

University of Texas at Austin

Institutional Animal Care and Use Committee

IACUC Procedure # 10.1

Title	The Committee		
Date of Approval	09/14/2020		
Date of Last Revision	N/A	Version	1.0

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.

This section will define the authority of the IACUC, committee composition based on federal regulations, conflicts of interest, quorum requirements, IACUC functions, liability, and making recommendations to the Institutional Official.

10.1.1 Authority of the IACUC

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.).

10.1.2 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.

10.1.3 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.

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 equity interest in the sponsor publicly valued at \$5,000 or greater or any equity interest in a non-publically traded sponsor.
- Has received payments or other incentives from any sponsor that when aggregated for the member, spouse and dependent children, total of \$5,000 or greater.
- Has identified him or herself for any other reason as having a conflict of interest.

Other possible examples of conflict of interest include cases where:

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

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

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

10.1.4 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.

10.1.5 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 Procedure 5.2.
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 Procedure 5.2.
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 Policy 5.3.
4. Review concerns involving the care and use of animals at the University. The IACUC procedures for reviewing concerns are described in Policy 6.2.
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 10.1.7 of this procedure.
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 Procedure 4.0.
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 Policy 4.3.
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 Procedure 7.3.
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 Policy 5.1.
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 Policy 6.3.

10.1.6 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.

10.1.7 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:

- Recommendations regarding any aspect of the University's animal program, facilities, or personnel training are formulated at convened meetings of the IACUC.
- Recommendations are prepared in writing by ORSC staff, 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.
- The IACUC Chair or his/her designee submits recommendations, including minority views that are approved by the IACUC to the IO.