ICWUC CENTER FOR WORKER HEALTH
AND SAFETY EDUCATION

Financial Conflict of Interest Policy

Promoting Objectivity in Public Health Service-Funded Research
42 CFR Part 50, Subpart F

Policy owner	Center Director / designated FCOI Official
Approved by	ICWUC President
Effective date	November 1, 2026
Revision date	October 2026
Review cycle	At least annually and whenever applicable requirements change
Applies to	All Investigators planning to participate in or participating in PHS-funded research administered by the Center

1. Purpose

This policy establishes standards and administrative processes designed to provide a reasonable expectation that the design, conduct, and reporting of research funded under Public Health Service (PHS) grants or cooperative agreements are free from bias resulting from Investigator financial conflicts of interest (FCOI).

2. Scope and Applicability

This policy applies to each Investigator who is planning to participate in or is participating in PHS-funded research administered by the ICWUC Center for Worker Health and Safety Education (Center). It applies to PHS grants and cooperative agreements, including applicable NIH and NIEHS awards, but not to SBIR or STTR Phase I applications or awards.

"Investigator" is determined by responsibility for the design, conduct, or reporting of the PHS-funded research, not by title, employment status, or payment source. The term may include the project director/principal investigator, collaborators, consultants, contractors, consortium participants, and subrecipient personnel.

3. Policy Statement

- The Center will maintain, enforce, and make publicly accessible an up-to-date written FCOI policy that meets 42 CFR Part 50, Subpart F.
- Investigators must disclose Significant Financial Interests (SFIs) related to their institutional responsibilities, including applicable interests of their spouse and dependent children.
- The Center will review disclosures, determine whether an SFI is related to PHS-funded research and whether it constitutes an FCOI, manage identified FCOIs, monitor compliance, and report required information to the PHS Awarding Component.
- No expenditure of funds under a PHS-funded research project may occur until required disclosures have been submitted and reviewed and any identified FCOI has been managed, except as permitted by the applicable award and regulation.
- If this policy imposes requirements more stringent than the federal regulation, the Center will follow this policy and report identified FCOIs in accordance with its standards and federal timeframes.

4. Key Definitions

Term	Definition
Financial conflict of interest (FCOI)	An SFI that the Center, through its designated official, reasonably determines could directly and significantly affect the design, conduct, or reporting of PHS-funded research.
Financial interest	Anything of monetary value, whether the value is readily ascertainable.
Institutional responsibilities	An Investigator's professional responsibilities on behalf of the Center or the Investigator's employing/appointing institution, as defined by that institution, which may include research, consultation, teaching, professional practice, committee service, and service on review or safety-monitoring bodies.
Investigator	The PD/PI and any other person, regardless of title or position, responsible for the design, conduct, or reporting of PHS-funded research or proposed research.
Manage	Taking action to address an FCOI, including reducing or eliminating it, to ensure to the extent possible that the research is free from bias.
PHS Awarding Component	The organizational unit of the PHS that funds the research subject to this policy.
Senior/key personnel	The PD/PI and any other person identified as senior/key personnel in the application, progress report, or other report submitted to PHS.
Significant Financial Interest (SFI)	A financial interest of the Investigator, spouse, or dependent children that reasonably appears related to the Investigator's institutional responsibilities and meets the thresholds or categories below.

5. Significant Financial Interest

5.1 Interests that must be disclosed

- For a publicly traded entity: remuneration received from the entity in the 12 months preceding disclosure plus the value of any equity interest as of the disclosure date, when aggregated, exceeding $5,000.
- For a non-publicly traded entity: remuneration received in the 12 months preceding disclosure exceeding $5,000, or any equity interest, regardless of value.
- Intellectual property rights and interests, such as patents and copyrights, upon receipt of income related to those rights and interests.
- Reimbursed or sponsored travel related to institutional responsibilities, including at minimum the purpose of the trip, sponsor/organizer, destination, and duration, unless an exclusion below applies. The FCOI Official may request additional information, including monetary value.

