TARLETON
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Institutional Animal Care and Use (IACUC) General Operations Manual (GOM)

Version
09/27/2019

Tarleton State University
Institutional Animal Care and Use Committee (IACUC)
General Operations Manual (GOM)

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Acknowledgment:
Tarleton State University acknowledges and appreciates the assistance from Texas A&M University – Corpus Christi in the structure and wording of this document.

Section 1: Introduction

1.0 Purpose and Scope of Manual

Tarleton State University is responsible for providing suitable orientation, appropriate materials, adequate resources, and training to enable research faculty and staff and Institutional Animal Care and Use Committee(IACUC) members to carry out their respective duties consistent with the Guide for the Care and Use of Laboratory Animals (the Guide),the Guide for the Care and Use of Agricultural Animals in Research and Teaching(Ag Guide), the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy), Office of Laboratory Animal Welfare IACUC Guidebook (OLAW), and the Animal Welfare Act and Animal Welfare Regulations (AWRs).

1.1 Institutional Animal Care and Use Committee (IACUC) Mission Statement

Tarleton State University's (TSU) IACUC oversees all aspects of TSU animal care and use programs for teaching and research. The IACUC reviews all animal use protocols, ensures compliance with federal regulations, inspects animal facilities and laboratories, and oversees training and educational programs. The IACUC serves as a resource to faculty, investigators, technicians, students, staff, and administrators and provides guidance for all animal use procedures with the highest scientific, humane, and ethical principles.

1.2 Office of Laboratory Animal Welfare (OLAW)

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.

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

1.3 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.

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

1.3.1 The Animal Welfare Act (AWA)

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.

1.4 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.

TSU has not sought AAALAC accreditation; however, TSU utilizes AAALAC guidance as best practices standards of care.

Section 2: The Institutional Animal Care and Use Committee

2.0 Authority

Institutional Animal Care and Use Committees (IACUC) derive their authority from the law. The Health Research Extension Act (HREA) of 1985 and the Animal Welfare Act (AWA) mandate the existence of IACUC's. IACUC members are appointed by and report to the Institutional Official (IO). The IO is the individual responsible for ensuring that an institution complies with all applicable federal laws, regulations and policies and has the administrative and operational authority to commit institutional resources to ensure compliance. Federal regulations consider the Chief Executive Officer (CEO) of an organization to be the IO unless delegated in writing to a different individual. The President and CEO of Tarleton State University has appointed the Associate Vice President for Research as TSU's IO.

Individuals are appointed by the IO to the IACUC for a term of three years. They may be reappointed an unlimited number of terms. The IO has the authority to remove an individual from the IACUC at any time.

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 recommendations 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., Risk Management, Occupational Health & Safety, department head, Biosafety committee, etc.).

TSU has established an IACUC, which is qualified through the experience and expertise of its members to oversee the institution's animal program, facilities, and procedures.

2.1 Committee Composition

The IACUC is composed of regular voting members. The IACUC may use consultants as necessary during review discussions. Some IACUC members fulfill specific regulatory requirements (e.g., veterinarian with program responsibility, a non-scientist, and an individual nonaffiliated with the institution); others have unique roles by virtue of their position (e.g., Chair, Veterinarian, etc.) There are no specific prohibitions regarding individuals filling more than one role on the IACUC.

Required categories of membership include:

> **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 agricultural and laboratory animal science and medicine or in the care of the species being used.

Chair. The Chair serves a term of two years; however, they may be reappointed an unlimited number of terms. The chair is a faculty member with research experience, with sufficient stature (e.g., seniority or tenure), and can perform the functions of this position without jeopardy to his/her career.

Nonaffiliated. The nonaffiliated member(s) represent general community interests. Neither they, nor their immediate family, have an affiliation with TSU. 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.

Scientist. PHS Policy requires that the IACUC include a practicing scientist experienced in research involving animals.

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.

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. Alternates may serve for regular members provided the alternate fulfills the specific membership requirements of the regular member they are substituting (i.e scientist, nonscientist, nonaffiliated). However, an alternate may not represent more than one member at a time. 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. Alternate members are expected to vote their conscience, and not represent the position of the regular member for whom they serve.

The TSU IACUC meets the compositional requirements set forth in section of IV.A.3.b. of PHS Policy.

