

**UNIVERSITY OF TENNESSEE GRADUATE SCHOOL OF
MEDICINE
INSTITUTIONAL REVIEW BOARD
CONFLICTS OF INTEREST**

I. PURPOSE

To document the policy and procedures used by the University of Tennessee Graduate School of Medicine Institutional Review Board for addressing conflicts of interest.

II. SCOPE

This SOP applies to IRB members, consultants, investigators and all key research personnel.

Personnel Responsible:

UTGSM IRB administrative staff, IRB members, investigators.

III. BACKGROUND

A conflict of interest occurs when there is a risk that the fulfillment of role-related professional obligations may be compromised by a person's other interests. In the context of research with human subjects, the professional obligations of researchers and research staff include the duties to conduct research in a manner that respects the integrity of the scientific method and protects the rights and welfare of human subjects. The professional obligations of IRB members and consultants include the duties to assure that research is conducted in accord with all applicable ethical, statutory, and regulatory requirements for protection for the rights and welfare of human subjects.

The individual interests that may compromise the fulfillment of professional obligations related to the integrity of the scientific method and the protection of human subjects include (a) significant financial interests, and (b) other interests that may undermine an individual's ability to meet role-related professional obligations. Other interests may include business associations, institutional affiliations, and collegial and personal relationships. The pertinent interests of individuals include their own interests, as well as those of their spouses, dependent and non-dependent children, parents, foster children and step children.

Therefore, the IRB requires disclosure of conflicts of interest to assure that investigators, key research personnel, and IRB members and consultants are able

to meet their obligations to maintain the integrity of the scientific process and to protect the rights and welfare of human subjects.

In addressing financial conflicts of interest, the IRB follows the University of Tennessee Health Science Center Fiscal Procedure, *F125 Conflicts of Interest*, effective 08/24/2012. According to this policy, a conflict of interest exists when a person has a significant financial interest that may affect the conduct of a research activity. A significant financial interest exists if:

- The value of any remuneration received from a publicly traded entity in the 12 months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000; or
- The value of any remuneration received from a non-publicly traded entity in the 12 months preceding the disclosure, when aggregated, exceeds \$5,000, or when an individual holds any equity interest in that entity; or
- Intellectual property rights and interests (patents, trademarks, licensing agreements, or copyrights) are held in the drug, device or other article being tested, and income related to such rights and interest has been received.

If any individuals among the key study personnel have significant financial interests that may affect the design, conduct or reporting of a sponsored activity, then they may not participate in the research unless an appropriate plan for management of the conflict of interest has been formulated in consultation with the Research Conflict of Interest Committee. The IRB will confirm that a satisfactory management plan has been formulated, approved, and signed by the key study personnel prior to final approval of studies in which key study personnel have financial 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 interest by the investigator or other individuals among the key study personnel.

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

In Accordance With:

45 CFR 46.107(e); 21 CFR 56.107(e); 45 CFR 46.109(b); 21 CFR 56.109(b);
21 CFR 312.64(d); 21 CFR 812.110(d)

HHS Regulations, 42 CFR 50, Subpart F – Promoting Objectivity in Research

<http://www.gpo.gov/fdsys/pkg/CFR-2011-title42-vol1/pdf/CFR-2011-title42-vol1-part50-subpartF.pdf>

HHS Guidance on Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection

<http://www.hhs.gov/ohrp/regulations-and-policy/guidance/financial-conflict-of-interest/>

FDA Regulations, 21 CFR 54 – Financial Disclosure By Clinical Investigators

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=54>

FDA Guidance for Clinical Investigators, Industry, and FDA Staff – Financial Disclosure by Clinical Investigators

<http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM341008.pdf>

The University of Tennessee Health Science Center, Conflicts of Interest, Fiscal Procedure F125, effective 8/24/12

http://www.uthsc.edu/policies/w932_document_show.php?p=155

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

IV. DEFINITIONS

Equity interest includes any stock, stock option or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.

