HEALTH CARE SYSTEM MEMORANDUM NO. 151-09-04

SUBJ:  CONFLICT OF INTEREST IN THE CONDUCT OF RESEARCH

1. **SUMMARY:** This Health Care System Memorandum (HCSM) replaces HCSM No. 151-07-05. Major changes have been made.

2. **PURPOSE:** To define the policy regarding objectivity in VA research and to define procedures for identifying and managing financial conflicts of interest (COI). Final approval by the Research and Development (R&D) Committee is contingent upon COI review and approval by the RCO or, when necessary, the COI Committee.

3. **POLICY:** Scientific objectivity in the conduct of research under VA auspices must be maintained. Principal Investigators (PIs) must disclose any financial interests that could potentially affect the conduct of the research project or reporting of the project’s results. Procedures for the identification, management and elimination of financial conflicts of interest are defined in this policy.

4. **DEFINITIONS:**

   a. **Conflict of Interest:** For purposes of research, 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. Situations resulting in a conflict of interest include, but are not limited to:

      (1) When an individual or organization may receive or derive a significant financial benefit from the performance of, outcome of or reporting of a research activity, or

      (2) When an individual or organization has any significant financial interest in the sponsoring party, or is the owner of rights to one of the materials being researched.

   b. **Significant Financial Interest or Benefit:** A significant financial interest or benefit is anything of monetary value including but 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); and intellectual property rights (e.g., patents, copyrights, and royalties from such rights). Unless the value of the financial interest or benefit might be affected by the conduct or outcome of the research, the term does not include:

      (1) Salary, royalties or other remuneration from the VAPAHCS or PAIRE;
(2) An equity interest that, when aggregated for the investigator and the investigator’s spouse and dependent children, does not exceed $10,000 in value as determined through reference to public prices or other reasonable measures of fair market value and does not represent more than a five percent ownership interest in any single entity.

(3) Salary, royalties, or other payments from any one entity (or a group of affiliated entities) that when aggregated for the investigator, spouse and dependents over twelve (12) months are not expected to exceed $10,000.

5. **PROCEDURES:**

   a. Prior to receiving initial and/or annual R&D Committee approval, all projects must receive COI review and approval on the research website by the Research Compliance Officer (RCO) and/or an ad hoc R&D Conflict of Interest Subcommittee. In order to request such approval, Principal Investigators (PIs) must complete and submit the “Research Financial Conflict of Interest Statement” (“COI Statement”) on the research website as part of the electronic application for R&D Committee review. The COI Statement must be completed for each project submitted for initial R&D approval and annual R&D renewal. To protect the PIs’ confidentiality, the electronic COI Statement will only be accessible to the Research Compliance Officer (RCO). Information contained in the COI Statement will only be shared with other individuals when necessary to evaluate and/or manage an identified conflict of interest.

   b. The RCO will provide a preliminary review of each COI Statement submitted on the research website. The RCO’s preliminary review will determine whether any of the financial interests disclosed in the COI Statement qualify as a conflict of interest.

   c. If the RCO identifies a conflict of interest, the following actions will be taken:

      (1) The RCO will conduct an initial inquiry that may include, but not be limited to, discussions with the PI, a review of relevant documentation, and a consultation to the VA Regional Counsel’s Office.

      (2) If the conflict of interest is identified for a human subjects research project, the RCO’s initial inquiry will include a review of the PI’s IRB protocol to determine whether the same conflict was disclosed in the PI’s IRB submission. If necessary, the RCO will contact Stanford IRB representatives in order to make this determination.

          a. If the same conflict was not disclosed to the IRB, the RCO may share information relevant to the conflict with Stanford’s COI Administrator or IRB representatives.

          b. If the same conflict was disclosed to the IRB, the RCO will gain information regarding any recommendations made by the IRB or Stanford’s COI Administrator for management or elimination of the conflict.
(3) The RCO will then refer the matter to the R&D Committee Chair. The RCO’s referral will include a summary of the identified conflict of interest, any supporting documentation, and recommendations for management of the conflict from the RCO and/or the Regional Counsel. When applicable, the referral will also include a description of any actions taken by the IRB or Stanford COI Administrator to manage the conflict of interest.

d. Once the RCO has referred the conflict of interest, the R&D Committee Chair may choose to accept the recommendations of the RCO and Regional Counsel and forward these recommendations in a written memorandum to the PI. The PI will be invited to write a response memorandum to the R&D Chair detailing how he or she plans to comply with the recommendations. While the PI works to comply with its recommendations, the R&D Chair may recommend that the R&D Committee approve the project contingent on the PI’s compliance with the recommendations.

e. For conflicts that require further scrutiny, the R&D Committee Chair may choose to convene an ad hoc R&D Conflict of Interest Subcommittee (“COI Committee”) to review the matter. The R&D Committee Chair will serve as Chair and voting member of the COI Committee and will appoint at least two other members of the R&D Committee to serve as voting members on the COI Committee. Whenever possible, the ACOS for Research and Development will be appointed as one of the voting members. Non-voting members will include the RCO and the Human Protections Administrator, a Regional Counsel representative and, if appropriate, the Executive Director of PAIRE. All documents, deliberations and recommendations of the COI committee will be kept strictly confidential.

