

WESTERN CONNECTICUT STATE UNIVERSITY FINANCIAL CONFLICT OF INTEREST IN RESEARCH POLICY

PRINCIPLES

Western Connecticut State University ("WCSU" or "Institution") is committed to the provision of exemplary graduate and undergraduate education. As an essential part of this mission, WCSU strives to facilitate high-quality research, scholarship, and public engagement by its students, faculty and staff.

PURPOSE

The Financial Conflicts of Interest in Research Policy ("Policy") promotes objectivity in research, and establishes standards to ensure that the design, conduct, and reporting of research funded by Public Health Service grants or cooperative agreements, or other extramural sponsors will not be biased by any conflicting financial interest on the part of WCSU research faculty and staff or others acting on its behalf. A financial conflict of interest can be any situation in which financial considerations have the potential to compromise a researcher's professional judgment and objectivity in the design, conduct or reporting of research. WCSU encourages research faculty and staff to engage in appropriate outside relationships, but Significant Financial Interests (as defined below) related to these relationships must be disclosed, reviewed and managed in accordance with this Policy.

WCSU has a responsibility to ensure that its teaching and research environment fosters new knowledge and positive learning opportunities for students while preserving the integrity of its research activities and the public's trust. Therefore, this Policy aims at facilitating research relationships with outside entities by increasing transparency and accountability so that WCSU research faculty, and staff and others acting on its behalf avoid or mitigate real or perceived financial conflicts of interest and reasonably expect that their activities and interests do not conflict with their obligations to WCSU or its mission. WCSU's Provost & Vice President for Academic Affairs is responsible for ensuring the implementation of this Policy.

SCOPE

This Policy is intended to carry out WCSU's financial conflicts of interest responsibilities related to academic affairs, research and sponsored projects covered under the Public Health Service ("PHS") Promoting Objectivity in Research, 42 CFR Part 50, Subpart F and 45 CFR Part 94, and financial conflicts of interest in other sponsor-funded research, although such cases may not be required to be reported to federal agencies. Other project sponsors may impose financial conflict of interest regulatory or contractual requirements. To the extent such requirements apply to specific instances of financial conflict of interest and are inconsistent with this Policy, WCSU will comply with the applicable regulatory or contractual requirements. For the avoidance of doubt, this Policy is intended to complement, not supersede, any existing Connecticut State Colleges and Universities Board of Regents policies, WCSU policies covering other business practices, or the laws outlined for state employees under Connecticut General Statutes §1-84 ("Prohibited Activities").

REQUIREMENTS

This document relates to the following, as mandated by federal policies and stipulations:

- I. Definitions
- II. Training Requirements

- III. Disclosure, Review, and Monitoring Requirements
- IV. Reporting Requirements to NIH and NSF
- V. Maintenance of Records
- VI. Sub-recipient Requirements
- VII. Enforcement Mechanisms and Remedies and Noncompliance
- VIII. Public Accessibility

I. DEFINITIONS The term “Institution” is used interchangeably with “WCSU”:

Designated Official means the person to whom SFIs are initially disclosed, and who is responsible for carrying out the initial review of SFIs in order to develop a Management Plan in coordination with the disclosing Investigator. WCSU hereby designates the Director of Sponsored Programs and Research as its Designated Official.

Entity means any domestic or foreign, public or private organization (excluding a federal agency) from which an Investigator (and spouse and/or dependent children) receives remuneration, or in which any person has an ownership or equity interest.

Equity Interest means any stock, stock option, or otherwise ownership interest as determined through reference to public prices, or other reasonable measures of fair market value.

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

Financial Conflict of Interest (“FCOI”) means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS- or other sponsor-funded research.

Financial Conflict of Interest (“FCOI”) Report means WCSU's report of a financial conflict of interest to a PHS Awarding Component.

Institutional Official means the person with university-wide authority who shall be responsible for carrying out final review and acceptance or rejection of the Management Plan developed by the Designated Official and the Investigator. WCSU hereby designates its Provost & Vice President for Academic Affairs as the acting Institutional Official.

Institutional Responsibilities means an Investigator's professional responsibilities on behalf of WCSU, and as defined by WCSU in its Policy on Financial Conflicts of Interest, which may include activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as the Institutional Review Board.

Intellectual Property Rights and Interests means income related to rights and interests by the Investigator and/or the Investigator's spouse and dependents to patents, copyrights, trademarks, trade secrets, inventions or discoveries from the research.

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 PHS- or other sponsor-funded research, or proposed for such funding, which may include, for example, collaborators or consultants.

