

FINANCIAL CONFLICT OF INTEREST (FCOI) IN PUBLIC HEALTH SERVICES SPONSORED GRANTS

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I. POLICY OBJECTIVE

This financial conflict of interest policy (FCOI Policy) will be managed by the College of Western Idaho (CWI) employee responsible for Grant Compliance. Individuals participating in research grants, subject to 42 CFR 50 Subpart F, are required to follow the requirements of this FCOI Policy.

The purpose of this policy is to establish 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 an Investigator's financial conflicts of interest.

II. DEFINITIONS

Authorized Organization Representative (AOR): The individual that certifies CWI 's compliance with the requirements of 42 CFR 50, Subpart F.

Financial Conflict of Interest: A financial conflict of interest exists when the recipient's Grant Compliance Coordinator reasonably determines that an investigator's significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

Investigator: Any individual, including the principal investigator or any other person, regardless of title or position who is responsible for the design, conduct, or reporting of research funded by PHS, or proposed for such funding which includes collaborators, consultants or students.

PHS: 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).

Significant Financial Interest (SFI): Defined specifically in Section C below.

III. Compliance Requirements

CWI will ensure that the latest FCOI Policy will be publicly made available on the CWI website and will be updated as required by the CWI Grant Compliance Analyst (Analyst).

A. Training and Compliance of Investigators:

Every Investigator participating in a Public Health Service Grant (PHS Grant) must:

1. Be provided a copy of this FCOI Policy by the CWI Grant Compliance Coordinator prior to performing work on any relevant grant.
2. Complete training regarding financial conflicts of interest on PHS Grants and reporting requirements prior to engaging in research related to any PHS-funded grant and at least every four years, and immediately when any of the following circumstances apply:
 - a. The Institution revises its financial conflict of interest policies or procedures in any manner that affects the requirements of Investigators;
 - b. An Investigator is new to an Institution; or
 - c. An Institution finds that an Investigator is not in compliance with the Institution's financial conflict of interest policy or management plan.

Investigators will not be permitted to apply for relevant grants or participate in grants until training has been completed.

3. SFI Form: Every Investigator must complete and submit a Financial Conflict of Interest Form (SFI Form) to the Analyst prior to engaging in any PHS-funded grant research.

The SFI Form must disclose the Investigator's significant financial interests (and those of the Investigator's spouse and dependent children) and must be submitted to CWI no later than the time of application for PHS-funded research, unless an exception applies.

4. SFI Form Annual Update: Each Investigator is required submit an updated disclosure of significant financial interests at least annually (SFI Form), in accordance with the specific time period prescribed by CWI, during the period of the award of the PHS Grant. Such disclosure shall include any information that was not disclosed initially to CWI on a previous SFI Form pursuant and shall include updated information regarding any previously disclosed significant financial interest.

5. If Investigator acquires a significant financial interest during the period of the grant then the Investigator must submit an updated SFI Form to the Analyst within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest.

B. Grant Compliance Analyst (Analyst) Duties:

1. *Submission of Initial Grant Application for PHS Supported Research*

The Analyst is the Authorized Organization Representative (AOR) that signs any initial PHS Grant application that certifies CWI's compliance with the requirements of 42 CFR 50, Subpart F.

2. *Review and Submission of SFI Form*

The Analyst or a designate will collect and review disclosures of significant financial interests from each Investigator. The Analyst is responsible for submission of SFI Form to the required federal agency if it is determined a conflict of interest exists.

3. *Training Compliance*

The Analyst: (1) shall ensure all required Investigators complete training and provide any follow up training as required by pertinent federal agencies; (2) shall promote and enforce Investigator compliance with the compliance requirements including those pertaining to disclosure of significant financial interests; and (3) shall be responsible for submitting initial and ongoing SFI Forms to the NIH consistent with applicable regulations.

4. *Determination of Presence of Significant Financial Interest by Investigator*

The Analyst will review all completed SFI Forms. When an Investigator reports a significant financial interest on the SFI Form, the Analyst will review the SFI Form to determine if the significant financial interest is related to the PHS funded research, and if related, will also determine if the significant financial interest creates a conflict of interest.

