HEALTH CARE SYSTEM MEMORANDUM NO. 151-05-03

SUBJ: CONFLICT OF INTEREST IN THE CONDUCT OF RESEARCH

1. **SUMMARY:** This Health Care System Memorandum (HCSM) replaces HCSM 151-02-03. Minor changes have been made.

2. **PURPOSE:** To define the policy regarding objectivity in VA research and to define procedures for identifying potential conflict of interest and addressing such instances.

3. **POLICY:** Scientific objectivity in the conduct of research under VA auspices must be maintained. Procedures to identify potential conflicts of interest are defined in this policy. If such are identified, there are procedures for managing, mitigating or eliminating them.

4. **SCOPE:** This policy is applicable to all VA research, regardless of administering entity. Actions will be coordinated with PAIRE and Stanford as appropriate.

5. **DEFINITIONS:**

   a. **Conflict of Interest** – For purposes of research objectivity, a conflict of interest exists when an individual may enjoy financial or non-financial benefit from the performance of, outcome of or reporting of a research activity. The appearance of such a conflict from the point of view of a disinterested party represents a potential conflict of interest.

   b. **Financial Interest** – This is defined as anything of monetary value including, but not limited to, salary; payments for services, e.g., consulting fees or honoraria; equity interests, e.g., stocks, stock options or other ownership interests; intellectual property rights, e.g., patents, copyrights and royalties from such rights; and service as an officer, director or other fiduciary role for a financially interested company.

   c. **Non-Financial Interest** - This is defined as interests personal to the investigators that may lead to a real or potential conflict of interest with proposed research. This may include service on boards or committees (e.g., scientific advisory boards), concurrent obligations, etc.

   d. **Financial Disclosure** – This is a complete listing of all financial and employment relationships between a Principal Investigator, his/her spouse or domestic partner, and
his/her dependent children or involved institutional employee, his/her spouse or domestic partner, and his/her dependent children and (1) the sponsor of a project OR (2) a profit or not for profit entity with a potential financial interest in the outcome or conduct of the research.

   e. VA Research – VA research is defined as all research and all other activities which even in part involve such research, regardless of whether the research is otherwise subject to VA regulation, if:

      (1) the research is sponsored by the VA, or

      (2) the research is conducted by or under the direction of any employee or agent of VAPAHCS (full-time, part-time, intermittent, consultant, without compensation (WOC), on-station fee-basis, on-station contract, or on-station sharing agreement basis) in connection with her/his VAPAHCS responsibilities, or

      (3) the research is conducted using any property or facility of VAPAHCS, or

      (4) the research recruits subjects at the VA, or

      (5) the research involves the use of the VA’s nonpublic information to identify or contact human research subjects or prospective subjects or to use such data for research purposes.

6. **RESPONSIBILITIES:**

   a. Principal Investigator – Is responsible for assuring that any potential conflict of interest, either for self or anyone on a project with responsibility for design, conduct or reporting of research, is disclosed in the electronic research project application process and that any subsequent financial conflict arising after initial application is also reported.

   b. Research Compliance Officer – Is responsible for managing the review process, including initial review of all Ad Hoc Disclosure Form for determination of referral to the Research and Development Committee; serving as staff for the review process; maintaining all records and official files for the conflict of interest process.

   c. Research and Development Committee – Is responsible, in addition to other duties, for reviewing, recommending resolutions and monitoring oversight of possible financial conflicts of interest; is responsible for annual program review and monitoring.

   d. ACOS for Research and Development – Is responsible for oversight of the entire program including serving as the Institutional Official; is the liaison for coordination with Stanford University for all disclosures involving Stanford faculty.

   e. Chief of Staff – Is responsible for acting on Research and Development Committee recommendations regarding conflict of interest, and for considering appeals and determining appropriate referral of such appeals.
7. **PROCEDURES:**

   a. In accordance with VA Central Office (VACO) requirements, all VA research must be approved by the Research and Development Committee before work may begin.

   All projects must have on file a completed electronic application package, including the certification as to whether there is any financial conflict of interest issue for individuals who have responsibility for the design, conduct or reporting of the research.

   (1) If the response to the electronic query is that there is no financial conflict of interest, the PI is certifying, “I am familiar with the requirements for objectivity in research defined in Health Care System Memorandum 151-05-03, Conflict of Interest in the Conduct of Research. To the best of my knowledge neither I nor any person responsible for the design, conduct or reporting of the activities in this proposal, or spouse, domestic partner or dependent children of such persons, individually or collectively, have significant financial interests that would reasonably appear to be affected by the activities proposed or in entities whose financial interests might be so affected.” No further action for this issue is required.

