



Stephen F. Austin State University

Institutional Animal Care and Use Committee

Policies and Procedures Manual

**Stephen F. Austin State University  
Institutional Animal Care and Use Committee  
Policies and Procedures Manual**

**Effective Date: March 9, 2018**

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## **Section 1: Introduction**

### **1.1 Purpose of Manual**

The purpose of this manual is to satisfy requirements of the Animal Welfare Act, Animal Welfare Regulations, and Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy), and to provide clarification and interpretation of these laws to SFASU Institutional Animal Care and Use Committee (IACUC) members, administrators and researchers.

This manual applies to funded or unfunded activities involving contact with or manipulation of live, vertebrate animals for research, research training, experimentation, teaching, biological testing or related purposes by any Stephen F. Austin State University (SFASU) faculty, staff or student, or by any researcher from an external institution collaborating with SFASU researchers or using SFASU facilities.

### **1.2 SFASU IACUC Statement (SFASU Policy 8.6)**

**Original Implementation:** April 17, 2012

**Last Revision:** January 29, 2019

The Stephen F. Austin State University Institutional Animal Care and Use Committee (IACUC) is responsible for the review of research and teaching activities that involve vertebrate animals.

This review process ensures that all university activities comply with government regulations set forth by the United States Department of Health and Human Services, Office of Laboratory Animal Welfare (OLAW) and by the United States Department of Agriculture-Animal and Plant Health Inspection Service (USDA-APHIS) under the Animal Welfare Act (AWA).

The IACUC will consist of a minimum of five (5) members, including: at least one faculty member representing an academic department utilizing vertebrate animals for research, testing, or training; one member from a department that does not utilize animals in research; one doctor of veterinary medicine; and one member of the community not associated with the university. The committee will meet at least twice per year and on an as-needed basis to review faculty research proposals that involve vertebrate animals and complete any additional tasks required by law.

The IACUC will establish and publish the processes that must be followed when vertebrate animals are to be used in research. The dean of research and graduate studies will serve as the institutional official (IO). The IACUC reports to the IO, who possesses administrative and operational authority to ensure compliance with relevant policies from OLAW and the AWA.

No activities involving vertebrate animals can be carried out without approval from the IACUC. This includes activities that may be considered exempt activities and/or exempt animals.

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This policy applies to all activities, teaching and research, that involve vertebrate animals that are: sponsored by the university; conducted by university faculty, staff, visitors, or students; and conducted using property and/or facilities owned by the university.

Failure to comply with applicable federal policies related to animal care and use may result in civil and/or criminal penalties, and may also result in loss of federal funding to the university.

**Cross References:** 9 C.F.R. § 2.31; Animal Welfare Act, 7 U.S.C. 2131 et. seq.; Office of Laboratory Animal Welfare, *Guide for the Care and Use of Laboratory Animals*, 8th edition; Office of Laboratory Animal Welfare, *Institutional Animal Care and Use Committee Guidebook*, 2nd edition; ORSP Grants and Contracts Procedures Manual; SFASU IACUC Policies and Procedures Manual.

**Responsible for Implementation:** Provost and Vice President for Academic Affairs

**Contact for Revision:** Dean of Research and Graduate Studies

**Forms:** Animals in Research Protocol; IACUC Application – short form

**Board Committee Assignment:** Academic and Student Affairs

### 1.3 Office of Laboratory Animal Welfare

The Office of Laboratory Animal Welfare (OLAW) implements Public Health Service (PHS) Policy. OLAW is organizationally located 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. OLAW issues policy guidance, interpretations, or general notices regarding PHS Policy, and co-sponsors animal welfare workshops held in different locations across the country.

Specific OLAW responsibilities include:

- Implementation of the PHS Policy;
- Interpretation of the PHS Policy;
- Negotiation of Animal Welfare Assurances;
- Evaluation of compliance with the PHS Policy; and
- Education of institutions and investigators receiving PHS support.

SFASU currently does not receive funding in support of animal research that requires an Animal Welfare Assurance with OLAW. SFASU voluntarily complies with the requirements set forth by OLAW.

### 1.4 United States Department of Agriculture (USDA)

In 1966, Congress passed the Laboratory Animal Welfare Act (PL 89-544) and the United States Department of Agriculture (USDA) was named the responsible agency for the enforcement of



the Animal Welfare Act (AWA) to protect certain animals from inhumane treatment and neglect. Congress passed the AWA in 1966 and strengthened the law through amendments in 1970, 1976, 1985, and 1990. The USDA's Animal and Plant Health Inspection Service (APHIS) administers the AWA, its standards, and its regulations.

SFASU voluntarily complies with the requirements set forth by the USDA.

#### ***1.4.1 The Animal Welfare Act***

The Animal Welfare Act (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. Although Federal requirements establish acceptable standards, they are not ideal. Regulated businesses are encouraged to exceed the specified minimum standards.

### **1.5 Association for Assessment and Accreditation of Laboratory Animal Care, International (AAALAC)**

The Association for Assessment and Accreditation of Laboratory Animal Care, International (AAALAC) is a private, nonprofit organization that promotes the humane treatment of animals in science through voluntary accreditation and assessment programs.

Institutions choose to participate in the AAALAC accreditation program for a variety of reasons. Some use accreditation as a symbol of quality—it shows that an institution is serious about setting, achieving and maintaining high standards for animal research programs. AAALAC accreditation also promotes scientific validity—when research involves animals, reliable results depend on healthy animals and superior animal care. And perhaps most importantly, accreditation demonstrates a willingness to go above and beyond the minimums required by law, and assures the public that the institution is committed to the responsible use and treatment of animals in science.

SFASU does not conduct animal research at a level for participation in AAALAC's program but utilizes AAALAC guidance as best practices standards of care.

### **1.6 Definitions**

The following are definitions for terms as used throughout these guidelines.

**Activities:** Include, but are not limited to, research, research training, biological testing, and instruction of students.

**Amendment:** A technical description of a proposed change to a previously approved protocol

**Animal:** PHS Policy defines an animal as “any live, vertebrate animal used or intended for use in research, research training, experimentation, or biological testing, or for related purposes”. The Animal Welfare Act Regulations (AWAR) define an animal as “any live or dead dog, cat, nonhuman primate, guinea pig, hamster, rabbit, or any other warm-blooded animal, which is being used or is intended for use for research, teaching, testing, experimentation, or exhibition purposes, or as a pet. This term excludes birds, and rats and mice bred for use in research.” The SFASU IACUC ensures the campus is in compliance with all regulations by applying the PHS and OLAW regulations to all vertebrate animal use on campus for teaching and research. Studies involving dead animals require reporting and justification to the IACUC but the IACUC does not require the PI to report the use of dead animals via a protocol unless the animals are killed for the purpose of the research or teaching activity. The SFASU IACUC considers embryos and fetuses as vertebrate animals if their central nervous system is sufficiently developed to feel pain. The SFASU IACUC has adopted an institutional-wide Assurance, which means that the policies stated herein apply to **all** vertebrate animal use in research and teaching.

**Animal Care and Use Program (ACUP):** The combined components of an institution’s operations involved in the care and use of animals for research, teaching, and testing. There may be many components to a Program, but it must include:

1. The designation of an Institutional Official (IO)
2. The appointment of an Institutional Animal Care and Use Committee (IACUC)
3. Administrative support for the IACUC
4. Standard IACUC procedures
5. Arrangements for a veterinarian with authority and responsibility for animals
6. Adequate veterinary care
7. Formal or on-the-job training for personnel that care for or use animals
8. An occupational health and safety program for those who have animal contact
9. Maintenance of animal facilities

**Animal Facility:** An animal facility is any and all areas, buildings, enclosures, rooms or vehicles, including satellite facilities used for: animal confinement, breeding, experiments including surgical manipulation, maintenance or transport. Animals may be held outside an animal holding facility for a period of less than 12 hours without IACUC approval except for survival surgery areas. Locations where animals are held for more than 12 hours become a satellite facility requiring justification of, and prior approval by, the IACUC, and approval of husbandry plans and physical plant.

**Animal Use:** Animal use refers to the conduct of research, teaching, or testing activities that involve the use of animals in any way.

**Animal Use Protocol:** The protocol is a written description of a planned research, teaching, or testing activity that involves the use of vertebrate animals. It must provide sufficient detail and documentation to allow members of the IACUC to understand exactly what will be done with/to the animals and why it is necessary; and to determine that the described activities will be conducted in accordance with applicable laws, policies, and regulatory requirements.

**Animal Welfare Act (AWA):** Public Law 89-544, 1966, as amended (P.L. 91-579, P.L. 94-279, and P.L. 99-198) 7 U.S.C. 2131 Et. Seq. Implementing regulations are published in the Code of Federal Regulations (CFR, Title 9, Chapter 1, Subchapter A, parts 1,2, and 3) and are administered by the U.S. Department of Agriculture.

**Assurance:** Assurance of Compliance with the U.S. Public Health Service Policy on Humane Care and Use of Laboratory Animals.

**Care and Use:** Petting, feeding, watering, cleaning, manipulating, loading, crating, shifting, transferring, immobilizing, restraining, treating, training, working and moving, or any similar activity with respect to any animal.

**Complainant:** An individual who reports a concern or complaint about the way in which animals at SFASU are being used or cared for.

**Designated Representative:** A project representative is someone appointed by the principal investigator to direct or oversee the project. Even though the PI may appoint someone to this role, the PI holds final responsibility for all aspects of the project.

**The Ag Guide:** The current edition of the *Guide for the Care and Use of Agricultural Animals in Research and Teaching*. The *Ag Guide* has been deliberately written in general terms so that the recommendations can be applied in the diverse institutions that use agricultural animals in agricultural research and teaching in the United States.

**The Guide:** The most current version of the National Research Council publication, *Guide for the Care and Use of Laboratory Animals*, which is intended to assist institutions in caring for and using animals in ways judged to be scientifically, technically, and humanely appropriate; and to assist investigators in fulfilling their obligation to plan and conduct animal experiments in accord with the highest scientific, humane, and ethical principles.

**Institutional Animal Care & Use Committee (IACUC):** A committee comprised of at least 5 members who are appointed by the President of the University, and that acts as an advisory board to the Institutional Official and is responsible for overseeing the university's adherence to all applicable requirements governing the use of vertebrate animals.

**Institutional Official (IO):** The formally designated senior official with the authority to administer the Animal Care and Use Program, to allocate the resources necessary to operate the Program, and to make commitments on behalf of the institution to ensure compliance with the Animal Welfare Act Regulations, the Public Health Service Policy, and any other applicable Federal, State, or local laws, policies, and regulations.

**Mistreatment:** Wrongful or abusive physical or psychological treatment of an animal.

**Non-compliance:** Failure to follow federal, state, local, or institutional regulations or fulfill official requirements. IACUC has the legal authority to stop a research project, either

temporarily or permanently, if noncompliance continues. The IO can initiate additional disciplinary action involving academic oversight authorities. Noncompliance must be reported to the IO, who must then report it to the PHS. Some instances might require reporting to other local, state, or federal departments or agencies.

**Principal Investigator (PI):** The researcher, instructor, or tester who conducts, and/or supervises others who conduct, activities involving animals. Only full-time SFASU faculty or staff members serve as PIs. Student investigators may be named as co-investigators, with appropriate direction and supervision provided by the PI. The PI accepts full responsibility for all aspects of the project.

**Protocol:** A technical overview of the animal care and use portions of a research project. Only full-time faculty members or qualified staff at SFASU that are sufficiently experienced in animal procedures are qualified to submit a protocol.

**Public Health Service (PHS):** The Public Health Service includes the Alcohol, Drug Abuse and Mental Health Administration; the Centers for Disease Control; the Food and Drug Administration; the Health Resources and Services Administration; the National Institutes of Health; and the Office of the Assistant Secretary for Health, Department of Health and Human Services.

**Quorum:** A majority (>50%) of the voting members of the IACUC. Certain official actions of the IACUC, such as full committee review of a research project or suspension of an activity, require a quorum. Abstentions from voting do not alter the quorum or change the number of votes required. For example, if the IACUC consists of 12 voting members and 8 are present at a particular meeting, approval of a protocol would require a minimum of 5 votes whether or not there are any abstentions.

**Respondent:** An individual who is allegedly responsible for the circumstances leading to a reported concern or complaint regarding the care and use of animals, and who may be asked to respond to the complaint.

**Satellite Facility:** A "satellite" laboratory animal facility is any containment outside of a core facility, centrally designated or managed area in which animals are housed for more than 12 hours.