C. Determination that Investigator has Significant Financial Interest Related to Research

1. All Investigators are required to complete a SFI Form to determine if the Investigator or the Investigator's spouse and dependent children have any significant financial interest as defined in Number 2 below. Investigators must complete and submit an SFI Form:

- a. No later than at the time of application for PHS-funded research
- b. At least annually during the period of the award
- c. Within 30 days of Investigator discovering or acquiring a new SFI

2. Disclosure of Significant Financial Interest: Investigators are required to complete a SFI Form disclosing any significant financial interests pursuant to the following definition below. The SFI Form will be disclosed to CWI Grant Compliance Analyst. Pursuant to 42 CFR Subpart F § 50.603 a financial interest consists 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 institutional responsibilities:

- 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 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.

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.

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, if the Institution is a commercial or for-profit organization; 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, 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.

3. The Analyst will review the completed SFI Form by submitted each Investigator. The Analyst will identify any significant financial interest noted on the SFI Form and determine if that potentially

creates a conflict of interest. The mere existence of a significant financial interest does indicate that a conflict of interest exists.

D. Management of Significant Financial Interest that Involves Conflict of Interest

1. The Analyst will review all completed SFI Forms to determine if an Investigator, the Investigator's spouse or dependent children have any significant financial interest.
2. If a significant financial interest exists then the Analyst will next determine if it is related to the PHS research. A significant financial interest is related to research if the Analyst 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. CWI may involve the Investigator in the designated official(s)'s determination of whether a significant financial interest is related to the PHS-funded research.
3. A financial conflict of interest exists when the Analyst, reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.
4. The Analyst will report the existence of a conflict of interest to the awarding agency thorough the online reporting system if CWI is a prime recipient. If CWI is a subrecipient, CWI will provide information to the awardee institution as the responsible entity for reporting to NIH. In this instance, the Analyst will not follow section E. below.

E. Reporting Requirements to NIH Regarding SFI Forms

1. The Analyst is responsible for management of an identified financial conflict of interest and development and implementation of a management plan and, if necessary, a retrospective review and a mitigation report pursuant to 42 CFR § 50.605(a).
2. Prior to CWI's expenditure of any funds under a PHS-funded research project, CWI shall provide to the awarding agency a report regarding any Investigator's significant financial interest found by CWI to be conflicting and ensure that CWI has implemented a management plan in accordance with this subpart.
3. In cases in which CWI identifies a financial conflict of interest and eliminates it prior to the expenditure of PHS-awarded funds, CWI shall not submit an FCOI report to the federal agency.
4. For any significant financial interest that CWI identifies as conflicting subsequent to the initial financial conflict of interest (FCOI) report during an ongoing PHS-funded research project (e.g., upon the participation of an Investigator who is new to the research project), CWI shall provide to federal agency, within sixty days, an FCOI report regarding the financial conflict of interest and ensure that the Institution has implemented a management plan.

5. When 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 Institution (e.g., was not timely reviewed or reported by a subrecipient), CWI 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. If bias is found, the Institution is required to notify the federal agency promptly and submit a mitigation report.
6. Elements of the FCOI report shall include, but are not necessarily limited to the following:
 - a. Project number;
 - b. PD/PI or Contact PD/PI if a multiple PD/PI model is used;
 - c. Name of the Investigator with the financial conflict of interest;
 - d. Name of the entity with which the Investigator has a financial conflict of interest;
 - e. Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
 - f. Value of the financial interest (dollar ranges are permissible: \$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;
 - g. A description of how the financial interest relates to the PHS-funded research and the basis for the Institution's determination that the financial interest conflicts with such research; and
 - h. A description of the key elements of the Institution's management plan, including:
 - i. Role and principal duties of the conflicted Investigator in the research project;
 - ii. Conditions of the management plan;
 - iii. How the management plan is designed to safeguard objectivity in the research project;
 - iv. Confirmation of the Investigator's agreement to the management plan;
 - v. How the management plan will be monitored to ensure Investigator compliance
7. For any financial conflict of interest previously reported by the Institution with regard to an ongoing PHS-funded research project, the Institution 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 Institution 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

F. Enforcement Mechanisms and Remedies Regarding Noncompliance

An Investigator's failure to properly disclose relevant financial interests or to adhere to a management plan will be considered a violation of this policy.

Alleged violations of this policy will be investigated by Compliance Coordinator, which will make recommendations for disciplinary action to the Investigator's supervisor. Breaches of policy include failure to file the necessary disclosure statements; knowingly filing incomplete, erroneous, or misleading disclosure forms; or failure to comply with procedures prescribed by the Coordinator including completion of training in timely fashion or failure to adhere to management plan.

