

RESEARCH SERVICE

February 13, 2008

RESEARCH STANDARD OPERATING PROCEDURES

Managing Financial Conflict of Interest in Research

1. PURPOSE: To outline the procedures for dealing with real, perceived, or potential Financial Conflict of Interest (FCOI) involving investigators or their staff who conduct VA research.

2. POLICY:

- a. An investigator may have a potential, perceived, or real FCOI in the conduct of research when the research is sponsored by an organization, agency, or company, with which the investigator has 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).
- b. A FCOI also 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.
- c. All research proposals submitted to the VA Research and Development Committee for review must contain a FCOI Disclosure Statement for all personnel involved in the research. FCOI involving spouses and dependent children of research personnel must also be reported.

3. ACTION

- a. Medical Center Director: The Medical Center Director will appoint a FCOI Administrator. In situations in which a FCOI cannot be resolved, it is the medical center Director who makes the final binding decision regarding the FCOI and its management.
- b. Principal Investigator: For all sponsored research, the Principal Investigator is responsible for the disclosure of any financial or other interest that he/she and/or key participants on the study, spouses, and dependents may have with the sponsor.
 - (1) The required FCOI disclosure to the STVHCS is accomplished through submission of a *Research Financial Conflict of Interest Statement* (attached) to the R&D Office, which is then forwarded to the FCOI Administrator.
 - (2) The Principal Investigator must inform the FCOI Administrator of any changes to the original disclosure, through submission of a revised *Research Financial Conflict of Interest Statement* to the R&D Office.
 - (3) The Principal Investigator is responsible for insuring all key study personnel comply with conflict of interest policies, and comply with the requirements of the R&D Committee for eliminating, minimizing, or managing FCOI.
 - (4) The Principal Investigator is also responsible to inform the IRB of any FCOI if the research involves human subjects.

Note: The VA Research Financial Conflict of Interest Statement refers to the evaluation of the Disclosure Statement by a FCOI Committee, however, guidance from VA Central Office in the form of a new FCOI Policy is forthcoming. As of April 2008, and until the new policy is provided by VA Central Office, the STVHCS will utilize a FCOI Administrator for the review of disclosures as described in this document. When the new policy is released, the STVHCS will transition to the use of a FCOI Committee, appointed by the Medical Center Director, for the review of FCOI disclosures.

- c. The FCOI Administrator is responsible for reviewing the *Research Financial Conflict of Interest Statement* for any perceived conflicts that could adversely affect the design, conduct, or reporting of a research project conducted under the auspices of the STVHCS. These disclosure statements will be reviewed and recommendations will be provided prior to or concurrent with the review of the protocol by the R&D Committee. The FCOI Administrator will:
 - (1) Evaluate whether there is an actual or potential conflict of interest that could impact on an investigator's proposed or current research. The FCOI Administrator will obtain input from the VA Regional Counsel concerning the evaluation and management of a disclosed FCOI.

POLICY MEMORANDUM 08-22

- (2) Determine what conditions or restrictions, if any, need to be imposed to manage, reduce, or eliminate the FCOI.
- (3) Report findings and recommendations for the management of the FCOI to the R&D Committee prior to the approval of the research protocol. The potential mediating measures recommended to the R&D Committee to reduce or eliminate the conflict of interest may include, but are not limited to, the following:
 - (a) Disclosure of the FCOI to research subjects in the Informed Consent document
 - (b) Disclosure of the FCOI in publications/presentations related to the research
 - (b) Monitoring of the research by independent reviewers
 - (c) Modification of the research plan
 - (d) Disqualification from participation in all or portion(s) of the research
 - (e) Divestiture of significant financial interest in the sponsor
 - (f) Severance of relationships that create actual or potential conflicts
- d. The R&D Committee may not approve a submitted protocol until the FCOI has been reduced and/or managed to the committee's satisfaction. The R&D Committee is responsible for the following:
 - (1) Developing, implementing and maintaining a process for identifying and managing conflicts of interest within the STVHCS research program.
 - (2) Ensuring that FCOI of an investigator or research personnel is considered during proposal reviews.
 - (3) Reviewing the findings and recommendations of the FCOI Administrator and the decisions and management plan from the IRB, and determining what actions, which may be in addition to those recommended by the FCOI Administrator and the IRB, that the institution or the investigator must take to manage, reduce, or eliminate the FCOI. The R&D Committee will review the information provided, including the nature of the research, the unique experience or qualifications required to conduct the research, the number of other investigators that may possess these qualifications, and the nature and magnitude of the FCOI. The Committee will also assess the magnitude of the risk to the human research subject posed by the FCOI and make a determination as to the resolution or management of the FCOI. The R&D Committee may not disallow any of the IRB's stipulations or required changes, but may add to them. In such cases, the R&D Committee will inform the IRB (and PI) in writing of its additional stipulations or required changes.
 - (4) Reviewing the effectiveness of the FCOI disclosure and management process, to include any compliance reports related to protocol audits.

