



Duke University & Duke University Medical Center Animal Care & Use Program Policy

EXPECTATIONS OF A DUKE IACUC MEMBER

PERFORMANCE STANDARD: The IACUC membership is engaged in fulfilling the institution's responsibilities to the NIH/PHS, USDA, AAALAC, the researchers, the animals, and the public.

BACKGROUND / PURPOSE: The Animal Welfare Act (AWA), Public Health Service (PHS) Policy, and the "Guide for the Care and Use of Laboratory Animals" (Guide) require the Institutional Animal Care and Use Committee (IACUC) to provide oversight of animal care and use activities. The roles and duties of the IACUC are described in the documents listed above.

POLICY: As a general statement of policy, IACUC members are expected to:

1. Uphold the precepts of humane and compassionate animal care and use in their research laboratories.
2. Be on guard for real or potential 'Conflicts of Interest' that could impact the integrity of the IACUC process of animal care and use oversight.
3. Be on guard for real or potential 'Confidentiality' conflicts that could impact the integrity of the IACUC process of animal care and use oversight.

There are three specific sections to this Policy that outline IACUC member expectations in detail:

1. **Expectations of Committee Participation:** The IACUC's expectations of its membership are as follows:
 - a. **Primary Members:**
 - i. **Expectation:** IACUC Primary Members are expected to participate regularly in business of the IACUC. When s/he is unable to participate, the Primary Member is expected to engage the Alternate Member to fulfill the obligations of the Primary Member.
 - ii. **Targeted participation:** Primary Members are expected to:
 1. **Routine Monthly Meeting:** A minimum of seven (7) IACUC meetings each fiscal year; and
 2. **Facility Inspections:** A minimum of two (2) Facility Inspections, and serve as a 'back-up' for a 3rd facility inspection each semi-annual cycle (Note: If physical limitations prevent participation in facility inspections, members can accomplish expectations with participation as a Subcommittee Member); and
 3. **Significant Change Subcommittee:** A minimum of two (2) Significant Change Subcommittee meetings each semi-annual cycle. (One or both of these meetings may be assigned to the Alternate Member by the Primary Member); and
 4. **Programmatic:** A minimum of one (1) Semi-Annual Program Review Meeting each fiscal year.

- iii. **Alternate Methods of Service:** Serving as a member of a 'focused issue' Subcommittee (e.g. investigation, policy, etc) can be equitable service to other expected participations.

b. Alternate Members:

- i. **Expectations:** IACUC Alternate Members are expected to participate regularly in 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 present recommendations and / or vote).
- ii. **Targeted participations:** Alternate members are expected to attend / participate in:
 - 1. **Routine Monthly Meeting:** A minimum of three (3) IACUC meetings every fiscal year; and
 - 2. **Facility Inspections:** A minimum of two (2) Facility Inspections every semi-annual cycle, and serve as a 'back-up' for a 3rd facility inspection each semi-annual cycle; and
 - 3. **Significant Change Subcommittee:** A minimum of one (1) Significant Change Subcommittee meeting each semi-annual cycle. (As assigned by the Primary Member); and
 - 4. **Programmatic:** A minimum of one (1) Semi-Annual Program Review Meeting each fiscal year.
- iii. **Alternate Methods of Service:** Serving as a member of a 'focused issue' Subcommittee (e.g. investigation, policy, etc) can be equitable service to other expected participations.

Note: Any alternate member can attend any, as many, or all IACUC meetings as a participant in all aspects of IACUC business, except the Alternate Member may not vote (be part of the decision) when the Primary Member is present. Alternate members may not review and present protocols if the Primary Member is present.

c. Failure to Achieve IACUC Member Expectations: Those members (primary or alternate) who are not able to meet the 'Expectations of Committee Participation' may be encouraged to reconsider their role on the Committee:

- i. Members may choose to increase their participation or may choose to request removal from the IACUC.
- ii. The IACUC may request the Department Chairman reconsider the recommendation of the individual to this institutional level Committee.
- iii. With continued disengagement, the IACUC may recommend the Institutional Official reconsider the appointment to the IACUC of the disengaged member.
- iv. Potential reasons for requesting reconsideration of the IACUC appointment, include, IACUC members that are:
 - 1. On sabbatical leave or other extended leave; or
 - 2. No longer members of the Duke campus or local community (if the Non-Affiliated Member); or
 - 3. Having continued disengagement and showing no desire to become more engaged in the activities of the IACUC.