Table A. Comparison of IACUC Membership Requirements

PHS Policy IV.A. 3. A,B	USDA Regulations 9 CFR, 2.31 (a) (b)
• Appointed by the IO • Minimum of five members (requiring the following): ▪ 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. ▪ One practicing scientist experienced in research involving animals. ▪ One member whose primary concerns are in a nonscientific area (for example, ethicist, lawyer, clergy). ▪ One member not affiliated in any way with the institution and not a member of the immediate family of a person who is affiliated with the institution. • The PHS Policy requires institutions to follow the Guide, which states that committee membership should include at least one public member to represent general community interests in proper care and use of animals, and that public members should not be laboratory animal users.	• Appointed by the IO • Minimum of three members: ▪ At least one Doctor of Veterinary Medicine with training or experience in laboratory animal science and medicine, and who has direct or delegated program responsibility for activities involving animals at the institution. ▪ One member not affiliated in any way with the institution and not a member of the immediate family of a person who is affiliated with the institution; person who represents the general community interests in the proper care and treatment of animals; and is not a laboratory animal user (USDA Policy 15) ▪ Not more than three members from the same administrative unit of the institution.

2.2 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 PIs).
- 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 $5,000 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 $5,000 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; and
- Are not counted towards quorum.

2.3 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 IACUC and the Office of Sponsored Projects (OSP) (administrative office that supports the IACUC) shall be considered privileged information and the IACUC shall assure the confidentiality of the data contained therein.

2.4 Quorum Requirements

Certain official IACUC actions require a quorum: full committee review of a research project (Policy IV.C.2. and AWR §2.31(d)(2)) and suspension of an activity (Policy IV.C.6. and AWR §2.31(d)(6)). TSU defines a "quorum" as more than half of the IACUC voting members.

A protocol is approved only if a quorum is present, and if more than 50% of the quorum votes in favor of protocol approval. For reasons other than conflict of interest, abstentions from voting do not alter the quorum or change the number of votes required. For example: If the IACUC has 9 voting members, at least 5 members must be present at a convened meeting to constitute a quorum and approval of a protocol would require a minimum of three votes whether or not there were abstentions.

2.5 Functions of the IACUC

The Institutional Animal Care and Use Committee (IACUC) will:

1. Review at least once every six months TSU's program for humane care and use of animals, using the Guide and Ag Guide as a basis for evaluation. The IACUC procedures for conducting semiannual program reviews are described in Section 6.1.

2. Inspect at least once every six months all of TSU's facilities using the Guide and Ag Guide as a basis for evaluation. The IACUC procedures for conducting semiannual facility inspections are described in Section 6.2.

3. Prepare reports of the IACUC evaluations as set forth in the PHS Policy IV.B.3 and submit reports to the Institutional Official. The IACUC procedures for developing reports and submitting them to the Institutional Official are described in Section 6.

4. Review concerns involving the care and use of animals at TSU. The IACUC procedures for reviewing concerns are described in Section 7.

5. Make written recommendations to the Institutional Official regarding any aspect of the institution's animal program, facilities, or personnel training. The procedures for making recommendations to the Institutional Official are described in Section 2.8.

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

7. Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the use of animals in ongoing activities as set forth in PHS Policy IV.C. The IACUC procedures for reviewing proposed significant changes in ongoing research or educational projects are described in Section 3.8.

8. Notify investigators and TSU in writing of its decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications required to secure IACUC approval as set forth in the PHS Policy IV.C.4. The IACUC procedures to notify investigators and the University of its decisions regarding protocol review are described in Section 3.8.

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

10. Be authorized to suspend an activity involving animals as set forth in the PHS Policy IV.C.6. The IACUC procedures for suspending an ongoing activity are described in Section 7.4.2.

2.6 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.

2.7 Use of Electronic Mail (Email) for Official Correspondence

Electronic mail (email), like postal mail, is a mechanism for official TSU communication. The IACUC will exercise the right to send email communications to all laboratory and/or agricultural animal users and the IACUC will expect that email communications will be received and read in a timely manner.

This policy applies to all faculty, staff, students, or any other person listed on an animal use protocol (AUP) submitted to the IACUC for review and approval. Official communications using email can include email to a group, or an email message to only one person.

2.8 Making Recommendations to the Institutional Official (IO)

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 IO are as follows:

1. Recommendations regarding any aspect of the TSU's animal program, facilities, or personnel training are formulated at convened meetings of the IACUC.
2. Recommendations are prepared in writing by the Research Compliance Officer (RCO), Research Compliance Coordinator (RCC), 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 RCO) submits recommendations, including minority views that are approved by the IACUC to the IO.

Section 3: IACUC Research Proposals

3.0 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.

