

The Foundation for AIDS Research (amfAR)

Policy: Financial Conflicts of Interest in Research Activities Funded through the U.S. Public Health Service

PURPOSE

The purpose of this Policy is to define the requirements and responsibilities associated with identifying and managing financial conflicts of interest to safeguard the integrity of amfAR research activities funded through the U.S. Public Health Service.

SCOPE

This Policy applies to amfAR staff, collaborators, and Subrecipients receiving funding from, planning to apply for funding from, have a salary funded by a grant or contract from, or contributing to research supported by funds from any U.S. Public Health Service (PHS) agency (Sponsor).

DEFINITIONS

1. **Financial Conflict of Interest** – a Significant Financial Interest that may directly and significantly affect the design, conduct or reporting of PHS-funded research.
2. **Public Health Service (PHS)**, hereinafter referred as “Sponsor”, is the operating division of the United States Health and Human Services Department (HHS) responsible for promoting the protection and advancement of the American population’s physical and mental well-being. PHS includes the following agencies: Agency for Healthcare Research and Quality (AHRQ), Agency for Toxic Substance and Disease Registry (ATSDR), Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), Health Resources and Services (HRSA), Indian Health Service (IHS), National Institutes of Health (NIH), Office of Inspector General (OIG), and Substance Abuse and Mental Health Services Administration (SAMSHA).
3. **PHS-Funded Investigator** – Project Director (Project Leader), Principal Investigator, any other person identified by amfAR as senior/key personnel and any other person, regardless of title or position, who is responsible for the design, conduct or reporting of research supported through PHS funds.
4. **Research** is a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term includes basic and applied research and product development. As used in this policy, the term includes any such activity for which research funding is available from a PHS Sponsor through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.
5. **Institutional Responsibilities** – A PHS-Funded Investigator’s professional responsibilities on behalf of amfAR or Subrecipient Institution (as applicable) including but not limited to

designing or conducting research (e.g., experiments, data collection), research consultation, teaching, clinical practice, institutional committee membership, supervision of staff, or service on panels such as Institutional Review Boards or Data Safety Monitoring Boards.

6. **Significant Financial Interest (SFI)** is defined as one or more Investigator Financial Interests (and those of the Investigator's spouse and dependent children) that reasonably appears related to the Investigator's Institutional Responsibilities, and where the aggregate value of such Investigator Financial Interest exceeds \$5,000, existing at the date of SFI disclosure and going back twelve (12) months.

For avoidance of doubt, amfAR does not include the following in the definition of an SFI: (a) salary, royalties or other remuneration from amfAR (or in the case of a Subrecipient, the Subrecipient institution); (b) salary, royalties or other payments from any source other than amfAR/Subrecipient institution that, when aggregated for the Investigator, spouse and dependent children in the twelve (12) months preceding disclosure, are not expected to exceed \$5,000; (c) income from seminars, lectures or teaching engagements, service on advisory committees or review panels sponsored by federal, state or local government agencies, 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; (d) an equity interest that, when aggregated for the Investigator, spouse and dependent children, does not exceed \$5,000 in value as determined through reference to public prices or other reasonable measures of fair market value; or (e) income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator (or spouse/dependent child) does not control such funds or the account's investment decisions.

7. **Subrecipient**, for the purposes of this policy, is any party that has entered into an Agreement with amfAR as a subgrantee, subawardee, subcontractor, collaborator, contractor or consultant on a project identified as contributing to PHS-funded research, whether PHS funds are used to support the party's expenses or not.

POLICY

amfAR requires that PHS-Funded Investigators who receive funding from, plan to apply for funding from, have a salary supported by U.S. PHS funds, or will contribute to or participate in research supported by U.S. PHS funds whether salary is supported by PHS funds or not, comply with the PHS rules on training, disclosure, and management of financial conflicts of interest in research (FCOI). The following requirements apply in fulfillment of compliance with the PHS rules and regulations.

1. Training Requirements

- a. PHS-Funded Investigators will complete a PHS-compliant FCOI training program prior to engaging in a PHS research project and every four years thereafter on an annual schedule (as long as they continue to be engaged in PHS-supported research), immediately if the FCOI policy training requirements are modified or if the investigator is found not to be in compliance with this policy or an FCOI management plan.
- b. amfAR staff who are PHS-Funded Investigators shall comply with these training requirements by completing the NIH Office of Extramural Research (OER) FCOI tutorial at <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>. The OER certificate documenting completion of said training tutorial shall be sent to amfAR's

Director of Grants Administration and Compliance.

c. PHS-Funded Investigators at Subrecipient Institutions that have not certified that a PHS-compliant policy on FCOIs is in place shall comply with this requirement by completing the NIH Office of Extramural Research FCOI tutorial or submitting a certified review of training materials supplied by amfAR. The OER certificate, or other forms as may be provided, documenting completion of such training shall be sent to the Director, Grants Administration and Compliance.

d. The Director, Grants Administration and Compliance, shall, in collaboration with amfAR and/or Subrecipient Program Directors or Principal Investigators, develop alternative FCOI training materials that are appropriate for PHS-Funded Investigators for whom English is not their primary language, if needed.

