

**The University of Texas at Austin
Institutional Animal Care and Use Committee
Handbook of Policies and Procedures (IACUC/HOPP)**

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Section 1: Introduction

1.0 Purpose and Scope of Manual

It is the responsibility of The University of Texas at Austin (University) to provide suitable orientation, appropriate materials, adequate resources and training to enable research faculty and staff and IACUC members to carry out their respective duties consistent with the *Guide for the Care and Use of Laboratory Animals* (the *Guide*), the *Public Health Service Policy on Humane Care and Use of Laboratory Animals* (PHS Policy) and the *Animal Welfare Act and Animal Welfare Regulations* (AWRs).

Local institutional policies and procedures need to be a part of the training and education program. Frequently, researchers and IACUC members find it confusing to understand the differences between the federal policies and requirements and institutional policies and procedures. The Institution is responsible for informing researchers and IACUC members of their responsibilities, providing training relative to their respective roles, and ensuring information to fulfill their duties is available.

1.1 Mission Statement

The University of Texas at Austin (University) recognizes the importance of animals in research and the scientific and ethical responsibility for their humane care and use. All those involved with the use of laboratory animals are responsible for insuring the health and well-being of the animals used in research and education at the University. The IACUC is responsible for overseeing the provisions for the care and well-being of animals used for research and educational purposes at the University and serves the public by ensuring compliance with all legal and ethical standards regarding the use of vertebrate animals in research and teaching at the University.

1.2 Office of Laboratory Animal Welfare (OLAW)

The Office of Laboratory Animal Welfare (OLAW) implements PHS Policy. While OLAW is located organizationally at the National Institutes of Health (NIH) in Bethesda, Maryland, OLAW's responsibility for laboratory animal welfare extends beyond NIH to all PHS-supported activities involving animals. From time to time, OLAW issues policy guidance, interpretation, or general notices regarding PHS Policy, and co-sponsors animal welfare workshops that are held in different locations across the country.

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.

1.2.1 Animal Welfare Assurance

Before the PHS may award a grant or contract that involves the use of animals, the recipient institution and all performance sites involving or using animals must have on file with OLAW an approved Animal Welfare Assurance (Assurance). The Assurance is the cornerstone of a trust relationship between the institution and the PHS. Included in the Assurance are:

- The designation of the Institutional Official responsible for compliance;
- A commitment that the institution will comply with the PHS Policy, with the *Guide*, and with the AWA and the Animal Welfare Regulations; and
- A description of the institution's program for animal care and use.

The PHS Policy applies to the use of live, vertebrate animals in any activity supported or conducted by the Public Health Service (PHS). PHS agencies include:

- Agency for Healthcare Research and Quality;
- Agency for Toxic Substances and Disease Registry;
- Centers for Disease Control and Prevention;
- Food and Drug Administration;
- Health Resources and Services Administration;
- Indian Health Service;
- National Institutes of Health;
- Office of Public Health and Safety;
- Office of the Secretary;
- Program Support Center;
- Substance Abuse and Mental Health Services Administration; and
- Office of the Assistant Secretary for Preparedness and Response.

The University of Texas at Austin has an Animal Welfare Assurance on file with OLAW. The Animal Welfare Assurance number is A4107-01.

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.

The University of Texas at Austin is a registered Class R Research Facility with the USDA (customer number 1453 under certificate number 74-R-0029).

1.3.1 The Animal Welfare Act

The Animal Welfare Act (AWA) requires that minimum standards of care and treatment be provided for certain animals bred for commercial sale, used in research, transported commercially, or exhibited to the public. Individuals who operate facilities in these categories must provide their animals with adequate care and treatment in the areas of housing, handling, sanitation, nutrition, water, veterinary care, and protection from extreme weather and temperatures. Although Federal requirements establish acceptable standards, they are not ideal. Regulated businesses are encouraged to exceed the specified minimum standards.

1.3.1.1 Inclusions

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

Animal shelters and pounds are regulated if they sell dogs or cats to dealers.

1.3.1.2 Exemptions

The AWA (Title 7, Chapter 54, Section 2132(g)) excludes birds, rats of the genus *Rattus*, and mice of the genus *Mus*, bred for use in research, horses not used for research purposes, and other farm animals, such as, but not limited to livestock or poultry, used or intended for use as food or fiber, or livestock or poultry, used or intended for use for improving animal nutrition, breeding, management, or production efficiency, or for improving the quality of food or fiber.

Retail pet shops are not covered under the Act unless the shop sells exotic or zoo animals or sells animals to regulated businesses. Pets owned by private citizens are not regulated.

1.3.1.3 Research Facilities

In addition to providing the required standards of veterinary care and animal husbandry, regulated research facilities must provide dogs with the opportunity for exercise and promote the psychological well-being of primates used in laboratories. Researchers must also give regulated animals anesthesia or pain-relieving medication to minimize the pain or distress caused by research if

the experiment allows. The AWA also forbids the unnecessary duplication of a specific experiment using regulated animals.

Research facilities must establish an Institutional Animal Care and Use Committee (IACUC) to oversee the use of animals in experiments. The IACUC is responsible for ensuring that the facility remains in compliance with the AWA and for providing documentation of all areas of compliance to the USDA/APHIS. The AWA also does not permit APHIS to interfere with research procedures or experimentation. To ensure that all licensed and registered facilities continue to comply with the AWA, APHIS inspectors make unannounced inspections at least once annually.

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

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

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

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.

The University voluntarily participates in AAALAC's program, in addition to complying with the local, state and federal laws that regulate animal research. Participating institutions receive an independent, unbiased expert assessment, and those that meet or exceed applicable standards are awarded accreditation.

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.

The University of Texas at Austin is an AAALAC International Accredited institution since October 29, 2001. AAALAC International has continued full accreditation for all programs and facilities of The University of Texas at Austin under file number 000988.

Section 2: The Institutional Animal Care and Use Committee

2.0 Authority

Institutional Animal Care and Use Committees (IACUC's) derive their authority from the law. The Health Research Extension Act (HREA) of 1985 and the Animal Welfare Act mandate the existence of IACUC's. The laws require the Chief Executive Officer (CEO) of an organization to appoint the IACUC, whose responsibilities are delineated in the law and federal policy and regulations. The Office of Laboratory Animal Welfare (OLAW) considers the CEO to be the highest operating official of the organization. The President of The University of Texas at Austin delegates authority through the Institutional Official (IO) to appoint the membership of the IACUC on an annual basis.