3.1 General Scope of Review

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

- Activities conducted by TSU faculty, staff, or students;
- Activities performed on the premises of TSU;
- Activities performed with or involving the use of facilities or equipment belonging to TSU;
- Activities satisfying a requirement imposed by TSU 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 TSU, including requirements for clinical or adjunct appointments.

3.2 Specific Types of Activities

Research

Many of the animals covered in IACUC review are used in research, including medical, biological, and behavioral research as well as agricultural research (i.e., the study of food and fiber production or diet manipulation). Most of these animals are acquired and housed by TSU; some may include free-ranging wildlife. 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).

Teaching

The use of animals in educational settings is subject to IACUC review. Examples include using animals to teach agricultural techniques, animal husbandry, and biological procedures.

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 Projects in Which the Investigator is a Consultant

In some instances, TSU faculty or staff may serve in an advisory capacity for a research project conducted outside the TSU 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; and
- The investigator holds no rights in the work; and
- Neither the investigator nor TSU 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.

3.3 Exemptions

Strictly observational studies do not require IACUC approval provided both criteria are met: A) the study will not interfere or alter in any way the animal's normal behavior or activities, B) the animal will not be handled or manipulated at any time, in any way, by any observers. Noninvasive observation of wild animals in their natural habitat is exempt from IACUC review provided the above criteria are met. Field studies that involve killing, trapping, banding, darting, implantation of telemetry devices, or any other invasive manipulation require IACUC approval.

3.4 Who can be a Principal Investigator?

All animal research that is conducted by or under the direction of any employee, faculty, staff, student, or agent of TSU in connection with his or her responsibilities must be under the direct supervision of a member of the TSU faculty. Generally, faculty are considered to be sufficiently knowledgeable to supervise and/or conduct research as determined by their appointment. The IACUC; however, may at its discretion determine that a faculty or member lacks sufficient expertise to carry out any particular research project based on their relevant training and experience.

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 (PI). 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 Associate Vice President for Academic Research 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 TSU policies for the conduct of research involving animal subjects.

3.5 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 as well as the 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 the Ag Guide provide 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 onus should be on the investigator to justify and explain his or her proposed experiments to the satisfaction of the IACUC.

3.6 Protocol Review Procedures

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

3.6.1 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.

3 business days prior to a meeting, the Research Compliance Coordinator in the Office of Sponsored Projects (OSP) 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.

3.6.2 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 OSP. 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 Research Compliance Coordinator (RCC) 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 Chair through the RCC, 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.

3.6.3 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.

3.6.4 Notification of Review Outcome

The Office of Sponsored Projects (OSP) 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 (PI) receives a written notification of review decisions (approved, modifications required (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.

3.7 Required Principal Investigator Certifications

By submitting an animal use protocol (AUP), to the IACUC for review, the PI 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, 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 TSU 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 PI has read and agrees to abide by the above obligations.

3.8 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 in (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.

3.9 Review of Modifications to Approved Protocols

3.9.1 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:

- 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 domestic animals used;
- in Principal Investigator;
- in anesthetic agent(s) or the use or withholding of analgesics;
- that impact personnel safety;
- in housing and or use of animals in a location that is not part of the animal program overseen by the IACUC;
- 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. IACUC may determine that the significant change proposed requires submission of a new protocol to accurately capture all required information to ensure the health and well-being of the experimental animals.

3.9.2 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. Amendment/modification applications to existing protocols that involve certain changes not considered significant (see Section 3.9.2) can be reviewed (and approved) administratively. Examples of non-significant changes include, but are not limited to, changes:

- in the funding source;
- in personnel (other than the PI);
- in the use of a new housing location (currently overseen by the IACUC); and
- in the approximate number of wild/field animals used.

Proposed non-significant changes require administrative review (and approval) by the Research Compliance Coordinator (RCC) prior to initiation.

3.10 Veterinary Consultation and Protocol Changes Addressing Humane Issues

On rare occasions, the method described in the IACUC-approved protocol for sedation, anesthesia, or euthanasia is found to be problematic during an ongoing study due to unanticipated side effects, inadequate efficacy, or other factors that impact humane animal care and use. As per NIH Notice NOT-OD-14-126 (Guidance on Significant Changes to Animal Activities), an IACUC-authorized

veterinarian can approve certain changes under these circumstances. Based on this guidance, the IACUC has determined that if significant humane issues arise during ongoing studies, at his/her discretion the attending veterinarian may consult with the research group and give approval for:

- changes in euthanasia from the method currently listed in the protocol to an alternative method that is considered species-appropriate based on the "Guidelines for the Humane Euthanasia of Laboratory Animals"; or
- a change in anesthesia, analgesia, and sedation methods as long as the new drug, dosage and method of administration are appropriate for the procedure and species. As stated in the Guide for the Care and Use of Laboratory Animals: "The selection of appropriate analgesics and anesthetics should reflect professional veterinary judgment as to which best meets clinical and humane requirements as well as the needs of the research protocol"; or
- changes in duration, frequency, type, or number of procedures performed on an animal.

