

West Virginia University Public Health Service-Specific Financial Conflict of Interest Policy

I. Introduction

This policy promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under Public Health Service (PHS) grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest (FCOI). As an institution applying for and receiving PHS research funding, the West Virginia University (“University” or “WVU”) applies this policy to each Investigator who is planning to participate in, or is participating in, such research. This policy does not apply to SBIR Program Phase I applications.

II. Definitions

As used in this policy:

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

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 the University'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.

Institutional responsibilities means an Investigator's professional responsibilities on behalf of the University.

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.

Manage means taking action to address an FCOI, which can include reducing or eliminating the FCOI, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

PD/PI means a project director or principal Investigator of a PHS-funded research project; the PD/PI is included in the definitions of senior/key personnel and Investigator under this policy.

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 policy.

Research means 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 published article, book or book chapter) and product development (e.g., a diagnostic test or drug). As used in this policy, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act 42 U.S.C. 201 et seq 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 PD/PI and any other person identified as senior/key personnel by the University in the grant application, progress report, or any other report submitted to the PHS by the University under this policy.

Significant financial interest means:

1. A financial interest, foreign or domestic, 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 reasonably appears to be related to the Investigator's *institutional responsibilities* performed on behalf of the University:

- a. 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;
- b. 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, domestic partner, or dependent children) holds **any** equity interest (e.g., stock, stock option, or other ownership interest); or
- c. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- d. Reimbursed or Sponsored Travel: 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 institutional responsibilities; 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 Institution's FCOI policy will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with the Institution's FCOI policy, the institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.

2. The term significant financial interest does not include the following types of financial interests: salary, royalties, or other remuneration paid by the University to Investigators currently employed or otherwise appointed by the University, including intellectual property rights assigned to the University and agreements to share in royalties related to such rights; 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; 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 as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with a United States institution of higher education; or 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 as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with a United States 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 Public Law 97-219, the Small Business Innovation Development Act, as amended. For purposes of this policy, the term SBIR Program also includes the Small Business Technology Transfer (STTR) Program, which was established by Public Law 102-564.

III. Responsibilities of Investigators

Each Investigator who is planning to participate in PHS-funded research must disclose to the University's designated officials, as outlined in the Policy for the Identification and Management of Conflicts of Interest in Research, Sponsored Projects, and Technology Transfer, the Investigator's significant financial interests, both foreign and domestic (and those of the Investigator's spouse, domestic partner, and dependent children) no later than the time of application for PHS-funded research.

Each Investigator who is participating in PHS-funded research must submit an updated disclosure of significant financial interests, both foreign and domestic, at least annually during the period of the award. Such disclosure shall include any information that was not disclosed initially to the University, 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).

Each Investigator who is participating in PHS-funded research must submit an updated disclosure of significant financial interests, both foreign and domestic, within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest.

Each Investigator must complete training regarding this policy, the Investigator's responsibilities regarding disclosure of significant financial interests, and 42 CFR Part 50 Subpart F. This training must be completed prior to engaging in research related to any PHS-funded grant, at least annually, and immediately when any of the following circumstances apply:

1. The University revises this policy or procedures in any manner that affects the requirements of Investigators;
2. An Investigator is new to the University; or
3. The University finds that an Investigator is not in compliance with this policy or management plan.

IV. **Responsibilities of the University regarding Investigator financial conflicts of interest**

The University maintains this up-to-date, written, enforced policy on financial conflicts of interest that complies with 42 CFR Part 50 Subpart F and makes this policy available via a publicly accessible website.

The University informs each Investigator of this policy on financial conflicts of interest, the Investigator's responsibilities regarding disclosure of significant financial interests, and of the regulations under 42 CFR Part 50 Subpart F. The University designates the University's Conflict of Interest Offices and Committees as "designated official(s)" to solicit and review disclosures of significant financial interests from each Investigator who is planning to participate in, or is participating in, the PHS-funded research. The designated official(s) are responsible for maintaining guidelines consistent with 42 CFR Part 50 Subpart F to determine 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 designated official(s) reasonably determine 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 designated official(s) reasonably determine that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

The University takes such actions as necessary to manage financial conflicts of interest, including any financial conflicts of a subrecipient Investigator. Management of an identified financial conflict of interest requires development and implementation of a management plan and, if necessary, a retrospective review and a mitigation report pursuant to 42 CFR Part 50 Subpart F, § 50.605(a).

The University provides initial and ongoing FCOI reports regarding identified FCOIs to the PHS Awarding Component within the timeframe prescribed by 42 CFR Part 50 Subpart F.