Once appointed, the IACUC reports to a senior administrator known as the Institutional Official (IO). The Vice President for Research is the appointed IO at The University of Texas at Austin. The IO is given the administrative and operational authority to commit institutional resources to ensure compliance with the PHS Policy and other requirements.

The IACUC's mandate to perform semiannual program evaluations as a means of overseeing the animal care and use program puts the IACUC in an advisory role to the IO. In its semiannual reports the IACUC advises the IO of the status of the Institution's compliance, establishes plans and schedules for correcting deficiencies necessary to either maintain or achieve compliance, and makes recommendation to the IO regarding any aspect of the Institution's animal program, facilities, or personnel training.

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

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

2.1 Committee Composition

The IACUC is composed of regular voting members, alternate voting members, and non-voting members. The IACUC may use, as necessary, non-voting members and consultants during review discussions. Some IACUC members fulfill specific regulatory requirements (e.g., veterinarian with program responsibility, 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, but OLAW strongly recommends against the same person serving multiple roles, because the responsibilities and authorities vested in each of the positions are distinct and often require different skills. Appointing one individual to more than one of these roles may circumvent intended checks and balances. Also of importance is the perception of conflict of interest, which can lead to allegations of improprieties from various sources.

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

Chair. The Chair is appointed annually and is a faculty member of the University with research experience.

Nonaffiliated. The nonaffiliated member(s) represent general community interests. Neither they, nor their immediate family, have an affiliation with The University of Texas at Austin. 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, and there is a specific one-to-one designation of IACUC members and alternates. An IACUC member and his/her alternate may not count toward

a quorum at the same time or act in an official member capacity at the same time. Alternates should receive training identical to the training provided to regular IACUC members.

The University of Texas at Austin 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 PHS Policy IV.A. 3. a., b.	USDA Regulations 9 CFR, 2.31 (a) (b)
<ul style="list-style-type: none"> • Appointed by the IO • Minimum of five members: <ul style="list-style-type: none"> ○ 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 <i>Guide</i>, 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. 	<ul style="list-style-type: none"> • Appointed by the IO • Minimum of three members: <ul style="list-style-type: none"> ○ 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 according to The University of Texas at Austin’s Handbook of Operating Procedures and Policy Memoranda (<http://www.utexas.edu/policies/hoppm/h0511.html>).

An investigator or IACUC member is said to have a conflict of interest whenever that person, his or her spouse, or dependent child falls under any of the following conditions:

- Is an investigator or sub-investigator on the protocol (IACUC members only, not applicable to PI's).
- Has entered into a financial arrangement with the sponsor or agent of the sponsor, whereby the outcome of the study could influence the value of the economic interest.
- Acts as an officer or a director of the sponsor or an agent of the sponsor.
- Has an equity interest in the sponsor of \$10,000 or greater or 5% or greater of the equity sponsor.
- Has received payments or other incentives from any sponsor that when aggregated for the investigator or member, spouse and dependent children, total of \$10,000 or greater.
- Has identified him or herself for any other reason as having a conflict of interest.

Other possible examples of conflict of interest include cases where:

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

If the investigator submitting a protocol believes that an IACUC member has a potential conflict, the investigator may request that the member be excluded. The Chair (or in his/her absence, the Vice-Chair) will present the declared conflict and the Committee will determine whether a conflict exists. Should an IACUC member declare involvement in any way in a research protocol under review by the IACUC, or state a conflict of interest with the research protocol, then the member(s):

- May remain in the meeting room to provide information requested by the IACUC;
- Leave the meeting room for discussion and voting; 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 Institutional Animal Care and Use Committee and the Office of Research Support (ORS) (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)).

The University of Texas at Austin defines a “quorum” as more than half of the regular 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 19 voting members, at least 10 members must be present at a convened meeting to constitute a quorum and approval of a protocol would require a minimum of six 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 the University’s program for humane care and use of animals, using the *Guide* as a basis for evaluation. The IACUC procedures for conducting semiannual program reviews are described in Section 7.1.
2. Inspect at least once every six months all of the University’s facilities, including satellite facilities, using the *Guide* as a basis for evaluation. The IACUC procedures for conducting semiannual facility inspections are described in Section 7.2.
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 7.3.
4. Review concerns involving the care and use of animals at the University. The IACUC procedures for reviewing concerns are described in Section 8.
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 3.9.
8. Notify investigators and the University in writing of its decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications required to secure IACUC approval as set forth in the PHS Policy IV.C.4. The IACUC procedures to notify investigators and the University of its decisions regarding protocol review are described in Section 3.6.4.
9. Conduct continuing review of each previously approved, ongoing activity covered by PHS Policy at appropriate intervals as determined by the IACUC, including a complete review in accordance with the PHS Policy IV.C.1-4 at least once every three years. 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 8.4.2.

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 withdrawal of Certification and assessment of monetary fines.

2.7 Use of Electronic Mail (Email) for Official Correspondence¹

Electronic mail (email), like postal mail, is a mechanism for official University communication. The IACUC will exercise the right to send email communications to all laboratory 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 utilization proposal (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

The IACUC will 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 as follows:

11. Recommendations regarding any aspect of the University's animal program, facilities, or personnel training are formulated at convened meetings of the IACUC.
12. Recommendations are prepared in writing by the IACUC Program Coordinator, 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 and approved at a convened meeting of the IACUC. Any minority views are noted and included in the final report.
13. The IACUC Chair or his/her designee submits recommendations, including minority views that are approved by the IACUC to the IO.

¹ Section 2.7 contains content that was adapted from the Information Technology Services (ITS) policy on "University Electronic Mail Student Notification Policy (Use of E-mail for Official Correspondence to Students", available at: <http://www.utexas.edu/its/policies/emailnotify.php>

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 Review²

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

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

3.2 Specific Types of Activities³

- Research

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

- Teaching

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

² This section contains content that was adapted from materials obtained from the University of Minnesota.