The veterinarian must notify the IACUC and provide documentation of the consultation and the changes made. Furthermore, in order to assure that the Animal Use Protocol (AUP, or protocol) is updated to remain consistent with current practices, once a satisfactory new method has been identified it is the responsibility of the Principal Investigator to promptly submit an amendment application to the protocol incorporating these changes so that they become part of the approved protocol.

NOTE: It is not the intent of this policy to circumvent the normal IACUC protocol approval process, which can and should be used to make significant changes to protocols. It should only be used when there is an urgent and time-critical need to institute changes to assure proper alleviation of pain or distress.

3.11 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/Ag Guide, the IACUC is mandated to critically evaluate research protocols to ensure that pain and distress are minimized in laboratory and agricultural 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.

3.11.1 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.

3.11.2 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 Attending Veterinarian (AV) 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.

3.12 Standard Operating Procedure Review Criteria

Standard Operating Procedures (SOPs) are stand-alone documents independent of protocol applications. SOPs are frequently a component of an animal care and use program because they efficiently define veterinary care and animal husbandry. SOPs must be submitted to and approved by the IACUC before they can be cited in a new protocol application. One major function of the IACUC is to receive, review, and ultimately approve or disapprove SOP's submitted to the committee. They are also charged with overseeing all animal care and use activities according to federal, System, and institutional policies and regulations. These SOP's can originate with investigators, teachers, veterinarians, or others.

3.12.1 New SOP Review Procedures

Upon the receipt of a new SOP the Chair will assign a member of the committee to review the document and present their findings at the next meeting. The IACUC will review the SOP at a convened IACUC meeting and can make recommendations for modifications or approve the SOP. The author of the SOP will be notified by the RCC of the committees decision either requiring modification or approval. SOPs will undergo re-review every 3 years. The 3rd-year review can be carried out by DMR if after sending the SOP out for notice to committee no committee members calls for FCR of the SOP after 5 days.

3.12.2 SOP Revisions Review Procedures

Upon the receipt of a revision to an existing SOP the document will go out to notice to the committee. Committee members are given at minimum five (5) business days to review the document and respond either allowing DMR review of the changes or to hold the document 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. If any one member votes to hold the document until the next IACUC meeting, then the SOP is placed on the agenda for the next IACUC meeting. Otherwise, the protocol is reviewed by the DMR. The Chair through the RCC, designates one or more qualified members to review the requested changes to the SOP. These designated member(s) have authority to approve, require modifications in (to secure approval), or request full committee review.

3.13 Collaboration with other Institutions

In the conduct of collaborative research projects, Tarleton State University acknowledges that each institution is responsible for safeguarding the rights and welfare of research animals and for complying with applicable federal regulations. When a cooperative agreement exists, Tarleton State University may enter into a joint review arrangement, rely on the review of another qualified IACUC, or make similar arrangements for avoiding duplication of effort. A formal relationship must be established between the University and the other institution through a Memorandum of Understanding (MOU). This relationship must be formalized before the University will accept any

animal research proposals from the other institution or rely on the review of the other institution. The IACUC provides a template MOU that may be utilized by the PI.

For collaborative research, the principal investigator must identify all institutions participating in the research, the responsible IACUC(s), and the procedures for dissemination of protocol information (initial approvals, annual progress report approvals, relevant reports of unanticipated problems, and protocol modifications) between all participating institutions. The PI will provide information regarding project funding in the MOU. The investigator is responsible for serving as the single liaison with outside regulatory agencies, with other participating facilities, and for all aspects of internal review and oversight procedures. The investigator is responsible for ensuring that all participating facilities obtain review and approval from their IACUC and adopt all protocol modifications in a timely fashion. The investigator is responsible for ensuring that the research study is reviewed and approved by any other appropriate committees at the collaborating facility and at the participating facilities prior to beginning the animal research activities.