If the Coordinator determines that this policy has been violated then disciplinary action may be pursued as well as notification of sponsor and possible termination of award; formal admonition; a letter to the Investigator's personnel file; suspension of the privilege to apply for external funding.

G. Subrecipient Requirements

If CWI carries out the PHS-funded research through a subrecipient (e.g., subcontractors or consortium members), the Institution (awardee Institution) CWI will ensure that all subrecipient Investigators comply with PHS regulations at 42 CFR 50.604 by the following:

1. Execute through a written agreement with the subrecipient terms that establish whether the financial conflicts of interest policy of CWI or that of the subrecipient will apply to the subrecipient's Investigators.
2. 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 this subpart. If the subrecipient cannot provide such certification, the agreement shall state that subrecipient Investigators are subject to the financial conflicts of interest policy of CWI for disclosing significant financial interests that are directly related to the subrecipient's work for CWI;
3. 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 CWI to comply timely with its review, management, and reporting obligations under this subpart.

H. Record Retention Requirements

CWI will maintain all FCOI-related records that meets or exceeds the regulatory requirements for at least 3 years from the date the final expenditures report is submitted to the PHS (NIH).

Disclosure of Significant Financial Interest Form for Investigators

Investigator Disclosure of Significant Financial Interests for PHS Grants

Investigators are required to answer the following questions and sign the declaration attesting to the truthfulness of their answers.

Please answer the following questions (first, see definitions above in Section C):

1. Publicly Traded Companies (remuneration and equity): Does the value of any remuneration received by you, your spouse, and/or your dependent children, from a publicly-traded company in the 12 months preceding this disclosure AND the value of any equity interest in that company held by you, your spouse, and your dependent children, when aggregated, exceed \$5,000?

If you answered “yes” to the question above: Is any such remuneration and/or interests in any way related, or appear to be related, to your institutional responsibilities?

2. Non-Publicly Traded Companies (remuneration): Does the value of any remuneration received by you, your spouse, and/or your dependent children, from a non-publicly traded company in the 12 months preceding this disclosure, when aggregated, exceed \$5,000?

If you answered “yes” to the question above: Is any such remuneration in any way related, or appear to be related, to your institutional responsibilities?

3. Non-Publicly Traded Companies (equity): Do you, your spouse, and/or your dependent children, hold or own any equity interest in a non-publicly traded company?

If you answered "yes" to the question above: Is any such interest in any way related, or appear to be related, to your institutional responsibilities?

4. Intellectual Property: Have you, your spouse, and/or your dependent children received income related to intellectual property rights and interests (e.g., patents, copyrights), other than intellectual property rights assigned to the College of Western Idaho?

If you answered "yes" to the question above: Is any such interest in any way related, or appear to be related, to your institutional responsibilities?

5. Travel: Have you, your spouse, and/or your dependent children received any sponsored or reimbursed travel related to your institutional responsibilities? Please review the definitions of sponsored and reimbursed travel in the "definitions" section above before answering this question.

Sponsored and Reimbursed Travel is EXEMPT from reporting when reimbursement is received from or travel is sponsored by a federal, state or local government agency, an institution of higher education, an academic teaching hospital, or a medical center or research institute that is affiliated with an institution of higher education WITHIN the United States of America.

All travel sponsored or reimbursed from an entity outside the United States must be reported. In addition, investigators must disclose reimbursed and sponsored travel for the previous 12 month period at the time of application for PHS sponsored funding. Have you received Sponsored or Reimbursed Travel that is not exempt and therefore must be reported?

Investigators: List all other individuals, regardless of title or position, who are in any way responsible for the design, conduct or reporting of research in which you are participating that is funded by the Public Health Service (including any related or sub-entity of PHS). Include full name and email address. Attach additional sheets, if necessary.

Training:

Conflict of Interest Training is done through CITI Program. Conflict of Interest Training was completed on _____ and expires on _____.



DECLARATION:

I, _____, declare that this declaration of financial interest and potential conflict of interest has been examined by me and to the best of my knowledge and belief is a true, correct and complete statement. I have received a copy of the federal regulations 42 CFR Part 50, and 45 CFR Part 94. I have undergone the required Conflict of Interest training from CITI Program. I am in compliance with federal conflict of interest policies and regulations. Also, I understand that the applicable policy states that failure to file this statement as required or intentionally filing a false statement may result in disciplinary action. Any changes to this statement, or new information related thereto, will be reported prior to any PHS-supported proposal submission, and at any time, on an ad hoc basis, as soon as practicable upon discovery and/or acquisition.