³ This section contains content that was adapted from materials obtained from the University of Minnesota.

Review is required even if the activity does not seem to qualify as “true research” (e.g. when the results are not intended for publication, will not advance work in another area, or will not contribute to generalizable knowledge).

- Research Conducted by “Affiliated Faculty”

Research conducted by “affiliated faculty”—those who hold clinical or adjunct appointments—is subject to the Institution’s guidelines for animal use and must be submitted for IACUC review.

Any research project that is conducted by or under the direction of any employee or agent of the institution, in connection with his or her institutional responsibilities, requires IACUC approval.

- Research Projects in Which the Investigator is a Consultant

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

- The investigator is hired on his or her own time;
- The investigator holds no rights in the work; and
- Neither the investigator nor the University 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.

With regard to activities supported by PHS funds, foreign institutions that serve as performance sites must also have Assurances on file with OLAW.

3.3 Exemptions

The following are exempt from IACUC review:

- Activities involving animals that perform tasks, participate in club activities, or appear in exhibits or demonstrations;
- Use of tissues, organs or other parts of dead animals if received as such; and
- Noninvasive observation of wild animals in their natural habitat. 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?⁴

All animal research that is conducted by or under the direction of any employee, faculty, staff, student or agent of The University of Texas at Austin in connection with his or her responsibilities must be under the direct supervision of a member of the Faculty of the University. 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 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. 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 Director of the Office of Research Support 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 University 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

⁴ Section 3.4 contains content that was adapted from materials obtained from the University of Pennsylvania.

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* 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* provides useful guidance on these and other practices.

If the IACUC does not have the scientific and technical expertise to evaluate all aspects of a proposal it may bring in outside expert consultants to provide information. Such consultants will not have a conflict of interest with the research activity and may not vote on any matters pertaining to the protocol. In all cases, the 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. The Institution 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 receive approval.

At least three (3) business days prior to a meeting, the Office of Research Support distributes copies of the protocols being presented or any other items of discussion to each IACUC member, including alternate and non-voting member(s). Protocols are assigned a primary reviewer, who at the meeting orally presents the protocol to the rest of the committee for review and discussion. In addition, each protocol is assigned to a veterinarian to conduct an in-depth review of the protocol. The Committee then 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.

Primary 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. Primary review differs from designated member review (see Section 3.6.2.), which delegates authority to approve a proposal to one or more members.

3.6.2 Designated Member Review (DMR)

To utilize designated member review (DMR), each IACUC member must be provided with, at a minimum, a list of the proposed research protocols or proposed significant changes to previously approved protocols prior to the review. Written descriptions of the research proposals must be made available to IACUC members upon request. Each IACUC member is provided a copy of the protocol document from the Office of Research Support. Committee members are given a five (5)-business day member consideration period 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. These responses are sent to the IACUC Program Coordinator via email. The IACUC Program Coordinator tallies the votes to ensure that more than half of the voting members respond, then at the end of the member consideration period, the IACUC Program Coordinator sends the protocol to DMR for review. 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. If all members vote to allow the DMR to review the protocol before the end of the member consideration period, then the IACUC Program Coordinator sends the protocol to DMR for review.

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

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.

Amendment/modification applications to existing protocols that involve certain changes not considered significant (see Section 3.9.2) can be reviewed (and approved) administratively.

3.6.4 Notification of Review Outcome

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

- Upon completion of the review process, each Principal Investigator receives a written notification of review decisions (approved, modifications required in (to secure approval), approval withheld, or tabled) and whether any special monitoring provisions will be required. Records of communication are maintained 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

In order to submit an animal utilization proposal (AUP), or protocol, to the IACUC for review, the Principal Investigator must certify the following:

- I assure that myself and 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*, 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, and that they have completed an approved UT-Austin Orientation Course [3198: Orientation] and received training in the biology, handling, and care of this species; aseptic surgical methods and techniques (if necessary); the concept availability and use of research or testing methods that limit the use of animals or minimize distress; the proper use of anesthetics, analgesics, and tranquilizers (if necessary), and procedures for reporting animal welfare concerns.
- I assure that all procedure will be conducted in accordance with The University of Texas at Austin safety procedures, including those pertaining to personal protective equipment.
- I assure that all individuals working on this proposal are participating in the Laboratory Animal and Biomedical Occupational Health Services Program (LABOHSP).
- 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. Such changes will not be implemented until approval is obtained from the IACUC. Animals will not be transferred between investigators without prior approval.

- I assure that I have reviewed the pertinent scientific literature and the sources and/or databases and have found no valid alternative to any procedures described herein which may cause more than momentary or slight pain, distress, or generalized discomfort to animals, whether it is relieved or not.
- I assure that every effort has been made to minimize the number of animals used and reduce the amount of pain, distress, and/or discomfort these animals must experience.
- I assure that the activities described with in this document submitted for IACUC review are consistent with those described in any related grant, contract, or subcontract.
- I assure that the information contained in this application for animal use is accurate to the best of my knowledge.
- I understand that this application and/or my animal use privileges may be revoked by the IACUC if I violate any of the aforementioned assurance statements.

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

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, based on the PHS Policy and AWRs, 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, changes:

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

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

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. Examples of non-significant changes include, but are not limited to, changes:

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

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

3.10 Weekly DMR Docket

The goal of the IACUC and Office of Research Support is to rapidly process protocols in an effort to provide faculty with the maximum amount of time possible to address Committee concerns and clarifications. In order to maintain an expeditious review process, proposed protocol modifications and annual renewal forms will be circulated to Committee members for one week (see Section 3.6.2) and only those items that are specifically asked to be reviewed at the FCR will be assigned to a meeting agenda.

3.11 Administrative Action on Termination of Reviewed (Pending/Not Yet Approved) Protocols and Amendments

The IACUC has the responsibility to require modification(s) to requests for animal use prior to approving a protocol or amendment to an existing protocol. To prevent the development of a collection of pending/not yet approved protocols or pending/not yet approved amendments, that results in slower service to all researchers, complicates the oversight process, and interferes with

support of active research, the IACUC has established a process for protocol and amendment review and approval (and amendment review and approval). The goal of the IACUC and Office of Research Support is to rapidly process protocols in an effort to provide faculty with the maximum amount of time possible to address Committee concerns and clarifications. This policy specifically addresses the duration of time at which point the IACUC will administratively inactivate an application for failure to respond for further clarification and queries.