Financial conflict of interest (FCOI) means a significant financial interest that could directly and significantly affect an individual's official University responsibilities. This includes a significant financial interest that could directly and significantly affect the design, conduct or reporting of research.

Financial Interest means anything of monetary value, whether or not the value is readily ascertainable and includes the interests of the covered individual's spouse (whether or not they commingle assets), parents, and children (both dependent and non-dependent, and including stepchildren and foster children).

Key research personnel include, but are not limited to,:

1. Principal investigators and Co-/Sub-Investigators;
2. Individuals listed on the grant or contract application;
3. Individuals listed on an FDA form 1572;
4. Individuals who are named as contact persons in the informed consent or recruitment materials;
5. Individuals who provide supervision of the people obtaining informed consent;
6. Individuals who obtain informed consent;
7. Individuals who perform study interventions, interactions, or observations of non-public behavior, or who review private, individually identifiable information or specimens from subjects, as defined at 45 CFR 46.102(f);
8. Individuals who are responsible for the overall conduct of the study; who play an essential role in study design, implementation, etc.; or who coordinate execution of study activities; and
9. Individuals who perform services that merit professional recognition or publication services

Individuals functioning within his/her regular work practice (e.g., phlebotomist, x-ray technician, etc.) who provide clinical care and whose involvement in the research is limited to only those work responsibilities without further contribution to the research, do not need to be listed as key study personnel.

Manage means to take action to address a disclosed financial conflict of interest, which can include reducing or eliminating the conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

Remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship).

Significant financial interest means anything of monetary value, including but not limited to:

- The value of any remuneration received from a publicly traded entity in the 12 months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000; or

- The value of any remuneration received from a non-publicly traded entity in the 12 months preceding the disclosure, when aggregated, exceeds \$5,000, or when an individual holds any equity interest in that entity; or
- Intellectual property rights and interests (patents, trademarks, licensing agreements, or copyrights) are held in the drug, device or other article being tested, and income related to such rights and interest has been received.

The term “significant financial interest” does not include the following types of financial interests: salary, royalties, or other remuneration paid by the University to the investigator if the investigator is currently employed or otherwise appointed by the HSC, including intellectual property rights assigned to the HSC and agreements to share in royalties related to such rights; income from investment vehicles, such as mutual funds and retirement accounts, as long as the investigator does not directly control the investment decisions made in these vehicles; income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education; or income from service on advisory committees or review panels for a Federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

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

V. PROCEDURES

A. Investigators and Other Key Research Personnel:

1. The UTGSM 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 financial conflict of interest in the research activity as defined in *F125 Conflicts of Interest*, effective 08/24/2012.
 - b. Reportable financial interests include those of key research personnel and their spouses, parents, and children as defined above.

The IRB will forward the conflict of interest information to the Office of the Vice Chancellor for Research. In addition, the Office of the Vice Chancellor for Research may discover a conflict of interest before the IRB when key study personnel sign the Research Conflict of Interest form that must be completed prior to signing the grant or contract.

In either case, the designated Conflict of Interest Committee will communicate with the IRB in a timely manner regarding whether the conflict is one that needs to be managed and whether a management plan has been formulated, approved, and signed by the key study personnel. Documentation including a description of the conflict of interest, the signed plan adopted to manage it, and approval of the plan by the Vice Chancellor for Research will be transmitted to the IRB and included in the IRB record for the study.

2. If the investigator or other key research personnel has a financial conflict of interest, then the IRB will not approve the study until the conflict of interest is reviewed by designated the Conflict of Interest Committee, a plan for managing those interests has been formulated and approved by the same under the provisions of *F125 Conflicts of Interest*, and the plan is signed by the key study personnel. The IRB will use this information during its review process. Further, the IRB retains the authority to add additional requirements to the proposed plan for managing the conflict of interest (see #3 below). The IRB also possesses the final authority for determining that the management plan is adequate to protect the integrity of the research and the rights and welfare of human subjects involved in the study.

