. An IACUC Amendment application is required for all proposed changes to previously approved IACUC protocols.

2. All changes to an IACUC-approved protocol must be reviewed and approved by the IACUC before they occur.

Procedures and Regulatory Guidance

1. PI's must complete and submit an IACUC Amendment application form
    a. IACUC Amendment application form can be found on the SAU IACUC website
    b. Completed applications can be emailed to the IACUC chairperson. The IACUC chairperson's contact information can also be found on the IACUC website

2. Amendment requests are reviewed by the IACUC chairperson and to determine if the requested change is significant or non-significant in nature.

3. Significant Changes
    a. The SAU IACUC interprets significant changes to mean those that have the potential to impact substantially and directly on the health and well-being of the animals. Significant changes include, but are not limited to, changes:
        i. In the methods of animal use
        ii. In the objectives of a study
        iii. From non-survival to survival surgery
        iv. In procedures that result in greater pain, distress, or degree of invasiveness
        v. In the species or in approximate number of animals used
        vi. In PI for the protocol
        vii. In anesthetic agent(s) or the use of withholding analgesics
        viii. In the method of euthanasia
        ix. In the duration, frequency, or number of procedures performed on an animal
        x. In housing and/or use of animals in a location that is not part of the animal program overseen by the IACUC.
        xi. Affecting the previously evaluated cost-benefit assessment (*Policy 2.60 Ethical Cost-Benefit Analysis*)
    b. Amendment requests involving significant changes are reviewed under the same procedures used for reviewing an initial (i.e., new) IACUC protocol (FCR or DMR), as described in *Policy 4.20: IACUC Protocol Review*.

4. Non-Significant Changes
    a. The SAU IACUC interprets non-significant changes to mean those that do not have the potential to impact substantially and directly on the health and wellbeing of the experimental animals. Examples of non-significant changes include, but are not limited to, changes in:
        i. Funding source
        ii. Personnel other than the PI

iii. Protocol title
iv. Proposed end date of a protocol, provided no additional changes to the care and use of the animals are proposed, and the protocol does not exceed three years in length

b. Amendment requests involving non-significant changes may be reviewed and approved via Administrative Review.

5. Administrative Review (AR)

a. The IACUC chairperson or an IACUC member designated by the Chairperson may administratively review and approve amendment requests that involve changes not considered significant by the IACUC for example:
i. Correction of typographical errors
ii. Correction of grammar
iii. Contact information updates
iv. Change in personnel, other than the PI. (Reviewer must ensure that all such personnel are appropriately identified and have completed the training requirements outlined in *Policy 3.20:Required Training for IACUC Protocol Personnel and SAU Animal Users*.)

b. Any significant concerns or questions raised through the AR process will result in the amendment request being reviewed under the same procedures used for an initial (i.e., new) IACUC protocol (FCR or DMR), as described in *Policy 4.20: IACUC Protocol Review*.

Policy 4.40: Continuing Review of Approved IACUC Protocols

Policy

1. IACUC protocols involving USDA-covered species are required to undergo an annual continuing review. The annual period begins on the first and second anniversary of the initial protocol approval date. Work cannot be performed after the anniversary date without an approved continuing review application.

2. A complete *de novo* review of all IACUC protocols must be conducted at least once every three years.

Procedures and Regulatory Guidance

1. PHS Policy IV.4.C.5 requires the IACUC to conduct continuing review of each previously approved, ongoing activity at appropriate intervals determined by the IACUC, including a complete review at least once every three years. The USDA (AWR §2.31(d)(5)) requires the IACUC to conduct continuing review of activities at appropriate intervals determined by the IACUC, but not less than annually.

2. Many animal use protocols under the oversight of the IACUC pose no more than minimal risk to the animals. Thus, it is unlikely that IACUC determinations about potential risks to the animals would be affected by new information gathered directly from the research interim results if the approval period were lengthened beyond one year. However, the IACUC may, at its discretion, choose to limit the approval period of any protocol to an interval of less than three years.

3. Federal requirements, research ethics, and moral obligations of the scientific community to society demand that IACUCs conduct appropriate and meaningful reviews of ongoing animal protocols in the same responsible manner that initial reviews are done. This means that the IACUC will not automatically approve a previously approved protocol during continuing review just because it has undergone a thorough initial review.