The Office of Research Support (ORS) staff will pre-review and process the proposed activity (protocol application or amendment application) within three (3) business days of receipt. The ORS staff will communicate the review status (as described in Section 3.6) within five (5) business days of the IACUC meeting or receipt of review comment(s) from the Designated Member Reviewer(s). ORS Staff will receive PI correspondence, when provided, and forward to the appropriate IACUC activity (Designated Member Reviewer(s), Chair, Vice Chair, Attending Veterinarian, etc.) within two (2) business days of receipt.

The process for PI notification of IACUC administrative actions is as follows (counting from the day of Full-Committee Review or the end of the Member Consideration Period as day 0):

Day 0-5 (Week 1): ORS staff will provide IACUC communication to Principal Investigator detailing the modifications required in (to secure approval), including specific IACUC clarifications, required training, etc. Email is the preferred method of communication. If there is no email address, then a facsimile or hard copy mailed letter may be used.

Day 10-15 (Week 3): If no response from the PI is received by this milestone, then the ORS staff will send a second correspondence to the PI requesting a response to the IACUC's previous correspondence. Email is the preferred method of communication. If there is no email address, then a facsimile or hard copy mailed letter may be used.

Day 20-25 (Week 5): If no response from the PI is received by this milestone, then the ORS staff will send a third correspondence to the PI requesting a response to the IACUC's previous correspondence. Email is the preferred method of communication. If there is no email address, then a facsimile or hard copy mailed letter may be used. A template letter is attached to this policy.

Day 30-35 (Week 7): If no response from the PI is received by this milestone, then the:

- a. ORS staff will send a fourth correspondence to the PI requesting a response to the IACUC's previous correspondence. Email is the preferred method of communication. If there is no email address, then a facsimile or hard copy mailed letter may be used.
- b. ORS Staff will place a phone call to the PI, and if the PI is not available, a message will be left on the voice messaging system.

Day 40 (Week 8): If no response by the PI is received by this milestone, then the ORS staff will send an email (facsimile or hard copy letter) to the PI advising them of the termination action and advising them that a new protocol / amendment must be submitted to the IACUC if they wish to pursue this proposed activity.

3.12 Minimization of Pain and Distress

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

As required by the PHS Policy and the AWRs, and reiterated in the *Guide*, the IACUC is mandated to critically evaluate research protocols to ensure that pain and distress are minimized in laboratory animals and assure that appropriate steps will be taken to enhance animal well-being. The AWRs stipulate that the IACUC determine that the principal investigator has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animal and has provided a written narrative description of the methods and sources used to determine that alternatives were not available. The *Guide* states that the IACUC should ensure the protocol addresses:

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

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

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

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

3.12.1 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.

3.12.2 Alleviation of Pain and Distress

Accepted best practices for dealing with the possibility of unrelieved pain and distress should be considered and incorporated into protocols unless there is a sound scientific rationale for deviation from those practices. The investigator must also provide an assurance that unrelieved pain will continue for only the minimum period of time necessary to attain the study objectives.

Protocol methodology should be considered that decreases the potential for pain or distress. In addition to thorough searches of the literature, this can be done through the careful use of pilot studies to determine earlier endpoints or less invasive alternatives.

Pharmacologic treatment of pain or distress should be given as consistent with the type of pain/distress and the needs of the research question. The veterinarian must be consulted for all such protocols and should provide guidance to investigators and the IACUC. Non-pharmacologic treatments should also be employed. This may include special housing considerations, dietary and other environmental enrichments, adjustments and careful supportive care.

It is the responsibility of the investigator to show s/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.

3.13 Guidance Documents

From time to time, the IACUC will issue guidance documents (a.k.a., Guidelines) to the University's animal research community. These guidelines have been written to assist faculty, staff, and students in performing vertebrate animal procedures in a humane manner and complying with pertinent regulatory requirements. Under some circumstances deviations from these procedures may be indicated but such variances must be approved in advance by the IACUC.

A current list of available guidelines is available at:

http://www.utexas.edu/research/rsc/iacuc/policies_index.html

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 The University of Texas at Austin, regardless of the species used, the IACUC requires an annual report on the status of each protocol. In doing so, the Investigator verifies that completed activities were conducted in accordance with the approved protocol, describes any proposed departures from the approved protocols, and solicits information about activities projected for the upcoming year. In addition, the number of animals used over the course of the previous protocol year needs to be provided.

When Annual Renewal Forms are submitted to the Office of Research Support prior to the protocol's expiration date, the protocol is considered active and experiments can be conducted while the annual renewal is under review.

4.0.1 Procedures for Conducting Annual Reviews

Sixty (60) days before the first and second anniversary of the protocol approval, the PI is sent a notification requesting the status of the protocol (active or inactive), requesting any proposed modifications to the protocol, and asking for the number of animals the PI has used in the previous 12 months. The PI must complete the Annual Renewal Form and return it to the Office of Research Support (ORS) by the first and second anniversary of the protocol approval. Review of the Annual Renewal Form is conducted as described in Section 3. If a PI fails to submit an Annual Renewal Form by the first and second anniversary of the protocol approval, the following action is taken:

1. Depending on the species covered in the protocol:
 - a. If the protocol covers species that are not regulated by the USDA, then the IACUC Chair (or in his/her absence, the Vice-Chair) will notify the PI, the Attending Veterinarian, and the Director of the Office of Sponsored Projects (if the project is externally funded), that all work under the animal protocol must cease until further notice. The Attending Veterinarian, in consultation with the IACUC Chair (or in his/her absence, the Vice-Chair), will determine if any threat to animal well-being is posed and if so will take the appropriate action.
 - b. If the protocol includes species that are regulated by the USDA, then the action described in Section 4.1.1 will be followed.
2. The PI must promptly provide, in writing, a statement that he or she will not use any animals under the protocol for teaching or research until the IACUC has reviewed and approved the annual renewal. If the PI fails to promptly provide such a

verification statement and continues animal work, then the University may report such incident, as described in Section 8.5.