3. The IRB may require implementation of additional plans for managing financial conflicts of interest that include, but are not limited to:
 - a. Public disclosure of the financial conflict of interest (e.g., when presenting or publishing the research);
 - b. Disclosure of the financial conflict of interest to prospective subjects in the informed consent process;
 - c. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the sponsored project against bias resulting from the financial conflict of interest;
 - d. Modification of the research plan;
 - e. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
 - f. Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
 - g. Severance of relationships that create the financial conflict of interest.

In the event that the IRB requires additional plans for managing financial conflicts of interest, then the Vice Chancellor will be duly notified regarding those additional requirements

4. Plans for managing financial conflicts of interest of investigators and other key research personnel on full board studies must be reviewed and approved

by the full Board. Plans for managing financial conflicts of interest of investigators and other key research personnel on expedited submissions must be reviewed and approved by the expedited reviewer and the Chair.

5. When an investigator has been determined to have a financial conflict of interest that must be managed under provisions of *F125 Conflicts of Interest*, the IRB will not provide final approval for the conduct of the study until it has verified that the investigator has completed the CITI training regarding conflicts of interest and/or NIH tutorial required under *F125 Conflicts of Interest*.
6. At the time of continuing review, the UTGSM IRB requires that investigators report whether any new financial conflicts of interest have developed for the investigator or any of the key research personnel (including spouses, parents, and children as defined above). If a new financial conflict of interest has developed as outlined under *F125 Conflicts of Interest*, then:
 - a. The investigator must briefly explain the new conflict of interest in the Form 3: Continuing Review Submission Form within iMedRIS.
 - b. The investigator must submit a Form 2: Change Request & Amendments via iMedRIS to revise the appropriate section of Form 1 application regarding Conflicts of Interest and must include appropriate documents regarding the conflict of interest (if applicable).
 - c. The IRB will forward the conflict of interest information to the Office of the Vice Chancellor for Research. The designated Conflict of Interest Committee will communicate with the IRB in a timely manner regarding whether the conflict is one that needs to be managed and whether a management plan has been formulated, approved, and signed by the key study personnel. Documentation including a description of the conflict of interest, the signed plan adopted to manage it, and approval of the plan by the Vice Chancellor for Research will be transmitted to the IRB and included in the IRB record for the study.
 - d. The IRB may require implementation of additional plans for managing the new significant financial interest as outlined in paragraph #3. In the event that the IRB requires additional plans for managing financial conflicts of interest, then the Vice Chancellor will be duly notified regarding those additional requirements as specified in #3.
7. Investigators must notify the IRB of any new financial conflict of interest that has developed for the investigator or any of the key research personnel (including spouses, parents, and children as defined above) within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new financial interest.

- a. The investigator must submit a Form 2: Change Request & Amendments via iMedRIS to revise the appropriate section of Form 1 application regarding Conflicts of Interest. The investigator must briefly explain the new conflict of interest and must include appropriate documents regarding the conflict of interest (if applicable).
 - b. The IRB will forward the conflict of interest information to the Office of the Vice Chancellor for Research. The designated Conflict of Interest Committee will communicate with the IRB in a timely manner regarding whether the conflict is one that needs to be managed and whether a management plan has been formulated, approved, and signed by the key study personnel. Documentation including a description of the conflict of interest, the signed plan adopted to manage it, and approval of the plan by the Vice Chancellor for Research will be transmitted to the IRB and included in the IRB record for the study.
 - c. The IRB may require implementation of additional plans for managing the new significant financial interest as outlined in paragraph #3. In the event that the IRB requires additional plans for managing financial conflicts of interest, then the Vice Chancellor will be duly notified regarding those additional requirements as specified in #3.
8. When a financial conflict of interest is not identified or managed in a timely manner, the IRB will conduct an audit of the research study (see UTGSM IRB SOP, Auditing of Research Studies).

