

**FINANCIAL AND NONFINANCIAL CONFLICT OF INTEREST**

**1. POLICY**

The Tuscaloosa VA Medical Center (TVAMC) Human Research Protection Program (HRPP) is committed to ensuring the disclosure of potential conflicts of interest, to evaluate the potential impact on the research and research participants, and to manage the conflicts so they do not negatively impact participants.

This policy establishes written procedures that ensure the identification, management, and minimization of conflicts of interest in human subject research, including but not limited to the investigator(s), Institutional Review Board (IRB) members, and Research & Development (R&D) Committee members.

**2. RESPONSIBILITIES**

**TVAMC Medical Center Director** is the institutional official responsible for the R&D Program, and as such, oversees the facility in issues related to conflict of interest in research and administers the facility's program related to financial conflict of interest.

**Coordinator for Research & Development (C/R&D)** is responsible for:

- Developing and implementing policies and procedures for identifying, reviewing, eliminating and/or managing conflicts of interest in research.
- Ensuring all potentially significant financial or non-financial conflicts of interest have been either eliminated or minimized to uphold federal and institutional compliance and ethical standards of human research at the TVAMC.
- Making final decisions in collaboration with the Director and Chief of Staff (COS) regarding investigator appeals of R&D Committee decisions for identifying and managing conflicts of interest.

**Research Personnel**, including the Principal Investigator, Sub- or Co-investigator(s), and all other personnel responsible for the study, are responsible for:

- Disclosing accurately, honestly, and completely all conflicts of interest, financial or non-financial, that they may have with a research project. If a conflict of interest, financial or non-financial, develops or exists at any other time during the conduct of an active research project, it must be reported to the IRB.
- Adhering to and implementing decisions made by the R&D Committee regarding minimizing, managing, monitoring, auditing and/or eliminating conflicts of interest financial or non-financial with the research project.

- Maintaining the protection of human research participants' and the TVAMC's best interests in conducting studies in which the investigator may have a conflict of interest.
- Disclosing, when appropriate, on the informed consent form that the investigator has a conflict of interest in the research project that may potentially affect the design of, decisions made, and/or actions taken surrounding the study.
- Submitting annual conflict of interest updates as requested by the IRB and R&D Committees.

**Institutional Review Board (IRB)** is responsible for ensuring that risks are minimized and the rights and welfare of research participants are protected through appropriate disclosure and effective management of conflicts of interest.

**Chair of the Compliance Business Integrity Committee (CBIC)** will annually review all R&D and IRB members' conflict of interest forms and bring any pertinent positive or negative findings to the committee for full review and discussion. Any identified vulnerabilities of conflict of interest or a negative report would then be communicated by memo to the R&D Committee as well as recorded in the R&D minutes.

**Institutional Officials**, such as the Director, COS, and C/R&D should not serve as voting members of the IRB unless there are compelling reasons.

### **3. DEFINITIONS**

**a. Conflict of Interest** is a situation in which financial or personal obligations may compromise or present the appearance of compromising an individual's or group's professional judgment in conducting, reviewing or reporting research. The appearance of a conflict of interest from the point of view of a disinterested party is considered a potential conflict of interest. This can be as serious and potentially damaging to the public trust as an actual conflict. Therefore, potential conflicts of interest must be disclosed, evaluated, and managed with the same thoroughness as actual conflicts.

**b. Personal Conflict of Interest** is a situation where personal obligations compromise or appear to compromise an individual's or group's professional judgment in conducting, reviewing, or reporting research. This may occur when the investigator serves dual roles such as investigator and health care provider. Other interests such as publications, promotion or tenure can also become conflicts of interest that may affect an investigator's judgment.

**c. Financial Conflict of Interest** is a situation where an individual, group, or institution may benefit financially from the performance of, outcome of, or reporting of a research project.

**d. Significant Financial Interest** means any ownership interest (equity or stock options) or compensation belonging to the investigator and his/her spouse and dependent

children, that is related to the research or sponsor of the research study under consideration by the IRB (see conflict of interest forms for detailed list).

- e. **Investigator** means the principal investigator, sub- or co-investigator, and other TVAMC staff, volunteer staff, and research collaborators (including visiting scientists) responsible for the design, conduct, or reporting of research or educational activities, or responsible for preparing a proposal for research funding. “Investigator” includes the investigator’s spouse and dependent children. This may also include post-doctoral fellows and other staff.
- f. **Consultants, research committee members, or research staff** includes all HRPP staff, IRB members, IRB alternates, R&D Committee members, R&D Committee alternates, and consultants to the IRB or R&D Committee.

