

## Financial Conflict of Interest Policy for PHS-supported Project Directors and Principal Investigators

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## Overview

CPWR – The Center for Construction Research and Training (CPWR) is a nonprofit dedicated to reducing occupational injuries, illnesses and fatalities in the construction industry. Through our research, training, and service programs, we serve the industry nationwide by collaborating with key partners, including workers, contractors, project owners, health and safety professionals, researchers, key government agencies, unions, and associations. Created by NABTU, CPWR is a world leader in construction safety and health research and training. CPWR has instituted this financial conflict of interest (FCOI) Policy for U.S. Public Health Service (PHS)-Supported Project Directors (PD) and Principal Investigators (PI) who are supported by PHS funding. This policy is posted publicly to satisfy the requirements of the U.S. Department of Health and Human Services FCOI Regulation for PHS-funded research (42 CFR Part 50 and 45 CFR Part 94). It aims to reflect a commitment to maintaining a culture that promotes the prevention, detection and resolution of instances of fraudulent, dishonest or other wrongful conduct.

## Scope of Policy

This *FCOI Policy for PHS-supported PD/PI* specifies guidance for PHS-Investigators only.

All employees of CPWR (including management, non-exempt staff, consultants, temporary employees, interns, and others working on behalf of the organization) hereinafter known as “employees” must comply with and abide by appropriate standards of ethical conduct in carrying out their duties and responsibilities for and on behalf of CPWR.

CPWR has established this FCOI policy to satisfy the requirements of the U.S. Department of Health and Human Services FCOI Regulation for PHS-funded research (42 CFR Part 50 and 45 CFR Part 94). Consistent with these regulations, this policy aims:

- To promote objectivity and integrity in the work of CPWR and its employees;
- To ensure that CPWR employees identify, disclose, and appropriately manage or eliminate situations in which their personal or familial interests might otherwise compromise or appear to compromise their objectivity as researchers or administrators.
- To establish reasonable standards of expectation that the design, conduct, and reporting of research funded under Public Health Service (PHS) grants, cooperative agreements or contracts will be free from bias resulting from Investigator financial conflicts of interest (FCOI).

## Oversight

The CPWR Board of Directors has overall responsibility for this policy. The CPWR Associate Director of Finance & Administration serves as the Conflict of Interest Officer. It is the obligation of any PHS-supported Investigator or staff with concerns or questions about this policy to seek guidance. Questions or concerns relating to this policy should be directed to the CPWR Associate Director of Finance & Administration.

## What is a Financial Conflict of Interest (FCOI)?

Financial conflict of interest (FCOI) means a significant financial interest (SFI) that could directly and significantly affect the design, conduct, or reporting of research.

## What is a financial interest?

In general, a financial interest is anything of monetary value, related to an PHS-Investigator’s employment responsibilities, whether or not the value is readily ascertainable, in any of these categories:

- Remuneration or compensation (e.g., salary, consulting fees, per diem, honoraria, etc.) from a non-profit organization, public or private company;
- Equity (e.g., stock, stock options or other ownership interest) in a public or private company;
- Intellectual property rights (e.g., patents, copyrights), and any royalties and licensing income from such rights;
- A position in an outside entity that gives rise to a fiduciary duty, such as director, officer,

- partner, trustee, employee or any position of management;
- For Investigators with PHS funding, also any reimbursed or sponsored travel.

## What is a significant financial interest?

As per 42 CFR 50.603, the following definitions for a financial interest and significant financial interest are operational:

1. 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:
  - i. 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:
    - a. salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, per diem, paid authorship);
    - b. 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:
    - a. the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or
    - b. 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
  - iii. **Intellectual property** rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
2. 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 organizational responsibilities; provided, however, that this disclosure requirement does not apply to:
  - a. travel that is reimbursed or sponsored by a Federal, state, or local government agency,
  - b. an Institution of higher education as defined at 20 U.S.C. 1001(a),
  - c. an academic teaching hospital, a medical center, or
  - d. a research institute that is affiliated with an Institution of higher education.

CPWR'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 CPWR's FCOI policy, the Conflict of Interest Officer (or Executive Director or Board of Directors) 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 PHS-funded projects.

## What does not count as a financial interest?

As per 42 CFR 50.605(a)(1), a financial interest **DOES NOT** include:

- Salary, royalties or other remuneration paid by CPWR to the PHS-Investigator if the Investigator is currently employed or otherwise appointed/contracted to CPWR, including intellectual property rights assigned to CPWR 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 (e.g. 403b plan or target date retirement fund);
- 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.

## Who is an Investigator?

A PHS-Investigator is any person who is responsible for the design, conduct, or reporting of research funded by or proposed to the PHS, regardless of title or position.