4. Annual Reviews
    a. PI's must complete and submit an IACUC Continuing Review application
        i. IACUC Amendment application form can be found on the SAU IACUC website
        ii. Completed applications can be emailed to the IACUC chairperson. The IACUC chairperson's contact information can also be found on the IACUC website
        iii. The IACUC will provide a reminder to PI's at 11 months and 23 months into their protocol to submit Continuing Review application
    b. The PI must verify that completed activities were conducted in accordance with the approved protocol, describe any proposed departures from the approved protocols, and provide information about activities projected for the upcoming year. In addition, the number of animals used over the course of the previous protocol year needs to be provided.
    c. The USDA considers continuing reviews to be compliant if they are completed within the anniversary month of the most recent previous approval or completion of a

continuing review. Even if the continuing review process begins in the preceding month, as long as it is *completed* within the anniversary month, the anniversary date will remain unchanged. For example:

i. October 1, 2019: A protocol is approved by the IACUC.

ii. September 30, 2020: If the continuing review is completed by this date, it is compliant with USDA requirements, but the anniversary date for the next continuing review becomes the date of approval of the continuing review.

iii. October 1-31, 2020: If the continuing review is completed anytime in October of 2020 (even if the IACUC began the review in September), it is compliant with USDA requirements, and the anniversary date for the next review will remain October 1, 2020.

iv. November 1, 2020: If the continuing review is completed on or after this date, it will be non-compliant with USDA requirements, and the protocol will be treated as permanently expired, per Procedure 4.f below.

d. When a Continuing Review application is submitted to the IACUC chair prior to the protocol's expiration date, the protocol is considered active and protocol work can be conducted while the annual renewal is under review, up until a month after the anniversary date of the protocol. The Continuing Review must be approved before the end of the anniversary month for work to continue beyond that date.

e. The IACUC will attempt to send the PI email notification reminder 30 days before the first and second anniversary of the protocol approval. Information requested includes: the status of the protocol (active or inactive), request of any proposed modifications to the protocol, and the number of animals used since the previous continuing review. The Continuing Review Form will be reviewed via the same method by which the initial protocol was approved (FCR or DMR).

f. If a PI fails to obtain continuing review approval by the end of the anniversary month of the most recent previous approval, the protocol will be treated as permanently expired, and the PI will be required to resubmit a new protocol in order to restart work. If the work is still ongoing and/or animals are still housed once the protocol lapses, the PI will be considered to be in noncompliance, and *Policy 5.10 Animal Welfare Concerns and Noncompliance* will be followed. Additionally, the IACUC may consider suspending or terminating that PI's animal use privileges. If a protocol is allowed to lapse, the IACUC, including the Attending Veterinarian, will make a determination (after possible consultation with the IO, relevant Deans and other University officers) regarding whether the animals can be safely and humanely maintained temporarily, or if they should instead be provided care via *Policy 5.30: Animal Holding Policy*, transferred to another study, placed with an outside agency, adopted out, or euthanized.

5. Three-Year Reviews

a. The three-year period begins on the initial date of IACUC approval; the IACUC may not administratively extend approval beyond the three years. If the PI plans to continue animal work beyond the original expiration date of the protocol, it is the responsibility of the PI to obtain approval of the third-year resubmission prior to protocol expiration. To aid investigators, the IACUC shall attempt to provide adequate warning of pending

protocol **60 days** before expiration. The IACUC requires the third-year resubmission to be submitted as a new proposal.

b. The third-year resubmission must be approved by the IACUC before the expiration date of the original protocol. If a PI fails to submit a third-year resubmission and receive approval by the expiration date of the protocol, the following actions are taken:
    i. The IACUC chairperson will notify the PI, the PI's dean (and/or unit head), the Attending Veterinarian, IO, the SAU Administration responsible for external grant funds (if the project is externally funded), that the animal protocol has expired. The PI will be notified in writing that all activities under the protocol must cease. Any ongoing work under the expired protocol is a serious violation and reportable to the appropriate agency.
    ii. The Attending Veterinarian will be notified of the expired protocol and any remaining animals under that protocol will be cared for according to *Policy 5.30: Animal Holding Policy*.
    iii. If the PI fails to successfully renew the protocol, the IACUC may consider suspension or recommending to the IO that the PI's animal use privileges should be terminated.

Policy 4.50: Withdrawal of Pending (Not Yet Approved) IACUC Submissions

Policy
The IACUC will administratively withdraw an application for failure to respond to a request for clarification and/or corrections. This includes initial submissions, amendment requests, and continuing review requests.

Procedures
The process for PI notification of IACUC administrative actions is as follows (measured in business days):

1. *Day 0:* The IACUC will communicate with the PI detailing the actions required to secure approval.

2. *Day 15:* If no response from the PI is received by this day, the IACUC will send a second correspondence to the PI requesting a response to the IACUC's previous correspondence.

3. *Day 30:* If no response from the PI is received by this day, then the:
    a. IACUC will send a third correspondence to the PI requesting a response to the IACUC's previous correspondence.
    b. IACUC will place a phone call to the PI.

4. *Day 45:* If no response by the PI is received by this day, then the IACUC will inform the PI of the withdrawal of the submission and indicate that a new protocol/amendment/continuing review must be submitted to the IACUC if they wish to pursue the proposed activity.

