

**UNIVERSITY OF TENNESSEE HEALTH SCIENCE CENTER
INSTITUTIONAL REVIEW BOARD
CONFLICTS OF INTEREST**

I. PURPOSE

To document the policy and procedures used by the University of Tennessee Health Science Center Institutional Review Board for addressing conflicts of interest.

II. SCOPE

This SOP applies to the IRB administrative staff, IRB members, investigators and all key research personnel.

Personnel Responsible:

UTHSC IRB administrative staff, IRB members, investigators.

III. BACKGROUND

Conflicts of interest exist when fulfillment of professional obligations may be undermined by personal or institutional interests. In the context of human research, investigators and IRB members have fundamental obligations to maintain the integrity and objectivity of the scientific process, to preserve public trust, and to protect the rights and welfare of human subjects. Personal interests, particularly financial interests, may conflict with fulfillment of these professional obligations. In particular, financial conflicts of interest may affect the choice and approval of research projects, the manner in which subjects are recruited, the extent of risk to which subjects are exposed, and the interpretation of study results. Therefore, the IRB requires disclosure of potential or actual conflicts of interest to assure that investigators, key research personnel, and IRB members are able to meet their obligations to protect the rights and welfare of human subjects.

In addressing conflicts of interest, the IRB follows the University of Tennessee Health Science Center policy on research-related conflicts of interest (“Conflicts of Interests: Research Related Issues,” 4/10/06). According to this policy, potential conflicts of interest exist when persons have significant financial interests in the conduct of a research activity. Three types of significant financial interest are identified: payments from the research sponsor expected to exceed \$10,000 in the next twelve months; equity interests in the sponsor of the research; and intellectual property rights in the drug, device or other article being tested. If investigators anticipate payments in excess of \$10,000 during the next twelve months from the sponsor of the research, have equity interests in excess of

\$10,000, or have any intellectual property rights in the article being tested, then they may not participate in the research. However, when investigators have equity interests of less than \$10,000 in the sponsor, then participation in the research is contingent on review and oversight by the University's Conflict of Interest Committee. Similarly, if the sponsor is a commercial entity formed as a result of the investigator's entrepreneurial activities and the investigator has significant financial interests in that entity, the research is permissible with oversight by the Conflict of Interest Committee.

The IRB may consult the UTHSC Conflict of Interest Committee to determine the appropriate way to manage an investigator's potential or actual conflicts of interest. Management strategies include, but are not limited to: disclosure of the conflict to prospective subjects; modification of the research plan; monitoring of the recruitment of subjects or the conduct of the research by independent reviewers; and divestiture of the significant financial interests by the investigator.

In order to assure proper protection for the rights and welfare of human subjects, the IRB applies the same conflict of interest rules to its members with respect to their role in reviewing applications to conduct research. A member who has significant financial interests in a particular commercial entity may not participate in the review, deliberations or voting on studies supported by that sponsor. Members' conflict of interest disclosures are updated annually.

In Accordance With:

45CFR46.107(e); 21CFR56.107(e); 45CFR46.109(b); 21CFR56.109(b);
45CFR46.111(a); 21CFR56.111(a).

HHS Guidance on Financial Relationships and Interests in Research With Human Subjects located at

<http://www.hhs.gov/ohrp/humansubjects/finreltn/fguid.pdf>

Compliance with this policy also requires compliance with state or local laws or regulations that provide additional protections for human subjects.

IV. DEFINITIONS

Significant financial interest means anything of monetary value, including but not limited to: (1) salary for services, or other payments from a single source (e.g., consulting fees or honoraria) when aggregated over the next twelve (12) months are expected to exceed \$10,000; (2) equity interests (e.g., stocks, stock options or other ownership interests); this includes gifted stock in a faculty/staff/student-owned company or a company proposing to sponsor research at the University; and (3) intellectual property rights (e.g., patents, copyrights and royalties from such rights). Financial interest includes the monetary interest of the employee,

employee's spouse (whether or not they commingle assets) and the interest of the employee's dependent children (including step- and foster children). In any given circumstance, a University employee's financial interest may also include the interest of nondependent children and parents.

Sponsored programs mean research or other activities (including clinical trials) that are funded by sources external to the University.

V. PROCEDURES

1. The UTHSC IRB requires that investigators report potential financial conflicts of interest in the Form 1 application for new studies. The application must address the following considerations:
 - a. It must explain whether any key research personnel have a significant financial interest in the research activity as defined in the UTHSC policy dated 4/10/06. Key research personnel include the principal investigator, co-investigators, research coordinators, and any persons involved in securing the informed consent of prospective subjects.
 - b. Reportable financial interests include those of key research personnel, their spouses (whether or not they commingle assets) and the interests of their dependent children (including step- and foster children). In any given circumstance, the financial interests of key research personnel may also include the interests of non-dependent children and parents.
 - c. The application must indicate whether the UTHSC Conflict of Interest Committee has formulated a plan for addressing any significant financial interests of key research personnel, and whether the Vice Chancellor for Finance and Operations has approved the plan. Documentation of the plan adopted and the approval of the Vice Chancellor must be attached to the application.
2. The UTHSC IRB will not approve a study application that includes key research personnel whose significant financial interests preclude participation in the study under the UTHSC Conflict of Interest policy.
3. If the investigator or other key research personnel has a significant financial interest that does not preclude participation in the research study under the UTHSC Conflict of Interest policy, then the IRB will not approve the study until the significant financial interests are reviewed by the UTHSC Conflict of Interest Committee and a plan for managing those interests has been formulated by the Committee and approved by the Vice Chancellor for Finance and Operations. However, the IRB retains the authority to reject the proposed plan for managing the conflict of interest as insufficient to assure proper protection for the rights and welfare of human subjects.

4. The IRB may require implementation of plans for managing significant financial interests that include, but are not limited to:
 - a. disclosure of the significant financial interests to prospective subjects in the informed consent process;
 - b. monitoring of research activities by independent reviewers;
 - c. removal of the study personnel with significant financial interests from participation in the study; and
 - d. divestiture of significant financial interests by study personnel.
5. Plans for managing the significant financial interests of investigators and other key research personnel must be reviewed and approved by the full Board.
6. Each IRB member shall complete a conflict of interest form annually and submit updates as necessary.
7. No IRB member may participate in the review, deliberation or voting for any study application if the member has a significant financial interest related to the test article or the sponsor of the study. IRB administrative staff will review members' conflict of interest disclosures prior to the assignment of primary and secondary reviewers to assure that reviewers have no significant financial interests related to the study.
8. A copy of any financial disclosure documents submitted by an investigator will be kept in the IRB files for the study. IRB members' conflict of interest disclosure forms will be maintained in the membership files.