## Requirements for PHS-Investigators to complete FCOI Training

As per 42 CFR 50.604(b), all PHS-Investigators have additional FCOI requirements including:

- Will review this policy before engaging in any PHS-funded grant, cooperative agreement or contract;
- Must undergo conflict of interest training before engaging in any PHS-funded grant, cooperative agreement or contract;
- Must undergo **conflict of interest (COI) training** every 4 years;
- Must have filed **an annual disclosure form** within the past 12 months;
- Must update their conflict of interest form within 30 (thirty) days of discovering or acquiring a new financial interest related to their Institute responsibilities;
- All Investigators of sponsored research to report financial interests **BEFORE** filing applications or proposals for funding;
- Must complete FCOI training immediately under the following circumstances:
  - o If CPWR revises its FCOI policy resulting in a change that affects Investigator requirements;
  - o An Investigator is new to CPWR;
  - o An Investigator is found to be noncompliant with the FCOI policy or management plan;
- Investigators with financial conflicts of interest must enter into a management plan before expenditures can begin.

## Disclosure, Review and Monitoring Requirements

### Investigators' Disclosure Requirements

As per 42 CFR 50.603 and 42 CFR 50.604(e)(1)-(3), Investigators are required to disclose to CPWR all of their significant financial interests (including those of the Investigator's spouse and dependent children) that reasonably appear to be related to their organizational responsibilities that meets or exceeds the regulatory definition of a significant financial interest:

- No later than at the time of application for PHS-funded programs;
- At least annually during the period of award;

- Within 30 days of discovering or acquiring a new significant financial interest (e.g., through purchase, marriage, or inheritance).

The conflicts of interest disclosure form and instructions is available from the Conflict of Interest Officer.

## Review of PHS-Investigator Disclosures

As per 42 CFR 50.604(d), PHS-Investigator disclosure forms will be reviewed by the Conflict of Interest Officer who will determine whether or not it identifies an actual or potential conflict of interest of the Investigator (including those of the Investigator's spouse and dependent children) that is related to an Investigator's institutional responsibilities and, if so, what action is required to appropriately manage the situation.

The Conflict of Interest Officer may request additional information from an employee to make these determinations. When a conflict is identified, the Conflict of Interest Officer may work with the staff to put in place and to document an appropriate conflict management plan. An employee who disagrees with the plan may seek review with the Executive Director.

## Considerations when determining whether a conflict of interest exists

CPWR recognizes that no guidelines can anticipate all situations in which a conflict of interest may exist. Guidelines have been established to aid with making these determinations and are listed below.

When reviewing a financial conflict of interest disclosure submitted by a PHS-supported investigator (including, on behalf of their spouse or dependent children):

- The determination of the existence of a significant financial interest will be based on the aggregation of all Financial Interests by the investigator (or the spouse or dependent children);
- The Conflict of Interest Officer may utilize several forms of review to reasonably determine whether an FCOI exists;
- The following financial interests may be considered to represent a conflict if they are in any way related, or appear to be related, to the investigator's institutional responsibilities at CPWR:
  - a. Any activities or business endeavors, whether paid or unpaid, that could pose a conflict with an investigator's responsibilities to CPWR;
  - b. PHS-Investigator or their immediate family members (spouse or dependent children) gives or accepts commissions, gifts, payments, entertainment, services, loans or promises of benefits from suppliers, government agencies or third parties that might influence the Investigator or the third party's decision-making or actions affecting the CPWR. However, gifts of nominal value, e.g., cookies for a holiday that can be shared, may be acceptable.
  - c. Occasional meals or social invitations that are in keeping with the highest standards of business ethics may be acceptable, as long as they do not obligate the PHS-Investigator in any way.
  - d. Receipt of remuneration from any **publicly traded entity**, received from the entity in the 12 (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:
    - i. Salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, per diem, paid authorship);
    - ii. Equity interest that includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
  - e. Receipt of remuneration from any **non-publicly traded entity** if:
    - i. The value of any remuneration received from the entity in the 12 (twelve) months

- preceding the disclosure, when aggregated, exceeds \$5,000, or
- ii. 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
- f. Receipt of income related to **intellectual property** rights and interests (e.g., patents, copyrights);
  - g. 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 an Investigator's institutional responsibilities provided, however, that this disclosure requirement does not apply to:
    - i. travel that is reimbursed or sponsored by a Federal, state, or local government agency,
    - ii. an Institution of higher education as defined at 20 U.S.C. 1001(a),
    - iii. an academic teaching hospital, a medical center, or
    - iv. a research institute that is affiliated with an Institution of higher education.
  - h. A Fiduciary role on behalf of an Outside Organization and/or equity in a privately held Outside Organization;
  - i. Equity with a value > \$50,000 or > 5% ownership in a publicly traded Outside Organization, if such entity is actively conducting or seeking to conduct business related to the research;
  - j. Intellectual property interests (not assigned to the CPWR or other Excluded Payers) if any income has been received from such Intellectual Property interest in the preceding 12 months.

