

## **NCIRE POLICY: PROMOTING OBJECTIVITY IN RESEARCH**

### **PURPOSE**

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

The purpose of the FCOI 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 U.S. Public Health Service ("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 FCOI Regulations. See [http://grants.nih.gov/grants/policy/coi/coi\\_faqs.htm](http://grants.nih.gov/grants/policy/coi/coi_faqs.htm)

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

### **DEFINITIONS**

**Disclosure of significant financial interests** means an Investigator's disclosure of significant financial interests to an institution, i.e., NCIRE.

**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 NCIRE. However, by virtue of their appointments with SFVAMC and/or UCSF, 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 UCSF if relevant to an NCIRE-administered award);

these may include research, research consultation, teaching, clinical activities, committee memberships or 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 of more of the following interests of the Investigator (and those of the Investigator's spouse 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.
4. **With regard to Travel Reimbursements:** 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 NCIRE is not subject to reporting requirements.

**Significant Financial Interest does not include:**

1. Salary, royalties, or other remuneration paid by the VA, UCSF or NCIRE to the Investigator if the Investigator is currently employed or otherwise appointed, including intellectual property rights assigned to the VA and/or UCSF 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.

## **GUIDELINES**

For consideration when completing disclosure forms, Personal Financial Interest with an entity considered reasonably related to an Investigator's research study could 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 the VA, UCSF or NCIRE 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 UCSF 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. Entity sponsors or makes a product that is under study in human subjects in which investigator is directly or indirectly involved.

## **DISCLOSURE AND REVIEW PROCESSES**

**Initial Proposal and Annual Report Related Submissions and Review:** The Principal Investigator must complete the Disclosure Form at Initial Proposal submission for new award applications and annually in conjunction with submission of non-competing continuation awards and no-cost extensions. 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 NCIRE 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 NCIRE's Executive Director. In coordination with VA and UCSF (for dually 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 will be made. If there is an FCOI a management plan will be developed in conjunction with the VA and/or UCSF and appropriate notifications and reporting will be made 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 an Investigator new to the project who might have a Significant Financial Interest or a change in an existing Investigator's situation that meets the threshold for 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 Form for review and processing as described above. If the Investigator is dually appointed, UCSF will be informed of such disclosures.

#### **AGENCY NOTIFICATIONS (PHS ONLY)**

Upon receipt of an award from the PHS and prior to the expenditure of any funds, as well as within 60 days for any interest that NCIRE identifies as conflicting subsequent to the Institution's initial report under the award, NCIRE is obligated to notify the sponsoring institute or agency of any FCOI associated with that award. In addition NCIRE 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, NCIRE 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).)

### **OTHER REQUIREMENTS**

**Public Accessibility:** Prior to the expenditure of funds, NCIRE 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 UCSF web-based training at <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm> or submit a training certificate from UCSF (if you have a faculty appointment) 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 NCIRE FCOI policy that affects requirements of investigators, b) an Investigator is new to NCIRE or, c) an Investigator is not in compliance with the policy or management plan. The training will be tracked through the website.

**Sub awards:** If NCIRE carries out PHS-funded research through sub awardees, contractors, or collaborators, NCIRE 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 NCIRE 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.