Section 5: Post-Approval Monitoring and Actions

Policy 5.05: Reportable Events: Protocol Deviations and Adverse Events

Policy

1. Reporting Requirements
    a. Protocol personnel must immediately report all protocol deviations and adverse events associated with the conduct of an IACUC protocol to the PI.
    b. The PI must ensure all protocol deviations and adverse events associated with the conduct of an IACUC protocol are reported to the IACUC within the appropriate timeframe for the type of event identified as outlined below in this policy.

2. The following definitions apply to this policy:
    a. Event or Problem: An incident, experience, or outcome that occurs during the conduct of an IACUC protocol that may require reporting to the IACUC, another reviewing IACUC, the OLAW, the USDA, and/or a sponsor.
    b. Protocol Deviation: Any change, divergence, or departure from an IACUC- approved protocol that is not implemented or intended as a systemic change; or any other, unplanned, instance of protocol noncompliance. The deviation may be accidental or due to negligence. Deviations may also include failure to comply with federal laws and regulations, SAU policies and procedures, and standards of professional conduct and practice. Protocol deviations are a form of noncompliance (see *IACUC Policy 5.10: Animal Welfare Concerns and Noncompliance*). Deviations may be considered major or minor, depending upon the circumstances.
        i. Minor Protocol Deviation: A deviation is considered minor if it does not have an impact on the animal's welfare and the completeness, accuracy, or reliability of the study.
        ii. Major Protocol Deviation: A deviation is considered major if it impacts an animal's welfare and/or the completeness, accuracy, or reliability of the study.
    c. Adverse Event (AE):
        i. An event or problem that negatively impacts animal welfare or poses a threat of harm to a live vertebrate animal and that meets any of the following conditions:
            1. Is related, or possibly related, to the husbandry conditions and/or procedures used in the IACUC protocol (possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures used in the protocol)
            2. Occurs at a rate or severity higher than indicated in the approved protocol
            3. Is not related to the husbandry conditions and/or procedures outlined in the approved IACUC protocol, but is unanticipated or due to a facility, physical plant, equipment, or personnel failure, malfunction, or mistake.
            4. Reflects a situation that could become more severe in the future
        ii. An event or problem that negatively impacts protocol personnel during their conduct of an IACUC protocol (e.g., animal bite, scratch, etc.).

3. Failure to report a protocol deviation or adverse event is considered noncompliance. Refer to *IACUC Policy 5.10: Animal Welfare Concerns and Noncompliance*.

4. Planned protocol deviations must be reviewed and approved by the IACUC prior to implementation. Refer to *IACUC Policy 4.30: Amendments to Approved IACUC Protocols*.

5. Reportable events received by the IACUC will be reviewed according to the procedures outlined in *IACUC Policy 5.10: Reporting and Review of Animal Welfare Concerns, Adverse Events, Protocol Deviations, and Noncompliance*.

Procedures and Regulatory Guidance

1. Reporting of AEs assists PIs, veterinarian, and the IACUC to find the cause of the event or problem and to prevent recurrence. Reporting also helps the IACUC meet its federal requirements to monitor animal activities.

2. Written notification of AEs and protocol deviations should be to the IACUC chair via email and must include the following items:
    a. Protocol number
    b. Funding source, if applicable
    c. Classification of the event (minor deviation, major deviation, adverse event)
    d. Full explanation of the situation, including what happened, when and where, the species of animal(s) involved, and the category of individuals involved (e.g., PI or co-investigator, technician, animal caretaker, student, veterinarian, etc.)
    e. Description of actions taken by PI to address the situation
    f. Description of short- or long-term corrective plans and implementation schedule(s)

3. Adverse Events and Major Protocol Deviations
    a. The PI must submit a written notification to the IACUC chair within seven (7) calendar days of first learning about the event.
    b. If the event is on-going, it must be stopped immediately to the extent possible.
    c. AEs and Protocol Deviations Affecting Animal Welfare
        i. If the AE or protocol deviation affects animal welfare, the PI must contact the Attending Veterinarian by email, phone, or in person within 12 hours of learning of the event.
        ii. The Attending Veterinarian will work with the PI as necessary to develop a resolution plan to ensure the welfare of the animals by circumventing or alleviating the impact of the adverse event.
    d. Examples of AEs and major protocol deviations include, but are not limited to:
        i. Morbidity or mortality resulting from complications not described in the IACUC protocol
        ii. Greater number of mortalities, more severe responses, or when animals appear to be in more pain or distress than expected or described in the IACUC protocol
        iii. Allergic reaction to a treatment
        iv. Inadequate anesthesia
        v. Development of an unexpected infection following surgery or treatment

vi. Facility or equipment failure that has a negative impact on animal welfare, such as loss of power
vii. Unauthorized animal use (i.e., using non-approved animals and/or using more animals than approved)
viii. Performing unauthorized surgery
ix. Failure to ensure death of animals after euthanasia procedures
x. Injecting drugs that the IACUC has not approved
xi. Failure to carry out veterinary orders (e.g., treatments)
xii. Failure to conduct daily health monitoring of animals or failure to check field traps within protocol-approved timeframe
xiii. Improper restraint
xiv. Conduct of IACUC activity by individuals not listed on the protocol
xv. Implementation of any protocol change without prior IACUC approval
xvi. Conduct of animal-related activities beyond the expiration date of the protocol