**Violation:** Disregard for or infringement of the rules or regulations.

## 1.7 Acronyms

<b>ACUP</b>	Animal Care and Use Program/Protocol
<b>AWA</b>	Animal Welfare Act
<b>AWRs</b>	Animal Welfare Act Regulations
<b>AV</b>	Attending Veterinarian
<b>BC</b>	Biosafety Committee
<b>CO</b>	Compliance Official

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<b>HP</b>	Holding Protocol
<b>IACUC</b>	Animal Care and Use Committee
<b>IO</b>	Institutional Official
<b>OLAW</b>	Office of Laboratory Animal Welfare, Office of Extramural Research, U.S. Department of Health and Human Services
<b>SFASU</b>	Stephen F. Austin State University
<b>PI</b>	Principle Investigator

## Section 2: The Institutional Official (IO)

*The U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training, which were incorporated into the PHY Policy in 1986, include the first reference to the Institutional Official – “Whenever U.S. Government agencies develop requirements for testing, research, or training procedures involving the use of vertebrate animals, the following principles shall be considered; and whenever these agencies actually perform or sponsor such procedures, the responsible Institutional Official shall ensure that these principles are adhered to:”*

*Neither the Animal Welfare Regulations nor the PHS Policy specifically prescribes the appointment of an Institutional Official; however the role of the Institutional Official is referred to throughout both documents. The following are just a few of those references:*

*AWR Section 2.31(c)(3) states that the IACUC shall, “Prepare reports of its evaluations ..., and submit the reports to the Institutional Official of the research facility;” ... “A significant deficiency is one which ... in the judgment of the IACUC and the Institutional Official, is or may be a threat to the health or safety of the animals.”*

*AWR Section 2.31(c)(5) states that the IACUC shall, “Make recommendations to the Institutional Official regarding any aspect of the research facility’s animal program, facilities, or personnel training;”*

*AWR Section 2.31(d)(7) – “If the IACUC suspends an activity involving animals, the Institutional Official, in consultation with the IACUC, shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to APHIS and any Federal agency funding that activity;”*

*PHS Policy Part III.G. defines Institutional Official as “An individual who signs, and has the authority to sign the institution’s Assurance, making a commitment on behalf of the institution that the requirements of this Policy will be met.”*

*PHS Policy Part IV.B.3. states that the IACUC shall “prepare reports of the IACUC evaluations conducted as required by ... and submit the reports to the Institutional Official.”*

*PHS Policy Part IV.F. – “At least once every 12 months, the IACUC, through the Institutional Official, shall report in writing to OLAW:”*

### 2.1 The Institutional Official (IO)

Ultimately, SFASU is accountable for the humane care and use of animals. The PHS Policy and the AWRs emphasize the responsibilities of an institution’s senior management through an individual designated and the Institutional Official (IO), and the use of the IACUC as an oversight committee to evaluate the Animal Care and Use Program. The IACUC reports directly to the IO who must provide appropriate resources to allow the IACUC to meet its responsibilities. The Attending Veterinarian also reports directly to the IO.

### 2.2 Responsibilities of the Institutional Official

While SFASU is responsible for maintaining an Animal Care and Use Program that is in compliance with the PHS Policy and the AWRs, the IO is the individual held responsible on behalf of the institution for ensuring compliance.

Penalties for non-compliance could include OLAW's withdrawal of the university's Assurance, which would result in loss of all PHS grant funding (including NIH); and the USDA may impose fines of up to \$10,000 for each violation of the Animal Welfare Act or the AWRs.

The Institutional Official must:

- provide appropriate resources for the Animal Care and Use Program based on the recommendations of the IACUC, the Attending Veterinarian, and the ACUP staff
- define and assign responsibilities and reporting channels for essential program areas such as personnel training, occupational health and safety, and facility maintenance
- sign as the individual responsible

The Dean of Research and Graduate Studies been designated by the Board of Regents/President to serve as the Institutional Official for SFASU's Animal Care and Use Program.

The IO meets on a regularly scheduled basis with the IACUC Chair to ensure that the program and facilities meet the highest possible standards for animal care and use, and that any identified deficiencies are corrected in a timely fashion.

### **2.3 Recommendations to the Institutional Official**

*Section 2.31 (c)(5) of the AWRs and Part IV.B.5.of the PHS Policy state that the IACUC is to “make recommendations to the Institutional Official regarding any aspect of the research facility’s animal program, facilities, or personnel training.”*

The Chair of the IACUC meets with the Institutional Official at least once every six months to discuss issues of concern regarding the Animal Care and Use Program and to review the status of the IACUC's recommendations included in the semi-annual program reviews and facility inspection reports. The chair will provide a written report to the committee regarding the meeting with the IO.

The Attending Veterinarian reports directly to the IO any problems he/she has identified with the health, safety, or veterinary care of the animals, making recommendations for corrections and improvements.

### **2.4 Liability**

Under PHS Policy, the primary responsibility for meeting applicable federal and state rules rests with the research facility or PHS awardee institution. The Institutional Official (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 institution's Animal Welfare Assurance, thereby making the institution ineligible to receive Federal funds for activities involving animals. Failure to comply with the Animal Welfare Act could result in the USDA's assessment of monetary fines.

### **Section 3: The Institutional Animal Care and Use Committee (IACUC)**

– Section 2.31 (a): *The Chief Executive Officer of the research facility shall appoint an Institutional Animal Care and Use Committee (IACUC), qualified through the experience and expertise of its members to assess the research facility’s animal program, facilities, and procedures. Except as specifically authorized by law or these regulations, nothing in this part shall be deemed to permit the Committee or IACUC to prescribe methods or set standards for the design, performance, or conduct of actual research or experimentation by a research facility.*

*(b) IACUC membership.*

*(1) The members of each Committee shall be appointed by the Chief Executive Officer of the research facility;*

*(2) The Committee shall be composed of a Chairman and at least two additional members;*

*(3) Of the members of the Committee:*

*(i) At least one shall be a Doctor of Veterinary Medicine, with training or experience in laboratory animal science and medicine, who has direct or delegated program responsibility for activities involving animals at the research facility;*

*(ii) At least one shall not be affiliated in any way with the facility other than as a member of the Committee, and shall not be a member of the immediate family of a person who is affiliated with the facility. The Secretary intends that such person will provide representation for general community interests in the proper care and treatment of animals;*

*(4) If the Committee consists of more than three members, not more than three members shall be from the same administrative unit of the facility*

*PHS Policy – Part IV.3. – Institutional Care and Use Committee (IACUC)*

*a. The Chief Executive Officer shall appoint an Institutional Animal Care and Use Committee (IACUC), qualified through the experience and expertise of its members to oversee the institution’s animal program, facilities, and procedures.*

*b. The Assurance must include the names, position titles, and credentials of the IACUC chairperson and the members. The committee shall consist of not less than five members, and shall include at least:*

*(1) one Doctor of Veterinary Medicine, with training or experience in laboratory animal science and medicine, who has direct or delegated program authority and responsibility for activities involving animals at the institution;*

*(2) one practicing scientist experienced in research involving animals;*

*(3) one member whose primary concerns are in a nonscientific area (for example, ethicist, lawyer, member of the clergy); and*

*(4) one individual who is not affiliated with the institution in any way other than as a member of the IACUC, and is not a member of the immediate family of a person who is affiliated with the institution.*

*c. An individual who meets the requirements of more than one of the categories detailed in IV.A.3.b.(1)-(4) of this policy may fulfill more than one requirement. However, no committee may consist of less than five members.*

The SFASU Institutional Animal Care and Use Committee (IACUC) serves as an advisory body to the university’s Institutional Official (IO), and acts to facilitate research that serves the mission and values of the university; to protect the health and safety of animals and humans involved in animal research, teaching and testing; and to ensure compliance with applicable laws, regulations, and policies governing the use of vertebrate animals in such activities.



### **3.1 IACUC Authority**

Institutional Animal Care and Use Committees (IACUC's) derive their authority from the law. The Health Research Extension Act (HREA) of 1985 and the Animal Welfare Act 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 Office of Laboratory Animal Welfare (OLAW) considers the CEO to be the highest operating official of the organization. The President of Stephen F. Austin State University delegates authority through the Institutional Official (IO) to appoint the membership of the IACUC.

Once appointed, the IACUC reports to a senior administrator known as the Institutional Official (IO). The Dean of Research and Graduate Studies is SFASU's IO. The IO is given the administrative and operational authority to commit institutional resources to ensure compliance with the PHS Policy and other requirements.

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 the Institution'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.

The IACUC's authority to review and approve protocols is independent of the IO, who may not overrule an IACUC decision to withhold approval of a protocol. If the IACUC approves a protocol, however, the Institution is not required or obligated to conduct the research activity. The Institution may also subject protocols to additional institutional review (e.g., department head, Biosafety committee, etc.).

SFASU has established an Institutional Animal Care and Use Committee, which is qualified through the experience and expertise of its members to oversee the Institution's animal program, facilities, and procedures.

### **3.2 IACUC Roles and Responsibilities**

The IACUC is responsible for reviewing all research, teaching, or testing activities in which animals are used as research subjects. IACUC oversight covers all use of live vertebrate animals by SFASU personnel whether in SFASU facilities, at other institutions, or in the wild as a part of field research. The IACUC is responsible for reviewing and approving all animal use prior to the start of the work, and for continuing oversight of approved projects. The IACUC conducts an annual review of each approved protocol, and if a project is continuing, requires submission of a new protocol every three years to comply with PHS policy as well as to vigilantly oversee the use of animals.

Not only is the IACUC responsible for ensuring that the protocols conform to acceptable standards and meet regulatory requirements, it also ensures that the animal care program is in

compliance. In this regard, the IACUC undertakes semi-annual program reviews and facilities inspections. This includes review and oversight of the activities of the Animal Care and Use Program Office as well as a review of animal care policies and procedures to ensure continued adherence to the highest standards of animal care and use. The results of these reviews are communicated to the Institutional Official for his/her consideration and action. Additionally, they form the basis for the required annual reporting to OLAW and USDA.

As part of its charge, the IACUC is expected to oversee the ACUP on a continual basis and to report problems to the Institutional Official.

The IACUC's many responsibilities can be summarized under the following general areas:

- Review the university's program for the humane care and use of animals at least every six months.
- Prior to commencement of animal work and at least every six months, inspect all of the University's animal facilities, including all locations in which animals are housed and/or manipulated.
- Prepare reports of program reviews and facility inspections that identify minor and significant deficiencies and that include a plan and schedule for correcting each noted deficiency.
- Review and investigate reported concerns involving the care and use of animals and reports of noncompliance received from laboratory or research facility personnel or employees.
- Make recommendations to the Institutional Official regarding any aspect of the animal program, facilities, or personnel training.
- Review and approve or disapprove those components of proposed activities, or modifications to previously approved activities, related to the care and use of animals, including post-approval monitoring of approved activities.
- Suspend activities involving animals they are not being conducted according to an approved protocol, applicable laws, regulations, and/or policies.
- Prepare and submit required reports to Federal regulating agencies.

### 3.3 IACUC Membership

The composition of the SFASU IACUC will be in accordance with the combined requirements of the PHS Policy and the USDA regulations. The size of the IACUC will be at the discretion of the Institutional Official (IO); but at a minimum, will always include no less than five members, and include at least one of the following required members:

1. **Veterinarian.** The PHS Policy and 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.

2. **Scientist.** PHS Policy requires that the IACUC include a practicing scientist experienced in research involving animals.
3. **Nonscientist.** PHS Policy requires that the IACUC include a member whose primary concerns are in a nonscientific area. Examples include, but are not limited to, ethicist, lawyer, member of the clergy, librarian, etc.
4. **Nonaffiliated.** The nonaffiliated member(s) represent general community interests. Neither they, nor their immediate family, have an affiliation with SFASU. 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.
5. **Chair.** The Chair is appointed and is a faculty member with research experience.

In accordance with the Animal Welfare Act Regulations, the IACUC will not include more than three members of the same school or administrative division of the University.

The institution should consider 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).

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

**Alternate members** may be appointed to the IACUC as long as they are appointed by the IO or other official with authority to appoint members, and there is a specific one-to-one designation of IACUC members and alternates. An IACUC member and his/her alternate may not count toward a quorum at the same time or act in an official member capacity at the same time. Alternates should receive training identical to the training provided to regular IACUC members.

### **3.4 IACUC Appointments, Qualifications, and Responsibilities**

As required by the Animal Welfare Act and the Health Research Extension Act, SFASU's President, acting as CEO, delegates authority through the Institutional Official (IO) to appoint the membership of the IACUC.

Based upon the recommendations the IACUC Chair, Institutional Official (IO) appoints all members and alternate members of the IACUC.

#### **3.4.1 Chairperson**

- a. **Appointment:**  
The Institutional Official (IO) appoints the chairperson for indefinite terms.
- b. **Qualifications:** The chairperson should:

- i. Be a full-time, tenured faculty member; however, if there is no qualified tenured faculty member available to serve as chair, the Institutional Official (IO) may choose to appoint an otherwise qualified faculty or administrative staff member.
  - ii. Have prior experience on an IACUC.
  - iii. Have IACUC training.
- c. Responsibilities: The Chairperson:
  - i. Consults with the Institutional Official to recommend membership changes to the President.
  - ii. Consults with the Institutional Official to make recommendations for the Vice Chair position.
  - iii. Advises the Institutional Official on matters relating to support for the IACUC.
  - iv. Establishes the agenda for IACUC meetings.
  - v. Convenes and chairs meetings or designates an acting chair if both the Chairperson and Vice Chairperson are unable to attend meetings.
  - vi. Guides IACUC deliberations.
  - vii. Leads the IACUC in investigations of complaints and allegations of non-compliance.
  - viii. Issues official communications regarding IACUC decisions and concerns to the Institutional Official, researchers, program staff, and the Attending Veterinarian as applicable.
  - ix. Acts as spokesperson on behalf of the IACUC.

### ***3.4.2 Vice Chairperson***

- a. Appointment:

The Institutional Official (IO) appoints the Vice Chairperson for indefinite terms. If, for any reason a chairperson is not able to serve his/her full duties, the vice chairperson assumes the duties and responsibilities of the chairperson until a new chair is appointed.
- b. Qualifications: The Vice Chairperson:
  - i. Is a full-time faculty member or other qualified staff member.
  - ii. Has served on the IACUC for at least one year.
  - iii. Attends some formal training, preferably during the first year as vice-chair.
- c. Responsibilities: The Vice Chairperson:
  - i. In the absence of the IACUC Chairperson, the Vice Chairperson:
  - ii. Serves as Chairperson at convened IACUC meetings.
  - iii. Attends administrative meetings upon request.
  - iv. Acts as Chairperson in any situation where it is a conflict of interest for the chair to perform his/her duties.

