Objectivity in Research – Investigator Disclosure of Financial Conflict of Interest

I. PURPOSE: To define PAVIR policy regarding objectivity in research and to define the procedures for reviewing potential financial conflicts of interest and addressing such identified instances.

II. POLICY: It is the policy of PAVIR that objectivity in the conduct of research must be maintained and that there are procedures to identify potential financial conflicts of interest. If such are identified, there will be procedures for managing, mitigating or eliminating them.

III. PROCEDURES:

A. When a project is initiated using the VA Palo Alto Research Administration website there is a specific investigator certification requirement regarding financial conflict of interest.
B. If potential financial conflict of interest is identified for any PAVIR administered project, the procedures defined in VA Palo Alto Health Care System (VAPAHCS) Memorandum 151-12-04 - Conflict of Interest in the Conduct of Research, will be effected.

Promoting Objectivity in Research – Additional Requirements for PHS Awards

I. PURPOSE

The intent of this document is to define policy and procedure for assuring PAVIR's compliance with requirements for Promoting Objectivity in Research found at 42 CFR Part 50, Subpart F (the "COI Regulations"). See http://www.gpo.gov/fdsys/pkg/CFR-2011-title42-vol1/xml/CFR-2011-title42-vol1-part50-subpartF.xml.

The purpose of the COI Regulations is to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded by the PHS under grants, cooperative agreements or contracts will be free from bias resulting from the financial conflicts of interest of an Investigator. The NIH Office of Extramural Research Conflict of Interest website contains helpful information and resources about the COI Regulations. See http://grants.nih.gov/grants/policy/coi/coi_faqs.htm.

The Department of Veterans Affairs (VA) is responsible for developing agency specific guidance regarding the management of financial conflict of interest in research. Because all research managed by PAVIR is VA research and because employees engaged in such research hold VA paid or VA Without Compensation (WOC) appointments the VAPAHCS policy on Conflict of Interest in the Conduct of Research is applicable to PAVIR activities. In addition, dually appointed faculty members are subject to the requirements of Stanford University regarding the management of financial conflict of interest. Any project that involves human subjects research is subject to both VA and Stanford (if applicable) policy and requirements regarding financial conflict of interest in the conduct of human research.

PHS agencies including the NIH require that each investigator disclose to a designated representative of the institution (PAVIR) all significant financial interests of the investigator that would reasonably appear to be related to the investigator's institutional responsibilities. Processes for disclosing and for managing any significant financial conflict of interest are described in this policy.

II. DEFINITIONS

Disclosure of significant financial interests (SFI) means an Investigator's disclosure of significant financial interests to an institution, i.e., PAVIR.

Financial conflict of interest (FCOI) means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

Institution for purposes of this policy means PAVIR. However, by virtue of their appointments with VAPAHCS and/or Stanford institution could include those two institutions.

Institutional responsibilities means an Investigator's professional responsibilities on behalf of the Institution (but also to include VA and Stanford if relevant to a PAVIR-administered award); these may include research, teaching/education, clinical activities, committee memberships or other administrative responsibilities.

Investigator means the Project Director or Principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding.

Significant financial interest (SFI) means: A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse/domestic partner and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities or that could impact the conduct of an award:

1. **With regard to Publicly Traded Entities**: remuneration or value exceeding $5,000 when aggregated for an Investigator and the Investigator's spouse/domestic partner and dependent children from a single entity, including salary, consultant payments, honoraria, paid authorship, equity interest (stock, stock option or other ownership interest) during the prior 12 months.
2. **With regard to Privately Held Entities**: payments or value exceeding $5,000 when aggregated for an Investigator and the Investigator's spouse/domestic partner and dependent children from a single entity during the prior 12 months or when the Investigator and the Investigator's spouse/domestic partner and dependent children hold any equity interest (stock, stock option, or other ownership interest).
3. **With regard to Intellectual Property**: intellectual property rights and interests (patents, copyrights) upon receipt of income related to such rights and interests if paid by an entity other than VA or Stanford.
4. **With regard to Travel**: any reimbursed or sponsored travel related to the Investigator's Institutional Responsibilities during the prior 12 months, with the exception of travel that is reimbursed or sponsored by a Federal, state, or local government agency; an institution of higher education; an academic teaching hospital; a medical center; or a research institute that is affiliated with an institution of higher education. Travel reimbursed by PAVIR is not subject to reporting requirements.

Significant Financial Interest does not include:

1. Salary, royalties, or other remuneration paid by the VA, Stanford or PAVIR to the Investigator if the Investigator is currently employed or otherwise appointed, including intellectual property rights assigned to the VA and/or Stanford and agreements to share royalties related to such rights;
2. Income from investment vehicles, such as mutual funds and retirement accounts;
3. Income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute affiliated with an institution of higher education;
4. Income from service on advisory committees or review panels for a Federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute affiliated with an institution of higher education.

III. GUIDELINES

For consideration when completing disclosure forms, Personal Financial Interest with an entity that is considered reasonably related to an Investigator's research study would be a case in which:

1. Entity sponsors research in which the investigator is directly involved;
2. Entity has financial interests that could reasonably be considered to have a potential influence on the design, conduct or reporting of investigator's research/scholarship;
3. Entity has a reasonable possibility of being financially affected by investigator's research/scholarship;
4. Entity makes gifts to VA, Stanford or PAVIR that benefit investigator's research/scholarship (including equipment gifts or loans);
5. Entity makes a product that is under study in research in which investigator is involved;
6. Entity licenses VA or Stanford intellectual property in which investigator has a financial interest;
7. Entity has a Materials Transfer Agreement or Human Tissue Agreement (MTA/HTA) to provide materials used in investigator's research or for materials provided by investigator to the company/organization;
8. H. Entity sponsors or makes a product that is under study in human subjects in which investigator is directly or indirectly involved.