4. Minor Protocol Deviations
   a. The PI must submit a written notification to the IACUC within fourteen (14)
   b. calendar days of first learning of any *minor* protocol deviation.
   c. Examples of minor protocol deviations include, but are not limited to:
      i. Failure to maintain appropriate animal-related records (e.g., identification, medical, husbandry)
      ii. Unauthorized personnel accessing facilities without authorization
      iii. Minor deviations in procedures that do not result in distress or suffering, such as site of injection, change in time frame, etc.

5. The following type of events do not require reporting to the IACUC
   a. Events involving injury or illness unrelated to the procedures in the approved IACUC protocol and which are being treated by the Attending Veterinarian or designee.
   b. Animal death or injuries related to manipulations that fall within parameters described in the IACUC-approved protocol, provided the rate of occurrence is equal to or below the rates indicated in the approved protocol
   c. Death of animals that have reached the end of their natural life spans
   d. Death or failure of neonates to thrive when husbandry and veterinary medical oversight of dams and litters was appropriate

Policy 5.10: IACUC Review of Animal Welfare Concerns, Adverse Events, Protocol Deviations, and Noncompliance

Policy

The IACUC must review and, if warranted, address any reported animal welfare concern related to SAU's animal care and use program, including those raised by members of the public and those self-reported by PIs (i.e., adverse events and protocol deviations; *see IACUC Policy 5.05: Reportable Events: Protocol Deviations and Adverse Events). Each concern must be reviewed in a timely and systematic manner and, when necessary, prompt, appropriate corrective actions shall be taken.*

Procedures and Regulatory Guidance

1. Protocol noncompliance occurs when procedures or policies approved by the IACUC are not being followed. Examples include, but are not limited to: use of unauthorized animals, performing unauthorized surgery, unauthorized persons participating in a research project or educational activity, and injecting drugs that the IACUC has not approved. When faced with protocol noncompliance, the IACUC's first step, if possible, should be to find a way to bring the protocol into compliance.

2. Methods of Reporting
    a. There are a number of options available to communicate concerns about animal care and use at SAU, or to report instances of suspected noncompliance with laws, rules, regulations and policies. The names and phone numbers of contact persons including the Attending Veterinarian, the IO, and the RIO should be posted in or near the entrance to animal facilities and readily available to institutional employees and protocol personnel.
    b. PIs who are self-reporting a protocol deviation or adverse event shall follow the reporting procedures outlined in *IACUC Policy 5.05: Reportable Events: Protocol Deviations and Adverse Events*.
    c. Requests for anonymity will be honored to the extent possible. This includes protecting the confidentiality of those who report concerns as well as anyone against whom allegations are directed, while allegations are under investigation. The policy of SAU is to prohibit retaliation against any individual as a consequence of good faith actions in the reporting of, or the participation in an investigation pertaining to, allegations of wrongdoing.

3. Review of Animal Welfare Concerns, Protocol Deviations, Adverse Events, and Reports of Noncompliance
    a. Initial Evaluation and Actions
        i. Concerns may include situations or activities ranging from those in which animals are reported to be in immediate, actual or perceived jeopardy to those in which violations of the SAU's Assurance with OLAW are alleged to be occurring but animals are not in apparent danger. They may focus on allegations of past policy and procedure violations or protocol noncompliance.
        ii. The course of action taken by the IACUC should be driven by the potential significance of the alleged situation. For example, conditions that reportedly

jeopardize the health or well-being of animals should be evaluated immediately. To cope promptly with such situations, the Attending Veterinarian, IACUC Chairperson, the IO, and RIO are authorized to halt procedures which they believe jeopardize the health and well-being of animals and/or do not comply with institutional policies, until such time the IACUC can be convened and consider the matter formally. Situations that may involve potential criminal activity or human safety shall be reported immediately to the institution's law enforcement or occupational health and safety officials. Allegations of other ongoing policy or procedural matters may not require such same-day attention, but should not be deferred merely as a matter of convenience. Emergency meetings of appropriate officials may be necessary in these cases to ensure prompt consideration of concerns.

