



THE UNIVERSITY OF TOLEDO

SUBJECT: Institutional Animal Care and Use Committee Membership, Roles and Responsibilities

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University of Toledo (UT) Institutional Animal Care and Use Committee Membership, Roles and Responsibilities

1. Introduction

Institutional Animal Care and Use Committees (IACUC) derive their authority from the Health Research Extension Act (HREA) of 1985, Animal Welfare Act (AWA) and Animal Welfare Regulations (AWR). The IACUC is authorized by these bodies to oversee the Institution's animal program, facilities, and procedures.

2. Functions of the IACUC

Institutional Animal Care and Use Committee (IACUC) responsibilities:

- a) In accordance with Public Health Service (PHS) Policy IV.C.1-3, the IACUC shall review and approve, require modifications (to secure approval), or withhold approval of activities related to the care and use of animals in research.
- b) Review and approve, require modifications (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.
- c) Notify investigators in writing of its decision to approve or withhold approval of those activities related to the care and use of animals, or modifications required to secure IACUC approval as set forth in the PHS Policy IV.C.4.
- d) 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.
- e) Authorized suspension of any activity involving animals as set forth in the PHS Policy IV.C.6.
- f) Review UT's program for humane care and use of animals, using the *Guide for the Care and Use of Laboratory Animals* (the "Guide") as a basis for evaluation at least once every six months.
- g) Inspect all of the UT's facilities using the Guide as a basis for evaluation at least once every six months.
- h) Make written recommendations to the Institutional Official (IO) regarding any aspect of the Institution's animal program, facilities, or personnel training.
 - a. The IACUC Chair or his/her designee submits recommendations, including minority views that are approved by the IACUC to the IO.

- i) Prepare reports of the IACUC evaluations as set forth in the PHS Policy IV.B.3 and submit reports to the Institutional Official.
- j) Review concerns and make recommendations involving the care and use of animals at UT.

3. Appointment of IACUC Members

The President of the University of Toledo (UT) is the highest operating official of the university, who is given the responsibility to appoint IACUC members according to the AWR. The President delegates this authority to the Institutional Official (IO), the Vice President for Research, to make membership appointments to the IACUC. The IO also has the administrative and operational authority to commit institutional resources to ensure compliance with the PHS Policy and other requirements. IACUC members each serve a three-year term; the appointment may be renewed upon completion of the term. A regular voting committee member may request in writing to be removed from the IACUC before their three-year term is complete.

4. Committee Composition

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

Required categories of membership include:

- a) *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.
- b) *Chair*. The Chair is appointed every three years and must be a faculty member with animal research experience and significant IACUC experience.
- c) *Vice Chair*. The Vice Chair is appointed every three years and must be a faculty member with animal research experience and significant IACUC experience. The Vice Chair is authorized to conduct official IACUC business in the absence of the Chair.
- d) *Nonaffiliated*. The nonaffiliated member(s) represent general community interests. Neither they, nor their immediate family, may have an affiliation with UT. 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. Nonaffiliated members must attend more than half of the committee meetings and participate in at least one semiannual program review activity per year.
- e) *Scientist*. PHS Policy requires that the IACUC include a practicing scientist experienced in research involving animals.
- f) *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.
- g) *Alternate members* may be appointed to the IACUC by the IO or other official. 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 will receive training identical to the training provided to regular IACUC members.

- h) *Ex officio members* may include individuals with expertise in specific areas pertinent to protocol review and program oversight such as statisticians and occupation health experts. These are non-voting members of the committee.
- i) *Consultants*: IACUC may utilize consultants as necessary to assist in protocol reviews, etc., for example, staff from UT's Environmental Health and Radiation Safety office.

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.

5. 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)). UT defines a "quorum" as more than half of the regular IACUC voting members. 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.

A protocol is approved or a protocol is suspended only if a quorum is present, and if more than 50% of the quorum votes in favor of protocol approval or suspension. For reasons other than conflict of interest, abstentions from voting do not alter the quorum or change the number of votes required.

6. IACUC Member Responsibilities

IACUC members ensure that the use of animals or testing on animals is conducted in a humane, ethical manner, with the highest standard of care according to applied Federal, State, local regulations and institutional policies and guidelines. In order to adequately evaluate the humane and ethical use of animals, a free and open exchange of information is necessary.

To protect the integrity of the institution and its researchers, IACUC members have an obligation to:

- a) Uphold the precepts of humane and compassionate animal care and use.
- b) Engage in assisting the institution in fulfilling responsibilities to the NIH/PHS, US Department of Agriculture (USDA), Association for the Accreditation and Assessment of Laboratory Animal Care (AAALAC), the researchers, the animals, and the public and in adherence to all applicable federal, state, local and institutional laws, guidelines and policies.
- c) Not disclose confidential or proprietary information (protocol or investigator specific information) to any non-IACUC member
- d) Not discuss, communicate, or disclose any details of IACUC business (e.g. protocol reviews, non-compliance discussion, subcommittee investigations or reviews, etc.) to third parties without the consent of the IACUC Chair or IO
 - o During the process of initial or continuing review of an activity (including, but not limited to, any annual reviews or protocol amendments), material provided to the IACUC and the IACUC Office shall remain confidential.

