

Department: UAMS Institutional Review Board
Policy Number: 3.3
Section: Committee Membership
Effective Date: July 31, 2002
Revision Date: March 5, 2004; June 1, 2005; January 24, 2011

SUBJECT: IRB Reviewer and Consultant Conflict of Interest

I. Purpose

To ensure the IRB obligation to protect the rights and welfare of subjects is not compromised by competing interests.

II. Definitions

A. Conflict: Exists when a Reviewer, or Immediate Family, has a Financial or Non-Financial Interest in the research or entity sponsoring the research.

B. Financial Interests: Exists when the Reviewer or Immediate family 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 where 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. Board or executive relationship related to the research, regardless of compensation.

C. Immediate Family: Reviewer's spouse, minor children, and other persons living in the same household or financially dependent on the Reviewer.

D. Reviewer: For purposes of this policy includes appointed IRB Reviewers and Consultants asked to assist the IRB.

E. Non-Financial Interest: Exists when a Reviewer 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 with the study team which would make it difficult to review his/her study with a non-biased eye.

III. Policy

A. No Reviewer may participate in the review of any study in which the Reviewer or Immediate Family has a Conflict, 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.

B. No individual may serve as a Reviewer if that person is employed to raise funds or obtain grants for research at UAMS, ACH/ACHRI or other affiliated institutions.

IV. Procedure for IRB Reviewers

A. Upon receipt of agenda, review assigned studies as well as the other studies on the agenda. Reviewer should notify the IRB if there are any studies in which he or she has a Conflict.

B. If a Conflict is discovered during the meeting, the Reviewer shall inform the Chair of the Conflict. The Reviewer will be asked to leave the room during the discussion and vote during the study in which there is a Conflict.

V. Procedure for IRB

A. Continuing Conflicts. The IRB Chair and IRB Staff shall determine which issues and situations constitute a continuing Conflict for any particular Reviewer. This information will be taken into account when assigning reviewers; however, it is still the Reviewer's responsibility to disclose all Conflicts.

B. Individual Study Conflicts

1. For any study in which the originally assigned reviewer indicates a conflict, the IRB will reassign the study review to a different reviewer.
2. IRB Chair or Staff will ask the Reviewer to leave the room during the discussion and vote on the study in which there is a Conflict. Upon the request of the Committee, the Reviewer may be asked to provide additional information relating to the study. Reviewers who are out of the room due to a conflict will not count towards quorum.
3. The minutes will note that the Reviewer was out of the room due to a conflict in accordance with IRB Policy 6.3.