POLICY MEMORANDUM 08-22

- e. Changes in FCOI Disclosure: If a FCOI is identified after a research protocol has been approved, the FCOI Administrator will review the revised *Research Financial Conflict of Interest Statement* and present to the R&D Committee and its subcommittees, e.g., IRB, any recommendations of corrective measures to be taken to decrease or manage the FCOI.
- f. Appeals: The investigator may appeal the decision of the R&D Committee in writing. The R&D Committee, in collaboration with the FCOI Administrator will re-address the FCOI Disclosure, including any additional information provided by the investigator, and management plan, and will seek input from VA Regional Counsel. In situations in which a financial conflict of interest cannot be resolved, it is the Medical Center Director who makes the final binding decision regarding the financial conflict of interest and its management.
- g. 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 the protocol, removal of the investigator from the protocol, and revocation of privileges to conduct research at the STVHCS.

4. RESPONSIBILITY: ACOS for Research and Development (151)

5. RECESSIO: Research Service Memorandum 04-22, dated Oct 12, 2004

6. RECERTIFICATION: February 2011

//signed//

PETER MELBY, M.D.

ACOS for Research and Development

Attachment (1)



Department of Veterans Affairs

RESEARCH FINANCIAL CONFLICT OF INTEREST STATEMENT

This completed form may only be reviewed by personnel on an "as needed" basis when required by the responsibilities of their position.

This form must be completed and submitted by each principal investigator, co-principal investigator, investigator and collaborator. The information will be used to determine if there is a perceived or real financial conflict of interest or if there is the potential for such financial conflicts of interest. The form will only be reviewed by persons on a need-to-know basis. The completed and signed document must be submitted to the financial conflict of interest (FCOI) committee.

Note: if any questions below are answered in the affirmative, the conflicts must be managed with the assistance of the VA Regional Counsel or, in Central Office, the Office of the General Counsel. Further, even if no question is answered in the affirmative, your financial holdings or arrangements may still pose a conflict of interest within the meaning of Chapter 11 of Title 18, United States Code, and the Executive Branch Standards of Conduct at 5 C.F.R. Part 2635. Compliance with the provisions in this handbook will not necessarily satisfy the requirements of these criminal and regulatory conflict of interest provisions. If you have questions regarding these requirements, you can contact your local Regional Counsel for assistance. If you are located in Central Office, you can contact the Assistant General Counsel for Professional Staff Group III (023).

LAST NAME- FIRST NAME- MIDDLE INTIAL

SECTION I

INSTRUCTIONS: If any of the following questions are answered in the affirmative you will be expected to provide such information as required to determine whether the financial holdings or business interests in question are sufficiently small that the potential conflict of interest should not preclude funding of or conducting VA research.

1. INCOME AND COMPENSATION. Do you or your spouse or dependent child receive income or other compensation for services (to include consulting fees, honoraria, gifts, and/or in kind compensation) from a single entity (or a group of affiliated entities) that when aggregated for you, your spouse and dependent child has in the prior year exceeded \$10,000 and/or is expected to exceed \$10,000 in the next 12 months? *NOTE:* An entity is any for profit organization, institution, corporation, partnership, or other entity (other than a Federal agency or university affiliate) that does or seeks to do business in an area related to your present research or research you are currently planning.

 YES NO

2. PATENTS. Do you or your spouse, or dependent child, or an organization (other than a Federal agency) in which you are an officer, director, trustee, general partner or employee own any patents or provisional patents that are related to your present research or research you are currently planning or to any of your other research duties?

 YES NO

3. COPYRIGHTS. Do you or your spouse, or dependent child, or an organization (other than a Federal agency) in which you are an officer, director, trustee, general partner or employee hold any copyrights that are related to your current research or research you are currently planning?

 YES NO

4. ROYALTIES. Do you or your spouse, or dependent child, or any organization in which you are an officer, director, trustee, general partner or employee receive any royalty payments or non-monetary considerations from a business or organization that does business in an area related to your current research or research you are currently planning?