### ***3.4.3 Attending Veterinarian with Program Authority***

Not having a veterinary college, SFASU contracts with a Doctor of Veterinary Medicine who is experienced in laboratory animal science to serve as the ACUP Attending Veterinarian and to fill the required veterinarian position on the IACUC.

a. Appointment:

The Attending Veterinarian (AV) is appointed for indefinite terms.

b. Qualifications: To fulfill the PHS and USDA requirements, the AV:

- i. Has graduated from a veterinary school accredited by the American Veterinary Medical Association's Council on Education, or
- ii. Has received a certificate issued by the American Veterinary Medical Association's Education Commission for Foreign Veterinary Graduates, or
- iii. Has received equivalent formal education as determined by USDA.
- iv. Is experienced or has received training in the care and management of species being attended.
- v. Has been given direct or delegated authority for activities involving animals at SFASU.

c. Responsibilities: Regarding his/her role on the IACUC, the Veterinarian has the same responsibilities as other members of the IACUC in addition to the following:

- i. Conducts a preliminary review of all new protocols, third-year resubmission protocols, and such other protocol actions as the Chairperson may request for the purpose of identifying problems and working with investigators to resolve concerns prior to distribution of protocols to the full committee.

### ***3.4.4 Voting Committee Members***

a. Appointments:

The Institutional Official (IO) appoints voting committee members for indefinite terms.

b. Qualifications:

- i. The individual(s) appointed to fill the role of scientist are practicing scientists experienced in research involving laboratory animals.
- ii. The individual(s) appointed to fill the role of unaffiliated member are not affiliated with SFASU in any way other than as a member of the IACUC, and are not a member of the immediate family of a person who is affiliated with the university.
- iii. The individual(s) appointed to fill the role of non-scientist bring a non-scientific perspective on the use of animals for laboratory research to the committee.

- c. Responsibilities:
  - i. Attend regularly scheduled IACUC meetings.
  - ii. Notify the IACUC Chair and the alternate member if attendance at a meeting is not possible.
  - iii. Read all protocols distributed to committee members.
  - iv. Review and respond in a timely manner regarding assigned protocols.
  - v. Attend and participate actively in program reviews and facilities inspections.
  - vi. Participate in investigations of complaints and allegations of non-compliance as requested.
  - vii. Lead and/or participate in subcommittees, as requested.
  - viii. Participate annually in IACUC-approved documented training.

#### ***3.4.5 Alternate Committee Members***

Each alternate member is appointed to represent one or more voting member(s). An alternate member must be qualified to fill the same role on the committee as the voting member he/she represents. An alternate member has only one vote and may be counted toward a quorum only once, regardless of the number of voting members he/she may represent. The alternate members vote counts only if they do not exceed the “3 from each unit” rule. Alternate members are encouraged to participate in all IACUC activities, but vote only when the regular members they represent are absent. An IACUC member and his/her alternate do not count toward a quorum or act in any official capacity at the same time. The alternate to the IACUC Chair votes for the Chair in his absence, but does not run the meeting.

- a. Appointments:

Alternate members are appointed to the IACUC following the same procedures for appointment of regular voting members.
- b. Qualifications:

Alternate members have the same qualifications as the regular members for whom they serve as the alternate.
- c. Responsibilities:

Alternate members are responsible for performing any duties of the regular voting members they represent when the regular voting members are absent or have a conflict of interest.

#### ***3.4.6 Ex-Officio Members***

The Office of Research & Sponsored Programs (ORSP) shall have a non-voting ex-officio member on the IACUC appointed by the Dean of Research & Graduate Studies.

### **3.4.7 Ad Hoc Members**

Non-voting attendees may be invited to participate in IACUC functions. Examples of such attendees include, but are not limited to, representatives from Building Trades, Environmental Health & Safety, or University Counsel.

### **3.4.8 Consultants**

The IACUC may choose to invite internal or external consultants to assist in its duties. Such consultants cannot vote, but can provide expert opinion on issues before the committee.

### **3.4.9 Removal of Members from the Committee**

The President of the University is the only individual authorized to remove a member of the IACUC from the committee; however, the IACUC may recommend removal of any IACUC member it determines is not responsibly fulfilling his/her duties.

Reasons for removal may include:

- Repeated failure to attend IACUC meetings.
- Failure to complete training *activities*.
- Repeated failure to complete assigned projects in a timely manner.

## **3.5 IACUC Meetings**

The IACUC meets at least once every 6 months, and a schedule is maintained by the IACUC Chair, which includes meeting dates, protocol review and annual review submission. The chair may call special meetings as needed.

Principal Investigators (PIs) or their designated representatives are encouraged to attend meetings at which their protocols are being reviewed in order to answer any questions and resolve concerns of IACUC members regarding the protocols.

## **3.6 Conflict of Interest**

Both the AWRs and PHS Policy state that no IACUC member “may participate in the IACUC review or approval of an activity in which that member has a conflicting interest, (e.g. is personally involved in the activity) except to provide information requested by the IACUC.”

All investigators, consultants, and/or IACUC members are required to disclose any conflicts of interest. An investigator or IACUC member is said to have a conflict of interest whenever that person, his or her spouse, or dependent child falls under any of the following conditions:

- Is an investigator or sub-investigator on the protocol (IACUC members only, not applicable to PI's).

- Has entered into a financial arrangement with the sponsor or agent of the sponsor, whereby the outcome of the study could influence the value of the economic interest.
- Acts as an officer or a director of the sponsor or an agent of the sponsor.
- Has an equity interest in the sponsor of \$10,000 or greater or 5% or greater of the equity sponsor.
- Has received payments or other incentives from any sponsor that when aggregated for the investigator or member, spouse and dependent children, total of \$10,000 or greater.
- Has identified him or herself for any other reason as having a conflict of interest.

Other possible examples of conflict of interest include cases where:

- A member is involved in a potentially competing research program.
- Access to funding or intellectual information may provide an unfair competitive advantage.
- A member's personal biases may interfere with his or her impartial judgment.

If the investigator submitting a protocol believes that an IACUC member has a potential conflict, the investigator may request that the member be excluded. The Chair (or in his/her absence, the Vice Chair) will present the declared conflict and the Committee 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(s):

- May remain in the meeting room to provide information requested by the IACUC.
- Leave the meeting room for discussion and voting.
- Are not counted towards quorum.

### **3.7 Confidentiality**

During the process of initial or continuing review of an activity (including, but not limited to, any annual reviews or protocol amendments), material provided to the Institutional Animal Care and Use Committee and the Office of Research and Sponsored Programs (ORSP) (administrative office that supports the IACUC) shall be considered privileged information and the IACUC shall assure the confidentiality of the data contained therein.

### **3.8 Making Recommendations to the Institutional Official**

The IACUC will make written recommendations to the Institutional Official (IO) regarding any aspect of the Institution's animal program, facilities, or personnel training. The procedures for making recommendations to the Institutional Official are as follows:

1. Recommendations regarding any aspect of the SFASU's animal program, facilities, or personnel training are formulated at convened meetings of the IACUC.
2. Recommendations are prepared in writing by the Compliance Officer (CO), the Attending Veterinarian, the IACUC Chair (or in his/her absence, by the Vice Chair),



and/or any IACUC member. A copy of these recommendations are reviewed by the IACUC. Any minority views are noted and included in the final report.

3. The IACUC Chair or his/her designee (generally the Compliance Officer) submits recommendations, including minority views that are approved by the IACUC to the IO.

## **Section 4: IACUC Research Proposals**

### **4.1 Protocol Review**

The IACUC is responsible for overseeing and evaluating all aspects of animal care and use, and is charged with reviewing proposals that involve animals to ensure that the criteria established in the PHS Policy and the Animal Welfare Regulations (AWRs) are implemented. In its review of proposals, the IACUC's primary goal is to facilitate compliance with applicable laws, regulations and policies consistent with the performance of appropriate and productive scientific endeavors.

### **4.2 General Scope of Review**

The following kinds of activities involving animals are subject to review by the IACUC prior to initiation:

- Activities conducted by SFASU faculty, staff, or students;
- Activities performed on the premises of the SFASU;
- Activities performed with or involving the use of facilities or equipment belonging to SFASU;
- Activities satisfying a requirement imposed by SFASU for a degree program or completion of a course of study; and/or
- Activities certified by a dean or department head to satisfy an obligation of a faculty appointment at SFASU, including requirements for clinical or adjunct appointments.

### **4.3 Types of Activities**

#### *Research*

Many of the animals covered in IACUC review are used in research, including medical, biological, and behavioral research. Most of these animals are acquired and housed by SFASU; some may include free-ranging wildlife.

#### *Teaching*

The use of animals in educational settings is subject to IACUC review. Examples include using animals to teach animal husbandry (see section 9.8) and biological procedures. Review is 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).

#### *Research Conducted by "Affiliated Faculty"*

Research conducted by "affiliated faculty"—those who hold clinical or adjunct appointments—is subject to the Institution's guidelines for animal use and must be submitted for IACUC review. Any research project that is conducted by or

under the direction of any employee or agent of the institution, in connection with his or her institutional responsibilities, requires IACUC approval.

*Research Collaborations and Use of Animals at Other Facilities*

Research collaborations involving SFASU faculty, staff or students and other institutions using laboratory animals must be reviewed by the SFASU IACUC, whether funded or not. If the funding for the project flows through SFASU, the SFASU IACUC will be the responsible IACUC and review the proposed activities.

If animal research activities involving SFASU personnel are conducted at domestic or foreign sites other than SFASU, the IACUC must be satisfied that PHS policies are being followed. The IACUC, at its discretion and depending on the nature of the study and the roles of SFASU personnel in the study, may choose one of three options to ensure appropriate oversight of the project:

- Accept the collaborating institution's IACUC approval, especially if that institution holds a current OLAW Assurance or is AAALAC certified.
- Conduct the review of the protocol submitted to the SFASU IACUC in the host institution's protocol format.
- Conduct a review of the research submitted on the SFASU protocol form.

In any case, the SFASU IACUC needs to review documentation from the collaborating institution that verifies IACUC review and approval of the project before the SFASU IACUC issues final approval for the SFASU Investigator to proceed.

*Research Projects in Which the Investigator is a Consultant*

In some instances, SFASU faculty or staff may serve in an advisory capacity for a research project conducted outside the SFASU community. IACUC review is required unless the investigator has a strict consulting relationship in which:

- The investigator is hired on his or her own time.
- The investigator holds no rights in the work.
- Neither the investigator nor SFASU retains any data.

Unless all three of these criteria are met, the IACUC must review the project. Review by another institution or facility's IACUC is insufficient unless a cooperative arrangement between that IACUC and the Institution's IACUC is agreed upon prior to initiating the consultant relationship.

### *Research in Foreign Countries*

Research conducted by the Institution's investigators in foreign countries falls under the Institution's purview and guidelines. Regardless of the setting, the standards for ethical and responsible use of animals in research will not be relaxed even if different customs prevail.

**All animal-based research conducted in foreign countries is subject to IACUC review.** This includes the use of animals in foreign research institutions, and fieldwork involving either domestic or wild animals.

Research projects must 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.

#### **4.4 Exemptions**

Noninvasive observation of wild animals in their natural habitat is exempt from IACUC review. Field studies that involve killing, trapping, banding, darting, implantation of telemetry devices, or any other invasive manipulation require IACUC approval.

#### **4.5 Principle Investigator**

The Principal Investigator (PI) is ultimately responsible for assuring compliance with applicable University IACUC policies and procedures, the Animal Welfare Act (AWA), the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals, the National Institute of Health (NIH), the *Guide for the Care and Use of Laboratory Animals*, and/or the *Guide for the Care and Use of Agricultural Animals in Research and Teaching*. Although the PI may delegate tasks to members of his/her research team, s/he retains the ultimate responsibility for the conduct of the study.

##### ***4.5.1 Who May Serve as a Principle Investigator***

All animal research that is conducted by or under the direction of any employee, faculty, staff, student or agent of SFASU in connection with his or her responsibilities must be under the direct supervision of a member of the SFASU faculty. Generally, faculty are considered to be sufficiently knowledgeable to supervise and/or conduct research as determined by their appointment. Because PI responsibilities involve direct interaction and supervision of the research team, the PI must be a current faculty or staff of the University and/or a person who is operating within their University. PIs leaving the institution are responsible for notifying the IACUC well in advance of their departure so that they can make arrangements to either close the study or name another appropriately qualified individual currently at the institution to serve as the PI.

The following individuals may serve as PI:

- **Faculty members:** All categories of compensated faculty members may serve as PI. Visiting faculty, adjunct faculty, lecturers, and instructors, are not permitted to serve as a PI but may serve as co-investigators.
- **Staff:** Staff may serve in this role if they have appropriate qualifications to conduct the research.

Given the responsibilities of PIs, at SFASU, students may not serve as principal investigators for their own research projects and cannot submit an IACUC application. At its discretion, the IACUC may determine that a faculty member lacks sufficient expertise to carry out any particular research project based on their relevant training and experience.

#### ***4.5.2 Co-Investigators and Research Staff***

Qualified co-investigators and research staff may perform tasks as delegated by the Principal Investigator (PI) but they do not accept primary responsibility for the research study. Research conducted by non-faculty, academic support staff, post-doctoral fellows, staff appointments, graduate students or undergraduate students must be under the direction of a faculty member, as defined above. In such cases, the faculty member shall be considered the Principal Investigator. The PI may delegate the performance of any or all components of the research to non-faculty if they certify to the IACUC that the individuals are sufficiently trained to perform the functions assigned.

Individuals that do not meet any of the above criteria may, by demonstrating sufficient cause and necessary expertise, petition the Dean of Research and Graduate Studies for permission to submit an application for approval of an IACUC protocol. Such agreement shall be in writing and require the individual to comply with all relevant IACUC and SFASU policies for the conduct of research involving animal subjects.

