

Financial Conflict of Interest Policy for Public Health Service Funding

Purpose

Federal regulations require that institutions applying for or receiving federal Public Health Service (PHS) grants, cooperative agreements, and contracts promote objectivity in research and adopt and comply with a Financial Conflict of Interest Policy to provide a reasonable expectation that the research performed by the institution will be free from bias resulting from financial conflicts of interest of a research investigator. Vitalant is committed to ensuring the integrity of the research process and maintaining the public trust and that of sponsors.

Application

This Policy applies to Vitalant and its operating divisions (hereinafter referred to as "Institution") when it is applying for, or receiving PHS research funding by means of a grant or cooperative agreement and, through implementation of the regulation, to each investigator who is planning to participate in or is participating in such research, including any subgrantee, subcontractor, or collaboratory investigator. This Policy does not apply to Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) Program Phase I applications.

Definitions

Administrative Director shall be the Administrative Director of Vitalant Research Institute responsible for soliciting and reviewing disclosures of Significant Financial Interests from each Investigator who is planning to participate in, or is participating in, the PHS-funded research.

Disclosure of significant financial interests means an Investigator's disclosure of significant financial interests to the Institution.

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.

FCOI report means an Institution's report of a financial conflict of interest to a PHS Awarding Component.

Financial interest means anything of monetary value, whether or not the value is readily ascertainable.

HHS means the United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.

Institution means Vitalant and its operating divisions, if applying for, or receiving, PHS research funding.

Institutional responsibilities means an Investigator's professional responsibilities on behalf of the Institution, including research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

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, which may include, for example, collaborators or consultants.

PHS means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).

PHS Awarding Component means the organizational unit of the PHS that funds the research that is subject to this subpart.

Public Health Service Act or PHS Act means the statute codified at 42 U.S.C. 201 et seq.

Research mean 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 encompasses basic and applied research (e.g., a diagnostic test or drug). The term includes any such activity for which research funding is available from a PHS Awarding Component through a grant, cooperative agreement, or contract, 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.

Senior/Key Personnel means the Project Director/Principal Investigator (PD/PI) and any other person identified as senior/key personnel by the institution in the grant application, progress report, or any other report submitted to the PHS by the Institution under the regulation.

Significant financial interest means:

- A financial interest consisting of one or 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 responsibilities with the Institution:
 - 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. For purposes of this definition, 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;
 - 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 or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
 - Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

- Investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their responsibilities with the Institution; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a 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. The disclosure will include the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. The Administrative Director may require further information, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.
- The term significant financial interest does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator; income from seminars, lectures, or teaching engagements sponsored by a 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 income from service on advisory committees or review panels for a 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.

Small Business Innovation Research (SBIR) Program means the extramural research program for small businesses that is established by the Awarding Components of the Public Health Service and certain other Federal agencies under federal law.

Policy

Vitalant shall inform each Investigator of the Institution's policy on financial conflicts of interest, the Investigator's responsibilities regarding disclosure of significant financial interests, and of these regulations, and require each Investigator to complete training prior to engaging in research related to any PHS-funded grant or contract and at least every four years, and immediately when any of the following circumstances apply:

- Vitalant revises its financial conflict of interest policies or procedures in any manner that affects the requirements of Investigators;
- An Investigator is new to the Institution; or
- The Institution finds that an Investigator is not in compliance with the Institution's financial conflict of interest policy or management plan.

Vitalant shall:

- Require that each Investigator who is planning to participate in the PHS-funded research disclose to the Administrative Director the Investigator's significant financial interests (and those of the Investigator's spouse and dependent children) no later than the time of application for PHS-funded research.
- Require each Investigator who is participating in the PHS-funded research to submit an updated disclosure of significant financial interests at least annually, in accordance with the specific time period prescribed by the Institution, during the period of the award. Such disclosure shall include any information that was not disclosed initially to the Institution pursuant to this section, or in a subsequent disclosure of significant financial interests (e.g., any financial conflict of interest identified on a PHS-funded project that was transferred from another Institution), and shall include updated information regarding any previously disclosed significant financial interest (e.g., the updated value of a previously disclosed equity interest).
- Require each Investigator who is participating in the PHS-funded research to submit an updated disclosure of significant financial interests within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest.

Investigators have an ongoing obligation to disclose Significant Financial Interests throughout the awarded project period.

- If Vitalant carries out the PHS-funded research through a subrecipient (e.g., subcontractors or consortium members) awardee Institution will take reasonable steps to ensure that any subrecipient Investigator complies with federal regulations by:
- (1) Incorporating as part of a written agreement with the subrecipient terms that establish whether the financial conflicts of interest policy of the awardee Institution or that of the subrecipient will apply to the subrecipient's Investigators.
 - If the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the subrecipient shall certify as part of the agreement referenced above that its policy complies with federal regulations. If the subrecipient cannot provide such certification, the agreement shall state that subrecipient Investigators are subject to the financial conflicts of interest policy of the awardee Institution for disclosing significant financial interests that are directly related to the subrecipient's work for the awardee Institution;
 - Additionally, if the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the agreement referenced above shall specify time period(s) for the subrecipient to report all identified financial conflicts of interest to the awardee Institution. Such time period(s) shall be sufficient to enable the awardee Institution to provide timely FCOI reports, as necessary, to the PHS as required by federal regulations;
 - Alternatively, if the subrecipient's Investigators must comply with the awardee Institution's financial conflicts of interest policy, the agreement referenced above shall

specify time period(s) for the subrecipient to submit all Investigator disclosures of significant financial interests to the awardee Institution. Such time period(s) shall be sufficient to enable the awardee Institution to comply timely with its review, management, and reporting obligations under federal regulations.

