



Financial Conflict of Interest Policy

Wabanaki Public Health and Wellness (WPHW) is dedicated to the objectivity of its research-related activities. The responsibility to manage financial conflicts of interest (FCOI) are important in ensuring the objectivity and compliance with federal regulations and Wabanaki policies.

Purpose

Wabanaki Public Health and Wellness wants to achieve objectivity in research by establishing standards to provide assurance that the design, conduct, and reporting of research funded under Public Health Service (PHS) grants or cooperative agreements shall be free of bias from Investigator financial conflicts of interest. Procedures described in this policy are to comply with the federal PHS requirements for institutions that seed funding. This Policy was developed to be in conformance with Federal regulation 42 CFR Part 50 Subpart F (Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought) and 45 CFR Part 94 (Responsible Prospective Contractors) and to fulfil WPHW's obligation under the FCOI regulations to maintain up to date, written, enforced policy and processes on Investigator conflicts of interest.

Application of Policy

This Policy applies to all Investigators, including subrecipient investigators (sub-grantees, subcontractors, collaborators, contractors, or consultants) and applicable research staff and contractors who are planning to participate in or are participating in PHS funded research. Compliance with this Policy is a condition of employment and/or relationship with WPHW. All Investigators planning to or participating in PHS-funded research are required to disclose to WPHW, his/her known significant financial interests (and those of his/her spouse and dependent children) that reasonably appear to be related to the Investigator's institutional responsibilities.

Definitions

For purposes of this Policy, the following definitions shall apply:

Financial Conflict of Interest exists when the recipient's designated official(s) reasonably determines that an investigator's significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research. See 42 CFR 50, Subpart F, Responsibility of Applicants for Promoting Objectivity in Research for which PHS funding is sought and Public Policy Requirements and Objectives.

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.

Institutional or Designated Official(s) is the person or persons appointed by WPHW to review the all SFI's that is related to the PHS/NIH-funded research. The designated official is to determine if the SFI could directly and significantly affect the design, conduct or reporting of the PHS/NIH-funded research. It is also the responsibility of the Institutional Official to inform Investigators their obligations under this policy.

Investigator means the project director or principal investigator (PD/PI) and any other person, including senior/key personnel, who are responsible for the design, conduct, or reporting of the research or proposed research, which may include, for example, collaborators, consultants or other Investigators.

Research means a systematic investigation, study, or experiment designed to develop or contribute to 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). For PHS-Funded Research, 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.

Significant Financial Interest (SFI) means a financial interest consisting of one or more of the following interests of the Investigator's - or other employee's immediate family (i.e., spouse and dependent children) which reasonably appear to be related to the Investigator's WPHW project responsibilities, including:

- **Publicly Traded Entities** - Regarding 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 options, or other ownership interests as determined through reference to public prices or other reasonable measures of fair market value.
- **Privately Held Entities** - Regarding any non-publicly traded entity, a financial interest consisting of any remuneration received from the entity in the 12 months preceding the disclosure, in which the value when aggregated exceeds \$5,000, or when the Investigator or his/her immediate family holds any equity interest (e.g., stock, stock option, or other ownership interest); or
- **Intellectual Property** - Intellectual property rights and interests (e.g., patents, copyrights), must be disclosed upon receipt of income (e.g., royalties) related to such rights and interests.
- **Sponsored/Reimbursed Travel** that meets the following criteria:



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- travel **within the United States** received from a U.S. entity that when aggregated exceeds \$5,000.

Note: Disclosure is not required for Sponsored/Reimbursed Travel stemming from a U.S. federal, state, or local government agency, a U.S. institution of higher education as defined in 20 U.S.C. 1001(a), a U.S. academic teaching hospital, a U.S. medical center, or a U.S. research institute that is affiliated with a U.S. institution of higher education.

- travel **outside the United States** received from a U.S. or foreign entity* regardless of dollar amount.

*Foreign entities include, but are not limited to, those stemming from a foreign company or government, including local, provincial or equivalent governments, government agencies, institutions of higher education, academic teaching hospitals, medical centers, or research institutes that are affiliated with an institution of higher education.

Significant financial interest does not include the following:

- Salary, royalties, or other remuneration paid by WPHW (or a subrecipient as applicable) to the Investigator if the Investigator is currently employed or otherwise appointed by WPHW, including that paid for intellectual property rights assigned or licensed to WPHW and agreements to share in royalties related to such rights;
- Any ownership interest in WPHW (or a subrecipient as applicable) held by the Investigator (e.g., Employee Stock Ownership Plan);
- Income from investment vehicles, such as mutual funds and retirement accounts, if 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; 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.

Investigator Training Requirements*

Each investigator for the purpose of objectivity in the research, shall be informed of this WPHW policy, along with the responsibilities written within said policy regarding the disclosure of significant financial interest relating to the investigator's responsibilities to the organization and the FCOI regulations. All Investigator's being funded by PHS source are required under this policy to undergo training requirements set forth by NIH as follows.