3. When PI has successfully submitted and obtained approval of the annual renewal after an appropriate review method (as described in Section 3.6), animal work may continue.
4. If the PI fails to successfully renew the protocol within 30 days of the protocol anniversary date, the protocol will be considered to be permanently expired and the PI will be required to resubmit a new protocol in order to restart work. Additionally, the IACUC may consider suspending (as described in Section 8.4.2) or terminating that PI's animal use privileges.

If a protocol is allowed to lapse while the associated vertebrate animals are still being housed on campus, they must be turned over to the custody of the Animal Resource Center (an IACUC-approved holding protocol is present to cover such situations). The ARC Director will make a determination (after possible consultation with the IACUC Chair, the relevant Dean, and/or the Vice President for Research) on whether the animals can be safely and humanely maintained temporarily by the ARC staff, or if they should instead be transferred to another study, placed with an outside agency, or euthanized.

If the animals have been used primarily for teaching or demonstration and were originally privately-held animals that were not purchased with university funds, they may be able to be returned back to the original owners or another experienced individual. Requests for such transfers can be made to the ARC Director.

4.0.2 The Purpose and Substance of Continuing Review

The purpose of continuing review is primarily threefold:

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

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

4.0.3 Ethical Cost-Benefit Analysis

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

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

4.1 The Third-Year Resubmission: *de novo* Review

The PHS Policy requires that a complete IACUC review of PHS-supported protocols 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 Office of Research Support shall attempt to provide adequate warning of pending protocol expiration. Although a sophisticated protocol database exists, the automatic warning system is not fail-safe. It is the responsibility of the investigator to submit the third-year

resubmission by the appropriate deadline date for a scheduled Full Committee Review (FCR) prior to protocol expiration. The IACUC requires a Third Year Resubmission be submitted as a new proposal, using the most recent version of the application.

4.1.1 Procedures for Conducting Triennial Reviews

Ninety (90) days prior to the three-year anniversary of the animal protocol approval date, the PI is sent a notification requesting a resubmission of the protocol. The PI must resubmit the entire protocol to the ORS. A *de novo* review of the third-year resubmission is conducted as Section 3.6. The third-year resubmission must be approved by the IACUC before the expiration date of the original protocol. If a PI fails to submit a third-year resubmission and receive approval by the expiration date of the protocol, the following action is taken:

1. On the third anniversary of the protocol approval, the IACUC Chair (or in his/her absence, the Vice-Chair) will notify the PI, the PI's dean (and/or department chair), the Attending Veterinarian, and the Director of the Office of Sponsored Projects (if the project is externally funded), that the animal protocol has expired. The PI will be notified in writing that all activities under the protocol must cease and any ongoing work under the expired protocol is a serious and reportable violation of PHS Policy.
2. The Attending Veterinarian will be notified of the expired protocol and any remaining animals under that protocol will be transferred to a holding protocol. Per diems for animal care will continue to be charged. In the event that animal care charges are being charged to a sponsored project, an alternate account must be identified for such charges.
3. When the PI has successfully obtained approval of the protocol animals will be transferred from the holding protocol to the new approved protocol.
4. If the PI fails to successfully renew the protocol, the IACUC may consider suspension or recommending to the IO that the PI's animal use privileges should be terminated.

4.2 Comparison of Protocols to Grants⁵

Public Health Service (PHS) agencies will not make an award for research involving live vertebrate animals unless the applicant organization and all performance sites are operating in accordance with an approved Animal Welfare Assurance and have provided verification that the IACUC has reviewed and approved those sections of the application that involve use of vertebrate animals, in accordance with the requirements of the Policy. Additionally, PHS agencies will not make an award for research involving live vertebrate animals to an individual unless that individual is affiliated with an organization that accepts responsibility for compliance with the Policy and has filed the necessary assurance with OLAW.

⁵ Sections 4.2, 4.2.1, 4.2.2, 4.2.3, and 4.2.4 contain content that was adapted from materials obtained from the University of Pennsylvania.

Regardless of when the review occurs, the investigator should ensure that the research described in the grant proposal application is consistent with any corresponding protocol(s) reviewed and approved by the IACUC. Therefore, a copy of the of the funded or unfunded grant proposal application may be requested by the IACUC and reviewed by designated member(s) 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 Office of Sponsored Projects (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 Principal Investigator's responsibility to explain how the changes relate to the original protocol. Because the determination of consistency between

the grant and original protocol has already been established, there will generally be no need to “re-verify” grant-to-protocol consistency for amendments.

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

4.2.4 Managing Grant-Protocol Inconsistencies

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

4.3 Post-Approval Monitoring

Periodically, the IACUC will identify certain protocols (usually new or recently revised protocols) that they feel would benefit from close veterinary oversight. The requirement of specific monitoring can be a provision of protocol approval and is communicated to the PI, as described in Section 3.6.4. The veterinary staff, through the Attending Veterinarian, is notified of the need for monitoring and provided with the pertinent details. The veterinary group coordinates this monitoring and periodically, and as necessary, provides updates to the IACUC. The veterinary group conducts random, but frequent, visits to high-use areas. The veterinary group has the philosophy that maintaining a friendly and collaborative presence in the research lab areas is a proactive way to ensure that minor issues are identified rapidly for quick and cordial correction, 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 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....

The PHS Policy, Section IV.C.1.f. places responsibility specifically with the IACUC to ensure that personnel conducting procedures on research animals are appropriately qualified and trained in those procedures.

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

5.1 Who Should Receive Training?

All personnel should receive training if they interact directly with or work in the vicinity of animals. Training made available for each type of staff should be specific to the animal species involved and to the kind of procedures to be performed or animal-related interactions.

For training purposes, staff can be grouped as:

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

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

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

5.2 Training Requirements for University Laboratory Animal Users

The IACUC requires all personnel that conduct any research and/or teaching that involves handling, manipulating, or performing procedures on live vertebrate animals, whether in the laboratory or in the field to complete this training. Protocols will not be reviewed until all personnel listed on a protocol are current with their training.