3.14 Cooperating Facilities or Individuals

A cooperating facility memo is required to assure the IACUC that the cooperating entity has provided permission for research activities conducted within the facility and will promote protection of research animals who associate with the cooperating entity. A cooperating facility memo is required if the PI is conducting research at an organization outside of Tarleton State University, or if the PI will be utilizing animals, equipment, personnel, land, or supplies from an organization outside of Tarleton State University for animal research.

For work that will utilize animals not owned or cared for by Tarleton State University the IACUC provides a template to be utilized by the PI. If the research involves using equipment, personnel, land, or supplies the following elements must be included in the memo:

- Date
- Addressed to Tarleton IACUC Committee
- Acknowledges activities to be performed
- Demonstrates a basic understanding of the activity being conducted
- Demonstrates a knowledge of the researcher's (or other responsible party's) expertise in relation to the activities being conducted
- Assures that the facility or area complies with all applicable laws and regulations in relation to animal health and safety
- Clearly delineates each parties responsibilities and liabilities (e.g. Party A agrees to maintain facilities in accordance with applicable laws and regulations; Party B is responsible for ensuring animal care and use is in accordance with applicable IACUC standards.)
- Original Signature and Authority or Office that qualifies the signatory official

3.15 Controlled Substance Notification

Upon submission of IACUC protocols that utilize a controlled substance, controlled substance analogue, or chemical precursors, the Office of Risk Management will be notified of the work by the RCC. Once approval has been granted to an Animal Use Protocol that contains a controlled substance, controlled substance analogue, or chemical precursor, the approval documents will be provided to the PI, the PI's department head, the PI's Dean, the Office of Risk Management, and the Associate Vice President of Research by the RCC. This notification is to ensure all parties are aware

of the work and the additional responsibilities. The PI is responsible for following all Federal, State, and University laws, regulations, and policies for the substance(s) being used. The PI holds this responsibility, unless the PI's department has a Texas Controlled Substance Registration Certificate, then the responsibility would fall to the individual listed on this document. The IACUC during semi-annual inspections may request access to the stored substance to check the expiration date and logs kept by the PI.

Section 4: Monitoring of Approved Protocols

4.0 Continuing Review: The Annual Review

Animal Welfare Regulations require an annual review of protocols. PHS Policy requires the IACUC to conduct continuing review of each previously approved, ongoing activity covered by PHS Policy at appropriate intervals as determined by the IACUC, including a complete review in accordance with the PHS Policy IV.C.1-4 at least once every three years.

At TSU, regardless of the species used, the IACUC requires an annual report on the status of each protocol. In doing so, the PI 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. In addition, the number of animals used over the course of the previous protocol year needs to be provided.

When Annual Progress Reports (APRs) are submitted to the OSP prior to the protocol's first and second anniversary, the protocol is considered active and experiments can be conducted while the annual report is under review.

APRs cannot be submitted after a protocol's anniversary date. If the PI fails to submit the annual progress report APR by the first and second anniversary, 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 IACUCs conduct appropriate and meaningful reviews of ongoing animal protocols in the same responsible manner that initial reviews are done. This means that the IACUC will not "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.

4.1 The Third-Year Resubmission: de novo Review

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 investigators, the OSP shall attempt to provide adequate warning of pending protocol expiration. It is the ultimate responsibility of the PI to submit the third-year resubmission by the appropriate deadline date for a scheduled review either by FCR or DMR, prior to protocol expiration. The IACUC requires a Third Year Resubmission be submitted as a new proposal, using the most recent version of the application.

4.2 Comparison of Protocols to Grants

Funded research involving live animals requires verification that the IACUC has reviewed and approved the AUP. Regardless of when the review occurs, the PI should ensure that the research described in the grant proposal application is consistent with any corresponding protocol(s) reviewed and approved by the IACUC. Therefore, a copy of the 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.

4.2.1 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.

4.2.2 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 OSP requests verification.

4.2.3 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 4.2.1).

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 PI's responsibility to explain how the changes relate to the original protocol. Because the determination of consistency between the grant and original protocol has already been established, there will generally be no need to "re-verify" grant-to-protocol consistency for amendments.

4.2.4 Managing Grant-Protocol Inconsistencies

The AV or IACUC Chair usually conducts the grant to protocol comparison. The PI, 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.

4.3 Post-Approval Monitoring

Periodically, the IACUC will identify certain protocols (Class D and E, based on USDA Classifications and 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. In addition, the RCO, RCC, IACUC Chair, and AV conducts random, but frequent, visits to high-use areas, including satellite facilities so as to ensure that minor issues are identified rapidly for quick resolve and that major issues are prevented.