#### ***4.5.3 Principal Investigator's Responsibilities and Assurances***

By submitting an animal utilization protocol (ACUP) to the IACUC for review, the Principal Investigator is certifying the following:

- I assure that all students, staff, and faculty on this project are familiar with the Animal Welfare Act (AWA) and the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals, the National Institute of Health (NIH) *Guide for the Care and Use of Laboratory Animals*, the *Guide for the Care and Use of Agricultural Animals in Research and Teaching*, and recognize their responsibility in strictly adhering to approved protocols.
- I assure that all individuals listed on this project are qualified or will be trained to conduct procedures involving animals under this proposal.

- I assure that all procedure will be conducted in accordance with SFASU safety procedures, including those pertaining to personal protective equipment.
- I assure that ANY change in the care and use of animals involved in this protocol, including ANY change in the personnel listed on this protocol, that would affect their welfare will be promptly forwarded to the IACUC for review via an amendment application. Such changes will not be implemented until approval is obtained from the IACUC. Animals will not be transferred between investigators without prior approval.
- I assure that I have 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.
- I assure that every effort has been made to minimize the number of animals used and reduce the amount of pain, distress, and/or discomfort these animals must experience.
- I assure that the activities described with in this document submitted for IACUC review are consistent with those described in any related grant, contract, or subcontract.
- I assure that the information contained in this application for animal use is accurate to the best of my knowledge.
- I understand that this application and/or my animal use privileges may be revoked by the IACUC if I violate any of the aforementioned assurance statements.

It is implicit upon submission of the protocol that the Principal Investigator has read and agrees to abide by the above obligations.

#### **4.6 Protocol Review Criteria**

In order to approve proposed research projects or proposed significant changes in ongoing research projects, the IACUC shall conduct a review of those components related to the care and use of animals and determine that the proposed research projects are in accordance with PHS Policy, AWRs, and the applicable US Government Principles. Since the PHS Policy further requires that the provisions of the *Guide* and *Ag Guide* apply, there are many other aspects of research that an IACUC should review, such as food and water deprivation, use of noxious stimuli, and physical restraint. The *Guide* and *Ag Guide* provides useful guidance on these and other practices.

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 will not have a conflict of interest with the research activity and may not vote on any matters pertaining to the protocol. In all cases, the responsibility should be on the investigator to justify and explain his or her proposed experiments to the satisfaction of the IACUC.

#### **4.7 Protocol Review Procedure**

The procedural review requirements of the PHS Policy or the AWRs take precedence even though they may differ from some commonly used parliamentary procedures. SFASU may

develop its own meeting procedures as long as the procedures do not contradict or are not inconsistent with the requirements of the PHS Policy or the AWRs.

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 (AV) or his or her designee during protocol development.

The PHS Policy and AWRs recognize two methods of protocol review: Full Committee Review (FCR) and Designated Member Review (DMR). The following pertains to review of initial protocols as well as to review of proposed significant changes in previously approved protocols.

#### ***4.7.1 Full Committee Review (FCR)***

Full committee review of protocols requires a convened meeting of a quorum of the IACUC members. The PHS Policy and AWRs are explicit that proposals reviewed by the full committee must receive the approval vote of a majority of the quorum present in order to receive approval.

A week prior to a meeting, the IACUC Chairperson distributes copies of the protocols being presented or any other items of discussion to each IACUC member. The Committee votes on protocol approval. A simple majority vote of the members present is required for approval.

The Committee has the authority to approve, require modifications in (to secure approval), disapprove, or table (defer until future meeting) any proposed activity. In many cases, the Committee finds the protocols approvable on certain conditions and votes to allow the protocol to be reviewed, and approved, using the Designated Member Review (DMR) process, as described in Section 3.6.2. Approval of the change from FCR to DMR must be unanimous (of a quorum of members (Section 2.4)) and is recorded in the minutes. Committee members are given the opportunity to require that the requested modification(s) be brought before the next committee meeting. Under no circumstances will animal work be permitted to resume or begin until final approval is granted.

Reviewers can also take the initiative to contact the investigator prior to the meeting for clarifications, additional information, or in anticipation of questions the IACUC may raise.

#### ***4.7.2 Designated Member Review (DMR)***

To utilize designated member review (DMR), each IACUC member must be provided with a copy of the protocol document from the IACUC Chair. Committee members are given at minimum five (5) business days to review the protocol document and respond either allowing the DMR to review the protocol or to hold the protocol for the next FCR. Members are reminded that failure to respond within the member consideration period is considered as approval to use DMR for review. Responses can be sent directly to the DMR or the IACUC Chair via email. If any one member votes to hold the protocol until

the next IACUC meeting, then the protocol is placed on the agenda for the next IACUC meeting. Otherwise, the protocol is reviewed by the DMR.

The IACUC Chair designates one or more qualified members to review the proposal (or proposed amendment or annual renewal). These designated member(s) have authority to approve, require modifications in (to secure approval), or request full committee review. A designated reviewer may not withhold approval; this action may only be taken if the review is conducted using the full committee method of review.

#### ***4.7.3 Administrative Review (AR)***

While Federal regulations allow for two types of review of animal use protocols (FCR and DMR), recent guidance from the Office of Laboratory Animal Welfare (OLAW) granted authority for a small number of items to be administratively approved. Amendment/modification applications to existing protocols that involve certain changes not considered significant can be reviewed (and approved) administratively.

#### ***4.7.4 Notification of Review Outcome***

The IACUC Chair will notify investigators of the IACUC's 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. The procedures to notify investigators of its decisions regarding protocol review are as follows:

- Upon completion of the review process, each Principal Investigator receives a written notification of review decisions (approved, modifications required in (to secure approval), approval withheld, or tabled) and whether any special monitoring provisions will be required. Records of communication are maintained electronically within the IACUC protocol files.
- Upon completion of the review process, a copy of the meeting minutes is provided to the IO. This informs the IO of all actions taken by the IACUC.

### **4.8 Range of IACUC Actions**

Upon review of protocols, the IACUC may take one of several different actions depending upon the findings of the committee: approval, modifications required in (to secure approval), and withhold approval. An IACUC may also defer or table review of a protocol. The PHS Policy and AWRs require the IACUC to notify investigators and the institution in writing of its decision to approve or withhold approval, or require modifications in (to secure approval) of a protocol. If approval is withheld the IACUC must provide the reasons for its decision and give the investigator an opportunity to respond.



## **Approval**

When the IACUC has determined that all review criteria have been adequately addressed by the investigator, the IACUC may approve the project, thus granting the investigator permission to perform the experiments or procedures as described. The IACUC-approved proposal 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.

## **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 (e.g., receipt of assurance that the procedure will be conducted in a fume hood), or clarification of a specific point, the IACUC may handle these modifications or clarifications as administrative details that any member, such as the Chair, could verify prior to granting approval.

If a study is unusually complex or involves untried or controversial procedures the IACUC may wish to 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, the IACUC can ask the investigator to revise the protocol to reflect the modifications imposed by the IACUC.

If the protocol is missing substantive information necessary for the IACUC to make a judgment, or the IACUC requires extensive or multiple modifications, then the IACUC can require that the protocol be revised and resubmitted. If the IACUC wishes to shift to the designated member reviewer mode for the approval of the modified protocol, that shift should be explicitly noted in the meeting minutes and the requirements for designated review must be met.

## **Withhold approval**

When the IACUC determines that a proposal 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 Committee may withhold approval. A designated reviewer may not withhold approval; this action may only be taken if the review is conducted using the full committee method of review.

As indicated above, a higher institutional authority may not administratively overrule an IACUC decision to withhold approval of a proposal.

## **Defer or table review**

If the protocol requires significant clarification in order for the IACUC to make a judgment, Committee members with certain expertise are not present, the IACUC wishes to seek external consultation, or any of a number of other reasons prevent the IACUC from conducting its review, then the IACUC may wish to defer or table review until a future FCR.

## **4.9 Review of Modifications to Approved Protocols**

### ***4.9.1 Significant Changes***

Significant changes to an IACUC-approved protocol must be reviewed and approved by the IACUC before they occur (PHS Policy IV.C.1., and AWR §2.31[d][1]). The Institution interprets significant changes to mean those that have the potential to impact substantially and directly on the health and well-being of the experimental animals. Examples of significant changes include, but are not limited to, changes:

- in the objectives of a study;
- from non-survival to survival surgery;
- resulting in greater discomfort or a greater degree of invasiveness;
- in the species or in approximate number of animals used;
- in Principal Investigator;
- in anesthetic agent(s) or the use or withholding of analgesics;
- in the method of euthanasia; and
- in the duration, frequency, or number of procedures performed on an animal.

Proposed significant changes require IACUC review (and approval) prior to initiation.

### ***4.9.2 Non-Significant Changes***

The University interprets non-significant changes to mean those that do not have the potential to impact substantially and directly on the health and well-being of the experimental animals. Examples of non-significant changes include, but are not limited to, changes:

- in the funding source;
- in personnel (other than the PI); and
- in the use of a new housing location.

Proposed non-significant changes require administrative review (and approval) by the IACUC Chair prior to initiation.

## **4.10 Minimization of Pain and Distress**

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.

As required by the PHS Policy and the AWRs, and reiterated in the *Guide*, the IACUC is mandated to critically evaluate research protocols to ensure that pain and distress are minimized in laboratory animals and assure that appropriate steps will be taken to enhance animal well-being. The AWRs stipulate that the IACUC determine that the principal investigator 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. The *Guide* states that the IACUC should ensure the protocol addresses:

- Appropriate sedation, analgesia, and anesthesia;
- Criteria for timely intervention, removal of animals from study, or euthanasia if painful or stressful outcomes are anticipated; and
- Details of post-procedural care.

The protocol must provide adequate information for the IACUC to assess the potential animal pain and/or distress resulting from the study and the effectiveness of the pain- and distress relieving agents proposed for use. Criteria for re-dosing the animal should also be established. The AV must be consulted for any procedure that has the potential to cause more than momentary pain or distress.

Examples of procedures which the *Guide* suggests may have the potential to cause pain or distress, include:

- physical restraint,
- survival surgeries,
- food or water restriction,
- death as an endpoint,
- noxious stimuli,
- skin or corneal irritancy testing,
- tumor burdens,
- intra-cardiac or orbital sinus blood sampling, and
- abnormal environmental conditions.

#### ***4.10.1 Assessing Pain and Distress***

Numerous references indicate that both laboratory 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. 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 animal care staff and researchers 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.

#### ***4.10.2 Alleviation of Pain and Distress***

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 investigator must also provide an assurance that unrelieved pain will continue for only the minimum period of time necessary to attain the study objectives.

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. 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 veterinarian must be consulted for all such protocols and should provide guidance to investigators and the IACUC. Non-pharmacologic treatments should also be employed. This may include special housing considerations, dietary and other environmental enrichments, adjustments and careful supportive care.

It is the responsibility of the investigator to show she/he has considered all the options for minimizing pain and distress that do not compromise the scientific validity of the experiment. The IACUC's deliberations regarding the management of potential pain and distress in a protocol will be documented. Personnel should be trained in pain and distress management. The IACUC should ensure that there is a mechanism in place for prompt reporting of sick animals to the veterinary staff.

#### **4.11 Appeal of an IACUC Decision**

If a PI wishes to appeal an IACUC decision, it must be done so in writing to the IACUC Chair, who will bring it to the next scheduled meeting for review. The PI will be informed in writing of the outcome within five working days of the IACUC meeting at which it was reviewed. The IACUC decision regarding an appeal is final. The IO is not authorized to overturn IACUC decisions.

## **Section 5: Monitoring of Approved Protocols**

### **5.1 Continuing Review: The Annual Review**

Protocols are reviewed annually or at appropriate intervals as determined by the IACUC.

#### *Non-exempt Protocols*

The IACUC requires an annual Continuation Application on the status of each non-exempt protocol. In doing so, the Investigator verifies that completed activities were conducted in accordance with the approved protocol, describes any proposed departures from the approved protocols, and solicits information about activities projected for the upcoming year. The number of animals used over the course of the previous protocol year needs to be provided as well.

When Annual Renewal Forms are submitted to the IACUC Chair prior to the protocol's expiration date, the protocol is considered active and experiments can be conducted while the annual renewal is under review. Continuation Applications cannot be submitted after a protocol's expiration date. The protocol is considered expired, and a new protocol application is required for consideration. The study must cease at the original expiration date and cannot be continued until a new protocol is approved.

#### *Exempt, Teaching and Tissue Protocols*

The IACUC requires a Continuation Application on the status of each exempt, teaching and tissue protocol every two years. In doing so, the Investigator verifies that completed activities were conducted in accordance with the approved protocol, describes any proposed departures from the approved protocols, and solicits information about activities projected for the upcoming approval period. The number of animals used over the course of the previous protocol year needs to be provided as well.

When Continuation Applications are submitted to the ORC prior to the protocol's expiration date, the protocol is considered active and experiments can be conducted while the annual renewal is under review. Continuation Applications cannot be submitted after a protocol's expiration date. The protocol is considered expired, and a new protocol application is required for consideration. The study must cease at the original expiration date and cannot be continued until a new protocol is approved.

#### *Purpose*

The purpose of continuing review is primarily threefold:

- To inform the IACUC of the current status of the project;
- To ensure continued compliance with PHS, USDA and institutional requirements; and
- To provide for re-evaluation of the animal activities at appropriate intervals.

Federal requirements, research ethics, and moral obligations of the scientific community to society demand that IACUC's 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 “rubber stamp” a previously approved protocol during continuing review just because it has undergone a thorough initial review. In a society where use of animals in research, testing and teaching is viewed with increasing concern, high standards of oversight must be maintained. Within the framework of federal regulations and policies, however, there is need for institutions to develop review procedures that are reasonable, meaningful and efficient, and that do not burden the IACUC or investigators with unnecessary requirements that do not contribute directly to the welfare of the animals or provide significant information relevant to the role of the IACUC.