b. Complaint Assessment

i. Upon receipt of a concern, the IACUC Chairperson shall convene a full committee

ii. The committee can either meet in person, teleconferencing, videoconferencing, or via email discussion.

iii. After initial review of the complaint, the committee will determine which of the following actions the complaint requires:

1. Further investigation and immediate action
2. Further investigation but no immediate action
3. No further investigation
4. No action

iv. Once this decision has been made, the committee will determine which individuals or other institutional or non-institutional offices may require notification.

v. Immediate Action

1. If immediate action appears warranted because animal or human welfare may be compromised, the IACUC shall notify the IO and RIO, respectively, and proceed accordingly.
2. Veterinary medical intervention, suspension of a research activity, and/or notification of appropriate safety, occupational health, or other officials, are examples of actions that may be taken immediately to protect animal or human welfare.
3. As applicable, and in accordance with the AWRs, if an activity is suspended, the IO shall report that action to any federal agency funding that activity. If the PHS supports the activity in any way, the IACUC, through the IO, must promptly notify OLAW.

vi. Further Investigation

1. Should the committee determine that further investigation is required, the chair shall appoint a subcommittee of at least 2 IACUC members and they shall conduct the investigation and report back to the IACUC.
2. The IACUC Chairperson shall assign a completion date.
3. The information to be collected during the investigation will vary depending on the circumstances, but will often include:

a. Interviewing complainants (if known), any persons against whom allegations were directed, and pertinent program officials
b. Observing the animals and their environment
c. Reviewing any pertinent records (e.g., animal health records, protocol, and other documents)

4. The subcommittee shall provide a report to the IACUC, which summarizes and includes:
    a. The concern(s)
    b. The results of interview(s)
    c. The condition of animals and their environment
    d. The results of records and other document reviews

c. IACUC Review

i. Upon receipt and evaluation of the subcommittee report, the IACUC may request further information, amend the report, or find that:
    1. There was no evidence to support the concern or complaint
    2. The concern or complaint was not sustained, but related aspects of the ` animal care and use program requires further review
    3. Other institutional programs may require review
    4. The concern or complaint was valid

ii. Following IACUC review, the IACUC will vote to approve the report. The report will then be shared with the PI. If the PI wishes to respond to the report, they must do so, in writing, within 10 business days.

iii. If the PI does not respond, or the response neither disputes facts provided in the report nor provides any additional information pertinent to the report, the previously approved subcommittee report will be treated as the final version of the report.

iv. If the PI responds, and that response includes additional information pertinent to the report and/or disputes facts provided in the report, the IACUC will review the report again, taking into consideration the PI's response. Following deliberations, the IACUC will make any necessary changes to the report, and vote to approve the final version of the report.

v. The final version of the report will be provided to the IO.

4. Outcomes and Final Actions

a. No Verifiable Findings of Noncompliance

i. If allegations of animal mistreatment or protocol noncompliance are not verified by the IACUC, the IACUC Chairperson will inform the PI of the IACUC's decision and the matter will be closed.

ii. A clearly minor and unintentional misinterpretation of an IACUC policy that has created no problem for an animal is an example of where a verified allegation of protocol noncompliance might lead to an explanation, not a sanction.

iii. The IACUC Chairperson will provide a final update to the individual(s) who originally reported the animal welfare/noncompliance concern, if such notification is determined to be warranted.

b. Verifiable Findings of Noncompliance

i. If allegations of animal mistreatment or protocol noncompliance are verified, the IACUC may vote to take subsequent action related to the protocol. These actions may include:
    1. Suspension or termination of animal activities/protocol (see *Policy 5.20: Suspension or Termination of Animal Activities*)
    2. Requiring changes to the animal activities/protocol
    3. Implementing measures to prevent recurrence

ii. Internal Reporting
    1. All investigations resulting in a finding of animal mistreatment or
    2. protocol noncompliance will be reported to the IO at the completion of the investigation.
    3. The IO is responsible for notifying the complainant, any persons against whom allegations were directed, and pertinent University officials about the decision of the IACUC.
    4. The IO will issue a final letter indicating the matter has been reviewed by the IACUC and outlining the results of the investigation, including any required actions pertaining to the protocol, as voted upon by the IACUC. The IO may not override the IACUC's actions pertaining to the protocol, but may choose to impose additional administrative actions beyond those recommended by the IACUC. The IO will share this information to the following individuals, as appropriate:
        a. Principal Investigator
        b. PI's Chair
        c. PI's College Dean
        d. IACUC Chairperson
        e. Supervisory and management staff
        f. Other pertinent University officials

iii. External Reporting
    1. Failure by SAU-affiliated individuals and/or IACUC protocol personnel to follow federal and SAU regulations, guidelines, policies, and procedures may require reporting to the appropriate institutional, local, state and/or federal agencies.
    2. Reportable violations may include, but are not limited to:
        a. Suspension or termination of a protocol
        b. Serious or continuing noncompliance with the PHS Policy
        c. Serious deviations from the *Guide*
        d. Serious deviations from IACUC policies and procedures
    3. If reporting is necessary, the IACUC Chairperson, ORCI staff, and IO will prepare the necessary report. The report should include a full description of the violation(s) and the appropriate corrective actions that have been taken and/or are planned. A timeline for the implementation of future planned corrective actions should be included as appropriate. The IO is responsible for submitting the report to the appropriate institutional or agency.

