



# POLICY

<b>TITLE:</b>	<b>Conflicts of Interest</b>
<b>Policy Number:</b>	2014-041
<b>Responsible Department:</b>	Institutional Animal Care and Use Committee
<b>Policy Contact:</b> <b>Designation:</b> <b>E-Mail:</b>	Donald E. Walters, Ph.D. Chair, Institutional Animal Care and Use Committee <a href="mailto:dewalters@westernu.edu">dewalters@westernu.edu</a>
<b>Approval Date:</b>	10/8/14
<b>Reviewed:</b>	10/11/17; 6/10/2020
<b>Revised:</b>	10/11/17 (Clarified definition of member); 6/10/2020 (Refined management under Other COIs)
<b>Legislation:</b>	Animal Welfare Act (Title 9 CFR Subchapter A, Part 2, Subpart C, § 2.31(d)(2))

**Purpose of Policy:** To prevent situations in which a member of the Institutional Animal Care and Use Committee (IACUC) or a consultant to the IACUC has a real or perceived personal or financial interest that may compromise, or have the appearance of compromising, the person’s professional judgment when performing any IACUC-related activities.

**Policy Information:** The [Animal Welfare Act](#) states that “No 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”. This policy is reiterated in Section IV.C.2 of the [Public Health Service Policy on Humane Care and Use of Laboratory Animals](#).

## I. Identification and Management of a Conflict of Interest (COI) during Protocol Review

- A. Identification:** An IACUC member or consultant has a COI with respect to a protocol when that person or an immediate family member of that person meets, or is perceived to meet, 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 ([42 CFR Part 50 Subpart F](#)):
    - 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 with fiduciary responsibility including senior managers (presidents, vice presidents, etc.) and members of boards of directors. Membership on a scientific advisory board is not considered 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 Principal Investigator (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.

## **B. Management**

1. An IACUC member or consultant who has a COI must disclose that COI to the IACUC chair prior to the protocol review. If said member is the IACUC chair, disclosure must be made to the vice-chair of the IACUC.
2. If the IACUC so requests, an IACUC member or consultant who has a COI may be present to provide information about the protocol. However, the member may be asked to leave the room prior to further discussion or voting on the protocol. If the member with a COI is the IACUC chair, the vice-chair of the IACUC will preside over the 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 regarding the inspection of a room or facility in which animals used in research or teaching are housed when that person or an immediate family member of that person meets any of the following criteria:

1. is key personnel on a protocol that lists the site as the location at which the described activities will be conducted.
2. is a manager of the facility or has significant managerial oversight or provides animal care within the room or facility.

## **B. Management:**

1. An IACUC member or consultant who has a COI may be present during an inspection but should not be a member of the inspection team. If, in order to meet regulatory requirements, that member must be a member of the inspection team, any actions taken must be referred to the full IACUC for resolution.
2. If an inspection concern is referred to the full IACUC, the IACUC member or consultant with the COI may be present to provide information about the concern but may be asked to leave the room prior to further discussion or voting on the issue.

## **III. Identification and Management of COIs during Discussions Pertaining to Disciplinary Actions or Reinstatement of Privileges or Activities by the IACUC**

- A. Identification:** An IACUC member or consultant has a COI during discussions pertaining to disciplinary actions or reinstatement of privileges of activities when said member or consultant or an immediate family member of that person meets any of the following criteria:
1. is the subject of the discussions or has a COI as defined in Section I.A. regarding a protocol under discussion.
  2. is a collaborator with the person under discussion.
- B. Management:** An IACUC member or consultant who has a COI may be present to provide information requested by the IACUC but may be asked to leave the room prior to further deliberations or voting.

#### **IV. Identification and Management of Other COIs**

- A. Identification:** Any member of the IACUC may request a decision from the IACUC as to whether or not a COI exists between an IACUC member or consultant and any matter before the committee. The IACUC must vote on any such request. The IACUC member in question may not participate in such a vote.
- B. Management:** If the IACUC determines that a COI does exist, the IACUC will decide by a majority vote on how to manage the issue. An IACUC member or consultant who has a COI may be present to provide information about the protocol but may be asked to leave the room prior to further deliberations or voting.

he member with the conflict may not participate in the vote.

#### **Definitions:**

- **Member:** a person duly appointed by Western University's President as a voting or nonvoting member of the IACUC.
- **Consultant:** a nonmember of the IACUC asked by the IACUC to provide advice.
- **Key personnel:** a person who has or will contribute substantively to the development or performance of a teaching or research activity.