The IACUC-required training is a three-fold process. The actions needed are not complicated and can be completed at the Investigator's own schedule. They involve:

14. Completing a brief online training tutorial for each of the species with which the Investigator will be working.
15. Completing a brief online training tutorial (3198: Orientation), specific to Investigators at The University of Texas at Austin
16. Enrolling in the Laboratory Animal and Biomedical Occupational Health Services Program (LABOHSP).

Refresher training for both Principal Investigator (PI) and Animal Users is required every three years.

5.2.1 AALAS Learning Library (ALL) Web-based Training Modules

This online training program was developed by the American Association for Laboratory Animal Science (AALAS) to provide required information on the humane care and use of lab animals as mandated by federal regulations. The AALAS Learning Library (ALL) provides training that is essential for technicians, veterinarians, managers, IACUC members, and investigators working with animals in a research or education setting. Researchers submitting IACUC documents (e.g., new proposals, protocol amendments, annual renewals, personnel modifications, etc.) are required to complete this training at least once every three years.

All researchers must complete the basic "3198: Orientation" (formerly the ARC Orientation Class). This module provides an orientation of the policies and procedures for animal research at The University of Texas at Austin. The topics covered include:

- Contact information and organizational structure of the ARC and other relevant University departments
- University guidelines for humane animal care and use

- IACUC functions and procedures
- Animal-related risks
- Reporting procedure for animal care and use concerns

In addition to the basic “3198: Orientation,” species-specific training is required if available for the species in use. If no species-specific module is available, then personnel must complete the “3199: Other Species Training Module (General Care and Use).”

To access these modules, the use of an EID and password to log into the system is required at the following link: <https://jerry.orsc.utexas.edu/iacuc/>

- Sign in using a UTEID and Password
- Navigate to the bottom right corner and click “AALAS Learning Library”
- Go to “Libraries” and click “Animal Care and Use Courses”
- Select the appropriate module and proceed by clicking the word “course” at the bottom.
- To receive credit, both the course and exam must be completed.

5.2.2 Enrollment in the Laboratory Animal and Biomedical Occupational Health Services Program (LABOHSP):

To enroll: <http://www.utexas.edu/hr/current/services/ohp.html>

See also Section 6: Occupational Health Program

5.3 Education and Training for IACUC Members

5.3.1 New Member Orientation

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

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.

5.3.2 Continuing Education

Continuing education for IACUC members usually occurs at each IACUC meeting. The objectives of providing ongoing training for IACUC members is to increase their knowledge, understanding, and awareness of current laws and regulations, new directives, best practice guidelines and institutional policies. It also provides a regular forum for the IACUC to discuss concerns or questions brought forth by the faculty, staff or members of the community. Information provided for these sessions will include questions and concerns brought to the attention of the IACUC, official directives, relevant publications, conference announcements, seminar proceedings, animal facility staff and/or veterinarian's observations/recommendations, issues involving facility inspections and program evaluations, and compliance issues.

Section 6: Occupational Health Program

6.0 Laboratory Animal and Biomedical Services (LABOHSP)

The health and safety of individuals working in animal care and use programs is an area of institutional concern requiring commitment from the senior officials of the institution. The goal of the Laboratory Animal and Biomedical Occupational Health Services Program (LABOHSP) is to prevent occupational injury and illness by avoiding, controlling or eliminating hazards in the workplace. The emphasis of such a program is the prevention of illness and injury, but it also includes provisions for early diagnosis and treatment when necessary.

6.1 The IACUC's Responsibility for Occupational Health and Safety

The PHS Policy places responsibility for ensuring a safe working environment for personnel involved in the animal care and use program with the institution. An effective Occupational Health Program works with many separate institutional components including animal care and use, research, environmental health and safety, occupational health, and administration and management. A natural point of convergence for these functionally distinct institutional elements at many institutions is the IACUC. Assurance of a safe working environment is one of the topics the IACUC should consider in each animal use proposal and as part of the semiannual program evaluation. It is generally necessary to involve health and safety specialists in the design and implementation of the IACUC review guidelines.

6.2 Role of the IACUC in the Occupational Health Program

Procedures should be developed for conducting a health and safety review of research activities that present hazards. These procedures should be incorporated into the IACUC protocol review process. Procedures to identify and address non-experimental hazards (e.g., during semiannual facility inspections and program reviews) should also be implemented. Communication and other procedural links between the IACUC and the environmental health and safety professional or office should be established, maintained and documented. The IACUC has a role in ensuring that personnel comply with health and safety requirements (e.g., ensuring personnel have received appropriate training, evaluating compliance with standard operating procedures or institutional policy during semiannual facility inspections, etc.).

6.3 Elements of the Occupational Health Program

An effective program design requires input from health and safety specialists and will include the following elements:

- Administrative procedures,
- Facility design and operation,
- Risk assessment,
- Exposure control,

- Education and training,
- Occupational healthcare services,
- Personal protective equipment,
- Equipment performance,
- Information management,
- Emergency procedures, and
- Program evaluation.

The details of each element will be dictated by the extent and nature of employees' exposure and the type of animal use program.

6.4 Participation in the Occupational Health Program

A wide range of personnel (e.g., animal care staff, investigators, technical staff, students, volunteers, engineers, housekeepers, security officers, and maintenance personnel who care for or use animals, their tissues or fluids, or who may be exposed to them as a consequence of their job) should be provided the opportunity to participate in the LABOHSP.

The extent and level of participation of personnel in the LABOHSP should be based on risk assessment, including:

- hazards posed by the animals and materials used;
- exposure intensity, duration, and frequency;
- susceptibility of personnel; and
- history of occupational illness and injury in the workplace.

Health and safety specialists should be involved in the assessment of risks associated with hazardous activities. At The University of Texas at Austin, the LABOHSP helps to protect the health and safety of faculty, students and staff who work with vertebrate animal species in the course of their research. The program is designed to customize the participation requirements based on the type and degree of exposure to animals. A set of questionnaires (one for initial entry and one for periodic updates) is used to assess this degree of risk.

Persons exposed to animals in a laboratory or vivarium environment or to fresh (unfixed) animal tissues must complete a health questionnaire and return it to the Occupational Health Nurse. After turning in the form, the individual will be considered "enrolled" in the LABOHSP, which satisfies initial IACUC requirements for being placed on a protocol.