c. Confidentiality

i. All deliberations of the IACUC related to a noncompliance investigation are confidential and should not be referenced in non-IACUC-related matters.
ii. Only the final report will be shared as deemed appropriate by the IO.

Policy 5.20: Suspension or Termination of Animal Activities

Policy

The IACUC will take appropriate action to minimize risks to the well-being of animals used for research and educational activities. These actions may include suspension or termination of some or all animal activities.

Procedures and Regulatory Guidance

1. The reasons an IACUC protocol may be subject to suspension or termination include, but are not limited to:
    a. Failure to comply with applicable laws, IACUC policies and procedures, or instructions from the IACUC
    b. Failure to submit required documents or reports in the time frame specified by the IACUC
    c. Failure to promptly and accurately disclose to the IACUC important material information concerning known or suspected risks to animal subjects
    d. Implementation of unapproved animal activities that require IACUC review and approval
    e. Falsification of documents or otherwise conceal information related to risks to animal subjects
    f. Failure to maintain records as required by the IACUC, including records of unexpected problems or adverse events
    g. New information revealing a significant increase in potential risk to animal subjects
    h. Serious unanticipated problems or adverse events

2. Suspension of Animal Activities
    a. When animal welfare concerns are identified, the IACUC Chairperson, the IACUC veterinarian, the IO, and/or the RIO may suspend an animal activity when, until such time that the IACUC can convene and formally consider the matter. See *IACUC Policy 5.10: Animal Welfare Concerns and Noncompliance*.
    b. The IACUC is authorized to suspend or terminate any activity involving animals if it determines that the activity is not being conducted in accordance with the approved protocol, provisions of PHS Policy, the *Guide*, or SAU's Assurance.
    c. In order to suspend or terminate an approved activity, it will be necessary to convene a meeting of the IACUC with a quorum present. A majority vote of the quorum present in favor of suspension is required to suspend or terminate an activity.
    d. If the IACUC votes to suspend or terminate an approved activity, the IO, in consultation with the IACUC, will notify in writing or by email the Provost, the RIO, the PI, and the PI's Chair that the ongoing activity has been suspended.

3. Reporting Requirements
    a. The suspension or termination of animal activities may require reporting to the appropriate local, state and/or federal agencies.
    b. If reporting is necessary, the IACUC Chairperson and IO will prepare the necessary report. The report should include a full description of the violation(s) and the appropriate corrective actions that have been taken and/or are planned. A timeline for

the implementation of the planned corrective actions should be included. The IO is responsible for submitting the report to the appropriate agency.

Policy 5.30: Animal Holding Policy

Policy

1. Circumstances can arise in which animals held for a study are no longer covered by an IACUC approved protocol. The IACUC provides approval under this policy to provide for the health and well-being of the animals. This policy establishes a mechanism for holding animals not assigned to a current SAU protocol. It is intended as a temporary mechanism to avoid euthanasia and assure animal well-being. During this time, investigators must take the necessary actions to gain approval of their animal use protocol in order to avoid forfeiture of their animals.

2. When animals are transferred to the holding policy, the following conditions exist:
    a. A member of the IACUC will be appointed by the chairperson to serve as the Acting Principal Investigator and will be responsible for the animals' care and well-being.
    b. Feeding, sanitation, and environmental enrichment will be performed as expected for the species.
    c. Animals cannot be used for research, instructional purposes, or testing.
    d. Animals must not be euthanized for research purposes. No tissue may be obtained from animals that are housed or euthanized under the Animal Holding Policy. Any use of animals housed under the Animal Holding Policy will be treated as serious noncompliance.
    e. The Attending Veterinarian has full discretion and authority for all veterinary treatment and euthanasia of animals on the Animal Holding Policy.

Procedures and Regulatory Guidance

1. Acting Principal Investigator
    a. The following individuals, in order, are responsible for the animals on the Holding Policy and will serve as the Acting Principal Investigator:
        i. IACUC Chairperson
        ii. IACUC Vice Chairperson
        iii. A member of the IACUC, appointed by the chairperson.
    b. In the event the individual listed is not able to fulfill the duties of Acting Principal Investigator (i.e., due to availability and/or a conflict of interest such as serving as personnel on the protocol from which the animals originated), the responsibility will fall to the next individual on the list.