The University takes reasonable steps to ensure that any subrecipient Investigator of PHS funded research complies with 42 CFR Part 50 Subpart F by:

1. Incorporating as part of a written agreement with the subrecipient terms that establish whether the financial conflicts of interest policy of the University or that of the subrecipient will apply to the subrecipient's Investigators.

a. 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 42 CFR Part 50 Subpart F. If the subrecipient cannot provide such certification, the agreement shall state that subrecipient Investigators are subject to this policy for disclosing significant financial interests that are directly related to the subrecipient's work for the University;

b. 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 University. Such time period(s) shall be sufficient to enable the University to provide timely FCOI reports, as necessary, to the PHS as required by 42 CFR Part 50 Subpart F;

c. Alternatively, if the subrecipient's Investigators must comply with this policy, the agreement referenced above shall specify time period(s) for the subrecipient to submit all Investigator disclosures of significant financial interests to the University. Such time period(s) shall be sufficient to enable the University to comply timely with its review, management, and reporting obligations under 42 CFR Part 50 Subpart F.

2. Providing FCOI reports to the PHS Awarding Component regarding all financial conflicts of interest of all subrecipient Investigators consistent with this subpart, i.e., prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.

The University maintains records relating to all Investigator disclosures of financial interests and the University's review of, and response to, such disclosures (whether or not a disclosure resulted in the University's determination of a financial conflict of interest) and all actions under this policy or retrospective review, if applicable, for at least three years from the date the final expenditures report is submitted to the PHS or, where applicable, from other dates specified in 2 CFR 200.334 for different situations.

The University has established adequate enforcement mechanisms and provides for employee sanctions or other administrative actions to ensure Investigator compliance as appropriate.

The University certifies, in each application for funding to which this policy applies, that the University:

1. Has in effect an up-to-date, written, and enforced administrative process to identify and manage financial conflicts of interest with respect to all research projects for which funding is sought or received from the PHS;
2. Shall promote and enforce Investigator compliance with the requirements under 42 CFR Part 50 Subpart F, including those pertaining to disclosure of significant financial interests;
3. Shall manage financial conflicts of interest and provide initial and ongoing FCOI reports to the PHS Awarding Component consistent with 42 CFR Part 50 Subpart F;
4. Agrees to make information available, promptly upon request, to the HHS relating to any Investigator disclosure of financial interests and the University's review of, and response to, such disclosure, whether or not the disclosure resulted in the University's determination of a financial conflict of interest; and
5. Shall fully comply with the requirements of 42 CFR Part 50 Subpart F.

V. **Management of financial conflicts of interest**

Prior to the University's expenditure of any funds under a PHS-funded research project, the designated official(s) of the University shall, consistent with 42 CFR Part 50 Subpart F, § 50.604(f): 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 specifies 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:

1. Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research,

2. Disclose to research personnel working on the study, to the Institution Review Board, Institutional Animal Care and Use Committee, Data and Safety Monitoring Board, etc.);
3. For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
4. 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;
5. Modification of the research plan;
6. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
7. Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
8. Severance of relationships that create financial conflicts.

Noncompliance Requirements

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 the University, the designated official(s) of the University shall, within 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, the University 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 University's review.

Whenever the University identifies a significant financial interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by the University during an ongoing PHS-funded research project (e.g., was not timely reviewed or reported by a subrecipient), the designated official(s) shall, within 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:

1. Complete a retrospective review within 120 days, as further described in Section VII, below, and
2. 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 going forward.

Whenever the University implements a management plan pursuant to this policy, the University shall monitor Investigator compliance with the management plan on an ongoing basis until the completion of the PHS-funded research project.

In addition to the types of financial conflicts of interest as defined in this policy that must be managed pursuant to this section, the University may require the management of other financial conflicts of interest, as the University deems appropriate.

VI. **Reporting of Financial Conflicts of Interest**

Prior to the University's expenditure of any funds under a PHS-funded research project, the University shall provide to the PHS Awarding Component an FCOI report regarding any Investigator's significant financial interest found by the University to be conflicting and ensure that the University has implemented a management plan in accordance with this policy. In cases in which the University identifies a financial conflict of interest and eliminates it prior to the expenditure of PHS-awarded funds, the University shall not submit an FCOI report to the PHS Awarding Component.

For any significant financial interest that the University identifies as conflicting subsequent to the University's 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), the University shall provide to the PHS Awarding Component, within 60 days, an FCOI report regarding the financial conflict of interest and ensure that the University has implemented a management plan in accordance with this policy. Pursuant to 42 CFR Part 50 Subpart F, paragraph (a)(3)(ii), 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 the University (e.g., was not timely reviewed or reported by a subrecipient), the University also 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, pursuant to 42 CFR Part 50 Subpart F, paragraph (a)(3)(iii), if bias is found, the

University shall notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component.