- Prior to engaging in research related to any PHS/NIH grant



- Training must be complete once every four (4) years at the least
- Immediately, if:
 - WPHW revises its FCOI policy, affecting the requirements of the Investigator
 - Investigator is new with WPHW
 - Investigator is not in compliance with the policy or management plan

*NIH has developed a training module and other resources that can be accessed through the NIH website. (https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html)

Disclosure, Review, and Monitoring

Requires each Investigator to disclose their SFI (and those of the Investigator's spouse and dependent children) related to the Investigator's organizational responsibilities. If the SFI meets or exceeds the regulatory definition of SFI as described within this policy, then the following applies:

- No later than at the time of application for PHS/NIH-funded research.
- At least annually during the period of the award
- Within thirty days of discovery or acquisitions of a new SFI

The Institutional official(s) appointed by WPHW shall:

- Solicit and review disclosures of the Investigator's SFI and determine whether the SFI is an FCOI.
- Develop and implement adequate management plans to manage FCOIs and take appropriate action as needed per this policy.
- Be responsible for ensuring the Investigators for subrecipients, such as subgrantees, subcontractors, or collaborators are informed of this policy and fully comply or provide WPHW with sufficient assurance of their own FCOI policy.
- Take such actions as necessary to manage FCOIs, including any financial conflicts of a subrecipient Investigator, if applicable, and monitor Investigator compliance with management plans until completion of the project.

Management of FCOI, Reporting, & Maintenance of Records

The management plan (created by the designated official) will include appropriate steps to manage, reduce, or eliminate the conflict of interest to ensure, to the extent possible, that the design, conduct and reporting of research will be free from bias.

- Will submit initial, annual, and revised FCOI reports to the PHS Awarding Component per the FCOI management plan.
- Provide FCOI reports to the PHS awarding component of all FCOIs for all Investigator's including subrecipients, within 60 days of the disclosure or discovery of a significant financial interest



- Notify NIH promptly if bias is found with the design, conduct or reporting of PHS/NIH-funded research and include the requirement to submit a Mitigation Report to explain what action(s) have been or will be taken to mitigate the effects of the bias in accordance with the regulation.
- The policy and/or procedures includes all reporting elements (e.g., entity name, name of the investigator with the FCOI, nature of SFI(s), value of the SFI(s), etc.) as required by the regulation.
- Maintain records of all disclosures of financial interests and WPHW's review of, and response to, such disclosures in a secured location for no less than 3 years after the end of the PHS/NIH-funding period.
- Or, where applicable, from other dates specified in 45 CFR 75.361 for different situations.

Enforcement Mechanisms, Remedies, and Noncompliance

Establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance (e.g., letters of reprimand, restriction on the use of funds, etc.). Complete a retrospective review within 120 days of the Institution's determination of noncompliance when an SFI is not disclosed timely or previously reviewed or whenever an FCOI is not identified or managed in a timely manner, including:

- Investigator fails to disclose an SFI that is later determined that it constitutes an FCOI by the Institution.
- Institution fails to review or manage a financial conflict of interest.
- Investigator fails to comply with the FCOI management plan set forth by the designated official.

The Institutional Officer shall document all retrospective reviews must include at the very least the following information of key elements:

- Project Number
- Project Title
- PD/PI or contact PD/PI if multiple PD/PI model is used;
- Name of the Investigator with the FCOI;
- Name of the entity with which the Investigator has an FCOI;
- Reasons for the retrospective review;
- Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documentation reviewed);
- Findings of the review; and
- Conclusions of the review

Ensure that in any case in which the Department of Health and Human Services determines that a PHS/NIH-funded research 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 an FCOI that was not managed or reported by the Institution as required by the regulation, the Institution shall require the Investigator involved to:

- Disclose the FCOI in each public presentation of the results of the research.
- Request an addendum to previously published presentations if required.

For Wabanaki Public Health & Wellness employees, sanctions may include suspension or dismissal, denial of eligibility to engage in the research at issue or other appropriate penalties. Such sanctions may require giving notice of relevant information to funding agencies, professional bodies or journals, or the public. The Designated Official will determine what sanctions, if any, are to be applied.

Public Accessibility Requirements

Wabanaki Public Health & Wellness will ensure that this policy is publicly available and will be posted to the organizations website: <https://wabanakiphw.org/>. WPHW will also ensure that all information concerning FCOIs held by senior/key personnel per reg. [42 CFR 50.605\(a\)\(5\)\(i\)-\(iv\)](#) will be made publicly accessible prior to the expenditure of funds per below:

- Include the minimum elements as provided by the regulation.
- Made available within five (5) business days of a written request.
- Remain available for three (3) years from the date the information was most recently updated.

Confidentiality

Wabanaki Public Health & Wellness will, to the extent possible, protect the confidentiality of disclosures. In every instance, WPHW will endeavor to balance the privacy interests of individuals with its responsibility and obligation to identify and manage conflicts of interest. Disclosures will be available to WPHW staff only on a need-to-know basis and will not be disclosed outside of WPHW unless necessary to comply with contractual, legal, or regulatory requirements.