

DEPARTMENT OF VETERANS AFFAIRS  
South Texas Veterans Health Care System  
7400 Merton Minter Boulevard  
San Antonio, Texas 78284

RESEARCH SERVICE  
MEMORANDUM 04-22

October 12, 2004

RESEARCH STANDARD OPERATING PROCEDURES

**Managing Conflict of Interest**

1. PURPOSE: To outline the Office of Research and Development procedures for dealing with the following areas of potential conflicts of interest:

a. During the review of research protocols by the Research and Development Committee or any of its subcommittees, members may find themselves in a personal conflict of interest when reviewing research such as:

- (1) When a member is an investigator on the research
- (2) When an investigator must report to or is under supervision of a member
- (3) A member competes for grants or contracts in the same/similar field as an investigator whose research is scheduled for review.

b. Investigators may have the potential conflict of interest when approached to conduct research sponsored by organizations with whom they have a financial interest. A financial conflict of interest exists when an individual, group, or institution may benefit financially from either the performance of, or the outcome of, or reporting of a research project. Financial and employment relationships include, but are not limited to, salary or other payments for services (e.g., consulting fees or honoraria), equity interests (e.g., stocks, stock options or other ownership interests), appointed position in the sponsoring agency (e.g., Directors, consultants, or advisory group), and intellectual property rights (e.g., patents, copyrights, and royalties from such rights).

c. A conflict of interest occurs when any financial arrangement, situation or action affects or is perceived to exert inappropriate influence on the design, review, conduct, results, or reporting of research activities or findings. Concerns are based on the potential effects the conflicts may have on the real or perceived quality of the research and the treatment of research participants. The perception that a conflict of interest exists may not affect the actual development, management and evaluation of the study but may negatively impact on the perceived validity of the study and the credibility of both the investigator and the institution.

2. POLICY:

a. Members of the R&D Committee and subcommittees having a conflict of interest are prohibited from participating in the initial or continuing review of research protocols.

b. For all sponsored research, the Principal Investigator is responsible for the disclosure of any financial or other interest that he and/or key participants on the study, spouses, and dependents may have with the sponsor. Principal investigator is responsible for bringing to the ACOS for R&D attention any potential conflict that occurs throughout the study.

c. A Conflict of Interest Administrator will review all Disclosure Statements for any perceived conflicts and advise/make recommendations to the R&D Committee and its subcommittees, e.g. IRB, regarding any conflicts that could adversely affect the design, conduct, or reporting of a research project conducted at STVHCS.

### 3. PROCEDURES

a. Financial Disclosure: All research proposals submitted to the VA Research and Development Committee for review must contain a Conflict of Interest Statement. Conflicts of interest involving key personnel, spouses and dependent children must be reported.

b. Research Conflict of Interest Administrator: The ACOS for Research and Development will serve as the Research Conflict of Interest Administrator responsible for reviewing financial disclosure statements submitted by investigators. These disclosure statements will be reviewed prior to the review of the protocol by the R&D Committee. The conflict of Interest Administrator will:

- (1) Determine whether there is an actual or potential conflict of interest that could impact on an investigator's proposed or current research.
- (2) Present any conflict of interest determinations and measures to mediate or remove the conflict to the R&D Committee at the meeting at which the proposal is being reviewed and to the R&D subcommittees, i.e., IRB, IACUC.
- (3) Provide written communication to the investigator when a conflict of interest is identified.
- (4) If the investigator appeals the required measures, the COI Administrator will convene and chair a COI committee composed of the Chair, AO/R&D (nonvoting), two researchers from the R&D Committee, and the Corporate Compliance Officer. The committee will review the information, including any additional input from the investigator and make a determination as to the conflict resolution.
- (5) Provide copy of COI determination to the IRB Office.

c. Mediating Measures. Potential mediating measures to reduce or eliminate the conflict of interest may include, but are not limited to, the following:

- (1) Public disclosure of significant financial interests; disclosure in publications/presentations
- (2) Monitoring of research by independent reviewers
- (3) Modification of the research plan and/or the informed consent documents
- (4) Disqualification from participation in all or portion(s) of the research
- (5) Divestiture of significant financial interest or
- (6) Severance of relationships that create actual or potential conflicts

d. R&D Committee. The R&D Committee will review the disclosure and the measures to be taken to mediate any conflict as part of its protocol review. The committee may grant approval contingent upon a conflict resolution endorsed by the committee.

e. After project approval. If conflicts of interests are identified after a research protocol has been approved, the COI Administrator will review the revised disclosure and present to the R&D Committee and its subcommittees, e.g., IRB, any corrective measures to be taken to decrease the impact.

f. Noncompliance. If an investigator fails to comply with the COI policy or the required mediating actions, the failure to comply will be reported to the medical center director. Measures may include, but are not limited to, other conditions or restrictions, termination of protocol, removal of investigator from protocol, and revocation of privilege to conduct research.

g. Committee Members. The member with a conflict of interest will verbally disclose the conflict of interest and will excuse himself from any discussion and voting on such research except when asked to be present to answer questions directed by the committee. Member's departure and return will be noted in the minutes of the committee meeting.

### 4. RESPONSIBILITIES:

a. The Associate Chief of Staff for Research and Development has been delegated the responsibility for the system's Research and Development Program by the STVHCS Director. As a function of these activities, the ACOS for R&D is responsible for developing, implementing and maintaining a process for identifying and managing conflicts of interest within the STVHCS research program. The Office of the IRB will be requested to notify the Office of R&D of any conflict of interest identified by the IRB.

b. The STVHCS Research and Development committee is responsible for insuring investigator conflict of interest is considered during proposal reviews and for member adherence to conflict of interest policy during proposal reviews.

c. Principal Investigators are responsible for insuring all key study personnel comply with conflict of interest policies.

5. REVIEW DATE: October 2007

A handwritten signature in black ink, appearing to read "Peter Melby", with a long horizontal flourish extending to the right.

PETER MELBY, M.D.

ACOS for Research and Development

Attachment: Disclosure Statement

# CONFLICT OF INTEREST DISCLOSURE STATEMENT

(Must be included with all research proposals)

**STUDY TITLE:**

**NAME:**

**ROLE:**        \_\_Principal Investigator    \_\_ Co-investigator        \_\_ Collaborator or key personnel

1. Except as noted below, I have no financial or employment relationships, to include salary or other payments for services (e.g., consulting fees or honoraria), equity interests (e.g., stocks, stock options or other ownership interests), appointed position in the sponsoring agency (e.g., Directors, consultants, or advisory group), and intellectual property rights (e.g., patents, copyrights, and royalties from such rights) with any organization or whose services or products would be affected by the outcome of the study.

(State "None" or identify any exceptions)

2. Except as noted below, neither my spouse, dependents, or any organization with which I am connected have any of the above relationships.

(State "None or identify any exceptions)

3. I am aware of my responsibilities for the maintenance of confidentiality of non-public information and for the avoidance of using any such information for my personal benefit or for the benefit of my associates or of an organization which I am connected with or with which I have a financial involvement.

I certify that, to the best of my knowledge and belief, all of the information on this disclosure is true, correct, complete and made in good faith. If financial interests change from the above during the course of the study, I will notify the R&D Committee promptly.

\_\_\_\_\_  
(Signature of investigator)

\_\_\_\_\_  
(date)

## Certification of Review by Conflict of Interest Administrator

This Conflict of Interest Statement and applicable protocol have been reviewed for compliance with applicable policies and regulations, and for a determination of the existence of a financial conflict of interest.

A financial conflict of interest ( ) has ( ) has not been identified for this investigator on this research protocol. If a conflict of interest has been identified, the following actions are recommended: (see attached)

\_\_\_\_\_  
Signature of Conflict of Interest Administrator

\_\_\_\_\_  
(date)