5.2 Exclusions from SFI

- Salary, royalties, or other remuneration paid by the Investigator's current employing or appointing institution, including intellectual property rights assigned to that institution and agreements to share royalties related to those rights.
- Income from investment vehicles, including mutual funds and retirement accounts, when the Investigator does not directly control the investment decisions.

- Income from seminars, lectures, teaching engagements, advisory committees, or review panels sponsored by a U.S. federal, state, or local government agency; a U.S. institution of higher education as defined at 20 U.S.C. 1001(a); an academic teaching hospital; a medical center; or a research institute affiliated with such an institution of higher education.
- Travel reimbursed or sponsored by the excluded U.S. entities listed immediately above.
- Any ownership interest in the applicant institution held by the Investigator when the institution is a commercial or for-profit organization.

6. Investigator Disclosure Requirements

Each Investigator must submit a complete SFI disclosure, including applicable interests of the Investigator's spouse and dependent children:

- No later than the time of application for PHS-funded research;
- At least annually during the period of the award, by the date established by the Center; and
- Within 30 calendar days of discovering or acquiring a new SFI, including through purchase, marriage, inheritance, or another means.

Investigators must disclose all foreign and domestic SFIs that meet this policy. Disclosure is made to the Center, not directly to NIH/NIEHS. The FCOI Official may request clarification or supporting documentation.

7. Investigator Training

The Center will inform each Investigator of this policy, the Investigator's disclosure responsibilities, and the federal regulation. Each Investigator must complete FCOI training:

- Before engaging in research related to any PHS-funded grant or cooperative agreement;
- At least every four years thereafter; and
- Immediately when this policy is revised in a manner affecting Investigator requirements, the Investigator is new to the Center or covered project, or the Center determines that the Investigator is not in compliance with this policy or an FCOI management plan.

Annual disclosure is distinct from the federal four-year training cycle. The Center may require refresher training more frequently as an institutional control.

8. Institutional Review and Determination

The Center will designate one or more FCOI Officials to solicit and review SFI disclosures. Before expenditure of PHS funds, the FCOI Official will determine whether each disclosed SFI:

1. Is related to the PHS-funded research because the SFI could be affected by the research or is in an entity whose financial interest could be affected by the research; and
2. Could directly and significantly affect the design, conduct, or reporting of the research and therefore constitutes an FCOI.

The FCOI Official will document the review and determination. Investigators must not make the institutional FCOI determination for their own disclosures.

9. Management and Monitoring

When an FCOI is identified, the Center will develop and implement a management plan and monitor Investigator compliance on an ongoing basis until completion of the project. Management actions may include:

- Public disclosure of the FCOI, including in publications and presentations;
- Disclosure to research participants when human-subject research is involved;

- Appointment of an independent monitor;
- Modification of the research plan;
- Change of personnel or responsibilities, or disqualification from all or part of the research;
- Reduction or elimination of financial interest;
- Severance of relationships that create the conflict; and
- Other conditions appropriate to protect the objectivity of the research.

The management plan will identify the Investigator's role, the conditions imposed, how the plan safeguards objectivity, the Investigator's agreement, how compliance will be monitored, and other information required by the PHS Awarding Component.

10. Reporting to the PHS Awarding Component

The Center will submit required FCOI reports through the applicable PHS/NIH reporting system, including:

- An initial FCOI report before expenditure of funds under a PHS-funded research project when an FCOI is identified;
- For an Investigator who is new to an ongoing project, a report within 60 calendar days after an FCOI is identified;
- For a newly disclosed or newly discovered SFI during an ongoing project, a report within 60 calendar days after an FCOI is identified;
- An annual update for each previously reported FCOI for the duration of the project, addressing the status of the FCOI and any changes to the management plan, at the time and in the manner specified by the PHS Awarding Component; and
- A revised report when required following retrospective review.

Reports will contain the information required by 42 CFR 50.605(b), including the project number, PD/PI, Investigator, entity, nature and value of the financial interest, the basis for the FCOI determination, and key elements of the management plan.

11. Late Disclosures, Noncompliance, and Retrospective Review

If an SFI is not disclosed or reviewed in a timely manner, the Center will, within 60 calendar days of identifying it, review the SFI, determine whether it is related to PHS-funded research, determine whether an FCOI exists, and implement an interim management plan when needed.