Management Plan means a plan developed by an Investigator, in coordination with a Designated Official, which outlines the steps that must occur on the part of the Investigator and/or WCSU to manage, to the extent possible, or eliminate a potential FCOI so that the design, conduct, and reporting of PHS- or other sponsor-funded research will be free from bias.

NSF means the National Science Foundation.

PHS means the Public Health Service of the US Department of Health and Human Services (HHS), including the following Awarding Components that fund the research subject to this Policy:

Agency for Healthcare Research and Quality (AHRQ)
Centers for Disease Control and Prevention (CDC)
Health Resources and Services Administration (HRSA)
Indian Health Services (IHS)
National Institutes of Health (NIH)
Substance Abuse and Mental Health Services Administration (SAMSHA)
Agency for Toxic Substances and Disease Registry (ATSDR)
Office of the Assistant Secretary for Health
Office of Global Affairs
Office of the Assistant Secretary for Preparedness and Response

Research means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge. 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 federal or other sponsor research funding is available from an awarding component through a grant, cooperative agreement, MOA or MOU, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

Significant Financial Interest (SFI) is defined as:

- a. For **PHS** and all sponsors following the PHS FCOI Regulations – A financial interest 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:
 - i. With regard to any *publicly traded entity*, a significant financial interest exists if the value of any remuneration received from this 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;
 - ii. With regard to any *non-publicly traded entity*, a significant financial interest exists if the value of any remuneration received from this 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) in the entity; or
 - iii. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- b. For **NSF** and all other **sponsors**:
 - i. An equity interest that, when aggregated for the investigator and the investigator's spouse/domestic partner and dependent children, meets both of the following tests: exceeds **\$10,000** in value as determined through reference to

- public prices or other reasonable measures of fair market value, and represents more than a 5% ownership interest in any single entity; or
- ii. salary, royalties or other payments that, when aggregated for the investigator and the investigator's spouse/domestic partner and dependent children, are expected to exceed **\$10,000** during the twelve-month period.
- c. Investigators must also 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 Western Connecticut State University Financial Conflict of Interest Disclosure Form specifies the details of this disclosure, which includes, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with WCSU'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.
- d. The term Significant Financial Interest **does not** include the following types of financial interests:
 - i. 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;
 - 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 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
 - iv. 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.

A **Significant Financial Interest** becomes a **Financial Conflict of Interest** if it may result in personal gain, advantage to others at the detriment of the Institution, or influence the design, conduct, and reporting of the Investigator's Research.

Sponsor means an individual company, or any entity which takes responsibility for the initiation, management, and/or financing of a research project, but which does not actually conduct the investigation.

II. Training Requirements

1. Investigators shall be informed of and will receive a copy of this Policy at the time of proposal submission for extramural funding through WCSU. Following review,

Investigators shall be asked to certify to the statement that reads as follows:

"I certify that I have reviewed WCSU policies and guidelines related to financial conflicts of interest. I understand that if I seek or receive federal or other extramural funds in support of this project, I have an obligation to adhere to applicable federal regulations and WCSU Financial Conflict of Interest Policy regarding the disclosure of financial conflicts of interest."

2. Certification is required prior to submission for administrative approval.
 - a. Investigators who are hired to an extramurally-funded project following the beginning of the grant period shall be informed of WCSU's Policy at that time.
 - b. Additional guidance concerning recognition and avoidance of FCOIs will be provided within each school to the deans and relevant administrators.
3. Investigators supported by PHS or NSF funding or other extramural or intramural funding shall complete FCOI training via the module offered through WCSU's subscription to the Collaborative Institutional Training Initiative (CITI), "Conflicts of Interest." This three-module course generates a certification, valid for four years, pertaining to Financial Conflicts of Interest, Institutional Responsibilities, and Conflicts of Commitment and Conscience. Investigators shall complete this training:
 - a. Prior to receipt of any PHS or NSF Funds; and/or
 - b. At least every four years; and/or
 - c. *Immediately*, if:
 - i. WCSU revises the Training Requirements of this Policy
 - ii. An Investigator is new to WCSU
 - iii. An Investigator is found to be not in compliance with this Policy or the FCOI Management Plan developed by WCSU.

III. Disclosure, Review and Monitoring Requirements

1. It is the responsibility of each Investigator to determine or identify the existence of a known SFI (including those of the Investigator's spouse/domestic partner and/or dependent children) that reasonably appear related to Institutional Responsibilities, and the Investigator must disclose the SFI within the following parameters:
 - a. **No later** than at the time of application for PHS- or NSF-funded research or other sponsor-funded research; and/or
 - b. **At least** annually during the period of the award; and/or
 - c. Within **thirty (30) days** of discovering or acquiring a new SFI.