7. Responsibilities of the Chair

The UT IACUC Chair is responsible for overseeing the coordination and implementation of effective, efficient systems for protocol review and program review by the IACUC in compliance with the PHS policy and the AWA. Other duties include:

1. Convene and chair meetings, ensure that there is a quorum present, and declare the loss of a quorum resulting in the end of official business if a sufficient number of members depart;
2. Prepare and/or oversee the preparation of meeting minutes, agendas and reports, and submit appropriate documents to the IO in accordance with PHS policy and the AWA;
3. Report to the IO any activities of serious or continuing non-compliance.
4. Recommend IACUC membership changes to the IO;
5. Ensure the establishment of a written system of communication with the investigators concerning the approval status of protocols and the steps necessary to secure approval;
6. Evaluate and champion policy and practice initiatives to improve UT's animal care and use program;
7. Participate in the assignment of designated reviewers for protocols;
8. Educate, advise and support IACUC members, PIs and others regarding the IACUC process;
9. Communicate regularly with the IO, Attending Veterinarian, and IACUC Administrator;
10. Serve as spokesperson for the UT IACUC.

8. Expectations for IACUC Member Participation

a) IACUC Members and/or Alternates

- 1) IACUC members are expected to participate regularly in the business of the IACUC; a quorum of members must be present (in person, via teleconference, or via videoconferencing) for business to be conducted.
 - i. Primary Members are expected to participate regularly in the business of the IACUC. Primary Members are expected to attend a minimum of 60% of scheduled IACUC meetings each year.
 - ii. Alternate Members are expected to participate regularly in the business of the IACUC. The Alternate member will assume all decision and voting privileges of the primary member, in the absence of the primary member (if the primary and alternate are both present, both can express opinion but only the primary can vote).
- 2) Targeted Participation
 - i. Program review and Facility inspections: participate in semi-annual program review and inspection for each semiannual review cycle—as assigned.
 - ii. Help implement governmental and Institutional policy regarding animal research.
 - iii. Actively participate in meeting discussions.
 - iv. Serve as primary or secondary reviewer-as assigned.
 - v. Serve as Designated Member review-as assigned.
- 3) Protocol Review - provide a complete and thorough protocol review-as assigned
 - i. Prepare prior to the meeting, by reading thoroughly and evaluating the protocols, amendments, and progress reports based on the principles and guidelines for the ethical care and use of animals as described in the federal regulations and Institutional policies. Directly communicate with submitting PIs as necessary to address protocol deficiencies. (Refer to: <https://olaw.nih.gov/guidance/faqs#628> for guidance on elements of protocol review).
 - a. The committee members may evaluate scientific elements of the protocol as they relate to the welfare and use of the animals including: hypothesis testing, sample size, group numbers, and adequacy of controls such that they relate directly to the prevention of unnecessary animal use or duplication of the experiment.

- ii. Vote to approve, require modifications to secure approval, or withhold approval for research activities reviewed, with full explanation to applicants.
 - iii. Serve as designated member reviewer for submitted revised protocols, as appropriate.
- b) Failure to Meet IACUC Member Expectations
- 1) Members or alternate members who are not able to meet the "Expectations for IACUC Participation" may have their committee appointment revoked.

9. Conflict of Interest

All IACUC members and/or consultants are required to disclose any conflicts of interest. An 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:

- a) Is an investigator or personnel on the protocol;
 - b) Has entered into a financial arrangement with the sponsor or agent of the sponsor;
 - c) Acts as an officer or a director of the sponsor or an agent of the sponsor;
 - d) Has an equity interest in the sponsor;
 - e) Has received payments or other incentives from any sponsor;
 - f) Has identified him or herself for any other reason as having a conflict of interest.
- g) Other possible examples of conflict of interest include cases where:
- 1) A member is involved in a potentially competing research program;
 - 2) Access to funding or intellectual information may provide an unfair competitive advantage;
 - 3) A member's personal biases may interfere with his or her impartial judgment;
 - 4) A member is in a supervisory role over the PI of the study.

If the investigator submitting a protocol believes that an IACUC member has a potential conflict, the investigator may request that the member be excluded from review of individual protocols. 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):

- a) May remain in the meeting room to provide information requested by the IACUC; and
- b) Leaves the meeting room for voting; and
- c) Are not counted towards quorum.