IV. DISCLOSURE AND REVIEW PROCESSES

Initial Proposal and Annual Report Related Submissions and Review: The Principal Investigator must complete the Disclosure of Financial Interests form at initial PHS-funded proposal submission for new award applications and annually in conjunction with submission of PHS-funded non-competing continuation awards. At that time s/he will determine whether any other person, regardless of title or position, **responsible for the design, conduct, or reporting of research** has a significant financial conflict of interest that could affect the conduct of the award. If such is a possibility then the Principal Investigator will identify those parties for appropriate follow-up by PAVIR Administration.

If a Significant Financial Interest that reasonably appears to be related to an Investigator's Institutional Responsibilities is disclosed that information along with supporting documentation shall be forwarded to PAVIR's Chief Executive Officer. In coordination with VA and Stanford (for duly appointed faculty) COI Managers and relevant policies or procedures, a determination as to whether any of the disclosed Significant Financial Interests of the Investigator are related to the project

and whether the financial interest could directly and significantly affect the design, conduct, or reporting of the project (a FCOI) will be made. If there is an FCOI it will be either eliminated, reduced or managed depending on the specific case. If managed, a management plan will be developed in conjunction with VA and/or Stanford and appropriate notifications will be reported to PHS.

Notice of Change in Investigator's Significant Financial Interests OR Addition of Investigator with Significant Financial Interest Submissions and Review: If at any point there is the addition of an Investigator new to the project who might have a Significant Financial Interest or a change in an existing Investigator's financial situation that meets the threshold for SFI disclosure and review of significant financial interest the Principal Investigator must disclose that change within 30 days of addition of the new Investigator or of discovering or acquiring a new SFI. That is accomplished through the use of the Disclosure of Financial Interests form for review and processing as described above. If the Investigator is dually appointed Stanford will be informed of such disclosures.

V. MANAGEMENT OF FCOI

Examples of conditions or restrictions that might be imposed to manage, reduce or eliminate conflicts of interest include but are not limited to:

1. public disclosure of significant financial interests
2. monitoring of research by independent reviewers
3. modification of the research plan
4. disqualification from participation in the portion of the NIH funded research that would be affected by significant financial interests
5. divestiture of significant financial interests
6. severance of relationships that create conflicts.

Enforcement mechanisms and sanctions will be managed in coordination with applicable PAVIR, VA and Stanford University policies.

VI. AGENCY NOTIFICATIONS (PHS ONLY)

Upon receipt of an award from the Public Health Service and prior to the expenditure of any funds, as well as within 60 days for any new interest that PAVIR identifies as conflicting subsequent to the Institution's initial report under the award, PAVIR is obligated to notify the sponsoring institute or agency of any FCOI associated with that award. In addition PAVIR will provide annual updates on any previously-identified FCOI for the duration of the research project. If an FCOI is identified at the time a proposal is submitted, and that proposal is subsequently awarded, or if an FCOI is identified subsequent to the award of the project, PAVIR must prepare a notification to the eRA Commons FCOI Module. That notification is to consist of the following:

- grant number;
- PD/PI or contact PD/PI;
- name of Investigator with the FCOI;
- name of the entity with which the Investigator has an FCOI;
- nature of FCOI, e.g. equity, consulting fees, travel reimbursement, honoraria;
- value of the financial interest (in pre-specified dollar ranges) or a statement that a value cannot be readily determined;
- a description of how the financial interest relates to NIH-funded research and the basis for the Institution's determination that the financial interest conflicts with such research;
- key elements of the Institution's management plan including:
    - role and principal duties of the conflicted Investigator in the research project;
    - conditions of the management plan;
    - how the management plan is designed to safeguard objectivity in the research project;
    - confirmation of the Investigator's agreement to the management plan;
    - how the management plan will be monitored to ensure Investigator compliance;
    - other information as needed.

A copy of the notification must be kept with the project records. (Note that this notification requirement currently applies only to the Public Health Service, including the National Institutes of Health (NIH).)

VII. OTHER REQUIREMENTS

Public Accessibility: Prior to the expenditure of funds, PAVIR will make certain that information concerning FCOIs held by senior/key personnel is publicly accessible by a written response to any requestor within five business days of a request.

Investigator Training: Each Investigator must have completed the PAVIR Power Point training or the Stanford web-based training (https://web.stanford.edu/group/coi/training/training.html) prior to engaging in research related to any PHS-funded grant. This training must be completed at least every four years after initial training. It must be completed immediately if: a) there is a revision to the PAVIR FCOI policy that affects requirements of investigators, b) an Investigator is new to PAVIR, or c) an Investigator is not in compliance with the policy or management plan. The training will be tracked through the Research Administration website.

Subawards: If PAVIR carries out PHS-funded research through subawardees, contractors, or collaborators, PAVIR must take reasonable steps to ensure that the entity has its own policies in place that meet the requirements of the PHS policy or that investigators working for such entities follow PAVIR policies.

Maintenance of Records: All FCOI-related records will be retained for at least 3 years from the date the final expenditure report is submitted to the PHS.