If the annual disclosure updates are not received, the Investigator will be notified that the project is at risk and that WCSU is required to notify PHS or NSF, or other sponsor of noncompliance with the FCOI Policy. The Investigator's Dean will additionally be notified. Continued delay may result in the sanctions outlined in Section V below, and/or termination of the funding.

2. The Designated Official is responsible for soliciting and reviewing all disclosures of SFIs of its Investigators (including those of the Investigator's spouse/domestic partner and/or dependent children) related to an Investigator's Institutional Responsibilities. An FCOI

must be eliminated or a Management Plan agreed to before a related award will be set up. Neither the Institution nor an Investigator may expend funds unless it has been determined that no FCOI exists or that the FCOI is manageable in accordance with the terms of a Management Plan. Whenever, in the course of an ongoing PHS- or NSF-funded, or other sponsor-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 Institution; or whenever WCSU identifies a significant financial interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by WCSU during an ongoing PHS-, NSF- or other sponsor-funded research project (e.g., was not timely reviewed or reported by a sub-recipient, the Designated Official shall, within 60 days:

- a. Review all Investigator SFI disclosures;
- b. Determine if an SFI exists related to PHS- or NSF-funded or other sponsor-funded research;
- c. Determine if an SFI is an FCOI that directly and significantly affects the design, conduct, or reporting of the PHS- or NSF-funded or other sponsor-funded research; 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 FCOI(s) going forward;
- d. Provide findings to the Institutional Official (WCSU Provost & Vice President for Academic Affairs), who may consult with Office of the Legal Affairs, Office of Research Integrity (ORI), Office and/or Human Resources as needed.
- e. If the Institutional Official agrees with the Designated Official's findings in relation to an FCOI, the Designated Official will work in cooperation with the Investigator to develop and implement a Management Plan that shall specify the actions that have been and shall be taken to resolve or mitigate the FCOIs. Examples of conditions or restrictions that the Management Plan may impose include, **but are not limited to:**
 - i. public disclosure of the SFI, including disclosure on manuscripts submitted for publication, on abstracts and posters submitted for presentation, an on informed consent documents;
 - ii. disclosure of SFI directly to participants, in the case of research involving human subjects;
 - iii. disqualification from participation in all or a portion of the activities that could be affected by the FCOI;
 - iv. appointment of an independent or external monitor capable of taking measures to protect the project design, conduct, and reporting of the research;
 - v. monitoring of involvement of students and postdoctoral appointees by independent reviewers or oversight committees;
 - vi. modification of the research plan; change of personnel or responsibilities;
 - vii. divestiture of the SFI; or
 - viii. severance of the relationship(s) that creates actual or potential SFIs.
- f. If an Investigator disagrees with the Management Plan, the Investigator may appeal in writing to the Institutional Official within ten (10) days of receipt of the notification, explaining why the Management Plan conditions are inappropriate. The Institutional Official may consult with the Designated Official and, if necessary, the Office of Legal Affairs, Office of Research Integrity (ORI), Office

and/or Human Resources to determine whether a modification is feasible.

However, the decision of the Institutional Official in this matter is final.

- g. The approved Management Plan shall be incorporated into a Memorandum of Understanding (MOU) between WCSU and the Investigator that details the conditions and restrictions imposed. The MOU shall be signed by the Investigator(s) and the Institutional Official. The Designated Official shall monitor Investigator compliance with the Management Plan on an ongoing basis until the completion of the sponsor-funded research project.

IV. Reporting Requirements to NIH or NSF

1. WCSU shall provide initial, annual (i.e. ongoing) and revised FCOI Reports, including all reporting elements required by the regulation, to PHS or NSF for WCSU and its sub-recipients, if applicable:
 - a. Prior to the expenditure of funds;
 - b. Within sixty (60) days of identification for an Investigator who is newly participating in the project;
 - c. Within sixty (60) days for new, or newly identified, FCOIs for existing investigators;
 - d. At least annually (at the same time as when the Institution is required to submit the annual progress report, multi-year progress report, if applicable, or at time of extension) to provide the status of the FCOI and any changes to the Management Plan, if applicable, until completion of the project; or
 - e. Following a retrospective review to update a previously submitted FCOI Report, if appropriate.
2. WCSU shall notify PHS or its Awarding Component, promptly or upon request, if bias is found within the conduct, design or reporting of PHS-funded research, and shall submit a mitigation report in accordance with all regulations.
3. WCSU is similarly obligated to notify NSF's Office of the General Counsel appropriately if it finds that it is unable to satisfactorily manage an SFI.

