

# FINANCIAL CONFLICT OF INTEREST POLICY

## 1. POLICY OVERVIEW

The Public Health Institute (PHI) is committed to forward-thinking research that supports some of the most complex public health challenges facing the world. PHI understands the responsibility it assumes in conducting research in a manner that promotes and preserves public trust. The purpose of this Financial Conflict of Interest (FCOI) policy is to assure the objectivity with which PHI's research programs are designed, managed, conducted, and reported on. This includes disclosing conflicts of interest between a Researcher and his/her personal financial interests.

This policy is written in accordance with Public Health Service regulations regarding Financial Conflict of Interest at [42 CFR 50 Subpart F](#). These regulations require that all individuals who participate in the design, conduct, or reporting of Research funded through a Public Health Service (PHS) entity to complete a conflict of interest training and disclose personal financial interests that could give rise to a perceived or real actual conflict of interest.

## 2. APPLICABILITY

This policy is applicable to all Researchers (as defined below) involved in designing, managing, conducting, or reporting on Research conducted through PHI. It is the responsibility of the Research Administration and Compliance Department to identify, monitor, and advise Researchers on compliance requirements under this policy.

This policy extends to any subcontractors, sub-grantees, or sub-awardees at partner institutions conducting or supporting research on behalf of PHI.

## 3. DEFINITIONS

- **Financial Conflict of Interest (FCOI)** means a Significant Financial Interest that could directly and significantly affect the design, conduct or reporting of Research.
  - ***Significant Financial Interest (SFI) means:***
    - (1) A financial interest consisting of one or more of the following interests of the Investigator (aggregated together with those of the Investigator's spouse, same-sex domestic partner and dependent children) that reasonably appear to be related to the Investigator's Institutional Responsibilities:
      - (i) With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. Remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
      - (ii) With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months

- /preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse, same-sex domestic partner or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest);
- (iii) intellectual property rights and interests (e.g., patents, copyrights), a significant financial interest exists upon receipt of income of related to such rights and interests;
- (iv) any third party reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and/or the Investigator's spouse, same-sex domestic partner and dependent children) that is related to the Investigator's Institutional Responsibilities. This disclosure requirement excludes travel paid for by ACS or travel that is reimbursed or sponsored by an U.S. Federal, state, or local government agency, an 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; or
- (v) holding any position of influence (e.g., director, officer, trustee, dean, or faculty) in a non-ACS entity.
- (2) The term significant financial interest does not include the following:
    - (i) Salary, royalties, or other remuneration paid by ACS to the Investigator if the Investigator is currently employed or otherwise appointed by ACS, including intellectual property rights assigned to the ACS and agreements to share in royalties related to such rights;
    - (ii) Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles;
    - (iii) Income from seminars, lectures, or teaching engagements sponsored by an U.S. Federal, state, or local government agency, an 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; or
    - (iv) Income from service on advisory committees or review panels for an U.S. federal, state, or local government agency, an 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.
  - **Financial Conflict of Interest Committee (FCOI Committee)** means a committee appointed to review and provide recommendations to senior management of Significant Financial Interests in accordance with this Policy. The FCOI Committee will be comprised of one representative from the Office of the Chief Financial Officer, the Office of the Chief Operations Officer and the Office of Chief Legal Counsel.

- **Financial Conflict of Interest Management Plan (FCOI Management Plan)** means a plan developed in accordance with this Policy for the management, reduction, or elimination of an identified Significant Financial Interest.
- **Financial Conflict of Interest Report (FCOI Report)** means PHI's report of a Financial Conflict of Interest to the awarding agency.
- **Financial Interest** means anything of monetary value, whether or not the value is readily ascertainable.
- **Researcher** means any principal investigator, program director or manager, research analyst, or member of the research team identified as senior/key personnel on the grant or contract application, progress report, or any other report; and/or other individuals that the principal investigator/project manager identifies as responsible for or having substantial independent decision making with respect to the design, conduct or reporting of Research, including collaborators or consultants.
- **Designated Official** means the individual(s) within PHI designated as responsible for management of this Policy, including the solicitation and review of disclosures of Significant Financial Interests, training of Investigators, record retention, and reporting to funding agencies, sponsors and the public as detailed herein. The Deputy Chief Legal Counsel for Research Administration and Compliance has been designated the institutional official for PHI.
- **Research** means a systematic investigation, study, or experiment designed to contribute to generalizable knowledge relating broadly to public health, including behavioral and social sciences research. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug).
- **Public Health Service (PHS)** means an Umbrella organization in the U.S. Federal Government consisting of eight [HHS](#) health Agencies, the Office of Public Health and Science, and the Commissioned Corps (a uniformed service of more than 6,000 health professionals). The NIH is the largest Agency within the PHS.

#### 4. FCOI TRAINING

Researchers participating in, or applying for, PHS-sponsored research are required to complete a training in accordance with applicable federal regulations. Training will review Significant Financial Interest (SFI) disclosure requirements and PHI's FCOI policy and procedures.

#### 5. DISCLOSURE PROCEDURE

Individuals who are planning to or participating in a research activity that is either partially or wholly supported by PHS funds must disclose their any Significant Financial Interests (SFI) in a timely fashion to the Grants and Contracts and Research Administration and Compliance departments. The Designated Official will review disclosures and will inform the FCOI Review Committee immediately if the SFI constitutes an FCOI, based on guidance outlined in the Protocol of Handling Financial Conflict of Interest addendum to Chapter 3 of the Policy Manual. If the SFI is determined to be an FCOI, the FCOI Review Committee will to inform PHI's Senior Management who will approve the implementation of an FCOI management plan consistent with government regulation and, furthermore, to promptly notify the PHS funding component (e.g., NIH) via a FCOI report.

As a part of the FCOI management plan, the FCOI Review Committee will decide one or more actions depending upon the situation, including requiring certain disclosure in public presentations, employee role reassignment, reduction or elimination of the financial interest sanctions (e.g., sale of an equity interest) or severance of relationships that create financial conflicts. Employees with an identified FCOI must comply with the FCOI management plan.

## **6. POLICY VIOLATIONS**

Violations of this policy, including failure to make a required disclosure of Significant Financial Interests or failure to comply with the requirements of any Management Plan, the Designated Official shall be responsible for enforcing this policy. Should any violations occur, the Designated Official will hall take reasonable steps to respond appropriately to violations, including, notifying the FCOI Committee who will determine the appropriate course of action including but not limited to: 1) suspending expenditures on applicable Research account; 2) administratively suspending approval; and 3) instituting disciplinary measures to include suspension or termination of such Researcher.