   (2) If the Principal Investigator responds affirmatively to the query, s/he is certifying “I am familiar with the requirements for objectivity in research defined in the VAPAHCS policy and have disclosed the potential financial conflict of interest for this project to the Research Compliance Officer.” In that case, s/he must submit the forms and documentation in accordance with the Ad Hoc Disclosure Template found at http://www.stanford.edu/dept/DoR/ad_hoc.html for each party who may have a conflict. The form and any accompanying documentation should be delivered to the Research Compliance Officer.

   b. The Research Compliance Officer will review the material and determine whether the proposed project could reasonably appear to be directly and significantly affected by the related financial interest of the investigator(s). A direct impact occurs when:

      (1) the project results would be directly relevant to the development, manufacturing or improvement of the products or services of an organization in which the investigator or research participant has a financial interest;

      (2) the organization in which the investigator or research participant has a financial interest is a proposed subcontractor or participant in the project;

      (3) there is a relationship between the project sponsor and the investigator or research participant outside the project that has the potential to affect performance in the project.

   c. If the Research Compliance Officer determines the conflict will not affect scientific objectivity, a copy of the review determination will be placed in the Research Administration project file. The original determination as well as all accompanying material will be maintained in a confidential manner.
d. If the Research Compliance Officer determines there is a potential financial conflict of interest the issue will be coordinated with review by the IRB and/or other Stanford entities. Any VA specific issues not addressed in Stanford practices, e.g., non-faculty investigators, will be referred to the Research and Development Committee for discussion and determination of appropriate action.

e. Minutes will be recorded and documentation used in deliberations will be maintained; this information will be strictly confidential and will be kept in a secure file maintained by the Research Compliance Officer.

   (1) If the committee determines there is no reasonable basis on which to conclude that a project could directly and significantly affect the interest and/or the interest is not likely to affect the design, conduct or reporting of the project, the Principal Investigator and Research Administration shall be informed in writing that the project has been cleared for conflict of interest. A copy of the notification will be placed in the Research Administration project file.

   (2) If the committee determines that the project could directly and significantly affect the financial interest and/or the financial interest could affect the design, conduct or reporting of the project, the disclosure and associated documentation along with the committee's recommendation for managing the potential conflict shall be forwarded to the Chief of Staff. In consultation with the ACOS for R&D, the Executive Director of PAIRE (if funds are to be administered by PAIRE) and a representative from Regional Counsel, a decision shall be made as to whether the project should proceed and under what conditions or restrictions that might occur. The Principal Investigator and Research Administration shall be informed in writing of the decision, including the conditions and/or restrictions on the project. A copy of the notification will be placed in the Research Administration project file. The IRB will be informed in writing of all committee reviews and determinations.

f. Possible remedies for managing or mitigating a conflict include:

   (1) Investigator severs relationships creating the conflict;

   (2) Investigator divests significant financial interests;

   (3) Investigator discloses relationship with sponsor on all publications, in the consent form provided to human subjects, and in other appropriate public fora;

   (4) Investigator separates research from consulting, providing an acceptable detailed written plan for achieving this;

   5) Investigator substitutes someone else to serve as project PI and is appropriately distanced from the conduct of the research.

g. Failure to comply with this policy or with any related restrictions or conditions imposed for the conduct of research will result in sanctions up to and including dismissal.
Relevant regulatory bodies or sponsors will be notified in accordance with contractual or regulatory requirements.

h. Appeals of the committee decisions may be made in writing to the Chief of Staff who will determine whether the matter should be referred to Stanford or to VA counsel for consideration.

i. If during the conduct of a project any new, related financial or non-financial interest described in V. should arise, the Principal Investigator must disclose this to the Research Compliance Officer. Review will be conducted as with the original disclosure.

j. On an annual basis the Research and Development Committee will review all disclosures determined by the Research Compliance Officer not to affect scientific objectivity and not referred for committee deliberation. They will certify that their review supports the decision in each case. A report will be submitted to the Research and Development Committee annually providing information on number of disclosures, cases referred for committee deliberation and disposition of each.

k. Compliance with this policy will be monitored through internal audits and other appropriate self-evaluation strategies.

8. REFERENCES:


9. RESCISSION DATE: February 9, 2008

10. RESPONSIBLE OFFICIAL: ACOS for Research and Development

Elizabeth Joyce Freeman
Director