2. Disclosure, Review and Monitoring Requirements

a. PHS-Funded Investigators covered by this policy will complete a U.S. PHS Significant Financial Interests Disclosure Form disclosing SFIs that could reasonably appear to be related to their Institutional Responsibilities at the time of the PHS funding application. PHS-Funded Investigators will provide an updated U.S. PHS Significant Financial Interests Disclosure Form on an annual schedule set by amfAR or within 30 days of a change in financial status (whichever comes first).

b. amfAR's Director, Grants Administration and Compliance, and Vice President and Director, Research, or Vice President and Director, TREAT Asia, in consultation with the Chief Financial Officer and Legal Department are the designated officials to review SFI disclosures and determine whether a disclosed SFI constitutes an FCOI.

c. In instances in which an FCOI has been identified, the Director, Grants Administration and Compliance, and Vice President and Director, Research or Vice President and Director, TREAT Asia, the PHS-Funded Investigator and the Principal Investigator of the PHS-funded research, in consultation with the amfAR's Legal Department, will develop an FCOI management plan prior to the expenditure of funds and in conformance with PHS standards and other applicable federal and sponsor requirements.

d. The Director, Grants Administration and Compliance, and Vice President and Director, Research, or Vice President and Director, TREAT Asia, or their designees, in consultation with the Legal Department shall monitor PHS-funded investigator compliance with established management plans.

3. Reporting Requirements

a. The Director, Grants Administration and Compliance, or designee, in consultation with the Legal Department, shall provide FCOI reports to Sponsors regarding disclosed and identified FCOIs in conformance with applicable Sponsor requirements and prior to the expenditure of funds.

b. The Director, Grants Administration and Compliance, or designee, in consultation with the Legal Department, shall submit an FCOI report prior to the expenditure of funds, within 60 days after its determination that a new FCOI exists. If an FCOI was not disclosed in a timely manner, amfAR shall submit a FCOI report to the Sponsor within 60 days of the discovery, as well as complete a retrospective review

of the PHS-funded investigator SFIs within 120 days of discovery of noncompliance and provide mitigation reports as required by PHS policy and regulations.

4. Subrecipient Requirements

- a. Subrecipients shall provide a certification that their FCOI policy complies with the U.S. PHS Financial Conflicts of Interest regulation and that their portion of the research project, as detailed in their subaward or subgrant agreement, is in compliance with their institutional policies. Links to the required public online posting and/or copies of such policies (including original language and certified English translations as applicable) shall be provided to amfAR upon request. If an FCOI is identified by the Subrecipient, the entity shall notify amfAR of the existence of the conflicting interest within 30 days of the identification of the interest. In addition, the Subrecipient must certify and assure that any reported conflicting interest has been managed, reduced or eliminated in accordance with U.S. PHS FCOI regulations.
- b. If a Subrecipient does not have a U.S. PHS-compliant FCOI policy, then this policy shall apply to PHS-Funded Investigators engaged in research supported by the subaward or subgrant, with FCOI disclosures made to amfAR, as described above in Policy Section 2 (Disclosure, Review and Monitoring Requirements) and with the agreement that the Subrecipient institution shall cooperate with FCOI management plans that are so developed.

5. Public Accessibility

- a. In accordance with the applicable regulations, this policy is posted on the www.amfar.org external website.
- b. Information concerning an identified FCOI will be available upon written request to the amfAR's General Counsel or Director, Grants Administration and Compliance; the information will be made available within five business days of such a request and will include the following information:
 - The PHS-Funded Investigator's name
 - The title and role of the PHS-Funded Investigator with respect to the research project;
 - The name of the entity in which the SFI is held or from which it derives;
 - The nature of the SFI;
 - The approximate dollar value of the SFI or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

6. Compliance Requirements

- a. PHS-Funded Investigator(s) working on clinical research projects to evaluate the safety and efficacy of a drug, medical device or treatment who fail to disclose an FCOI, or where an FCOI is not managed in accordance with this policy, shall disclose the FCOI in each public presentation or publication of the results of the research and request an addendum to previously published papers or presentations.
- b. amfAR shall follow Sponsor regulations regarding the notification of the sponsoring agency in the event that a PHS-funded Investigator has failed to comply with this policy
- c. Failure to comply with this Policy may result in disciplinary action up to and

including termination of employment at amfAR, or the termination of a subaward or subgrant agreement to support the PHS-funded research.

7. Responsibilities in Addition to those Identified Above

- a. The General Counsel or designee shall recommend actions when PHS-Funded Investigators covered by this policy are found to be in violation of it.
- b. The Director, Grants Administration and Compliance, and other Grants Administration department staff shall
 - i. Maintain records of and related to financial interest disclosures, FCOI determinations, and documentation of required training for a minimum of three years from the date of the final expenditures report for PHS-funded research;
 - ii. Inform PHS-Funded Investigators of training requirements and resources
 - iii. Verify completion of training required by this policy
 - iv. Obtain and review assurances and certifications from Subrecipients that such subrecipient has a PHS-compliant FCOI policy
 - v. Obtain U.S. PHS Significant Financial Interest Disclosure forms and updates from PHS-Funded Investigators as required by this policy
 - vi. Ensure, in collaboration with amfAR's Public Information and Information Technology departments, that the required public information is maintained on the www.amfar.org external internet site.