- (2) Providing FCOI reports to the PHS Awarding Component regarding all financial conflicts of interest of all subrecipient Investigators. i.e., prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.
- (3) Vitalant shall provide initial and ongoing FCOI reports to the PHS as required by federal regulations.

Management of Conflicting Interests

The Administrative Director shall review all disclosures of significant financial interests and determine with assistance from General Counsel whether an Investigator's significant financial interest is related to PHS-funded research and, if so related, whether the significant financial interest is a financial conflict of interest. An Investigator's significant financial interest is related to PHS-funded research when the Administrative Director reasonably determines 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. A financial conflict of interest exists when the Administrative Director reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

- Prior to the Institution's expenditure of any funds under a PHS-funded research project, the Administrative Director shall review all Investigator disclosures of significant financial interests; determine whether any significant financial interests relate to PHS-funded research; determine whether a financial conflict of interest exists; and, if so, develop and implement a management plan that shall specify the actions that have been, and shall be, taken to manage such financial conflict of interest
- Examples of conditions or restrictions that might be imposed to manage a financial conflict of interest include, but are not limited to:
 - Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research)
 - For research project involving human subjects research, disclosure of financial conflicts of interest directly to participants
 - Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest
 - Modification of the research plan
 - Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research

- Reduction or elimination of the financial interest (e.g., sale of an equity interest)
- Severance of relationships that create financial conflicts
- Whenever, in the course of an ongoing PHS-funded research project, an Investigator who is new to participating in the research project discloses a significant financial interest or an existing Investigator discloses a new significant financial interest to Vitalant, the Administrative Director shall, within sixty (60) days: review the disclosure of the significant financial interest; determine whether it is related to PHS-funded research; determine whether a financial conflict of interest exists; and, if so, implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest. Depending on the nature of the significant financial interest, Vitalant may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded research project between the date of disclosure and the completion of the Institution's review.
- Whenever Vitalant identifies a significant financial interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by Vitalant during an ongoing PHS-funded research project (e.g., was not timely reviewed or reported by a subrecipient), the Administrative Director shall, within sixty (60) days: review the significant financial interest; determine whether it is related to PHS-funded research; determine whether a financial conflict of interest exists; and, if so implement, on at least an interim basis, a management plan that shall specify the actions that have been taken to manage the financial conflict of interest going forward. In addition, the Institution shall within 120 days, complete a retrospective review of the Investigator's activities and the PHS-funded research project, as required by federal regulations.
- Prior to Vitalant's expenditure of any funds under a PHS-funded research project, Vitalant shall provide to the PHS Awarding Component an FCOI report regarding any Investigator's significant financial interest found to be conflicting and implement a management plan.
- For any significant financial interest that Vitalant identifies as conflicting subsequent to the initial FCOI report during an ongoing PHS-funded research project (e.g., upon the participation of an Investigator who is new to the research project), Vitalant shall provide to the PHS Awarding Component, within sixty (60) days, an FCOI report regarding the financial conflict of interest and implement a management plan. Where such FCOI report involves a significant financial interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed or managed by Vitalant (e.g., was not timely reviewed or reported by a subrecipient), Vitalant shall complete a retrospective review to determine whether any PHS-funded research, or portion thereof, conducted prior to the identification and management of the financial conflict of interest was biased in the design, conduct, or reporting of such research. Additionally, if bias is found, Vitalant shall notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component.

- For any financial conflict of interest previously reported by Vitalant with regard to an ongoing PHS-funded research project, Vitalant shall provide to the PHS Awarding Component an annual FCOI report that addresses the status of the financial conflict of interest and any changes to the management plan for the duration of the PHS-funded research project. The annual FCOI report shall specify whether the financial conflict is still being managed or explain why the financial conflict of interest no longer exists. Vitalant shall provide annual FCOI reports to the PHS Awarding Component for the duration of the project period (including extensions with or without funds) in the time and manner specified by the PHS Awarding Component.

Reminders and Acceptance

The Administrative Director shall send this Policy to each Investigator annually. Upon receipt of the Policy, each Investigator shall send to the Administrative Director an acknowledgement that the Investigator:

- Has received a copy of the Policy
- Understands the Policy
- Agrees to comply with the Policy, and
- Provides a written report of financial conflicts of interest required by the Policy or a statement that no financial conflicts of interest exist under the Policy

Records

Records of all financial disclosures and all actions taken by the Institution with respect to each conflict of interest shall be maintained for at least three (3) years from the date of submission of the final expenditures report to HHS.

Public Accessibility

Vitalant shall post this FCOI policy on their publicly available website: www.research.vitalant.org. In addition, Vitalant shall make publicly available information concerning FCOIs held by senior/key personnel as defined above in accordance with applicable federal regulations.