The Occupational Health Nurse who will evaluate the risks and review the person's health information and vaccination status will review the questionnaire. The individual may be contacted to clarify certain items. Once the questionnaire has been reviewed, the person is considered to be "participating" in the LABOHSP, unless they specifically sign a declination statement.

If the Occupational Health Nurse determines that there is a particular reason for a follow-up screening appointment, one will be arranged. An example of this would be in the case of reported animal allergy symptoms or other potentially work-related health problems associated with animals. If there is no need for a direct visit, the Occupational Health Nurse will make note of any follow-up items, such as a recommended tetanus booster or required tuberculosis (TB) test, and will coordinate arrangements to provide any follow-up services.

If for any reason the individual would like to meet with the Occupational Health Nurse, regardless of the risk analysis, there is a section of the questionnaire that allows for that to be requested.

6.5 Occupational Health Program Education and Training

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

Training should include information about:

- Zoonoses,
- Chemical safety,
- Microbiologic and physical hazards (e.g., allergens and radiation),
- Hazards associated with experimental procedures,
- Handling of waste materials, and
- Personal hygiene.

Training on the above items is provided via the "3198: Orientation" module and in each of the species-specific training modules in the AALAS Learning Library.

Section 7: Semiannual Program Review and Facility Inspections

7.0 Semiannual Reviews

The PHS Policy and Animal Welfare Regulations (AWRs) stipulate that the IACUC must review the program for humane care and use of animals at least once every six months, using the *Guide* as the basis for evaluation. Federal requirements also state that the IACUC must inspect all institutional animal facilities at least once every six months

7.1 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. It also includes a review of the adequacy and appropriateness of the veterinary medical care program, the training program for personnel, and the occupational health and safety program.

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

1. During the regular convened meetings of the IACUC in May and November of each year, the IACUC reviews the University's animal care and use program using a Program Review Worksheet (PRW). The PRW is designed to evaluate occupational health and safety; training for IACUC members, research staff, and husbandry staff; the institutional disaster plan; sanitation and cleaning practices; surgical support and post-operative analgesia; compliance with approved protocols; procedures for reporting allegations of inappropriate animal care or use; and accessibility to veterinary care during and after typical working hours. Each area of evaluation 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, including a Deficiency Correction Schedule (See Section 7.3), are compiled and prepared for IACUC review and discussion at a regular, convened IACUC meeting following the Program Review, usually in June and December. The IACUC Program Coordinator requests additional comments and minority views from all members present.

7.2 Facility Inspections

The facility inspections are a physical inspection of all buildings, rooms, areas, enclosures and vehicles (including satellite facilities in which animals are housed for more than 24 hours) that are used for animal confinement, transport, maintenance, breeding, or experiments inclusive of

surgical manipulation. The Animal Welfare Regulations apply to animal study areas where animals are maintained for more than 12 hours (applicable only to USDA-covered species).

Laboratories in which routine procedures, such as immunization, dosing, and weighing, are conducted may be evaluated by other means such as random inspections. The institution, however, through the IACUC, is responsible for all animal-related activities regardless of where animals are maintained or the duration of the housing. The IACUC must have reasonable access to these areas for the purpose of verifying that activities involving animals are being conducted in accordance with the proposal approved by the IACUC.

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

1. Every six (6) months, usually during April and October, the IACUC Program Coordinator organizes the inspection schedule of the animal facilities located on campus and any satellite facilities. These inspections are conducted using the *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. Inspections are conducted during the first three weeks of May and November. 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., Principal Investigator, hereinafter referred to as PI) is notified, in writing, of any minor or significant deficiency identified in their 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, including a Deficiency Correction Schedule (see Section 7.3), are compiled by the IACUC Program Coordinator and prepared for IACUC review and discussion at a regular, convened IACUC meeting following the inspections, usually in June and December. The IACUC Program Coordinator requests additional comments and minority views from all members present.

7.2.1 Staffing and Scheduling the Facility Inspections

The IACUC must conduct inspections of facilities at least once every six months. This may be accomplished by assigning specific facilities to subcommittees, which must consist of at least two IACUC members. No IACUC member should be excluded should she or he wish to participate in an inspection. Ad hoc consultants may be used although the IACUC remains responsible for the evaluations and reports. The inspection team should have a working knowledge of the *Guide* and AWRs in order to fully evaluate the facilities that are being inspected.

7.2.2 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,
- 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.

7.2.3 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 satellite areas, a contact person is useful.
- 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.

7.3 Deficiency Correction Schedule

All deficiencies identified in during the Facility Inspection and/or Program Review are designated by the IACUC as minor or significant. A significant deficiency is defined as a situation that is or may be a threat to animal health or safety. The IACUC, through the IO, is obligated to promptly report to OLAW any serious or continuing noncompliance with the PHS Policy or any serious deviation from the provisions of the *Guide* (See Section 8.5).

For both categories of deficiencies, a reasonable and specific plan and schedule with dates for correction must be included in the final report. All individuals to be involved in the corrections should be consulted to ensure that the plan is realistic. If the institution is unable to meet the plan, the IACUC, through the IO, will inform Animal and Plant Health Inspection Service (APHIS) officials within fifteen business days of the lapsed deadline (AWRs). Federally funded projects will have their relevant funding agency informed.

7.4 Documentation

A written report of the semiannual program review and facility inspection is prepared. The AWRs require the report to be signed by a majority of the IACUC members at a convened meeting. The report describes the institution's adherence to the AWRs, PHS Policy, the *Guide*, and identifies specifically any deviations from these documents.

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 Office of Research Support. The University notifies OLAW of the dates of the semiannual program evaluations and facility inspections in the annual report to OLAW.

Section 8: Animal Welfare Concerns And Non-Compliance Situations

8.0 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 the public or 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.

8.1 Methods for Reporting

To facilitate communication, there are a number of options available to communicate concerns about animal care and use at The University of Texas at Austin, or to report instances of suspected non-compliance with laws, rules, regulations and policies. The names and phone numbers of contact persons including the Attending Veterinarian, the Director of the Office of Research Support, and University Compliance Services should be posted in or near the entrance to animal facilities and are listed on the ARC website, readily available to institutional employees. This information has also been provided to participants in the AALAS Learning Library “3198: Orientation” training module.

