DEPARTMENT OF VETERANS AFFAIRS
South Texas Veterans Health Care System
San Antonio, Texas 78229

Research Service Policy Memorandum 11-22

April 20, 2011

RESEARCH STANDARD OPERATING PROCEDURES (SOP)
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, 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 financial or other interest that he/she and/or key participants on the study, spouses, and dependents may have with the sponsor, as described in the *Research Financial Conflict of Interest Statement* (attached).

      (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. This means disclosing to the IRB any potential, actual, or perceived conflict of interest of a financial, professional, or personal nature that may affect any aspect of the research, and complying with all applicable VA and other federal requirements regarding conflict of interest.

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. **FCOI Administrator**: 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 as needed.

(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

(c) Monitoring of the research by independent reviewers

(d) Modification of the research plan

(e) Disqualification from participation in all or portion(s) of the research

(f) Divestiture of significant financial interest in the sponsor

(g) Severance of relationships that create actual or potential conflicts

d. **R&D Committee:** 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.

(4) In all cases the IRB has the final authority in determining the FCOI management plan for protocol approval by the IRB. The R&D Committee may not disallow any of the IRB's requirements, however may require additional stipulations that must be met for R&D Committee approval to conduct the study at the STVHCS. Because the IRB requires disclosure of an ownership interest or compensation of any value, there may be instances where a FCOI is disclosed to the IRB that does not meet the threshold for reporting to the VA. In these instances, the R&D committee will accept the management plan determined by the IRB.

(5) Reviewing the effectiveness of the FCOI disclosure and management process, to include any compliance reports related to protocol audits.

e. **R&D Office:**

(1) The R&D office will receive and route the FCOI Disclosure form from the Investigator or research personnel to the research office personnel coordinator.

(2) The R&D office personnel coordinator will forward the FCOI Disclosure form to the FCOI Administrator.

(3) The FCOI Administrator will review the disclosure form, and if no disclosure is identified, the form will be signed and routed back to the personnel coordinator for update of the personnel database and filing.

(4) If a disclosure is identified, the FCOI Administrator will develop a management plan as described above and upon concurrence from the Regional Council will route it to the R&D Committee through the R&D Committee coordinator.

(5) Once approved by the R&D Committee, the disclosure form with management plan will be scanned and routed by the R&D Committee coordinator to the PI, R&D office personnel coordinator for updating in the personnel database and folder, and to the appropriate R&D office staff for filing with an approved protocol, if applicable.

(6) The R&D office staff will communicate any protocol specific FCOI disclosure and management plans to the PI and IRB (human subjects protocols) in the approval letter or amendment/ progress report acknowledgment and will document that communication in the protocol folder.

(7) If a protocol specific FCOI disclosure is identified on a project personnel form, the disclosure and management plan will be verified in the personnel database, and the PI will be notified by the appropriate R&D office staff of the management plan as it pertains to the specific protocol and filed in the protocol folder. If the disclosure and management plan is not verified in the personnel database a new FCOI disclosure form will be requested.

f. **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.

g. **Appeals**: The investigator may appeal the decision of the R&D Committee in writing. The R&D Committee, in collaboration with the FCOI Administrator and IRB 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 where the R&D Committee management plan is disputed and cannot be resolved, it is the Medical Center Director who makes the final binding decision regarding the financial conflict of interest and its management at the STVHCS.

h. **Noncompliance**: If an investigator fails to comply with the research FCOI policy or the required mediating actions, the failure to comply will be reported as detailed in the Research Service SOP 08-49.

4. **REFERENCES:** None

5. **RESPONSIBILITY:** ACOS for Research and Development (151)

6. **RECESSIONS:** Research Service Memorandum 10-22, dated November 11, 2010

7. **RECESSION:** April 2016

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Attachment (1)