## **5.2 The Third-Year Resubmission: *de novo* Review (Non-exempt protocols)**

IACUC review of protocols must be conducted at least once every three years. This triennial review is interpreted by OLAW as a requirement for *de novo* review, meaning that the criteria and procedures for review specified in IV.C. of the PHS Policy must be applied not less than once every three years.

The three-year period begins on the actual date of IACUC approval; the IACUC may not administratively extend approval beyond the three years. Since protocol approval period cannot be extended, investigators must be cognizant of the protocol approval period. To aid PIs, the IACUC Chair shall attempt to provide adequate warning of pending protocol expiration. It is the ultimate responsibility of the investigator to submit the third-year resubmission by the appropriate deadline date for a scheduled Full Committee Review (FCR) prior to protocol expiration. The IACUC requires a Third Year Renewal Application be submitted as a new proposal, using the most recent version of the application.

If the annual renewal form and/or triennial renewal application is not submitted before the expiration date, approval of the protocol lapses and animals may no longer be used or ordered for that research project. All animals are placed on a Holding Protocol (see 5.4) until full approval is secured.

## **5.3 Termination or Closing IACUC Protocols**

A protocol is automatically terminated after three years. A protocol is also terminated if no annual report is received by the IACUC on or before the anniversary of the protocol approval date. The investigator may terminate a project at any time by notifying the IACUC by email that the project is completed. Please notify the Compliance Officer as soon as your project is completed to keep records up to date. When a project is completed or a protocol expires, all animal use on that protocol must stop. No further purchase of animals can be made under the specified protocol number. The PI, AV, and Compliance Officer will receive official notice of the termination. Access to existing study animals on the terminated protocol will not be permitted (see Holding Protocol 5.4). Terminated protocols records are held in the Office of Research and Sponsored Projects (ORSP) for a 3-year period from date of closure.

## **5.4 Holding Protocol**

For situations that require suspension and animals remain in the vivarium, to avoid euthanasia of those animals and to remain in compliance with regulatory requirements, the IACUC allows the transfer of animals to a holding protocol for a maximum of 60 days. During this time, the PIs are asked to take the necessary actions to gain re-approval of their animal use protocol in order to avoid forfeiture of their animals. Use of the Holding Protocol (HP) is intended to be temporary.

### ***5.4.1 Management of Animals on a Holding Protocol***

No research or teaching procedures are allowed on animals maintained on the holding protocol. Any use of animals for research, teaching, or testing purposes while on the holding protocol will be treated as serious regulatory noncompliance. Breeding may be performed only to maintain viability of specific lines occurring under this protocol. Breeding to expand a colony is not authorized. Feeding, sanitation and environmental enrichment will be performed as expected for the species. Husbandry duties may be performed by the Animal Care staff, the PIs or designated personnel.

### ***5.4.2 For Expiring Protocols***

All animals at SFASU used in research, teaching, or testing must be held or used under an approved protocol. If animals are in-house under an expiring protocol, and the PI fails to transfer them to the holding protocol, the AV, IACUC Chair or designee must transfer the animals to the SFASU holding protocol five business days prior to expiration.

## **5.5 Comparison of Protocols to Grants**

Funded research involving live animals requires verification that the IACUC has reviewed and approved the associate ACUP. Regardless of when the review occurs, the investigator 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 of the funded or unfunded grant proposal application will be requested by the IACUC and reviewed to confirm that all research outlined in the grant is included in the approved IACUC protocol.

### ***5.5.1 Verification of Protocol and Proposal Consistency***

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:

- Are the species used in the grant proposal included in the IACUC protocol?
- Are animal care and use procedures described in the grant proposal included in the IACUC protocol?

Verification of grant and protocol consistency concentrates on animal care and use and **will not** include a judgment of scientific merit.

### ***5.5.2 Timing of Verification***

The IACUC will compare the grant to the protocol during the review of the protocol. The verification will not add additional time to the review process. In addition, the IACUC will compare the grant to the protocol when a new funding source for a protocol is proposed, or when the Office of Research and Sponsored Programs (ORSP) requests verification.

### ***5.5.3 Protocol Amendments***

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 (see Section 5.2.1).

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 Principal Investigator'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.

### ***5.5.4 Managing Grant-Protocol Inconsistencies***

The Attending Veterinarian or IACUC Chair usually conducts the grant to protocol comparison. The Principal Investigator, through the IACUC, will be consulted regarding any apparent inconsistency. As noted above, significant changes require that the PI notify the extramural Program Official. Verification of this request and subsequent approval must be shared with the IACUC.

## **5.6 Post-Approval Monitoring**

Periodically, the IACUC will identify certain protocols (usually new or recently revised protocols) that they feel would benefit from close IACUC or veterinary oversight. The requirement of specific monitoring can be a provision of protocol approval and is communicated to the PI.



## Section 6: Program Review & Inspection of Animal Facilities

*AWRs Section 2.31(c)(1) – The IACUC shall, “Review, at least every six months, the research facility’s program for humane care and use of animals, using title 9, chapter I, subchapter A – Animal Welfare, as a basis for evaluation;”*

*AWRs Section 2.31(c)(2) – the IACUC shall, “Inspect, at least once every six months, all of the research facility’s animal facilities, including animal study areas, using title 9, chapter I, subchapter A – Animal Welfare, as a basis for evaluation; Provided, however, That animal areas containing free-living wild animals in their natural habitat need not be included in such inspection:”*

*AWRs Section 2.31(c)(3) – the IACUC shall “Prepare reports of its evaluations conducted as required by paragraphs (c)(1) and (2) of this section, and submit the reports to the Institutional Official of the research facility; Provided, however, That the IACUC may determine the best means of conducting evaluations of the research facility’s programs and facilities; and Provided further, That no Committee member wishing to participate in any evaluation conducted under this subpart may be excluded. The IACUC may use subcommittees composed of at least two Committee members and may invite ad hoc consultants to assist in conducting the evaluations, however, the IACUC remains responsible for the evaluations and reports as required by the Act and regulations. The reports shall be reviewed and signed by a majority of the IACUC members and must include any minority views. The reports shall be updated at least once every six months upon completion of the required semiannual evaluations and shall be maintained by the research facility and made available to APHIS and to officials of funding Federal agencies for inspection and copying upon request. The reports must contain a description of the nature and extent of the research facility’s adherence to this subchapter, must identify specifically any departures from the provisions of title 9, chapter I, subchapter A--Animal Welfare, and must state the reasons for each departure. The reports must distinguish significant deficiencies from minor deficiencies. A significant deficiency is one which, with reference to Subchapter A, and, in the judgment of the IACUC and the Institutional Official, is or may be a threat to the health or safety of the animals. If program or facility deficiencies are noted, the reports must contain a reasonable and specific plan and schedule with dates for correcting each deficiency. Any failure to adhere to the plan and schedule that results in a significant deficiency remaining uncorrected shall be reported in writing within 15 business days by the IACUC, through the Institutional Official, to APHIS and any Federal agency funding that activity;”*

*PHS Policy Part IV.B.1. – the IACUC shall, “review at least once every six months the institution’s program for humane care and use of animals, using the Guide as a basis for evaluation;*

*PHS Policy Part IV.B.2. – the IACUC shall, “inspect at least once every six months all of the institution’s animal facilities (including satellite facilities) using the Guide as a basis for evaluation.*

*PHS Policy Part IV.B.3. – the IACUC shall, “prepare reports of the IACUC evaluations conducted as required by IV.B.1. and 2. of this Policy, and submit the reports to the Institutional Official;(NOTE: The reports shall be updated at least once every six months upon completion of the required semiannual evaluations and shall be maintained by the institution and made available to OLAW upon request. The reports must contain a description of the nature and extent of the institution’s adherence to the Guide and this Policy and must identify specifically any departures from the provisions of the Guide and this Policy, and must state the reasons for each departure. The reports must distinguish significant deficiencies from minor deficiencies. A significant deficiency is one which, consistent with this Policy, and, in the judgment of the IACUC and the Institutional Official, is or may be a threat to the health or safety of the animals. If program or facility deficiencies are noted, the reports must contain a reasonable and specific plan and schedule for correcting each deficiency. If some or all of the institution’s facilities are accredited by AAALAC International or another accrediting body recognized by PHS, the report should identify those facilities as such.)*

The IACUC reviews the program for humane care and use of animals at least once every six months, using the *Guide* and *Ag Guide* as the basis for evaluation. The IACUC also inspects all institutional animal facilities at least once every six months

## **6.1 Semi-annual Program Reviews**

The semi-annual reviews of the University's Animal Care and Use Program are conducted during scheduled IACUC meetings, and are led by the IACUC Chair. Prior to a scheduled review, all members of the IACUC are provided with the ACUP Review Form so that they may note any concerns they may have regarding the program and be prepared to discuss them during the review.

The program review is started by presenting the status of deficiencies noted in the previous review. All members of the IACUC are encouraged to participate in the reviews and to voice their opinions.

Key aspects of the ACUP covered in the reviews include:

- IACUC membership, functions, and procedures
- IACUC records and reporting
- Personnel qualifications and training
- Occupational health and safety of personnel
- Veterinary care
- Veterinary medical care
  - Preventive medicine and animal procurement and transportation
  - Surgery
  - Pain, distress, analgesia, and anesthesia
  - Euthanasia
  - Drug storage and control

The IACUC procedures for conducting semi-annual program reviews are as follows:

1. The IACUC reviews the SFASU's animal care and use program using a program review checklist. Each program area is evaluated and any deficiencies are categorized as minor or significant. No member is involuntarily excluded from participating in any portion of the program review.
2. Findings from the Program Review are prepared by the CO and submitted to the IO.

## **6.2 Facility Inspections**

The facility inspections are a physical inspection of all buildings, rooms, areas, enclosures and vehicles that are used for animal confinement, transport, maintenance, breeding, or experiments inclusive of surgical manipulation for periods longer than 12 hours. SFASU, through the IACUC, is responsible for all animal-related activities regardless of where animals are maintained for 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. Investigators are responsible for informing the IACUC of all areas where manipulations are performed or animals housed as

stated in their approved protocol. An updated list of all areas requiring inspection is maintained by the IACUC Chair.

Inspection teams include at least two members of the IACUC, usually the attending veterinarian and at least one additional IACUC member.

The inspection schedules will be announced by email to all committee members, and no member will be excluded from an inspection should he/she want to participate. All members of the IACUC are encouraged to participate in inspections and to express their opinions.

At least one week prior to scheduled inspections, the IACUC Chair will provide members of inspection teams with lists of the facilities they are to inspect, including room number, function of the room, species, and any deficiencies identified during the previous inspection and the current status of those deficiencies.

### ***6.2.1 Categories to be Inspected***

Following the AWRs, the *Guide*, and the *Ag Guide*, inspection teams review each area for issues such as general cleanliness, proper storage of food, proper storage of drugs, proper disposal of animal waste, lack of clutter, and conditions that pose a threat to the wellbeing of animals (e.g., storage of flammable or toxic substances next to animal cages). The teams also determine whether surgical procedures are performed using proper aseptic techniques (e.g., use of gloves, masks, sterile instruments, isolated area for surgery) as required, whether the areas where the animals are maintained satisfy the criteria for sanitation and impervious surfaces, and whether animals are being housed outside of approved housing facilities.

### ***6.2.2 Performing Inspections***

In addition to inspecting the facilities, inspection teams may question the ACUP Manager or PIs and members of their research teams about the standards of animal care and use, the specific procedures being performed (e.g., means of euthanasia, pain/distress experienced by the animals, or the training and qualifications of persons handling the animals) and the content of the approved protocol. All members of the research team should be familiar with their protocols, and PIs are to have copies their approved protocols readily available as reference tools in their laboratories. The IACUC Chair will maintain copies of approved protocols.

Each team completes an inspection form and indicates, by room, any deficiencies that are identified, providing a detailed description of each deficiency and designating it as minor or significant. The completed inspection forms are then submitted to the IACUC Chair who prepares a report for review by the full committee at the next scheduled meeting.

### **6.3 Deficiency Correction Schedule**

All deficiencies identified in during the Facility Inspection and/or 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.

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.

### **6.4 Documentation**

A written report of the semiannual program review and facility inspection is prepared. The report is digitally signed by a majority of the IACUC.

The report will indicate whether or not any minority views were filed, and minority views will be included in the final document. A copy of the report is sent to the IO and is kept on file for a minimum of three years in the ORSP.

## **Section 7: Welfare Complaints & Non-Compliance**

### **7.1 Evaluation of Animal Care and Use Concerns**

To help ensure that laboratory animals receive humane care, use or treatment in accordance with the highest ethical standards, laws, regulations and policies governing animal research, the IACUC must review and, if warranted, address any animal-related concerns raised by the institutional employees. Procedures must be established to ensure that concerns are communicated to the IACUC. The Committee must review each concern in a timely systematic manner and, when necessary, take prompt, appropriate corrective actions.

### **7.2 Methods for Reporting**

To facilitate communication, there are a number of options available to communicate concerns about animal care and use at SFASU, or to report instances of suspected non-compliance with laws, rules, regulations and policies. The names of contact persons including the IACUC Chair and Compliance Officer are listed on the IACUC and ORSP websites.

Although written concerns are more convenient to handle, complainants may not be willing to submit them in this manner. In such cases, the individuals who receive concerns should document them fully to ensure that the issues are clear and to prevent misunderstandings. Concerns may be submitted to any member of the IACUC.