B. IRB Members and Consultants:

1. An IRB member or consultant will be considered to have a conflict of interest with respect to any item under review when any of the following conditions apply to the member, the consultant, or a family member thereof:
 - a. The member, consultant or family member has a significant financial interest as defined above that could directly and significantly affect the design, conduct or reporting of research.
 - b. The member, consultant or family member is a member of the research team engaged in the study under review.
 - c. The member, consultant or family member has direct supervisory responsibility in the employment setting for any of the investigators engaged in the study.
 - d. The member, consultant or family member is under the direct supervision in the employment setting of the principal investigator for the study.
 - e. The member, consultant or family member is the spouse of any of the investigators engaged in the study.

- f. The member, consultant or family member serves as an officer of the agency, company or other entity sponsoring the research.
- g. The member, consultant or family member has some other interest that, in his or her individual judgment, constitutes a conflict of interest.
- h. The member, consultant or family member has some other interest that, in the judgment of the IRB chair, or the judgment of the convened Board as determined by a majority vote of those present, is determined to constitute a conflict of interest as defined in this policy.

The status of the member, consultant or family member as a departmental colleague of any investigator engaged in a study under review is not considered, in and of itself, to constitute a conflict of interest.

- 2. The IRB will implement the following procedures to identify any members or consultants who may have a conflict of interest related to any actionable item under review:
 - a. All members of the IRB must complete the IRB's Member Conflict of Interest Disclosure Statement annually indicating that each Board member must disclose the existence of any conflict of interest related to any items for which that individual is assigned review responsibilities.
 - b. When initiating assigned reviews, Board members will be asked to confirm in the electronic reviewer form that they have no conflict of interest related to the review item.
 - c. When initiating assigned reviews, Board consultants will either sign a paper Consultant Conflict of Interest Disclaimer confirming that they have no conflict of interest related to the review item for which they have accepted the consultancy, or they will be asked to confirm this in the electronic reviewer form.
 - d. At the beginning of each meeting of the convened IRB, the chair of the meeting will remind members and consultants to recuse themselves from the deliberation and voting regarding any actionable item with respect to which they have a conflict of interest. Board members will be asked to notify the chair, as individual agenda items are presented for review, in the event that they have a conflict of interest, so that they may be excluded from the proceedings related to these agenda items.
- 3. When Board members or consultants are identified as having a conflict of interest, the following provisions apply:
 - a. Board members or consultants may not serve as reviewers for any actionable items with respect to which they have a conflict of interest.
 - b. This prohibition applies to the review of new applications of all types (exempt, expedited and full Board); expedited and full Board continuations; exempt, expedited and full Board revisions; advertisements; terminations; Documents from Primary IRB submissions; miscellaneous

- submissions; unanticipated problem reports; DSMB/annual reports; audit reports; and suspected cases of non-compliance with applicable law, regulation and/or the determinations of the IRB.
- c. The name of the Board member or consultant and the nature of the conflict of interest will be documented in the Notebook section for the relevant study.
4. When Board members or consultants with an identified conflict of interest participate in a meeting of the convened Board, the following procedures will be utilized:
 - a. The other Board members in attendance will be informed of the fact that the member or consultant has a conflict of interest and the nature of that conflict will be explained to them.
 - b. The member or consultant with an identified conflict of interest may not participate in the deliberations of the committee regarding the item in question, except to provide information requested by the IRB when the member or consultant has special expertise or knowledge related to issues being addressed by the IRB in its review.
 - c. A member with an identified conflict of interest will be excluded from voting on the item in question.
 - d. The member or consultant with an identified conflict of interest will be required to leave the meeting room during the deliberation and voting regarding the item in question.
 - e. The member with an identified conflict of interest will not be counted towards the quorum.
 - f. In the minutes of the meeting, the member or consultant will be documented as being absent due to an identified conflict of interest.
 5. No individual may serve as a member of or consultant to the IRB, or otherwise be involved in the daily operations of the IRB, if that individual is responsible for the business interests of the University or its affiliated institutions with respect to the business development of human research studies, the recruitment of study sponsors, or the solicitation of funding for human research activities. Individuals will be considered to have such responsibilities if the evaluation of their work performance is at least partly dependent on their ability to successfully engage in these sorts of activities.