



Objectivity in Research Investigator - Financial Conflict of Interest

I. PURPOSE: To define Denver Research Institute's (DRI) 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 DRI that objectivity in the conduct of research must be maintained and that there are procedures to identify potential financial conflicts of interest. If COIs are identified, there will be procedures for managing, mitigating, or eliminating them.

III. PROCEDURE: If a potential financial conflict of interest is identified for any DRI administered project, the procedures defined in VA Eastern Colorado Health Care System (ECHCS) VA Directive 1663 and VHA Handbook 1660.01 will be in effect.

THE CODE OF FEDERAL REGULATIONS

I. PURPOSE

The intent of this document is to define policy and procedure for assuring DRI'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 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 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 DRI is VA research and because employees engaged in such research hold VA paid or VA Without Compensation (WOC) appointments the VA ECHCS policy on Conflict of Interest in the Conduct of Research is applicable to DRI activities.

PHS agencies including the NIH require that each investigator disclose to a designated representative of this institution, DRI, 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., DRI.

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 DRI.

Institutional Responsibilities means an Investigator's professional responsibilities on behalf of the Institution (but also to include VA and any other University, if relevant to a DRI-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.

Institutional Official means the designated official affiliated with DRI responsible for soliciting and reviewing Investigator's SFI disclosures (and those of the Investigator's spouse and dependent children) related to an Investigator's institutional responsibilities for a determination of FCOI.

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 appears to be related to the Investigator's institutional responsibilities or that could impact the conduct of an award:

- A. **Regarding 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.
- B. **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).
- C. **Regarding 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 other universities.
- D. **With regard to Travel:** any reimbursed or sponsored travel that exceeds \$5,000 and is 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 DRI is not subject to reporting requirements.
- E. **With regard to Disclosure of Funds Received from Foreign Entities:** Investigators must disclose all foreign financial interests (which includes income from seminars, lectures, or teaching engagements, income from service on advisory committees or review panels, and reimbursed or sponsored travel) received any foreign entity, including foreign Institution of higher education or a foreign government (which includes local, provincial, or equivalent governments of another country) when such income meets the \$5,000 threshold for disclosure.

Significant Financial Interest does not include:

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

III. GUIDELINES

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

- A. Entity sponsors research in which the investigator is directly involved;
- B. 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;
- C. Entity has a reasonable possibility of being financially affected by investigator's research/scholarship;
- D. Entity makes gifts to VA, other universities, or DRI that benefit investigator's research/scholarship (including equipment gifts or loans);
- E. Entity makes a product that is under study in research in which investigator is involved;
- F. Entity licenses VA or other universities intellectual property in which investigator has a financial interest;
- G. 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;
- H. 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

DRI's Institutional Official will review all financial disclosures by Investigators and determine whether any additional Significant Financial Interest is related to PHS-funded research and a Financial Conflict of Interest exists by making a reasonable determination that the Significant Financial Interest could be affected by the PHS-funded research or is in an entity whose financial interest could be affected by the research.

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 DRI Administration.

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 using the Disclosure of Financial Interests form for review and processing as described above. If the Investigator is dually appointed with another university will be informed of such disclosures.

Travel Disclosure Requirements: Any Investigator submitting a proposal to or receiving funding from the PHS must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid by an outside entity directly to or on behalf of the Investigator so that the exact monetary value may not be readily available) that falls within the following guidelines:

- Travel must demonstrate research relevance and be related to institutional responsibilities.
- Travel is not reimbursed through DRI or VA ECHCS.
- Travel is not being reimbursed or sponsored by a federal, state, or local government agency, or domestic or U.S.-based institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.
- Investigator has an aggregate of significant financial interests and travel reimbursements that exceed \$5000 in the previous twelve months from a single entity. As an example, \$4500 in non-travel significant financial interests and \$1000 in travel reimbursements would exceed \$5000 when aggregated from a single entity, and, therefore, would need to be disclosed.

Investigators must provide the following details regarding reimbursed sponsor travel related to institutional responsibilities:

- purpose of the trip,
- the identity of the sponsor/organizer,
- the destination, and
- the duration.

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:

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

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

DRI will not expend funds in support of a research project until any significant financial interest has been reviewed by the Designated Institutional Official and any conflict of interest has been satisfactorily managed or eliminated.

VI. FCOI Compliance Failures

DRI will comply with sponsor requirements for ongoing reporting of FCOIs including management plans, retrospective reviews, and mitigation reports. If the Institution or an investigator fails to comply with the DRI FCOI Policy or mitigation plan, DRI will, within 120 days:

1. Complete a retrospective review of the Investigator's activities and the PHS funded research project to determine any bias in the design, conduct, or reporting of research;
2. Document the retrospective review consistent with the regulation; and

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3. Document DRI's determination as to whether any PHS-funded research, or portion thereof, conducted during the period of time of the Investigator's non-compliance with DRI's FCOI policy or a FCOI management plan, was biased or might appear to be biased in the design, conduct, or reporting of such research.

If a bias is found, the Institution shall notify the PHS Funding agency promptly and submit a mitigation report that shall address the impact of the bias on the research project, and DRI's plan of action or actions taken to eliminate the effect of the bias.

Thereafter, DRI will submit FCOI reports annually, in accordance with the regulation.

Clinical Research Requirements: DRI shall require the Investigator involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations. The conflict of interest shall be disclosed in any case in which the HHS determines that a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a financial conflict of interest that was not managed or reported by DRI.

Any violation of this policy may require reporting to a sponsoring entity and affiliated institutions as appropriate.

VII. 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 DRI identifies as conflicting subsequent to the Institution's initial report under the award, DRI is obligated to notify the sponsoring institute or agency of any FCOI associated with that award. In addition, DRI 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, DRI must prepare a notification to the eRA Commons FCOI Module. That notification is to consist of the following:

- grant number;
- project title;
- 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;
- findings of the review;
- conclusions of the review.

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).)

VIII. OTHER REQUIREMENTS

Public Accessibility: Prior to the expenditure of funds, DRI will make information available concerning FCOIs held by senior/key personnel is publicly accessible by a written response to any requestor.

Subawards: If DRI conducts PHS-funded research through subawardees, contractors, or collaborators, DRI 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 DRI 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 or as required by applicable government regulations, whichever is longer.

Mandatory Training: All Investigators involved in the design, conduct, or reporting of research will complete training prior to engaging in research funded by PHS and at least once every four years thereafter. Investigators are also required to complete training immediately if: the Institution revises the FCOI policy that affects the requirements of Investigators; an Investigator is new to the Institution; an Investigator is in non-compliance with the policy or management plan.