At a minimum, the concern should identify:

- individual(s) against whom the concern is directed, if known
- the alleged misconduct
- evidence that would allow the IACUC to determine if the complaint warrants further investigation to support allegations
- names and contact information for any additional persons, if any, who are capable of providing supporting information.

Requests for anonymity should 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.

### **7.3 Procedures for the Investigation of Animal Care and Use Concerns**

#### ***7.3.1 Conflict of Interest***

If a concern is submitted against an IACUC member, that member recues him/herself from all proceedings concerning that complaint. If the subject of a complaint is the Chair of the IACUC, the Vice Chair will act as Chair during review of the complaint

### ***7.3.2 Initial Evaluation and Actions***

Concerns of possible misuse or harm to animals or non-compliance should be brought to the attention of the IACUC. 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 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 non-compliance. The course of action taken by the IACUC should be driven by the potential significance of the alleged situation.

Conditions that reportedly jeopardize the health or well-being of animals should be evaluated immediately. To cope promptly with such situations, the Attending Veterinarian is authorized to halt procedures which they believe do not comply with institutional policies until the IACUC can be convened and consider the matter formally.

Similarly, situations that may involve potential criminal activity or human safety should be reported promptly 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 may be necessary in these cases to ensure prompt consideration of concerns.

### ***7.3.3 Role of the IACUC Chair***

Upon receipt of a concern, the IACUC Chair should convene a meeting of the IACUC. The IACUC can either meet in person, or via email discussion. After initial review of the complaint, the IACUC will determine whether it requires further investigation and immediate action, further investigation but no immediate action, or no action. Once this decision has been made, the IACUC should determine which individuals or other institutional or non-institutional offices may require notification at this time.

If immediate action appears warranted because animal or human welfare may be compromised, the IACUC should notify the IO and proceed accordingly. 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 (see Section 8). If an activity is suspended, the IO shall report that action any federal agency funding that activity. If the PHS supports the activity in any way, the IACUC, through IO, must promptly notify OLAW.

### ***7.3.4 Investigation of Concern***

The initial investigation is to take place within three days of receiving the initial complaint. The IACUC should charge a designated person or group with its requirements for information gathering and impose a completion date. The assigned completion date will depend on the IACUC's determination of whether immediate remedial action may be

required. The nature of the information required will vary depending on the circumstances, but often involves:

- Summarizing the nature of the complaint or dispute;
- Summarizing steps taken during the course of the investigation;
- Stating whether there has been a violation of an approved protocol, university or ACUP policies/procedures, the governing federal regulations/policies, or any pertinent state or local law;
- Interviewing complainants (if known), any persons against whom allegations were directed, and pertinent program officials;
- Observing the animals and their environment; and
- Reviewing any pertinent records, (e.g., animal health records, protocol, and other documents).

The investigation report is submitted to the IACUC Chair for review by the IACUC. The IACUC should review:

- The concern(s),
- The results of interview(s),
- The condition of animals and their environment, and
- The results of records and other document reviews.

The review should also contain:

- Any supporting documentation such as correspondence, reports, and animal records,
- Conclusions regarding the substance of the concerns vis-à-vis requirements of the AWRs, the PHS Policy, the *Guide*, the *Ag Guide*, and institutional policies and procedures, and
- Recommended actions, if appropriate.

### **7.3.5 Outcome and Actions**

Upon receipt and evaluation of the report, the IACUC may take one of the following actions:

**1. The protocol is allowed to continue.**

This action is taken when the IACUC determines there is no concern of noncompliance. Written notice of the decision is sent by the Chair to the investigator, the complainant, and the IO stating that the IACUC determined there was no merit to the complaint.

**2. The protocol is suspended pending corrective action.**

This action is taken only when a quorum of the IACUC determines by a majority vote that animal health or welfare is or may be in danger or that activities are being conducted that are not compliant with an approved protocol, but that corrective action could be implemented to resolve the problem(s).

Written notice of a vote to suspend is immediately sent by the Chair to the respondent, the respondent's Director and Dean, and to the IO stating that:

- a) The protocol is immediately suspended and the specific reason(s) for the suspension;
- b) All work other than routine daily animal care is stopped;
- c) All animals are being transferred to a holding protocol pending corrective action; and
- d) Within two weeks the investigator will be notified of the corrective action that will be required to reinstate the protocol.

Following a suspension, the IACUC informs the IO to review the reasons for suspension and to appropriate corrective action. Within two weeks of the notice of suspension, the Chair notifies the respondent of the required corrective action, and the schedule for completing it, to seek reinstatement of protocol approval. If corrective action is not completed by the scheduled dates, the protocol will be terminated.

The Chair prepares a report of the suspension, describing a full explanation of events from the time the complaint was received, and explaining the reasons for suspension and the corrective action taken. The report is submitted by the Institutional Official to the USDA APHIS if USDA covered species were involved, to the PHS if the suspended activities were supported by PHS funding, and/or to any Federal agency funding the activities.

3. The committee may review and respond to the Institutional Official with concerns regarding animal care and use at SFASU.

#### **7.4 Non-Compliance with IACUC Protocol, Policies, Procedures, or Decisions**

Protocol non-compliance occurs when procedures or policies approved by the IACUC are not being followed. Examples include performing unauthorized surgery, unauthorized persons participating in a research project, or 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.

If allegations of animal mistreatment or protocol non-compliance are verified, the IACUC can apply sanctions. If, in the opinion of the IACUC, sanctions are not appropriate, they need not be applied. 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 non-compliance might lead to an explanation, not a sanction.

#### **7.5 Consequence of Non-Compliance**

Subsequent actions of the IACUC may include:



- Implementing measures to prevent recurrence;
- Notifying the IO of its actions;
- Notifying funding or regulatory agencies, as required; and/or
- Notifying the complainant, any persons against whom allegations were directed, and pertinent program officials (appropriate supervisory and management staff, the public affairs office, institutional attorneys, etc.).

#### **7.5.1 Institutional Sanctions**

Examples of institutional sanctions that have been devised include:

- counseling;
- issuing letters of reprimand;
- mandating specific training aimed at preventing future incidents;
- monitoring by the IACUC or IACUC-appointed individuals of research, testing, or training that involving animals;
- temporary revocation of privileges to provide animal care or to conduct research, testing, or training that involves animals, pending compliance with specific, IACUC-mandated conditions;
- permanent revocation of privileges to provide animal care or to conduct research, testing, or training that involves animals; and
- recommending to the IO that institutional (e.g., reassignment, termination of employment) sanctions be imposed.

## **7.6 Reporting**

Failure by research personnel to follow Federal and/or SFASU regulations, guidelines, policies and/or procedures may require reporting to the appropriate institutional, local, state and/or Federal agencies. Violations may include, but not limited to:

- Serious or continuing non-compliance with the PHS Policy;
- Serious deviations from the *Guide for the Care and Use of Laboratory Animals*; and
- IACUC suspensions.

#### **7.6.1 Principal Investigator Reporting**

The Principal Investigator and protocol personnel must report any serious or continuing non-compliance with an IACUC protocol, policies, procedures, decisions, or deviations from the *Guide*. The report should be on SFASU /departmental letterhead, addressed to the IACUC Chairperson, and emailed (preferred) to the Compliance Officer. The self-report of non-compliance should include the following information:

- relevant grant or contract number(s);
- 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.,

- principal or co-principal investigator, technician, animal caretaker, student, veterinarian, etc.);
- description of actions taken by PI to address the situation; and
- description of short- or long-term corrective plans and implementation schedule(s).

### **7.6.2 IACUC and IO Reporting**

All investigations by the IACUC will be reported internally at the completion of the investigation to the following individuals, as appropriate:

- Principal Investigator (PI)
- PI's Department Chair
- PI's Director and/or College Dean
- IACUC Chair
- Director, Office of Research and Sponsored Projects (ORSP) (if project is externally funded)
- Institutional Official (IO)

### **7.6.3 Response to External Requests for Information**

In accordance with applicable policies, guidelines and regulations, upon request, SFASU will make available to the public all IACUC meeting minutes and any documents submitted to or received from funding agencies with the latter are required to make available to the public. Redaction of proprietary and private information is allowed but “must be done so judiciously and consistently for all requested documents.” In addition, the IACUC will adhere to requirements for providing copies of documents as specified in the Texas Public Information Act.

## Section 8: Suspension of Animal Activities

*Section 2.31 (c)(8) of the AWRs states that the IACUC is to “be authorized to suspend an activity involving animals in accordance with the specifications set forth in paragraph (d)(6) of this section.*

*Section 2.31 (d)(6) states that “The IACUC may suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with the description of that activity provided by the principal investigator and approved by the Committee. The IACUC may suspend an activity only after review of the matter at a convened meeting of a quorum of the IACUC and with the suspension vote of a majority of the quorum present.*

*Part IV.B.8 of the PHS Policy states that the IACUC is to “be authorized to suspend an activity involving animals in accordance with the specifications set forth in IV.C.6 of this Policy.”*

*Part IV.C.6. states that “the IACUC may suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with applicable provisions of the Animal Welfare Act, the Guide, the institution’s Assurance, or IV.C.1.a.-g. of this Policy. The IACUC may suspend an activity only after review of the matter at a convened meeting of a quorum of the IACUC and with the suspension vote of a majority of the quorum present.”*

### 8.1 Suspension of Animal Use

Although rare, a suspension of animal use may be necessary when evidence exists that harm has occurred, or is believed likely to occur, to an animal being used in a research, teaching, or testing activity; or that animal activity is being conducted that is not in compliance with an approved protocol, with the AWRs, or the PH Policy. In such circumstances, and when the IACUC Chair or Attending Veterinarian (AV) determine there is probable concern for the **immediate** welfare of animals, the IACUC, through this policy, authorizes the IACUC Chair to temporarily suspend animal use. In cases of animal welfare issues, the AV is authorized to temporarily suspend the use of animals.

If there is a suspension issued by the IACUC Chair or AV as outlined in this policy, the matter is referred to the full committee at the next scheduled meeting. A full suspension by the IACUC is imposed only after review of the issue at a convened meeting of a quorum of the full committee with a vote for suspension by a majority of the members present.

### 8.2 During Suspension of Animal Use

During a suspension of a protocol, animals are placed on a Holding Protocol (see 5.3). While on a Holding Protocol all research, teaching, or testing activities involving animals are stopped. The routine care and maintenance of the animals continues to be the responsibility of those same individuals who were responsible prior to the suspension, unless it was deficiencies in the routine care and maintenance that caused the suspension, in which case the IACUC Chair, the Attending Veterinarian, or the person designated by the Chair take over animal care.

When a protocol is suspended, no further research or activities involving animals may be undertaken. The PI has 30 days from the date of the suspension to determine disposition of the animals, during which time the routine care and maintenance of the animals is taken over by the

IACUC Chair and the Attending Veterinarian or their designees. If animals' disposition has not been determined after 30 days, the IACUC Chair and/or the Attending Veterinarian may perform or oversee euthanizing or other disposition of the remaining animals, and the PI is charged a per animal or per cage fee based on current standard rates for like animals. The IO and appropriate funding agencies are then notified.

## **Section 9: Miscellaneous Items**

### **9.1 Anesthesia and Analgesia**

In designing the experimental protocol, the applicant investigator is obligated to consult a USF veterinarian regarding research animal issues, including anesthesia and analgesia. The applicant investigator is compelled to institute adequate practices of anesthesia and analgesia. Preemptive and/or postoperative/post procedural analgesia must be administered whenever procedures are identified that are assumed to produce more than momentary or slight pain and discomfort for an appropriate interval, unless the protocol precludes such practice (Research Pain Category C), the investigator has justified such in writing, and the IACUC has approved such practice.

Guidelines, dosages, and comments regarding historically common anesthetics and analgesics for laboratory animal species can be found in *Guidelines: Anesthesia and Analgesia in Laboratory Animals*.

### **9.2 Animal Acclimation**

Investigators are encouraged to use specific pathogen free animals for research and teaching, and recognize that co-morbidities complicate and interfere with the interpretation of research data.

All animals should be acclimated a minimum of seven days prior to use. Animal conditioning should be implemented whenever animals with unspecified clinical history or health status are requested.

### **9.3 Animal Blood and Tissue Use**

If animals are euthanized for a research project for the purpose of obtaining the blood or tissue, an IACUC protocol is required. IACUC approval is not required if tissue collection takes place postmortem as a by-product of a commercial enterprise, like a slaughterhouse. IACUC approval is not required for the harvest of tissues from dead animals from other research projects as long as the collection of tissues does not alter the approved procedures in any way and the animals were used exclusively for the other research project.

PIs should be aware that if the “use of vertebrate animals” box is not checked on the face page of a PHS grant application form, references to the use of animals in the grant proposal may trigger questions about IACUC approval. To avoid delays in peer review of a proposal, the PI is advised to explain in the grant application the source of the tissues.

PIs interested in sharing blood and tissues from animals euthanized after a project is completed should network to maximize the use of such

#### **9.4 Animal Euthanasia**

Euthanasia is the induction of humane death without pain, anxiety, or distress. Acceptable techniques safely result in rapid animal unconsciousness, cardiac and respiratory arrest, and loss of brain activity.

Anxiety and distress can be minimized, and safety assured by careful handling, calming, and gentle restraint, and by the appropriate selection of, and training and experience in euthanasia technique suitable to the research protocol and the species used.

Acceptable, conditionally acceptable, and unacceptable euthanasia agents, methods and techniques have been described by the *American Veterinary Medical Association Guidelines on Euthanasia*, 2013. These recommendations provide the basis for acceptable euthanasia techniques and are adopted as such. These recommendations and those in the *Guideline of the American Society of Mammalogists for the Use of Wild Mammals in Research*, the *Guidelines for Use of Fishes in Research*, the *Guidelines for Use of Live Amphibians and Reptiles in Field and Laboratory Research*, and the *Guidelines to the Use of Wild Birds in Research* provide the basis for acceptable euthanasia techniques of wild, avian, aquatic, and ectothermic animals, and are adopted as such.