Section 5: Training in the Humane Care and Use of Laboratory Animals

5.0 Training

All staff working with laboratory and/or agricultural 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 under this section and section 2.31."

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.

All personnel working with laboratory and/ or agricultural animals must complete the CITI program "Working with IACUC". All individuals must also complete the CITI program "Responsible Conduct of Research" training. These course trainings will be renewed every 3 years after the original completion date. When submitting an IACUC proposal, training must be up to date. If training is valid at time of proposal submission, training will remain valid up to the next annual review and progress report. Species specific trainings will be assigned at the discretion of the PI.

5.1 Who Should Receive Training?

All personnel interacting directly with or working in the vicinity of animals should receive training and be named on an Animal Use Protocol (AUP). Training made available for each faculty, staff, and/or student should be specific to the animal species involved and to the kind of procedures to be performed or animal-related interactions.

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

5.2 Education and Training for IACUC Members

5.2.1 New IACUC Member Training

New IACUC member training consists of the following via online and in person training: 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.

All new IACUC members are required to complete the “Essential for IACUC Members” training course available through CITI programs.

5.2.2 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.

All IACUC members must maintain a valid “Essential for IACUC Member” training, while being an active committee member. This course will be renewed every 3 years after the original completion date.

Section 6: Semiannual Program Review and Facility Inspections

6.0 Semiannual Reviews

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

6.1 Program Review

The animal care and use program review includes an evaluation of institutional policies and responsibilities (lines of authority and reporting channels), IACUC membership and functions, and IACUC recordkeeping and reporting procedures.

The IACUC will review at least once every six months TSU's program for humane care and use of animals, using the Guide/Ag Guide as a basis for evaluation. The IACUC procedures for conducting semiannual program reviews are as follows:

1. The IACUC reviews the TSU'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 RCC and IACUC Chair and submitted to the IO/RCO.

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. TSU, 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.

The IACUC inspects at least once every six months all of the TSU's animal facilities using the Guide/Ag Guide as a basis for evaluation. The IACUC procedures for conducting semiannual facility inspections are as follows:

1. Every six (6) months, the RCC and IACUC Chair organizes the inspection schedule of the animal facilities located on campus. These inspections are conducted using the Guide/Ag Guide, the PHS Policy on Humane Care and Use of Laboratory Animals, and as applicable, 9 CFR Chapter I, subchapter A, as a basis for evaluation. Deficiencies are categorized as minor or significant. All IACUC members are invited, and encouraged, to attend the facility inspections. At a minimum, two (2) members are present for each inspection. No member is involuntarily excluded from participating in any portion of the facility inspections.

2. A responsible party (e.g., PI) is notified, in writing, of any minor or significant deficiency identified in his/her laboratory, facility, or designated space. Responsible parties are required to promptly provide a response to the deficiency notification with a description of how the deficiency has been corrected or to submit a written plan with a timeline outlining how the deficiency will be corrected.

3. Findings from the Facility Inspections are compiled by the RCC and IACUC Chair and prepared for IACUC review following the inspections. The RCC requests additional comments and minority views from all members present.

6.2.1 Categories to be Inspected

It is helpful for the inspection team to use a list of categories such as:

- sanitation,
- food and water provisions,
- animal identification,
- waste disposal,
- animal health records,
- controlled and/or expired drugs,
- environmental control,
- occupational health and safety concerns,
- staff training, and
- knowledge of applicable rules and regulations, and security.

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

6.2.3 Performing Inspections

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

- An updated list of all facilities to be inspected should be maintained by the IACUC.
- All proposals submitted to the IACUC should specify locations where animal procedures will be performed.
- It is helpful to maintain a list of all facilities including room number, function of the room, species, and deficiencies identified during the previous inspection.
- For facilities with multiple rooms, a floor plan can assist the inspectors.
- If a subcommittee is performing the inspection, a blend of Committee members who last inspected the area with members who did not participate in the last review can improve the process.
- Apparent deficiencies should be discussed with the person in charge of the facility to ensure that the team's perception of the situation is accurate. In some cases, an apparent deviation will be due to the experiment in progress, e.g., withholding of food prior to surgery.
- Use of a checklist provides consistency and helps document that all categories were assessed.

6.3 Deficiency Correction Schedule

All deficiencies identified 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 with scheduled dates for correction are approved by the IACUC, and 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 and approved by the IACUC at convened meetings.

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 OSP.

Section 7: Animal Welfare Concerns and Non-Compliance Situations

7.0 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 institutional employees. Procedures must be established to ensure that concerns are communicated to the IACUC. The Committee must review each concern in a timely and systematic manner and, when necessary, take prompt, appropriate corrective actions.