2) Expectations of Member Conflict of Interest (COI): The IACUC membership is engaged in fulfilling the institution's responsibilities to the NIH/PHS, USDA, AAALAC, the researchers, the animals, and the public. The IACUC must remain above conflicts of interest to assure the integrity of the institution's animal care and use program. Duke University IACUC members are responsible for making known any potential or perceived conflict of interest (COI) concerning all business conducted by the IACUC.

- a. Member Roles Where a Conflict of Interest Could Occur:** While no list can be exhaustive, IACUC member participation in any of the following categories could result in a COI for a specific protocol under review, or a COI for specific business issues under discussion:
- i. Principal Investigator;
 - ii. Co-Investigator, or Sponsor;
 - iii. Investigator receiving funding from the study, as listed in the study budget;
 - iv. In a supervisory role over the PI of the study;
 - v. Family member of PI; and/or
 - vi. IACUC members listed on the accompanying grant proposal; and/or
 - vii. A financial interest (as defined by the Duke University Conflict of Interest Policy) in the sponsor funding the project; and/or

Note: Peripheral knowledge or indirect involvement in certain activities may not rise to the level of a COI but might result in member abstention from a vote or discussion.

b. If a Conflict of Interest Is Recognized By the Member:

- i. **COI Recognized Prior to Discussion of the Issue:** Committee members should make known any conflict of interest prior to the beginning of the Committee's discussion of the business. This can be accomplished by notifying the IACUC Chairman, or Director, OAWA. Members with a specific conflict are obligated to leave the meeting room prior to the Committee's deliberation on the conflicted issue.
- ii. **COI Recognized During Discussion of the Issue:** Declare the potential conflict and depart the meeting room for the remainder of this discussion and vote.

c. IACUC Chairman / Vice Chairman Meeting Acknowledgement: The chair or vice chair will read or paraphrase the statement below at the beginning of each convened meeting (IACUC or Significant Chance Sub-Committee):

"If you are aware of a conflict of interest involving any investigator, protocol or business item that is under consideration today, you must leave the room during the IACUC's deliberations and vote on the issue. Should you realize during a discussion that you have a conflict of interest, you should declare it and depart the meeting room for the remainder of this discussion and vote. The actual nature of the conflict does not need to be disclosed. Members unsure of whether a particular situation is a potential conflict may present the issue to the IACUC for consideration during the meeting, or prior to the meeting they may present the issue to the Chairman, IACUC or Director, OAWA."

Note: The IACUC minutes will reflect the above meeting announcement, along with any declarations of COI made by the members.

- 3) Expectation of Member Confidentiality:** Duke University Institutional Animal Care and Use Committee (IACUC) members have the role of assessing the humane use of animals in research, teaching, or training conducted at Duke University and its collaborative institutions where work funded through Duke is being performed. IACUC members ensure that the use of 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. 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:
- a. Members must not disclose Confidential or Proprietary Information (protocol or investigator specific information) to any non-IACUC member; and
 - b. Members must 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; Director, OAWA; Director, DLAR; or the Institutional Official.

Note: Use of IACUC discussion concepts or issues in faculty & staff meetings are considered acceptable and encouraged uses of the member's experience. The IACUC views sharing of process information (without specific personnel, confidential, or proprietary information) an important benefit of Department representation to the Committee.

Approved by the Duke IACUC: 28 June 2007

Endorsed by the Institutional Official: _____ 1 August 2007
R. Sanders Williams, M.D.