#### **9.5 Animal Facilities**

Each college or research institute which hosts a facility for animal care and use is responsible for all physical structural maintenance and repairs, and all major equipment maintenance, repairs, and replacements within their respective facilities, including, but not limited to exterior roof, walls and doors, utilities, lighting, heating/ventilation/air conditioning, interior wall/floor/ceiling surfaces and doors, cage washers, sterilizers, boilers, steam generators, water conditioners/softeners, animal water treatment and distribution systems, isolation cubicles, and security/environmental monitoring systems, so as to meet the requirements of the *Guide*, AWA, and the standards of accreditation by AAALAC.

#### **9.6 Animal Identification and Medical Records**

Adequate animal care includes adequate animal medical record keeping. Although veterinary, animal care, and husbandry staff may make contributions to research protocols involving animals, the PI and associated research staff named on an IACUC-approved protocol serve as the primary attending clinicians of all animals housed on behalf of that protocol. As such, research staff are responsible for providing adequate clinical oversight, and post-operative or post-procedural care of the animals, for anticipating and alleviating animal pain or discomfort whenever possible, and for maintaining complete animal medical records, with entries made in sufficient detail and at intervals specified by these IACUC Principles and Procedures.

Animals are identified on cage cards as to the requesting PI, the IACUC file #, date of arrival, source, and physical findings, including species, strain, sex, weight or age, and should include any identifying features, and/or permanent markings.

When clinical abnormalities are recognized in USDA regulated species, the PI and research staff must make entries in the medical record, which at least document, the abnormal physical/physiological parameters observed, a description of specimens taken for diagnosis, the laboratory/diagnostic findings, and treatment(s) initiated.

Post-operatively/procedurally, following recovery from a surgical plane of anesthesia, nonrodent mammals must be clinically evaluated (e.g., heart or pulse rate, respiratory rate, mucous membrane color or capillary refill time, and body temperature) and observations recorded by the research staff at least once between post-operative/procedural days 1-3. Daily entries of animal health assessment must be made on post-operative days 1, 2, and 3 for all USDA regulated species. This must be done in the medical log, on forms provided by Comparative Medicine. In addition, the dose and route of all post-operative/procedural analgesics, antibiotics, and treatments, and the date of skin suture removal, when applicable, must be noted.

The PI and associated research staff should maintain written records of activities whenever painful or stressful outcomes are anticipated or possible in any animal. Records should be kept within the animal facility on forms provided by Comparative Medicine, with entries that describe when the painful or stressful outcome is first recognized, what treatments are instituted, and when the discomfort is resolved, or when the animal is euthanatized.

Unanticipated clinical abnormalities or complications in any animal must be resolved through the cooperative interaction of research, animal care, and veterinary staff.

Research staff must make entries to the medical records of USDA regulated species that summarize the clinical diagnostic and necropsy findings of an unanticipated animal morbidity or mortality that occurs unrelated to the protocol, so that research methods can be refined.

Inadequate animal care or inadequate animal medical record keeping can result in the suspension of animal use privileges.

## **9.7 Animals from Non-Approved Sources**

Animals may not be brought to campus to the main animal facility from a non-approved source as there is a chance the animal is harboring infectious disease(s) even though it may appear healthy. Non-approved sources of animals include wild-caught animals and animals from non-approved animal vendors or other institutions. Animals requested from non-approved vendors will need to be quarantined at an off-site facility that can manage such animals for at least eight weeks. Researchers are required to pay for any quarantine costs. Animals may not be used for research projects until they are cleared from quarantine. Animals must have a recent documented health screening from the place held for quarantine for review by the AV prior to being shipped to SFASU after the quarantine period. Breeding is not allowed for animals in quarantine.

## **9.8 Animal Use in Agricultural Instruction**

Flocks and herds of agricultural animals are often maintained by agricultural schools to teach husbandry, production, and showmanship. Animals used for these practices are not covered by the *PHS Policy* (unless supported by PHS) or the AWRs. However, research procedures should

have committee review. IACUC in reviewing the use of animals in activities with agricultural applications will find *A Guide for the Care and Use of Agricultural Animals in Agriculture Research and Teaching (Ag Guild)* useful in conducting their evaluation. The IACUC shall monitor and have oversight regarding all activities, teaching, research, welfare, and care of all agricultural animals sponsored by the university; conducted by university faculty, staff, visitors, or students; and conducted using property and/or facilities owned by the university.

## 9.9 Breeding Colonies

Investigators maintain breeding colonies for a variety of reasons. A breeding colony may be required for an established animal model because:

- the animal model is not commercially available,
- young animals have very specific age or weight requirements that cannot be fulfilled by a commercial breeding colony, or
- physiological status of the mutant animal is too severely affected for it to survive shipment.

To review standard operating procedures for breeding colonies, the IACUC will need information about colony management. Examples of necessary information include:

- number of breeders and number of young per cage,
- breeding system including number of females per male or continuous versus interrupted mating,
- weaning age,
- separation of animals at weaning, and
- methods for identification of individual animals.

Large numbers of animals may be required to maintain a breeding colony. The exact number of animals can only be approximated because it is impossible to predict in advance the exact number and sex of offspring. The estimated number of animals should clearly distinguish between:

- breeders,
- young that cannot be used in experiments because they are of the wrong genotype or sex, and
- animals that will be subject to experimental manipulations.

Colony management practices should be briefly described in the investigator's animal protocol, and justification provided for departure from standard institutional practices.

## 9.10 Categories of Animal Use Subject to IACUC Review

The IACUC reviews all classroom and research projects, sponsored or unsponsored, involving the use of living non-human vertebrate animals, or animals euthanized for the



purposes of the study, to ensure the humane care and use of animals including, but not limited to, the following:

- Classroom exercises, demonstrations, and lab projects unless the demonstrations and projects are of routine care of animals that is part of their normal husbandry;
- Faculty or staff research projects;
- Graduate student projects;
- Undergraduate student honor projects; and
- University-approved research by investigators not affiliated with the university who propose to involve university students, staff, or faculty in a proposed research project

### **9.11 Communication**

Communication among all the people involved in animal care and use is vital to keep everyone informed and in compliance with SFASU policies and procedures. PIs must be notified for various reasons about policy and regulatory changes, the status of applications or amendments, the condition of their research animals, or issues with their students, technicians, or staff.

All parties listed on a protocol should be included for all communication related to it so that all parties are aware of the status of the project and the likelihood of violations is reduced. The contact list should always include the PI, co-PI, students, staff, and technicians listed on the protocol or amendments and the Compliance Officer, IACUC Chair, and AV. This will help resolve questions or alleviate problems that need to be addressed quickly that can arise from miscommunication.

For example, when an animal is in distress and action needs to be taken, the PI and all other contacts provided on the protocol or amendment will be contacted to notify them of the condition of the animal and provide them with 24 hours to address the problem. After 24 hours, the IACUC Chair, AV will authorize euthanasia of the animal if the PI has not responded. The cadaver of the animal in question will be refrigerated to allow the PI to collect any tissue at a later date.

The PI must read and approve all communications sent to IACUC prior to review by the IACUC. Often amendments are written by students or technicians. Communication among the entire group ensures that the PI sees all correspondence and is aware of any proposed changes to a protocol. An approval will not be issued until the IACUC Chair receives the appropriate documentation from the PI. This record verifies to the IACUC that the PI is aware of and approves all amendments and procedural changes.

### **9.12 Field Studies**

PHS Policy does not distinguish between field and laboratory studies and covers all vertebrate animals. Therefore, before a field study can start, the PI must submit a Protocol Review Form for IACUC review and approval. All personnel listed on a field study protocol must complete training for researchers who work with wildlife.

## **9.13 Hazardous Materials**

Hazardous materials may be used for different aspects of animal research. Projects may include materials that are biological, radiological, or chemical in nature. When these materials are required, approval and appropriate oversight by SFASU Environmental Health, Safety & Risk Management (EHSRM) may be required before IACUC approval is granted.

### ***9.13.1 Biological Agents***

Use of any biological or biohazardous agents in animals, including recombinant DNA, is limited to activities which can be safely carried out with consideration for the available laboratory facilities and personnel training. All projects that involve biological-originated materials are reviewed by the SFASU Biosafety Committee and must be approved by the Biosafety Committee before final IACUC approval is granted.

### ***9.13.2 Radiological Agents***

Any project using radiation emitting devices or radioactive materials must be approved by the SFASU Biosafety Committee (BC) prior to starting the project. The Radiation Safety Office's (RSO) mandate is to ensure that individuals using radioactive materials have appropriate safety training and that they use, store, and dispose of the radioactive material in accordance with regulations. The procurement, use, and disposal of radiological materials shall be coordinated through the (RSO) in accordance with the applicable federal, state, and municipal regulations. The procurement, use, and disposal of radiological materials shall be coordinated through the (RSO) in accordance with the applicable federal, state, and municipal regulations. Anyone interested in performing animal experiments using radioactive materials must 1) register and undergo general radiation safety training with the Radiation Safety Office at SFASU, and 2) have their laboratory registered with the Radiation Safety Office for compliance. Information on the SFASU Radiation Safety Office may be found in the SFASU Environmental Health, Safety & Risk Management webpage.

### ***9.13.3 Chemical Materials***

Use of any hazardous materials (toxic chemicals or drugs) in animals is limited to activities which can be safely carried out given the available facilities and personnel training. The SFASU Biosafety Committee (BC) reviews and approves of the use of any hazardous chemicals. Use and handling of hazardous chemicals must be cleared with the EHSRM. Investigators using hazardous agents in animals must have knowledge in the use of the hazardous material in accordance with the Material Safety Data Sheet (MSDS), federal and state regulations, and SFASU EHSRM policies. Contact EHSRM for a training schedule other information about the proposed material. Before a project involving hazardous materials is approved, the IACUC requires review of the project by the BC for management of the material to prevent exposure of the investigators, animal care, and veterinary staff and to prevent release of any hazardous agent into the environment. Those individuals involved with or who may face potential exposure to hazardous materials must undergo training by EHSRM or the principal investigator to understand proper laboratory practices and potential health concerns from working with such substances. Vaccinations and/or health screening may be necessary before, during, and/or after employee involvement in such activities.

#### **9.14 Instructional Use of Animals**

It may be appropriate for students, at both undergraduate and graduate levels, to participate in the conduct of experiments involving laboratory animals for the purpose of education. All instructional proposals should clearly identify the learning objectives and justify the particular value of animal use as part of the course, whether it is demonstration of a known phenomenon, acquisition of practical skills, or exposure to research. In all cases, consideration must be given to alternative approaches to attaining the desired educational objectives, in accordance with the U.S. Government Principles.

Adequate supervision and training are especially important as the techniques learned by students may be carried into subsequent research careers. It is recommended that students receive instruction in the ethics of animal research and applicable rules and regulations prior to undertaking any experimentation. When students work in an investigator's laboratory, the IACUC must ensure that the students receive appropriate supervision and training in animal care and use. The *PHS Policy* and AWRs have specific training requirements that apply to all animal users, including students. Student projects involving protocols different from those approved for the instructor's laboratory must be reviewed and approved on their own merits by the IACUC.

Experiments sometimes entail behavioral observation with no intervention, or minor painless interventions, such as choices of food or living accommodations. Such projects teach the rigors of conducting a research project and the variability inherent to biological or biobehavioral systems. These exercises generally involve little or no distress to the animals, but still require IACUC approval.

#### **9.15 Ordering Animals**

A current IACUC approved protocol or amendment is required before animals can be purchased or housed. Animals may not be ordered until the protocol has received final approval and the PI has received approval from the IACUC.

#### **9.16 Photographing Animals**

Photography is allowed with prior IACUC approval only. The Animal Research Compliance Manager or designee must be present for all photographs taken. Appropriate handling and restraint methods for the species must be used and procedures described in the protocol. No references to personal or institutional information should be visible in the photograph. Animals should be in clean surroundings, clean cages, or clean pens and water bottles and feeders should be visible in the photograph if applicable. No animals that are ill or have visible lesions or alterations are to be photographed without specific permission from the AV, PI or IACUC Chair. If the purpose is to disseminate research results, then appropriate care should be taken to drape the animal and if possible show only the area of interest in the photograph. Cell phones are restricted from use in the facility to prevent unauthorized photography. Incoming calls may be received outside of the facility.

### ***9.16.1 Use of Animal Images for Non-Research Purposes***

The use of photographs, videotapes, or other types of animal images for purposes other than scientific research (e.g., recruiting, website information, documentaries) must be submitted to and approved by the Dean of Research and Graduate Studies and the Chief Public Affairs Officer as the use of such photographs or images could impact the public reputation of the university. Since the use of images for the purpose of public relations types of activities is outside of the IACUC responsibility of assuring ethical use of animals in research, SFASU Administration will be responsible to approve these types of activities. Notification of the administrative decision will be sent to the PI and copied to the Compliance Officer and IACUC Chair.

### **9.17 Release of Protocol Information**

Information on protocols is released only to the PI or co-PI listed on the protocol, the Institutional Official, animal care staff with valid reason, IACUC members, Compliance Officer, and authorized regulatory or accreditation site visitors.

### **9.18 Satellite Facilities**

The IACUC attempts to centralize animal facilities as much as possible, but in some circumstances, it may be necessary to establish a decentralized facility. Approval to establish a decentralized facility will only be allowed with adequate justification. Such facilities must be constructed to meet the standards outlined in the *Guide*, federal law, and current institutional policies.