 YES NO

5. BUSINESS CONCERNS. Do you or your spouse, or dependent child, or an organization in which you are an officer, director, trustee, general partner or employee have any business or financial relationship with any person or organization for which the results of your current research or research you are currently planning may be reasonably expected to affect the development or marketing of that person's or organization's product or service?	<input type="checkbox"/> YES
	<input type="checkbox"/> NO
6. NON-PUBLICLY TRADED COMPANIES. Do you or your spouse, dependent child, or any organization in which you are an officer, director, trustee or general partner own or have any equity interests by way of stock ownership or stock options in a non-publicly traded company that does business in an area that is related to your present research or research you are currently planning?	<input type="checkbox"/> YES
	<input type="checkbox"/> NO
7. PUBLICLY TRADED COMPANIES. Do you or your spouse, dependent child, or any organization in which you are an officer, director, trustee or general partner own or have an equity interest valued at more than \$15,000 (stock ownership or stock options, etc.) in a publicly traded company that does business in an area that is related to your present research or research you are currently planning? <i>NOTE: This does not include stock that is controlled through a widely diversified mutual fund or a blind trust.</i>	<input type="checkbox"/> YES
	<input type="checkbox"/> NO

IF YOU ANSWERED YES IN SECTION 1, PROCEED TO PAGE 3; IF NO, SIGN BELOW AND SUBMIT PAGES 1-2.

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. I understand that false or fraudulent information on this disclosure may be grounds for not accepting the research proposal and may be punishable by fine or imprisonment (U.S. Code, Title 18, section 1001).

Signature of Investigator	Date
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SECTION II: SUPPLEMENTAL INFORMATION

1. INCOME & COMPENSATION. If you answered yes in Section I, explain source, and reason for compensation:
(NOTE: the FCOI committee may request information on the values or amounts.)

2. PATENTS. If you answered yes in Section 1 provide additional information below. For additional patents provide same information on a separate sheet and attach.

2A. PATENT NUMBER:

2B. IS THIS A PROVISIONAL PATENT?

YES

NO

2C. DATE OF PATENT:

2D. PERIOD COVERED:

2E. TITLE OF PATENT:

2F. PROJECTED ROYALTIES BY YEAR:

2G. HAVE ANY ACTIVE OR PENDING LICENSE AGREEMENTS BEEN ISSUED? (If yes, attach a copy of each license.)

YES

NO

SECTION II: SUPPLEMENTAL INFORMATION Continued

3. COPYRIGHTS. If you answered yes in Section 1, provide additional information below.

4. ROYALTIES. If you answered yes in Section 1, provide additional information below.

4A. SOURCE:

4B. AMOUNT:

5. BUSINESS CONCERNS. If you answered yes in Section I, provide additional information below including specific information on the business and on the development or marketing of the product or service.

6. NON-PUBLICLY TRADED COMPANIES. If you answered yes in Section I, provide additional information below.

YES

VALUE OF STOCK/STOCK OPTIONS: Does this value represent more than a 5% ownership of the company?

NO

7. PUBLICLY TRADED COMPANIES. If you answered yes in Section I, provide additional information below.

YES

VALUE OF STOCK/STOCK OPTIONS: Does This Value Represent More Than A 5% Ownership Of The Company?

NO

PRIVACY ACT STATEMENT

Title I of the Ethics in Government Act of 1978 (5 U.S.C. App.), Executive Order 12674, and 5 CFR 2634, Subpart I, of the Office of Government Ethics regulations require the reporting of this information. The primary use of the information on this form is for review by the VHA Conflict of Interest Committee to determine compliance with applicable Federal conflict of interest laws and regulations and the impact of any real or perceived financial conflicts of interest on VA research. Additional disclosures of the information in this report may be made:

- (1) to other VA research review committees and VA officials responsible for the approval or funding of research protocols;
- (2) if there is an indication of a violation or potential violation of law, whether civil, criminal or regulatory in nature and whether arising by general statute or particular program statute, or by regulation, rule or order issued pursuant thereto, to the appropriate Federal, State or local agency charged with the responsibility of investigating or prosecuting such violation or charged with enforcing or implementing the statute or rule, regulation or order issued pursuant thereto;
- (3) to qualified reviewers for their opinion and evaluation of a proposal as part of the application review process when a proposal is submitted for funding;
- (4) to the National Archives and Records Administration of the General Services Administration in records management inspections; and
- (5) to the Department of Justice (DOJ) upon official request in order for VA to respond to pleadings, interrogatories, orders or inquires from DOJ and to supply to DOJ the information to enable DOJ to represent the U.S. Government in any phase of litigation or in any case or controversy involving VA.

Failure to file or report information or the falsification of required information may subject you to disciplinary action by the VA or other appropriate authority. This may include limitation on or revocation of the privilege to conduct VA-approved research. It may also be subject to criminal prosecution.