V. Maintenance of Records

All records related to the implementation of this Policy (e.g., *Financial Conflict of Interest Disclosure Forms*, *Sub-recipient Disclosure Forms*, notifications to funding agencies, actions taken to resolve or mitigate FCOIs, etc.) will be maintained securely by the Designated Official for a period of at least three (3) years beyond the termination or completion of the sponsored award to which they relate, unless any litigation, claim or negotiation, audit, or other action involving the records is commenced before expiration of the three-year period, in which case, records will be retained until completion of the action and resolution of all issues involving those records, whichever is longer. FCOI records shall be subject to periodic review for compliance with this Policy by the Designated Official or by any funder per applicable regulations or contractual obligation.

VI. Sub-recipient Requirements

1. Prior to the expenditure of awarded funds, WCSU shall establish, via written agreement, whether a sub-recipient will follow the WCSU FCOI Policy as the awardee Institution or the FCOI policy of the sub-recipient. It shall be the Designated Official's responsibility to report the FCOI to the funder on the sub-recipient's behalf.
2. If the sub-recipient will follow its own FCOI policy, WCSU shall obtain certification from all sub-recipients that its FCOI policy complies with the applicable regulation. Sub-recipient(s) are required to report to WCSU identified FCOI for its Investigators within ten

(10) days of discovery to permit WCSU to report the identified FCOIs to the appropriate funder.

3. If the sub-recipient cannot provide such certification, the agreement shall state that sub-recipient Investigators are subject to the WCSU FCOI Policy for disclosing significant financial interests that are directly related to the sub-recipient's work for WCSU. WCSU shall include in its written sub-recipient agreement a requirement to solicit and review sub-recipient Investigator disclosures to directly identify, manage and report sub-recipient's identified FCOIs to the funder pursuant to this Policy.

VII. Noncompliance Enforcement Mechanisms, Retrospective Review and Remedies

1. Whenever a FCOI is not identified or managed in a timely manner including failure by the Investigator to disclose a significant financial interest that is determined by WCSU to constitute a FCOI; failure by WCSU to review or manage such a FCOI; or failure by the Investigator to comply with a FCOI Management Plan, WCSU shall, within one hundred and twenty (120) days of its determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS-, NSF-, or other sponsor-funded research project to determine whether any sponsor-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.
2. After completing the retrospective review, the Designated Official shall promptly inform PHS, NSF or other sponsor of the findings; if a bias is found, the Designated Official shall notify PHS, NSF, or other sponsor as applicable, and submit a mitigation report that includes key elements of the retrospective review, a description of the impact of the bias on the research, and WCSU's Management Plan to impose conditions or restrictions to eliminate or mitigate the bias to the extent possible in accordance with the applicable regulation or contractual obligation.
3. If an Investigator fails to comply with the Institution's FCOI policy or a Management Plan that appears to have biased the design, conduct, or reporting of funded research, WCSU shall promptly notify the affected project funder in compliance with the applicable regulation or contractual obligation. In addition, WCSU reserves the right to take corrective action for noncompliance under the disciplinary procedures established by Article 16 of the CCSU-American Association for University Professors (AAUP) Collective Bargaining Agreement or other applicable disciplinary procedures. Corrective actions may include, but are not limited to:
 - a. Written notice of reprimand
 - b. Notification to professional and/or scientific societies, funding agencies and/or professional journals
 - c. Termination of grant support
 - d. Reassignment of duties
 - e. Adjustment of salary
 - f. Adjustment of research space allocation
 - g. Suspension
 - h. Dismissal

4. Public Accessibility

This Policy shall be publically available and accessible on the WCSU website and provided to all faculty members during the internal electronic administrative approval process prior to submission for external funding consideration. Prior to expending any funds under a PHS-funded or other sponsor-funded grant or cooperative agreement, WCSU shall ensure public accessibility, via a publicly accessible website or written response to any requestor within five

(5) business days of a request, of information concerning any SFI disclosed to WCSU that meets the following three criteria:

1. The SFI was disclosed and is still held by the Investigator as defined by the applicable regulation;
2. WCSU determines that the SFI is related to the PHS- or NSF-funded research; and
3. WCSU determines that the SFI is a FCOI.

The information that WCSU posts on the website shall be updated at least annually. The website shall note that the information provided is current as of the date listed and is subject to updates, on at least an annual basis and within sixty (60) days of WCSU's identification of a new FCOI. Information concerning the SFIs shall remain available, for responses to written requests or for posting via WCSU's publicly accessible website for at least three (3) years from the date that the information was most recently updated.