

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

**I. PURPOSE**

To document the policy and procedures used by University of Tennessee Graduate School of Medicine Institutional Review Board (UTGSM IRB) regarding the conflicts of interest.

**II. SCOPE**

This SOP applies to the IRB administrative staff, IRB members and investigators.

**Personnel Responsible:**

UTGSM IRB administrative staff, IRB members, investigators

**III. BACKGROUND**

[The University of Tennessee Conflict of Interest Policy](#) (date effective August 24, 2012) requires employees to report specific outside activities that may or may not represent conflicts of interest. The policy also states that a prohibited conflict of interest occurs when employees have outside financial interests that affect the design, conduct or reporting of research. It is the policy of UTGSM IRB to protect the integrity of clinical research by identifying, managing or eliminating all conflicts of interest related to the review, conduct and/or reporting of human research. The IRB requires disclosure of conflicts of interest to assure that investigators, key research personnel, and IRB members are able to meet their obligations to maintain the integrity of the scientific process and to protect the rights and welfare of human subjects.

According to the University of Tennessee Fiscal Policy, *F10125 Conflicts of Interest*, potential conflicts of interest exist when persons have significant financial interests in 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 previous 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 any individual among the key study personnel holds any equity interest in that entity; or

- Intellectual property rights and interests (patents, trademarks 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 Chief Business Officer (CBO) of UTHSC. The IRB will confirm that a satisfactory management plan has been formulated 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 subject, 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 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);  
45 CFR 46.111(a); 21 CFR 56.111(a).

**Financial Conflicts of Interest**

<http://grants.nih.gov/grants/policy/coi;>

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

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

**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>

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*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 performance of official University responsibilities. This includes a significant financial interest that could directly and significantly affect the design, conduct or reporting of research and/or other sponsored projects.

**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 step children and foster children).

**Key research personnel** include the principal investigator, co-investigators, research coordinators, and any persons involved in securing the informed consent of prospective subjects.

**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 previous 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 any individual among the key study personnel holds any equity interest in that entity; or
- Intellectual property rights and interests (patents, trademarks or copyrights) are held in the drug, device or other article being tested, and income related to such rights and interest has been received.

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

## V. PROCEDURES

### A. Investigators:

1. UTGSM IRB requires that investigators address potential financial conflicts of interest in the [Form 1](#) application for new studies. The conflict of interest section of [Form 1](#) must address the following considerations:
  - a. It must explain whether any key research personnel have a reportable economic interest (as defined in University policy *F10125 Conflicts of Interest* effective August 24, 2012)
  - b. Reportable financial interests include those of key research personnel and their spouses, parents, and children.
  - c. The IRB record will indicate whether the UTHSC Finance and Operations Office has formulated a plan for addressing any financial conflicts of interest of key research personnel and whether the plan has been approved. Documentation of the plan adopted and the approval by the UTHSC Finance and Operations Office will be included in the IRB record.
  
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 the UTHSC Finance and Operations Office and a plan for managing those interests has been formulated and approved by the same under the provisions of *F10125 Conflicts of Interest*. However, the IRB retains the authority to add additional requirements to the proposed plan for managing the conflict of interest if necessary to assure proper protection for the rights and welfare of human subjects.
  
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/sponsored project plan;

- e. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the sponsored project plan;
- 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.

Plans for managing financial conflicts of interest of investigators and other key research personnel must be reviewed and approved by the full Board. UTGSM IRB has the authority to form a subcommittee to evaluate completed Conflict of Interest forms and any other information pertaining to potential conflicts in interest in clinical investigations. The subcommittee shall consist of two IRB members who will meet prior to the IRB meeting. The subcommittee shall notify the IRB as to whether the financial interests or other potential or actual conflicts could directly or significantly or appear to affect the study. The subcommittee findings, along with recommendations of the full Board will be read into the minutes of the convened meeting. The IRB Assistant Director/designee may perform the review of financial disclosure forms and present to the IRB in lieu of a subcommittee. Recommendations will come from the full IRB.

- 4. When an investigator has been determined to have a financial conflict of interest that must be managed under provisions of *F10125 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 required under *F10125 Conflicts of Interest*.
- 5. 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, parent, and children). If a new financial conflict of interest has developed as outlined under *F10125 Conflicts of Interest*, then;
  - a. The investigator must briefly explain the new conflict of interest in the Form 3: Continuing Review Submission Form;
  - b. The IRB record will indicate whether the UTHSC Finance and Operations Office has formulated a plan for addressing the new financial conflict of interest of key research personnel and whether the plan has been approved. Documentation of the plan adopted and the approval by the UTHSC Finance and Operations Office will be included in the IRB record.
  - c. The IRB may require implementation of additional plans for managing the new significant financial interest as outlined in item #3 of this policy.

6. 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, Audits of Research Studies)
7. A copy of any financial disclosure documents submitted by an investigator will be kept in the IRB files for the study.

## **B. IRB Members**

8. IRB members sign a [Conflict of Interest Statement and Confidentiality Agreement](#) annually indicating that each member will make known the existence of any possible conflicts of interest regarding a protocol under review. Any disclosed information will be used in determining whether a member may participate in or be recused from the review, deliberation or voting of the protocol submitted to the board..
9. No IRB member may participate in the deliberations or voting of any protocol in which the member has a conflicting interest, except to provide information to the IRB when requested.
10. No IRB member may participate in the deliberations or voting of any protocol in which the member has a financial conflict of interest, except to provide information to the IRB when requested.
11. IRB member conflict of interest forms will be kept in the IRB office files.