

Department: UAMS Institutional Review Board
Policy Number: 3.3
Section: Committee Membership
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February 15, 2016; June 1, 2020; August 15, 2022

SUBJECT: IRB Reviewer and Consultant Conflict of Interest

POLICY

The IRB recognizes and will carry out its obligation to ensure human research subjects' rights and welfare are not compromised by competing interests. No Reviewer may participate in the review of any study in which the Reviewer or Immediate Family has a Conflicting Interest, except to provide information regarding the study as requested. This applies to all IRB review functions, including new, expedited, review of unanticipated problems and noncompliance. No individual may serve as a Reviewer or participate in daily IRB operations if that person's primary employment is as a professional fund-raiser to raise funds or solicit grants for research at UAMS, AC/ACRI or other affiliated institutions.

DEFINITIONS

- A. **Conflicting or Competing Interest:** An IRB reviewer or their immediate family has a financial or non-financial interest in the research or entity sponsoring the research.
- B. **Financial Interest:** A reviewer or their immediate family member has one of the following in the research study or the entity sponsoring the research.
 - 1. Ownership interest, stock options, or other financial interest related to the research unless it meets two tests:
 - a. The interest is publicly traded on a stock exchange.
 - b. No arrangement has been entered into whereby the value of the ownership interests will be affected by the outcome of the research.
 - 2. Compensation (received or anticipated) where the value may be affected by the outcome of the study.
 - 3. Proprietary interest related to the research including, but not limited to, a patent, trademark, copyright or licensing agreement.
 - 4. Received payments from a study sponsor for which the reviewer has a conflict of interest management plan.
 - 5. Board or executive relationship related to the research, regardless of compensation.
- C. **Immediate Family Member:** Reviewer's spouse, minor children, and other persons living in the same household or financially dependent on the Reviewer.
- D. **Reviewer:** As used in this policy, this term describes appointed IRB reviewers and consultants asked to assist the IRB, as described in IRB Policy 3.9, Consultants.
- E. **Non-Financial Interest:** Exists when a reviewer or their immediate family member is involved in the design, conduct and reporting of the research study. This includes but is not limited to roles such as investigator, coordinator, or data manager. Also exists when a Reviewer has (or had) interactions or relationships with the study team which would may influence the reviewer's study review.

PROCEDURE

A. Procedures for individual reviewers

1. Reviewers shall, when they receive notice of an agenda, review the entire agenda to determine whether they have a conflict with any of the agenda items.
 - a. If so, they shall contact the IRB chair and an IRB administrator to report the conflict.
 - b. The chair and administrator shall make reassignments and/or call on alternates as needed to remove the individual from any reviews where s/he has a conflict while ensuring an appropriate quorum is maintained.
 - c. The agenda item shall be reassigned to a reviewer with no competing interests.
2. The IRB chair shall be notified immediately if a conflict is discovered during a meeting.
 - a. The Reviewer will be asked to leave the room during the discussion and vote during the study in which there is a Conflict.
 - b. The reviewer's absence will be documented in the meeting minutes, as described in IRB Policy 6.3, Meeting Minutes.
 - c. Reviewers who are out of the room due to a conflict will not count towards quorum. The review may proceed only if quorum is maintained and the remaining membership includes the appropriate expertise and experience to review the research.
 - d. The IRB may call the reviewer back into the room to answer specific questions or to provide specific information.

B. Procedures for IRB office and Chair

1. The IRB chair retains the authority to make the final determination regarding whether a relationship constitutes a conflict. The chair may consult with other IRB reviewers, the vice chair, or the IRB director or staff in making this determination.
2. The IRB chair, director, and staff shall determine which issues and situations constitute a continuing conflict for any particular reviewer.
 - a. This continuing conflict will be taken into account when assigning reviewers.
 - b. Reviewers remain ultimately responsible for disclosing any conflicts the chair, director, or office staff may not be aware of.
3. When identifying consultants, the IRB chair, director, and/or study staff shall seek confirmation from the potential consultant that s/he has no competing interest in the research to be reviewed. No consultant with a conflict shall participate in a study review.

REFERENCES

45 CFR 46.107(d)

21 CFR 56.107(e)

AAHRPP Element II.1.D

AAHRPP Tip Sheet 13: IRB or EC Member and Consultant Conflict of Interest

OHRP Guidance: Financial Conflict of Interest: HHS Guidance (2004)