

Policy on Identifying and Managing Conflict of Interest

Purpose

This policy is for identifying and managing conflicts of interest (COI) of the Institutional Animal Care and Use Committee (IACUC) members and consultants that may affect or appear to affect their contributions to protocol review, facility inspections, the suspension or termination of animal activities or privileges, or other IACUC-related activities. The Attending Veterinarian is deemed to have no conflict of interest in facility inspections and program reviews. Federal regulations under the Animal Welfare Act (9 CFR 2.31(d)(2)) provide: "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, nor may a member who has a conflicting interest contribute to the constitution of a quorum." Similarly, the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Section IV.C.2) provides: "No [IACUC] member may participate in the IACUC review or approval of a research project in which the member has a conflicting interest (e.g., is personally involved in the project) except to provide information requested by the IACUC; nor may a member who has a conflicting interest contribute to the constitution of a quorum."

Definitions

- immediate family member – a spouse, domestic partner, parent, child, or sibling.
- member – a person duly appointed as a voting or nonvoting member to the IACUC.
- consultant – a nonmember asked by the IACUC to provide advice.
- key personnel – a person who contributed or contributes substantively to the scientific development or execution of a research activity. Key personnel typically includes, but is not limited to, principal investigator (PI), co-investigator (Co-PI), and other personnel listed on the protocol as research or teaching staff expected to work with the animals.

Policy

A voting member with a COI as determined by this policy does not count towards quorum for voting on the conflicted matter.

I. Identification and Management of COIs during Protocol Review

- A. Identification: An IACUC member or consultant has a COI with respect to a protocol when that member or consultant, or an immediate family member of that member or consultant, meets any of the following criteria:
 1. Is key personnel for, or has substantially contributed to the design or authorship of, the protocol under review.
 2. Has an interest that is related to the research described in the protocol, and that interest meets or exceeds one or more of the following.

- a. Compensation and/or ownership in a publicly traded company that, either individually or combined, equals \$5,000 or more in a calendar year.
 - b. Compensation of \$5,000 or more from a privately held company in a calendar year.
 - c. Any ownership interest in a privately held company.
 - d. Any leadership position, where leadership positions are defined as positions with fiduciary responsibility including senior managers (presidents, vice presidents, etc.), and members of boards of directors. Membership on a scientific advisory board is not a leadership position.
3. Has a proprietary interest of any value including but not limited to a patent, trademark, copyright, or licensing agreement.
 4. Has a competitive conflict with the research activity, whether financial, scholarly, or professional. The PI on a protocol may request that an IACUC member be declared as having a competitive COI, and such a request will be decided by a vote of the IACUC. The IACUC member with the potential conflict may not participate in such vote.
 5. Is in a subordinate position within the direct supervisory chain of management to the named Principal Investigator of the animal protocol.
- B. Management:
1. An IACUC member or consultant who has a COI must disclose that COI to the IACUC chair in advance of the meeting when possible. If the IACUC member with a COI is the IACUC chair, disclosure must be made to the vice-chair of the IACUC.
 2. An IACUC member or consultant who has a COI must recuse themselves from the meeting before discussion and voting begins. The IACUC may invite them back into the meeting to provide information about the protocol, but they will again be required to leave the meeting before any subsequent discussion or voting on the protocol. If the IACUC member with a COI is the IACUC chair, the vice-chair of the IACUC will preside over IACUC discussion and action on the protocol.

II. Identification and Management of COIs during Facility Inspections

- A. Identification: An IACUC member or consultant has a COI with respect to the inspection of (II.A.1) a room or (II.A.2) a facility when that member or consultant, or an immediate family member of that member or consultant, meets any of the following criteria:
1. Is key personnel on a protocol with activities listed as occurring within the room.
 2. Is a manager of the facility, or has a substantial role in managing, directing, or otherwise providing animal care within the facility.
- B. Management:
1. An IACUC member or consultant who has a COI may be present during the inspection of the room or facility, but should not be a member of the inspection team. If, however, that member must act as member of the inspection team for the

purpose of satisfying regulatory requirements, then action on all deficiencies and correction dates must be referred to the full ACUC.

2. If an inspection matter is referred to the full IACUC for action, the conflicted IACUC member or consultant may be present to provide information about the matter requested by the IACUC, and will be requested to leave the room for further discussion or vote on that matter.

III. Identification and Management of COIs during Deliberations Regarding the Suspension or Termination of Animal Activities or Animal Use Privileges, or the Restoration Thereof

- A. Identification: An IACUC member or consultant has a COI during deliberations regarding the suspension or termination of animal activities or animal use privileges, or the restoration thereof, when that member or consultant, or an immediate family member of that member or consultant, meets any of the following criteria:
 1. Is the subject of the deliberations or has a COI as defined in Section I.A. with respect to a protocol implicated in the deliberations
 2. Has significant research collaborations (e.g., co-author, grant collaborator) with the subject of the deliberations.
- B. Management:
 1. An IACUC member or consultant who has a COI may be present to provide information requested by the IACUC, and will be requested to leave the room for further discussion or vote.

IV. Identification and Management of Other COIs

- A. Identification: On any matter, any IACUC member may request a determination of whether an IACUC member or consultant has a COI with respect to that matter. The IACUC will vote on that request. The IACUC member with the potential conflict may not participate in such vote.
- B. Management: If a COI is determined to exist, the IACUC will decide by vote on how that COI should be managed. The IACUC member with the potential conflict may not participate in such vote.

References

1. University of Wisconsin-Madison, IACUC Policy on Identifying and Managing Conflicts of Interest, 2015.