Once the facility is identified, the IACUC schedules an inspection and uses the facility inspection guidelines to document any deficiencies. Deficiencies are formally communicated in writing to the PI. The deficiencies must be addressed and/or corrected before a follow up IACUC inspection is conducted. Once the IACUC approves the facility, a written approval notice is sent to the PI. Animals may only be procured after the facility is inspected and approved for animal use.

It is the PI's responsibility to ensure that all federal and institutional regulations are implemented and followed. This includes the care and use of all animals, seven days a week, including weekends and holidays. The PI must ensure that all personnel involved in animal handling are properly trained in animal care and use and have completed training. Veterinary and IACUC Compliance oversight continue as if the animals were in a core facility. Failure to meet required expectations may result in the loss of the privilege to have a decentralized facility.

The IACUC will check periodically to make sure that SOPs are being followed, and that the maintenance of the facility, husbandry practice, and animal care are in line with those of the core facility. The daily health checks are the responsibility of the decentralized facility personnel and those personnel should be identified and coordinated to operate the facility in the absence of the PI. These person(s) are required to have the appropriate training on animal handling and clinical observation, as well as knowledge regarding emergency procedures in case there are issues with

the facility and/or animals. Semi-annual facility inspections are conducted by the IACUC. All deficiencies noted in semi-annual inspections are communicated in writing to the PI and must be addressed as soon as possible in accordance with SFASU IACUC policies and regulatory guidelines

### **9.19 Visitor Policy**

No person may enter an animal facility without appropriate authorization from the IACUC Chair or Compliance Officer. Authorization must be requested and approved prior to any visit. In addition, visitors must be accompanied at all times by a SFASU full-time faculty or staff. This is, in part, to prevent transmission of any pathogens to the SFASU facility should someone visit more than one animal facility on the same day, and to ensure that all visiting personnel are performing business directly relevant to research being conducted by faculty in the facility or affiliated with SFASU administration.

### **9.20 Matters not covered in the SFASU IACUC Policies and Procedures Manual**

For all matters not covered by the SFASU IACUC Policies and Procedures Manual, the IACUC shall consult OLAW's current *Institutional Animal Care and Use Committee Guidebook*.

## Section 10: Transportation of Research Animals

**The Guide for the Care and Use of Animals 8th Edition (the Guide) states:**

*“Animal transportation may be intra-institutional, inter-institutional or between a commercial or non-commercial source and a research facility. For wildlife, transportation may occur between the capture site and field holding facilities. Careful planning for all types of transportation should occur to ensure animal safety and well-being. The process of transportation should provide an appropriate level of animal biosecurity while minimizing zoonotic risks, protecting against environmental extremes, avoiding overcrowding, providing for animal physical, physiologic or behavioral needs and comfort, and protecting the animals and personnel from physical trauma. Movement of animals within or between sites or institutions should be planned and coordinated by responsible and well-trained persons at the sending and receiving sites to minimize animal transit time or delays in receipt. Defining and delegating this responsibility to the appropriate persons, who are knowledgeable about the needs of the species being shipped, will help ensure effective communication and planning of animal transport. For non-commercial sources of animals, in particular, it is important for the veterinarian or the veterinarian’s designee to review the health status and other housing and husbandry requirements prior to authorizing shipment of animals. This will ensure that effective quarantine practices are implemented for incoming animals as well as addressing any special requirements needed to ensure animal well-being”.*

### 10.1 General SFASU IACUC Policies on Laboratory Transportation

- The performance site for all animal procedures must be described in the IACUC Protocol and reviewed and approved by the IACUC.
- Methods for transporting animals to and from transport sites must be reviewed and approved by the IACUC unless from SFASU approved commercial vendor (e.g. Charles River Laboratories, Jackson Laboratories).
- All personnel assisting in transport must be listed on the approved IACUC protocol.

#### ***10.1.1 Guidelines for transporting animals within a building:***

- A cart must be used for transporting 3 or more cages and cages should never be stacked.
- The cages and cart must be completely shielded from public view by use of a drape or other covering.

#### ***10.1.2 Guidelines for transporting animals between buildings:***

Transporting rodents in personal vehicles is not recommended, if proposed the procedure must be described in the IACUC protocol and approved by the IACUC

- Standard cages must be placed inside of a secondary container with a secure lid, the container must be opaque and sanitizable.
- The transport vehicle as well as the transport site must provide adequate heating/cooling to maintain general animal comfort.

- The secondary container must be placed inside the vehicle, never in the trunk or truck bed and must be secured to the inside of the vehicle to prevent movement (e.g. bungee cord).
- Animals should be protected from direct sunlight and public view.
- Animals must be transported directly to the other building - no stops should be made.

***10.1.3 Guidelines for transporting animals to another institution:***

- Approval from the other institution must be obtained from the SFASU Compliance Officer prior to scheduling transport of the animals to another institution.
- Animals transported to another institution and returning to SFASU will require IACUC Approval from both institutions. If PHS funds are involved the performance site may be deemed a satellite facility and therefore included on the SFASU Semi-Annual Facility Inspection schedule
- Animals transported to another institution and not returning to SFASU will require approval from the both Attending Veterinarians.
- Primary and secondary enclosures, as described above, must be used.
- The transport vehicle as well as the transport site must provide adequate heating/cooling to maintain general animal comfort, temperatures must be monitored while in transit as well as at transport site
- The secondary container must be placed inside the vehicle, never in the trunk or truck bed and must be secured to the inside of the vehicle to prevent movement (e.g. bungee cord)
- Animals should be protected from direct sunlight and public view.
- If stops are necessary, animals must never be left unattended in the car for more than a few minutes.

## **Section 11: Training**

### **11.1 Training**

All staff working with laboratory animals must be appropriately qualified to do so in order to ensure the humane treatment of animals. Training is a classic performance standard where the emphasis is on the outcome (i.e., all personnel are qualified to do their jobs). Although the PHS Policy and Animal Welfare Regulations (AWRs) do not specify a particular program or the frequency with which a program should be offered, the requirement for competence is mandatory.

*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....*

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.

SFASU has subscribed to the Collaborative Institutional Training Initiative (CITI) Program, which provides research ethics education courses. All faculty, staff, and students are strongly encouraged to access CITI and enroll in applicable courses for the purpose of their research, services and institutional activities.

### **11.2 Personal Needing Training**

All personnel should receive training if they interact directly with or work in the vicinity of animals. 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.

For training purposes, staff can be grouped as:

- Researchers (including Principal Investigators),
- Animal care technicians, and
- Other (e.g., maintenance or support staff).

In some instances, staff may not be clearly divisible into these groups if job responsibilities are more diversified than this classification suggests. For example, facility staff such as animal health technicians may have job functions that include both animal care and research procedures.



Training should also be made available to temporary staff, such as students and visiting scientists. PI's are responsible for identifying these people and assuring that appropriate training is accomplished.

### **11.3 Training for IACUC Members**

#### ***11.3.1 New Member Orientation***

New IACUC member orientation consists of the following: a description of the IACUC and responsibilities; U.S. Government Principles; criteria for membership; authority of the IACUC; protocol review process; monitoring of approved protocols, periodic review; protocol modifications; records; semiannual reviews; roles and responsibilities; and federal regulations.

The objectives of providing this information are the following:

- To introduce members to the role of the IACUC and its evolution;
- To provide the basic information necessary for IACUC members to discharge their responsibilities; and
- To provide a forum for response to, and discussion of, members' concerns and questions.

#### ***11.3.2 Continuing Education***

Continuing education for IACUC members usually occurs throughout the year. The objectives 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. 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.

## **Section 12: Recordkeeping**

### **12.1 Maintaining IACUC Records**

The institution is responsible for maintaining:

- Minutes of IACUC meetings;
- Records of IACUC activities and deliberations;
- Minority IACUC views;
- Documentation of protocols reviewed by the IACUC, and proposed significant changes to protocols;
- IACUC semiannual program evaluations and facility inspections, including deficiencies identified and plans for correction; and Accrediting body determinations.

All records are to be kept for a minimum of three years, with the exception of records that relate directly to protocols, which must be kept for the duration of the activity and for an additional three years after completion of the activity. Records documenting such activities as the provision of adequate veterinary care, training, and occupational safety, are expected to conform

### **12.2 Meeting Minutes**

Review of proposals by the IACUC invokes a deliberative process, and the PHS Policy and AWRs require that the institution maintain “minutes of IACUC meetings, including records of attendance, activities of the Committee, and Committee deliberations” (PHS Policy IV. E; 9 CFR Part 2 Subpart C 2.35 (a)(1)). The IACUC has some latitude in the degree of detail in these minutes.

Recorded minutes from IACUC Full Committee Reviews (FCR) 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 Committee such as recent discussions about a protocol in previous minutes. Historical evidence of compliance or non-compliance 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 Committee 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.

Minutes of each FCR are recorded in writing and include records of attendance, a summary of the issues discussed and the resolution of issues, and the results of IACUC votes on protocols.

- 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.

- **Activities of the Committee**

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

- **Deliberations of the Committee**

A deliberation of the Committee 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 (e.g., FCR) and the Committee 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.

### **12.3 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.

### **12.4 Other Records**

Both the PHS Policy and the AWRs require that SFASU retain the semiannual Program Review and Facility Inspections Report and any recommendations of the IACUC. PHS Policy also requires that the OLAW Assurance and reports of accrediting agencies (e.g., AAALAC) be kept on file. Animal health records are not usually maintained by the IACUC but are kept in the animal facility or in research laboratories. All these records must be kept for at least three years; and must be accessible to OLAW, USDA/APHIS, and funding agencies for inspection or copying.

## Appendix A: Contact Information

### Dr. Steven Westbrook

*SFASU Interim President*

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### Dr. Steve Bullard

*Provost and Vice President of Academic Affairs*

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Office Phone#: 936.468.2707

### Dr. Pauline Sampson

*Dean of Research and Graduate Studies*

*Institutional Official (IO)*

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### Dr. Robert Polewan

*IACUC Chair*

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Office Phone#: 936.468.1483

Dept. Phone#: 936.468.4402

### Ms. Amanda Roming

*ORSP, Compliance Coordinator*

Email: [romigad@sfasu.edu](mailto:romigad@sfasu.edu)

Office Phone#: 936.468.1067

### SFASU Campus Police

*Police services available 24 hours a day*

Email: [updemail@sfasu.edu](mailto:updemail@sfasu.edu)

Office Phone#: 936.468.2608 & 800.816.4657

Calling 911: In the event of an emergency, you should call 911. If you dial 911 from any University phone, you will be connected to campus police. If you wish to reach the Nacogdoches Police Department, dial 911 from your cell phone.

## **Appendix B: Online Resources**

### **SFASU Online Resources**

SFASU IRB/IACUC/Biosafety Website:  
<http://www.sfasu.edu/Researchcompliance>

SFASU Office of Research and Sponsored Programs:  
<http://www2.sfasu.edu/orsp/index.html>

SFASU IACUC Policy (8.6):  
[http://www.sfasu.edu/policies/institutional-animal-care-and-use-committee\\_8.6.pdf](http://www.sfasu.edu/policies/institutional-animal-care-and-use-committee_8.6.pdf)

SFASU Biosafety Manual:  
[http://www.sfasu.edu/safety/documents/2017\\_Biosafety\\_Manual.pdf](http://www.sfasu.edu/safety/documents/2017_Biosafety_Manual.pdf)

SFASU Animals on University Property Policy (13.2)  
<http://www.sfasu.edu/policies/animals-on-university-property-13.2.pdf>

SFASU Department of Agriculture  
<http://ag.sfasu.edu/>

SFASU Department of Biology  
<http://www.sfasu.edu/biology/>

SFASU Department of Forestry  
<http://forestry.sfasu.edu/>

SFASU Department of Psychology  
<http://www.sfasu.edu/sfapsych/>

SFASU Environmental Health, Safety & Risk Management  
<http://www.sfasu.edu/safety/>

### **US Federal Agencies**

National Institutes of Health (NIH):  
<https://www.nih.gov/>

Office of Laboratory Animal Welfare (OLAW):  
<https://grants.nih.gov/grants/olaw/olaw.htm>

Public Health Service (PHS):  
<https://usphs.gov/>

SFASU IACUC Policy and Procedures Manual (Updated: 2019)

USDA Animal and Plant Health Inspection Service:

<https://www.aphis.usda.gov/aphis/home/>

Animal Welfare Act & Regulations:

<https://www.nal.usda.gov/awic/animal-welfare-act>

PHS Policy on Humane Care and Use of Laboratory Animals:

<https://olaw.nih.gov/policies-laws/phs-policy.htm>

### **Online Guides**

OLAW's Institutional Animal Care and Use Committee Guidebook:

<https://grants.nih.gov/grants/olaw/GuideBook.pdf>

Guide for the Care and Use of Laboratory Animals: Eighth Edition (The Guide):

<https://grants.nih.gov/grants/olaw/Guide-for-the-Care-and-Use-of-Laboratory-Animals.pdf>

Guide for the Care and Use of Agricultural Animals in Research and Teaching (Ag Guide):

[https://aaalac.org/about/Ag\\_Guide\\_3rd\\_ed.pdf](https://aaalac.org/about/Ag_Guide_3rd_ed.pdf)

AVMA Guidelines for the Euthanasia of Animals (2013 Edition):

<https://www.avma.org/KB/Policies/Documents/euthanasia.pdf>

Resource Book for the Design of Animal Exercise Protocols, Copyright 2006, APS:

<http://www.the-aps.org/mm/SciencePolicy/AnimalResearch/Publications/Animal-Exercise-Protocols/book14824.pdf>

### **Accreditation Organizations**

Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC):

<https://aaalac.org/>