Any FCOI report shall include sufficient information to enable the PHS Awarding Component to understand the nature and extent of the financial conflict, and to assess the appropriateness of the University's management plan. Elements of the FCOI report shall include, but are not necessarily limited to the following:

1. Project number;
2. PD/PI or Contact PD/PI if a multiple PD/PI model is used;
3. Name of the Investigator with the financial conflict of interest;
4. Name of the entity with which the Investigator has a financial conflict of interest;
5. Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
6. Dollar value range of the financial interest (i.e., \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), 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;
7. A description of how the financial interest relates to the PHS-funded research and the basis for the University's determination that the financial interest conflicts with such research; and
8. A description of the key elements of the University's management plan, including:
 - a. Role and principal duties of the conflicted Investigator in the research project;
 - b. Conditions of the management plan;
 - c. How the management plan is designed to safeguard objectivity in the research project;
 - d. Confirmation of the Investigator's agreement to the management plan;

- e. How the management plan will be monitored to ensure Investigator compliance; and
- f. Other information as needed.

For any financial conflict of interest previously reported by the University with regard to an ongoing PHS-funded research project, the University 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. The University 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.

In addition to the types of financial conflicts of interest as defined in this policy that must be reported pursuant to this section, the University may require the reporting of other financial conflicts of interest as the University deems appropriate. West Virginia University Public Health Service-Specific Financial Conflict of Interest Policy

VII. **Retrospective Review**

Whenever a financial conflict of interest is not identified or managed in a timely manner including failure by the Investigator to disclose a significant financial interest that is determined by the University to constitute a financial conflict of interest; failure by the University to review or manage such a financial conflict of interest; or failure by the Investigator to comply with a financial conflict of interest management plan, the University shall, within 60 days: review the significant financial interest; determine whether it is related to PHS-funded research; determine whether a financial conflict of interest exists. If the University determines that a financial conflict of interest exists, the University shall, within 120 days of the University's determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.

The University shall document the retrospective review; such documentation shall include, but not necessarily be limited to, all of the following key elements:

1. Project number;
2. Project title;
3. PD/PI or contact PD/PI if a multiple PD/PI model is used;
4. Name of the Investigator with the FCOI;
5. Name of the entity with which the Investigator has a financial conflict of interest;
6. Reason(s) for the retrospective review;
7. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
8. Findings of the review; and
9. Conclusions of the review.

Based on the results of the retrospective review, if appropriate, the University shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the financial conflict of interest going forward. If bias is found, the University shall notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report shall include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and the University's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). Thereafter, the University will submit FCOI reports annually, as specified in this policy. Depending on the nature of the financial conflict of interest, the University may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded research project between the date that the financial conflict of interest or the Investigator's noncompliance is determined and the completion of the University's retrospective review.

VIII. Public Accessibility of FCOI Information

Prior to the University's expenditure of any funds under a PHS-funded research project, the University shall ensure public accessibility, via written response to any requestor within five business days of a request to

COI@mail.wvu.edu, of information concerning any significant financial interest disclosed to the University that meets the following three criteria:

1. The significant financial interest was disclosed and is still held by the senior/key personnel as defined by this subpart;
2. The University determines that the significant financial interest is related to the PHS funded research; and
3. The University determines that the significant financial interest is a financial conflict of interest.

The information that the University makes available via written response to any requestor within five business days of a request, shall include, at a minimum, the following:

1. The Investigator's name;
2. The Investigator's title and role with respect to the research project;
3. The name of the entity in which the significant financial interest is held;
4. The nature of the significant financial interest; and
5. The approximate dollar value range of the significant financial interest (i.e., \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), 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.

When responding to written requests, the University will note in its written response that the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within 60 days of the University's identification of a new financial conflict of interest, which should be requested subsequently by the requestor.

Information concerning the significant financial interests of Investigators shall remain available for at least three years from the date that the information was most recently updated.

IX. Remedies

If the failure of an Investigator to comply with either the University's financial conflicts of interest policy or with a financial conflict of interest management plan

appears to have biased the design, conduct, or reporting of the PHS-funded research, the University shall promptly notify the PHS Awarding Component of the corrective action taken or to be taken.

The University shall comply with inquiries from the PHS Awarding Component and/or HHS at any time before, during, or after award into any Investigator disclosure of financial interests and the University's review (including any retrospective review) of, and response to, such disclosure, regardless of whether the disclosure resulted in the University's determination of a financial conflict of interest. The University shall submit, or permit on-site review of, all records pertinent to compliance with this policy.

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 the University as required by 42 CFR Part 50 Subpart F, the University 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.

X. Resources

[NIH FCOI Training](#)

Public/external requests for PHS FCOI information must be sent to:
COI@mail.wvu.edu