7.1 Methods for Reporting

To facilitate communication, there are a number of options available to communicate concerns about animal care and use at TSU, or to report instances of suspected non-compliance with laws, rules, regulations and policies. The names of contact persons including the AV, the Chair, and RCC are listed on the IACUC website. Information about how to report concerns are also listed at each animal facility. EthicsPoint(www.ethicspoint.com), a Risk, Fraud, & Misconduct Hotline established by the Texas A&M University System, may also be utilized when reporting concerns.

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.

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. The policy of TSU is to prohibit unlawful retaliation against employees as a consequence of good faith actions in the reporting of, or the participation in an investigation pertaining to, allegations of wrongdoing.

7.2 Procedures for the Investigation of Animal Care and Use Concerns

7.2.1 Initial Evaluation and Actions

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. For example, conditions that reportedly jeopardize the health or well-being of animals should be evaluated immediately. To cope promptly with such situations, the AV 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 dealt with merely as a matter of convenience. Emergency meetings may be necessary in these cases to ensure prompt consideration of concerns.

7.2.2 The Role of IACUC Chair

Upon receipt of a concern, the IACUC Chair will review the complaint and notify the IO. The IACUC Chair will determine whether the concern requires further investigation and immediate action, further investigation but no immediate action, or no action.

If the concern requires further investigation, the IACUC chair will assign a subcommittee as described in 7.2.3, notify the IACUC, and convene an IACUC meeting once the investigation subcommittee has completed their report.

If immediate action is warranted because animal or human welfare may be compromised, the IO may halt animal activities until such time as the IACUC committee may investigate, and make a determination. 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. If an activity is suspended, the IO shall report that action to any federal agency funding that activity. If the PHS supports the activity in any way, the IACUC, through IO, must promptly notify OLAW.

If no action is required, the concern will be added to the agenda, and discussed at the next convened IACUC meeting. After meeting and reviewing the concern, the IACUC may assign a subcommittee as described in 7.2.3.

In the event of a conflict of interest with the IACUC Chair, the IACUC Vice Chair will perform the duties outlined in 7.2.2 in place of the conflicted party.

7.2.3 Investigation

A subcommittee of the IACUC should conduct further investigation as required. It is important to avoid actual or perceived conflicts of interest in this process.

The IACUC (or IACUC Chair as described in 7.2.2) should charge a designated person or group with its requirements for information gathering as well as constructing a report of the investigation 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:

- 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 report presented to 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 report reviewed 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 and institutional policies and procedures, and
- recommended actions, if appropriate.

7.2.4 Outcomes and Final Actions

Upon receipt and evaluation of the report, the IACUC may request further information or find that:

- there was no evidence to support the concern or complaint,
- the concern or compliant was not substantiated, but
    - related aspects of the animal care and use program requires further review or
    - other institutional programs may require review, or
- the concern or complaint was valid.

7.3 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.

7.4 Consequences 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, TAMU System attorneys, TAMU System Office of Research Compliance, etc.).

7.4.1 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 sanctions be considered.

7.4.2 Suspension of Animal Activities

The IACUC is empowered to suspend a project if it finds violations of TSU procedures, AWA requirements, PHS Policy, the Guide, the Ag Guide, Assurance, or Animal Welfare Regulations. Suspension may occur only after review of the matter at a convened meeting of a quorum of the IACUC, and a vote for suspension by a majority of the quorum present. Further, the IACUC must consult with the IO regarding the reasons for the suspension. The IO is required to take appropriate corrective action, and report the action and the circumstances surrounding the suspension to OLAW if necessary.

7.5 Reporting Requirements

Failure by research personnel to follow Federal and/or TSU regulations, guidelines, and/or procedures may require reporting to the appropriate institutional, local, state, and/or Federal agencies. Reportable violations may include, but are 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/Ag Guide;
- IACUC suspensions; and
- failure to correct a significant deficiency in accordance with the specified schedule and plan.

7.5.1 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/Ag Guide. The report should be on TSU/departmental letterhead, addressed to the IACUC Chair, the RCC, and emailed (preferred) to the RCC. 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).

7.5.2 IACUC and IO Reporting

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

- Principal Investigator (PI)
- PI's Department Chair
- PI's Director and/or College Dean
- Director, Office of Faculty Research (if project is externally funded)

7.5.3 Response to External Requests for Information

In accordance with applicable policies, guidelines, and regulations, upon request, TSU 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: Recordkeeping

8.0 Maintaining IACUC Records

The Office of Sponsored Projects is responsible for maintaining:

- minutes of IACUC meetings;
- 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 with the recommendations of the Guide/Ag Guide and with commonly accepted professional standards.