2. Use of the Animal Holding Policy
   Situations when the Animal Holding Policy can be utilized include, but are not limited to, the following:
    a. Animals from an expired or terminated protocol
    b. Animals on a protocol that has been suspended or is under investigation for potential noncompliance issues where the welfare or well-being of the animals are in question
    c. Investigators new to SAU who do not have an IACUC-approved protocol, but need immediate housing of animals at SAU.
    d. Investigators leaving SAU, but who do not have the necessary approvals to transfer animals to the new institution

e. Investigators whose ability to serve as an active PI is unexpectedly compromised

3. Conditions and Limitations of Work with Animals on the Animal Holding Policy

a. Animal Care Details

The Acting Principal Investigator and Attending Veterinarian must be notified of any significant research or health-related conditions prior to the transfer of animals to the Animal Holding Policy. Examples of important information include, but are not limited to:

i. Existing surgical implants
ii. Zoonotic and/or infectious disease potential
iii. Special dietary needs
iv. Past surgical history
v. Genetic anomalies that affect the appearance, health and normal behavior of the animal
vi. Viral vectors
vii. Poor fecundity

b. Maintenance/Husbandry of Animals

The Acting Principal Investigator may delegate maintenance/husbandry responsibilities (e.g., feeding, sanitation, environmental enrichment, etc.) to other qualified individuals, such as investigators from other animal protocols, personnel from the protocol from which the animals originated (depending upon the circumstances), or other persons with sufficient knowledge about the particular species being held.

c. Necessary Special Diets or Oral Medications

Special diets or necessary medications may continue to be provided to the animals while on the Animal Holding Policy under veterinary oversight.

d. Euthanasia

The Acting Principal Investigator does not have the authority to euthanize any animals on this policy without prior explicit permission from the Attending Veterinarian.

e. Time on Holding Policy

Animals remaining on the Animal Holding Policy for over 60 days will initiate a review by the IACUC. The IACUC will determine if ongoing maintenance on the Animal Holding Policy is appropriate or, if disposition of the animals is necessary, an appropriate course of action for disposition.

f. Reporting to the IACUC

Faculty will report any transfers that have occurred in accordance with this policy to the IACUC at its next scheduled meeting.

g. Costs

Costs associated with maintaining animals on this Animal Holding Policy will be the responsibility of the PI and/or the academic unit(s) from which the protocol originated. If animals are being housed under this policy for a new SAU investigator, the costs will be the responsibility of the academic unit(s) to which the new investigator will locate.

Policy 5.40: Animal Adoptions

Policy

Retired animals used in research and/or educational activities may be adopted out of SAU by the PI of the protocol of record for that animal. All IACUC animal adoptions require approval from the Attending Veterinarian before the animal may be released for adoption.

Procedures and Regulatory Guidance

1. Retired animals are defined as animals obtained or bred during an approved IACUC protocol that are no longer needed for completion of the protocol and which will not be transferred to a different protocol or to another animal facility for further research or educational purposes.

2. A SAU IACUC Adoption Form (Appendix 1) must be completed for any animal adopted from an IACUC protocol. No animal may be adopted out without a completed form and prior approval of the Attending Veterinarian. The PI shall provide a copy of the completed form IACUC chairperson within five (5) business days of removing the animal from SAU property.

3. The SAU IACUC shall retain the adoption documents for a minimum of three years from the date of adoption.

Policy 5.50: Post-Approval Compliance Review

Policy

1. The purpose of post-approval compliance review is to ensure adequate protection of animal subjects used in research and educational activities. The principal use is in monitoring the implementation of approved protocols, identifying areas that need improvement, targeting education needs of researchers, and gathering information for continuous improvement of IACUC processes. This compliance review program is separate from the IACUC continuing review process.

2. Compliance review of approved research protocols may be conducted either randomly or for cause at any time. Compliance review authority may include, but is not limited to, the following:
    a. Observation of animal husbandry
    b. Observation of procedures involving animals
    c. Inspection of physical spaces (animal storage rooms, laboratories, food storage locations, etc.) and all equipment associated with the protocol
    d. Review of all documents and materials pertaining to the permission for or conduct of research activities, including training records of protocol personnel

Procedures

1. Selection of protocols for compliance review
    a. Reports of animal welfare concerns
    If an animal welfare concern or complaint is discovered or reported to any member of the IACUC, the IO, or the University RIO, *Policy 5.20: Animal Welfare Concerns and Noncompliance* will be followed.
    b. For-cause compliance reviews
    If a concern or complaint unrelated to animal welfare is discovered or reported to any member of the IACUC, the IO, or the University RIO, a for- cause compliance review may be initiated. The determination of the need for a for-cause compliance review shall be made by the IACUC Chair in consultation with the IO, and the RIO. A for-cause compliance review may occur at any time.
    c. Selected not-for-cause compliance reviews
    Certain animal use protocols may be selected for a compliance review based on the following study factors: USDA oversight; external sponsorship; and/or the use of animals meeting USDA Reporting Code Category D or E.
    d. Random compliance reviews
    Animal use protocols may be randomly selected for a compliance review at any time. No more than 30 percent of all open research protocols shall be chosen for selected not-for-cause and random compliance reviews per academic year.
    e. Requests from PIs for voluntary post-approval compliance reviews will be considered.