When an FCOI is not identified or managed in a timely manner, including because of failure to disclose, failure of institutional review, or failure to comply with a management plan, the Center will complete and document a retrospective review of the Investigator's activities and the research project within 120 calendar days of the determination of noncompliance to determine whether the research was biased in its design, conduct, or reporting.

If bias is found, the Center will promptly notify the PHS Awarding Component and submit a mitigation report addressing the impact of the bias and the actions taken or planned to eliminate or mitigate it. The Center will also submit or revise FCOI reports as required and take appropriate corrective action.

12. Public Accessibility

The Center will post this policy on a publicly accessible website. Before expenditure of funds, the Center will also make required information concerning identified FCOIs held by senior/key personnel publicly accessible on a website or provide it in writing within five business days of a request. Public information will be updated at least annually and within 60 calendar days of identifying an FCOI for senior/key personnel newly disclosed to the Center. Posted information will remain available for at least three years from the date it was most recently updated.

13. Subrecipient Requirements

When PHS-funded research is conducted through a subrecipient, the written agreement will establish whether the subrecipient Investigator will comply with the subrecipient's FCOI policy or this policy.

- If the subrecipient relies on its own compliant policy, the agreement will certify that the policy complies with 42 CFR Part 50, Subpart F and will establish a reporting period that permits the Center to meet all PHS reporting obligations.
- If the subrecipient relies on this policy, the agreement will establish a disclosure period that permits the Center to review, manage, and report any FCOI within the required federal timeframes.

The Center will take reasonable steps to ensure subrecipient Investigator compliance and will report subrecipient FCOIs to the PHS Awarding Component as required.

14. Records Retention and Access

The Center will maintain records relating to Investigator disclosures, institutional review and response, management plans, retrospective reviews, mitigation reports, and actions under this policy for at least three years from the date the final expenditures report is submitted to PHS, or longer when required by 45 CFR 75.361, 2 CFR Part 200 as applicable to the award, litigation, audit, or another retention requirement. The Center will make records available promptly to HHS or the PHS Awarding Component upon request.

15. Enforcement and Remedies

Failure to comply with this policy or an FCOI management plan may result in corrective action consistent with applicable employment, contractual, subaward, and organizational requirements. If noncompliance appears to have biased the design, conduct, or reporting of PHS-funded research, the Center will promptly notify the PHS Awarding Component of corrective action taken or planned.

For clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, if HHS determines that the research was designed, conducted, or reported by an Investigator with an undisclosed or unmanaged FCOI, the Center will require disclosure of the FCOI in each public presentation and request an addendum to previously published presentations as directed by HHS.

16. Confidentiality

The Center will protect financial disclosure information to the extent permitted by law. Information will be shared only as needed to administer this policy, comply with public-access requirements, respond to governmental review, or meet other legal obligations.

17. Roles and Responsibilities

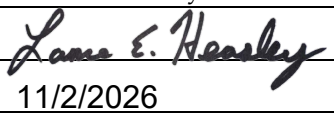
Role	Primary responsibility
Investigator	Submit complete and timely disclosures; complete training; comply with management plans; provide requested information; update disclosures within required timeframes.
FCOI Official	Solicit and review disclosures; make relatedness and FCOI determinations; develop management plans; monitor compliance; maintain records; coordinate reports and public disclosures.
Authorized Organizational Representative / Grants Office	Certify institutional compliance in applications; ensure required reports are submitted; incorporate compliant terms into subrecipient agreements; maintain award documentation.

Role	Primary responsibility
Center leadership	Approve and enforce this policy; provide adequate administrative oversight; address noncompliance and corrective action.

18. References

- 42 CFR Part 50, Subpart F, §§ 50.601–50.607
- NIH Financial Conflict of Interest Policy and Compliance Resources
- NIH FCOI Policy Development Checklist, revised June 29, 2026
- Applicable NIH Grants Policy Statement provisions
- Applicable award terms and conditions

19. Approval

Approving official	Lance E. Heasley
Signature	
Date	11/2/2026