f. In reviewing the referred conflict of interest issue, the COI Committee will determine how the identified conflict can be managed or eliminated so that the research project may receive R&D approval. For human subjects research projects, the COI Committee will consider any actions taken by the Stanford COI Administrator and/or IRB to manage the conflict. However, the COI Committee may choose to require additional actions by the PI before recommending approval to the R&D Committee.

g. Examples of conditions that might be recommended for elimination or management of the conflict of interest include, but are not limited to:

(1) Modification of the research plan;
(2) Disclosure of financial interests to potential subjects when securing informed consent;
(3) Disclosure of financial interests in publications or presentations;
(4) Reduction or elimination of financial interests or relationships;
(5) Disqualification from participation in the research project;
(6) Limiting participation in the research project (e.g., subject contact, data analysis); and/or
(7) Monitoring of research by independent reviewers.

h. If the Committee determines that the conflict of interest may affect the safety of research subjects or staff, management of the conflict should not be limited to disclosure.
i. The COI Committee’s recommendations for management of the conflict will be communicated to the PI in a written memorandum. The PI will be invited to write a response memorandum to the COI Committee detailing how he or she plans to comply with the recommendations. While the PI works to comply with its recommendations, the COI Committee may choose to table the project or recommend that the R&D Committee approve the project contingent on the PI's compliance with the recommendations.

j. Once the PI has complied with the recommendations for management of the conflict of interest, the RCO will record the recommendation for R&D approval on the research website.

k. If any new conflicts of interest arise after R&D approval has been granted for a research project, the PI must disclose these to the RCO and amend the COI Statement on the research website. Review of these additional disclosures will be conducted in the same way as the original COI review.

l. For a sponsored award administered by PAIRE, at the time of application, the PI will complete the PAIRE document entitled "Principal Investigator Certifications and Assurances." If any conflict of interest is disclosed, PAIRE will simultaneously email the completed form and description of the conflict to the RCO for review and to the appropriate Stanford Conflict of Interest Office if a faculty member is involved. Prior to acceptance of any award, PAIRE will assure that any COI issues have been managed or mitigated through the procedures described elsewhere in this policy and that such is documented on the R&D website and communicated to the sponsor.

6. RESPONSIBILITIES:

a. The Principal Investigator who submits a project for R&D approval is responsible for the following:

   (1) Completing the “Research Financial Conflict of Interest Statement” on the research website for each project submitted for R&D Committee initial review and approval, and each project submitted for R&D Committee annual review and renewal.

   (2) When a conflict of interest is identified, responding to the recommendations put forth by the COI Committee.

   (3) Notifying the RCO and updating the COI Statement on the research website when a new potential conflict of interest arises after R&D approval and/or renewal has been granted.

b. Research Compliance Officer is responsible for the following:

   (1) Performing a preliminary review of each completed “Research Financial Conflict of Interest Statement” submitted on the research website.
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(2) Determining whether any of the financial interests disclosed in the COI Statement qualify as a conflict of interest.

(3) Providing recommendations from the Research Compliance Office and the Regional Counsel for the management of any conflict of interest. These recommendations will be provided to the R&D Chair for consideration by the COI Committee.

(4) Managing the COI review process of the COI Committee.

(5) Corresponding with Stanford’s COI Administrator and IRB representatives for COI issues involving human subjects research projects.

(6) Maintaining the confidentiality of all records and official files during the COI review process.

(7) Assuring that notifications and website documentation related to the COI review are maintained.

c. R&D Committee Chair is responsible for the following:

(1) Assembling an R&D ad hoc COI Committee after receiving a COI referral from the Research Compliance Officer.

(2) Serving as Chair of the ad hoc COI Committee.

(3) Appointing at least two R&D Committee members to serve on the COI Committee on a rotating basis. Whenever possible, the ACOS for Research and Development will be appointed as one of the voting members. Non-voting members will include the RCO and the Human Protections Administrator, a Regional Counsel representative and, if appropriate, the Executive Director of PAIRE.

d. The COI Committee is responsible for meeting when a conflict of interest has been referred to the R&D Chair. During such meetings, the COI Committee is responsible for the following:

(1) Reviewing conflicts of interest referred by the Research Compliance Officer.

(2) Issuing recommendations for management or elimination of the referred conflicts of interest.

(3) Submitting its recommendation for tabling, contingent approval or approval of a research project on the research website.

(4) Ensuring that the proceedings and findings of the meetings are to be kept in the strictest of confidence by the membership, both during the time they serve as
active members of the COI Committee and thereafter. Members must declare any potential conflict they may have with any item discussed during the meeting.

e. The R&D Committee is responsible for oversight of the COI Committee and providing final approval to VA research projects.

7. REFERENCES:


b. AAHRPP Accreditation Element 1.3.G and III.1.A.


8. RESCISSION DATE: February 29, 2012

9. RESPONSIBLE OFFICIAL: Research Compliance Officer

Elizabeth Joyce Freeman
Director