2. Conducting a compliance review
    a. The IACUC has the principal responsibility for conducting compliance reviews of protocols involving animal subjects.

b. Due to the nature of the work involved, routine compliance review of field studies may be limited to review of records and an interview with the PI (and, if applicable, other study team members).

c. External sponsors of animal protocols may conduct research compliance audits, investigations, site visits, or evaluations as detailed in the sponsor contract. Such audits, investigations, site visits and evaluations may be random or for-cause and must be coordinated in advance through the SAU Office of the Provost under the direction of the IO. The procedures detailed in this policy are applicable only to internal audits of protocols; audits conducted by an external sponsor may be carried out via different procedures than those described in this policy.

3. Confidentiality

The content of any findings resulting from compliance review proceedings shall be kept appropriately confidential by all parties involved in the compliance review, provided no animal welfare issues are identified during the review. A signed confidentiality agreement may be requested of participating parties. Aggregate, de-identified summary of routine reviews (i.e., those not identifying animal welfare issues) will be periodically provided to the IACUC; see Section 7 for more details. If an animal welfare issue is identified during the review, confidentiality cannot be promised; see Section 8 below for more details.

4. Notification of Investigators

The PI of a protocol selected for random or selected not-for-cause compliance reviews shall be notified at least ten (10) working days in advance of the compliance review visit and will be provided with a self-assessment checklist at the time of notification. The PI of a protocol who has been selected for a for-cause compliance review will generally, but not always, be notified at least one (1) working day in advance of the compliance review visit; a self-assessment checklist may, but not always, be provided at the time of notification of a for-cause compliance review.

5. Compliance Review Visit and Final Report

IACUC, along with any identified experts if needed, will meet with the PI and other team members as appropriate to conduct an in-person compliance review visit. Informal feedback will be given to the PI during the visit; following the completion of the compliance review, IACUC will draft a final written report. This report will be sent to the PI for review. If the PI wishes to respond to the report, they must do so, in writing, within five (5) business days. Pertinent documents related to the compliance review visit, including any subsequent written response from the PI following the final report, will be stored with the IACUC chairperson.

6. Reporting to the RIO

If subsequent to the conduct of a compliance review, the IACUC has reasonable suspicion of serious or continuing noncompliance, or of research misconduct as defined by SAU policy, the final written report shall be submitted to the RIO.

Policy 5.60: Closure of IACUC Protocols

Policy

1. Once a study has concluded and/or the protocol has expired, the PI is responsible for submitting a closure report to the IACUC.

2. The PI may close an IACUC protocol at any time during the approval period of the protocol. If a protocol is voluntarily closed, but the PI wishes to restart the animal work, a new protocol must be submitted to the IACUC for approval.

3. Unless a protocol has been previously closed, it will be considered closed upon the third anniversary of its approval date. PIs who wish to continue protocols beyond the three- year approval period must submit a new protocol to the IACUC for approval.

4. Failure to submit a clos3ure report within 30 calendar days after the protocol expiration date is considered noncompliance. Refer to *IACUC Policy 5.10: IACUC Review of Animal Welfare Concerns, Adverse Events, Protocol Deviations, and Noncompliance*.

Procedures

1. Report Submission
    a. PIs must complete and submit the closure report and submit to the IACUC chairperson.
    b. The IACUC will attempt to send the PI email notification reminders at 90, 60, 30, and 7 days before protocol expiration, on the date of protocol expiration, and if the closure report is not submitted, at 20 and 30 days after protocol expiration.
    c. No research, testing, or instructional use of animals may occur upon protocol closure.

2. Report Review
    a. Upon receipt of a closure report, the report and all supporting documents are sent to the IACUC Chair, or delegate IACUC member, for review.
    b. The reviewer will ensure that:
        i. The protocol was conducted in accordance with the approved protocol.
        ii. Modifications received IACUC approval prior to implementation.
        iii. No unanticipated or adverse events were experienced, or such events were documented and reported appropriately.
    c. Any potential compliance issues identified in the review will be further investigated by the IACUC. Refer to *IACUC Policy 5.10: IACUC Review of Animal Welfare Concerns, Adverse Events, Protocol Deviations, and Noncompliance*.