

Department: UAMS Institutional Review Board
Policy Number: 3.3
Section: Committee Membership
Effective Date: July 31, 2002
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SUBJECT: Conflict of Interest

It is recognized that real, potential and apparent conflicts of interest [hereinafter referred to as "Conflict(s)"] naturally occur from time to time in the course of conducting the affairs of the Institutional Review Boards (IRBs) of University of Arkansas for Medical Sciences (UAMS). It is the IRB's responsibility to safeguard the rights and welfare of persons participating in research projects (Research Subjects) within UAMS. This policy is intended to guide the conduct of the IRB when conflicts arise.

Any discrepancies will be solved by referring to the UAMS Faculty Handbook at http://www.uams.edu/academic_affairs/facultyhandbk/contents.asp.

Definitions.

1. "Conflict(s)" exist under this policy when an IRB member also has a Financial Interest, or any other professional or personal relationship (a "Relationship"), which may make it difficult for the member to exercise independent judgment in safeguarding the rights and welfare of Research Subjects.

More specifically, Conflict(s) exist under this policy when an IRB member or his/her immediate family has a direct or indirect Financial Interest in:

- a. The sponsor of any research project which the IRB is reviewing;
- b. The provider of any product being investigated through any research project which the IRB is reviewing;
- c. Other entities whose financial interests would reasonably appear to be affected by the outcome of any research, which the IRB is reviewing.

For purposes of this policy, the IRB's review includes all aspects of review, including the review of continuing review reports, adverse event reports, and similar reports, and is not limited to the review of new protocols. The immediate family means the (1) spouse of the IRB member, (2) minor children of the IRB member, and (3) parents, children and spouses of children, brothers and sisters, or spouses of brothers and sisters of the IRB member, if such individuals reside in the same household as the IRB member or if the IRB member has knowledge of such an individual's Financial Interests.

Financial Interests include the following:

1. Any ownership interest in a publicly traded company held by the IRB member or his/her immediate family (excluding any interest arising solely by reason of investment in a business by a mutual, pension, or other institutional investment

- fund over which the IRB member or his/her immediate family does not exercise control);
2. Any interest in a non-publicly traded company held by the IRB member or his/her immediate family;
 3. A position held by the IRB member or his/her immediate family as employee, director, officer, partner or any position of management;
 4. Any income (e.g. consulting, salary to the IRB member or his/her immediate family) received or promised;
 5. Any loan to the IRB member or his/her immediate family; and
 6. Any gift to the IRB member or his/her immediate family.

Policy Statement. As a consequence of the potential for Conflicts to arise and the significance of Conflicts, University of Arkansas for Medical Science's affirmative policy shall be to require that (a) all direct and indirect Relationships which may pose a potential Conflict be disclosed promptly and fully to all necessary parties, and (b) all direct and indirect Financial Interests be disclosed promptly and fully to all necessary parties. It shall also be University of Arkansas for Medical Science's affirmative policy to prohibit involvement, except as set forth in this policy, in the IRB's review of the specific research project forming the basis of the Conflict by persons having such a Conflict.

Implementation of Policy. IRB members shall complete the annual disclosure questionnaire as required in Section 4 of this policy. IRB members shall also disclose all current Conflicts to other IRB members at meetings of the IRB. An IRB member shall not participate in the IRB's review of any research project in relation to which the IRB member has a conflict, except to provide information requested by the IRB, if any.

IRB Disclosure Required. Each Relationship or Financial Interest must be presented to the chairperson of the IRB and to a designated representative(s) of the University of Arkansas for Medical Sciences IRB Administrative Office for review. Completing and/or updating the questionnaire shall fulfill this requirement. The questionnaire will be checked against information on file with the Office of Research and Sponsored Programs (ORSP). Any discrepancies will be conveyed to the chairperson of the IRB, and the representatives(s) of the IRB Administrative Office shall determine whether a conflict exists or can reasonably be construed to exist.

If a Conflict is deemed to exist, the following procedures shall be followed:

1. The disclosing person shall make a prompt, full, and frank disclosure of his/her Conflict to the IRB prior to its action on the research project forming the basis of the Conflict
2. An IRB member shall not participate in the IRB's review of any research project in relation to which the IRB member has a Conflict, except to provide information requested by the IRB, if any. Specifically, the IRB member shall not participate in discussions and/or votes relating to the research project forming the basis for the Conflict
3. The IRB shall determine any action to be taken on the research project in question by a vote of the non-interested members present

4. The IRB shall take appropriate disciplinary action against any IRB member who violates this policy to protect University of Arkansas for Medical Science's best interests
5. The minutes of all IRB meetings involving Conflicts shall include the names of the persons who disclosed the existence of a Conflict. In addition, the minutes shall set forth the names of the persons who were present for discussions and/or votes relating to the research project forming the basis of the Conflict; the content of those discussions; and a record of the vote

The requirements of this Section apply to all research projects involving Conflicts, whether or not the action on such studies, in the absence of a Conflict, would be subject to IRB approval in the normal course of business.

Direct or Indirect Involvement Prohibited. IRB members are prohibited from being directly or indirectly involved in any research project where a Conflict exists. This includes discussions with other IRB members regarding the research study and voting. This section shall not be construed to prohibit IRB members who are also principal investigators with regard to a particular study from presenting such study to the IRB and interacting with the IRB as required for the protection of Research Subjects. Any other exceptions to this may be made on a case-by-case basis only by the IRB.

Annual Disclosure. Each year, the University of Arkansas for Medical Sciences IRB Administrative Office shall prepare and submit a Conflict of Interest Questionnaire to all IRB members. Each person who receives a questionnaire shall submit the completed questionnaire to the IRB Administrative Office for review by the IRB chairperson and a designated Research Department representative(s). The IRB chairperson and the designated IRB Administrative Office representative(s) shall determine which issues and situations constitute a Conflict for any particular IRB member.