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 the University 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.

8.2 Procedures for the Investigation of Animal Care and Use Concerns

8.2.1 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 of the AWRs or institutional Animal Welfare Assurance 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 Attending Veterinarian is authorized to halt procedures which they believe do not comply with institutional policies until the IACUC can be convened and consider the matter formally. Similarly, situations that may involve potential criminal activity or human safety should be reported promptly to the institution's law enforcement or occupational health and safety officials. Allegations of other ongoing policy or procedural matters may not require such same-day attention, but should not be deferred merely as a matter of convenience. Emergency meetings may be necessary in these cases to ensure prompt consideration of concerns.

8.2.2 The Complaint Assessment Subcommittee

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

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

8.2.3 Investigation

Should the IACUC determine that further investigation is required, the CAS should conduct the investigation and report back to the IACUC. It is important to avoid actual or perceived conflicts of interest in this process.

The IACUC should charge the designated person or group with its requirements for information gathering and impose a completion date. The assigned completion date will depend on the IACUC's determination of whether immediate remedial action may be required. The nature of the information required will vary depending on the circumstances, but often involves:

- 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 CAS should provide a report to the IACUC, which summarizes:

- 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 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

8.2.4 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 complaint was not sustained, 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.

8.3 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.

8.4 Consequences of Non-Compliance

Subsequent actions of the IACUC may include:

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

8.4.1 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 (e.g., reassignment, termination of employment) sanctions be imposed.

8.4.2 Suspension of Animal Activities

The IACUC is empowered to suspend a project if it finds violations of University policy, PHS Policy, the *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 Institutional Official regarding the reasons for the suspension. The Institutional Official is required to take appropriate corrective action, and report the action and the circumstances surrounding the suspension to OLAW. Because an IACUC action to suspend a project is a serious matter, the action must be reported to OLAW promptly.

8.5 Reporting Requirements

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

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

8.5.1 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*. The report should be on University/departmental letterhead, addressed to the IACUC Chairperson, and emailed (preferred) to IACUC@austin.utexas.edu or mailed to the Office of Research Support. 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).

8.5.2 IACUC and IO Reporting

The IACUC, through the IO, will submit an annual report to OLAW by January 31 of each year. The University's reporting period is January 1 – December 31. The report will include:

- Any change in the accreditation status of the University (e.g. if the University obtains accreditation by AAALAC or AAALAC accreditation is revoked), any change in the description of the University's program for animal care and use as described in the Assurance, or any change in the IACUC membership. If there are no changes to report, the University will provide written notification that there are no changes.
- Notification of the dates that the IACUC conducted its semiannual evaluations of the University's program and facilities (including satellite facilities) and submitted the evaluations to the IO.

The IACUC, through the IO, will promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to:

- Any serious or continuing non-compliance with PHS Policy.
- Any serious deviations from the provisions of the *Guide*.
- Any suspension of an activity by the IACUC.

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

- Principal Investigator (PI)
- PI's Department Chair
- PI's School Director and/or College Dean
- Chair, IACUC
- Vice-Chair, IACUC
- Director, Office of Research Support
- Director, Animal Resources Center
- Director, Office of Sponsored Projects (if project is externally funded)
- Associate Vice President for Legal Affairs
- Director, University Compliance Services
- Vice President for Research

8.5.3 Response to External Requests for Information

In accordance with applicable policies, guidelines and regulations, upon request, the University 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 9: Recordkeeping

9.0 Maintaining IACUC Records

The institution is responsible for maintaining:

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

All records are to be kept for a minimum of three years, with the exception of records that relate directly to protocols, which must be kept for the duration of the activity and for an additional three years after completion of the activity.

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

9.1 Meeting Minutes⁶

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

⁶ This section contains content that was adapted from materials obtained from the University of Illinois at Urbana-Champaign.

reviewers for protocols involving similar procedures (where their questions were answered), or participated in past IACUC discussions about the procedures.

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

- Records of attendance

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

- Activities of the Committee

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

- Deliberations of the Committee

A deliberation of the Committee refers to the discussion and reasons leading to particular IACUC decisions. Minutes should include as a minimum a summary of the key points discussed prior to a committee decision.

Completed minutes are distributed to all IACUC members. Minutes are discussed at a subsequent convened meeting of the IACUC (e.g., FCR) and the Committee votes on approval. A copy of the approved meeting minutes is then provided to the IO. This informs the IO of all actions taken by the IACUC.

9.2 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.

9.3 Other Records

Both the PHS Policy and the AWRs require that the University 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. USDA requires additional records on dogs and cats acquired, transported, sold, or euthanized by the research facility. 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.

9.4 Record Retention Policy at The University of Texas at Austin

No official state records may be destroyed without permission from the Texas State Library as outlined in Texas Government Code, Section 441.187

(<http://www.statutes.legis.state.tx.us/?link=GV>) and 13 Texas Administrative Code, Title 13, Part 1, Chapter 6, Subchapter A, Rule 6.7

([http://info.sos.state.tx.us/pls/pub/readtac\\$ext.TacPage?sl=R&app=9&p_dir=&p_rloc=&p_tloc=&p_ploc=&pg=1&p_tac=&ti=13&pt=1&ch=6&rl=7](http://info.sos.state.tx.us/pls/pub/readtac$ext.TacPage?sl=R&app=9&p_dir=&p_rloc=&p_tloc=&p_ploc=&pg=1&p_tac=&ti=13&pt=1&ch=6&rl=7)). The Texas State Library certifies Agency retention schedules as a means of granting permission to destroy official state records.

The University of Texas at Austin Records Retention Schedule (UTRRS; <http://www.utexas.edu/business/accounting/retention/ret.html>) is certified by the Texas State Library and Archives Commission. It has been adopted as an administrative rule of the university. All official state records (paper, microform, electronic, or any other media) listed on the UTRRS must be retained for the minimum period designated. Once official university records have met their retention periods, they must be disposed of in accordance with the policies and procedures of Office of Accounting's Division of Records Management Services.