#### 4. **PROCEDURES**

- a. **Requirements for Financial Disclosure and Conflict of Interest Form:** The TVAMC HRPP requires that all HRPP staff, IRB members/alternates/consultants and R&D members/alternates/consultants to submit a financial disclosure and conflict of interest form annually, or if significant changes emerge during the year. In addition to financial conflicts of interest, a conflict of interest would exist if an IRB member were an investigator or co-investigator, research assistant, or spouse of an investigator. The annual form will be kept on file in the IRB office along with their curriculum vitae (CV) and certification of education on the protection of human subjects in research. All IRB and R&D members/alternates/consultants shall submit an updated financial disclosure and conflict of interest disclosure form on an annual basis.

The IRB requires all investigators to submit a financial disclosure and conflict of interest disclosure form at the initial and continuing review submission, in order for the IRB to identify and manage any potential conflicts of interest to ensure that the protection of human research participants is the primary interest of those engaged in conduction and reviewing research. The investigator shall promptly update this information if any relevant changes occur in the course of the investigation or for 1 year following completion of the study.

- b. **Non-financial Conflict of Interest:** A non-financial conflict of interest may exist for members or investigators for interests that may affect an investigator’s judgment or committee member’s vote, such if their career advancement is based on the outcome (i.e. positive or negative results) of the study. Non-financial conflict of interests must also be disclosed on the financial disclosure and conflict of interest form.
- c. **Financial Conflict of Interest:** Potential for a financial conflict of interest is outlined in a detailed conflict of interest form and may exist when one or more of the items on the conflict of interest form are present (see conflict of interest forms).

- d. **Review of Financial Disclosure and Conflict of Interest Form:** The Chair of the CBIC will annually review all research staff, R&D and IRB members/alternates/consultants' conflict of interest forms and bring any pertinent positive or negative findings to the R&D Committee for full review and discussion. Any identified vulnerabilities of conflict of interest or a negative report would then be communicated by memo to the R&D Committee as well as recorded in the R&D minutes. A conflict of interest is acceptable as long as remedies are in place and appropriate to minimize or negate these potential conflicts of interest in R&D matters.

At the beginning of each IRB meeting, the IRB Chair shall ask the IRB members if anyone has potential conflict of interest related to any protocols that the IRB is about to consider. The IRB members are given opportunity to self-disclose a potential financial conflict of interest and subsequently abstain from the deliberations and voting on studies that may have a conflict of interest (financial or non-financial). IRB members who have a conflict of interest are required to absent themselves from deliberations and abstain from voting (financial or non-financial). This includes being a simultaneous IRB member and an investigator on the study. No IRB or R&D member may participate in the initial or continuing review of any project in which that member has a conflict of interest, except to provide information requested by the IRB or R&D Committee. Abstentions are recorded in the minutes of meetings.

At initial and continuing review, the IRB reviewer will consider the potential for a financial conflict of interest of the investigator(s) by examining 1) the investigators' financial disclosure and conflict of interest forms and 2) source of funding for the study. The IRB may request additional information (i.e. budget, contract) if needed to determine whether the financial interests of parties involved in research could affect the rights and welfare of subjects. The IRB may also request additional information if needed to determine whether an investigator's non-financial interests could affect the rights and welfare of subjects. In the event of a financial conflict of interest, the IRB can specify allowable remedies.

- e. **Allowable Remedies for Investigator Conflict of Interest:** The IRB may place restrictions on the investigator or study, if necessary, or outline allowable remedies. Any restrictions or allowable remedies will be conveyed to the investigator in writing. Conflict of interests may be managed by eliminating them or mitigating their potential negative impact. Allowable remedies for an investigator or IRB member who has a conflict of interest may include, but are not restricted to:
- Reduction of the financial or nonfinancial interest
  - Disclosure of the financial or nonfinancial interest to prospective subjects
  - Separation of responsibilities for financial decisions and research decisions
  - Addition of further oversight or monitoring of the research
  - Establishment of independent data and safety monitoring board
  - Modification of role(s) of particular research staff (i.e. change the person who seeks consent to a non-biased party or change of investigator)
  - Elimination of the financial or non-financial interest

5. **REFERENCES**

- VHA Handbook 1200.13

6. **ATTACHMENTS**

- Investigator Financial Disclosure and Conflict of Interest Form
- Research Consultants, Research Staff or Committee Member Financial Disclosure and Conflict of Interest Form

7. **RESCISSIONS**

HRPP SOP#9A dated May 7, 2007.

8. **REVIEW DATE**

January 1, 2012

Signature on File in the R&D Office

Lori L. Davis, MD

Coordinator of Research and Development