8.1 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 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
  Generally a member is marked as either present or absent, if the member arrives late or leaves during a meeting the time is noted in the minutes. 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 a member recuses themselves due to a conflict of interest this is noted in the meeting minutes. 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 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.

8.2 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

Protocols and standard operating procedures (SOPs) that have been submitted for review but have not been acted on by the PI will be terminated after 45 days of inactivity. Terminated protocols and SOPs will require resubmission, and be received as new submissions. These new submissions will receive a new protocol number, and begin the review process anew.

8.3 Other Records

Both the PHS Policy and the AWRs require that TSU 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.

Section 9: IACUC Occupational Health & Safety (OH&S) Program

9.0 Description and Purpose

Tarleton State University is committed to providing a safe, secure, and healthy environment for all faculty, staff, students, and visitors. Any employee who, based on job function and risk assessment or named on an Animal Use Protocol, may be exposed to occupational health risks, may participate in the IACUC Occupational Health and Safety (OH&S) Program. Students not employed by TSU but who encounter health risks due to their academic or research activities are also eligible to participate. The program focuses on occupations and research activities involving exposure to animals and those who handle biological materials or chemicals or are exposed to other health risks.

9.1 Enrollment Requirements

All faculty, staff, and students who are, or will be, working with animals are required to enroll in the IACUC OH&S Program. Through communication with PI and Employee Services, the OSP will verify enrollment of all relevant personnel. No personally identifiable health information will be accessed by the OSP. The OHS enrollment is valid for one year and must be updated annually. When submitting an IACUC protocol, OHS enrollment must be up to date. If the enrollment is valid at time of protocol submission, it will remain valid up to the next annual review and progress report.

9.1.1. Opting Out or Declining Participation

After completing the enrollment process through the OSP individuals may elect to opt out or decline the medical surveillance portion of the program. The requirement to complete the online evaluation process prior to declination is to ensure that employees are fully informed about risks associated with their work activities and to be informed of the services available through the program.

9.2 Administration of Program

The IACUC OH&S Program is administered by the OSP. The IACUC OH&S Program facilitates awareness of, and appreciation for, safe conduct of work and research activities so that accidents and occupational injuries and illnesses will be minimized. The IACUC OH&S Program, in conjunction with the Department of Risk Management and Compliance, shall identify and control, to the extent possible, any safety, public health, and environmental hazards presented by work and research activities.

Section 10: Quick References

10.0 Links

OLAW Institutional Animal Care and Use Committee Guidebook
http://grants.nih.gov/grants/olaw/GuideBook.pdf

Public Health Service Policy on Humane Care and Use of Laboratory Animals
http://grants.nih.gov/grants/olaw/guide-for-the-care-and-use-of-laboratory-animals.pdf

The Guide for Care and Use of Agricultural Animals in Research and Teaching (Ag Guide)
http://www.fass.org/docs/agguide3rd/Ag_Guide_3rd_ed.pdf

The Guide for Care and Use of Laboratory Animals (The Guide)
http://grants.nih.gov/grants/olaw/guide-for-the-care-and-use-of-laboratory-animals.pdf

USDA- AWA/AWR Guidebook
http://www.aphis.usda.gov/animal_welfare/downloads/Animal%20Care%20Blue%20Book%20-%202013%20-%20FINAL.pdf

TAMU System Policy and Regulations
https://www.tamus.edu/legal/policy/policy-and-regulation-library/

TSU Rules, Procedures, and Standard Administrative Procedures
http://www.tarleton.edu/policy/index.html

10.1 IACUC SOP References

SOP 001 Observation and Monitoring

SOP 008 Whistle Blower Policy

SOP 009 Equine Center Care- Livestock

SOP 010 Maintenance of Fish Room

SOP 0011 Allergy Prevention and Control

SOP 0014 Beef Cattle Enterprise

SOP 0015 Goat Enterprise

SOP 0016 Sheep Enterprise

SOP 0021 SOP Control

SOP 0022 Controlled Substances for Dpt. Biological Sciences

SOP 0023 Frog Care and Feeding

SOP 0024 Quail Care

SOP 0025 Guillotine Use and Maintenance

SOP 0026 General Care- Rodents

SOP 0042 Field Collecting Methods for Fish

SOP 0043 Emergency Management Procedures