## Management of Conflict of Interest

As per 42 CFR 50.604(f) and 42 CFR 50.605(a)(1), if the Conflict of Interest Officer in conjunction with the Executive Director determines that a financial conflict of interest exists relating to PHS research then:

- Submission of a conflict of interest disclosure by a PHS-Investigator shall not constitute approval for the purpose of this policy, nor be deemed to constitute compliance with any applicable provisions of this policy.
- A *Conflict Management Plan* shall be developed and implemented by the Conflict of Interest Officer;
- No PHS-Investigator having a financial conflict of interest may participate in research without prior written approval from the Executive Director;
- All financial conflict of interest reviews, including any required *Conflict Management Plan*, must be completed before any research activity begins or research expenses are incurred under an award;
- In the event the Conflict of Interest Officer concludes that a financial conflict of interest cannot be reduced, eliminated or managed, the research project may not be allowed to proceed, unless (or until) a satisfactory *Conflict Management Plan* can be implemented;
- The Conflict of Interest Officer shall confirm with the PHS-Investigator as part of the review process that the Disclosure on file is current as of the date of the conflict of interest review.

All Conflict Management Plans shall:

- Consist of measures that in the reasonable judgment of the Conflict of Interest Officer will reduce, eliminate, or manage the effects of the financial conflict of interest;
- As part of their development, the Conflict of Interest Officer may conduct factual inquiries and consult with and receive recommendations from such persons as the officer deems necessary and appropriate;
- Include terms that are consistent with all legal and regulatory requirements, and the requirements of this policy;



- May include one or more of the following:
  - a. Disclosure of financial conflict of interest, including to the public, human subjects, researchers and other participants, publishers, and conference organizers;
  - b. Monitoring or oversight of the research by independent co-researchers, reviewers, disinterested individuals, or committees;
  - c. Maintaining copies of research data with a neutral party;
  - d. Restricting participation in any activity affecting or affected by a research project;
  - e. Requiring that the significant financial conflict of interest creating the financial conflict of interest be divested, restructured, or placed in a blind trust;
  - f. Modification or severance of relationships that create or are likely to create financial conflict of interest(s);
  - g. Modifying the terms of written agreements relating to the project;
  - h. Reduction (or cessation) of the CPWR appointment/contract;
  - i. Requiring additional disclosures or actions with respect to matters before the CPWR Board of Directors;
  - j. Requiring that the PHS-Investigator not participate in any business transactions between CPWR and parties to agreements involving the research.

The above process for determining and managing FCOIs will apply to all of the following:

- Investigators who are new to participating in the research projects, as per 42 CFR 50.605(a)(2)
- An existing Investigator who discloses a new significant financial disclosure, as per 42 CFR 50.605(a)(2)
- A situation in which CPWR identifies a significant financial conflict of interest that was not disclosed in a timely manner by an Investigator, or was not previously reviewed by CPWR, in which case the process as described above will occur and a Conflict Management Plan developed within **60 (sixty) days**, as per 42 CFR 50.605(a)(3) and (I) –(iii)
- To complete and document a retrospective review within 120 days of CPWR’s determination of noncompliance for significant financial conflicts of interest not disclosed in a timely manner or previously reviewed or whenever an FCOI is not identified or managed in a timely manner and to document the reviews consistent with the regulation, pursuant to 42 CFR 50.605(a)(3).

## Management of Conflict of Interest for subrecipients

As per 42 CFR 50.604 (g), 42 CFR 50.605(a)(4), if CPWR conducts PHS-supported research or other activities through a subrecipient (e.g., subgrantees, contractors, or collaborators), CPWR will take reasonable steps to ensure compliance with 42 CFR 50.604(c), 42 CFR 42.50.604(c)(1)(1)-(iii), and NIH Grants Policy Statement 15.2.1, including:

- a. Confirming that the subrecipient has its own policies in place that meet all conflict of interest requirements of the PHS sponsor;
- b. Require via a written agreement, acknowledging whether the subrecipient will follow the FCOI policy of the awardee Institution or the FCOI policy of the subrecipient, where applicable;
- c. Obtaining a written certification from the subrecipient that stipulates:
  - i. Its FCOI policy complies with the PHS and all applicable federal regulations;
  - ii. A requirement for the subrecipient to report identified FCOIs for its PHS-Investigators to CPWR (as the awardee Institution) in a timeframe that allows CPWR to report identified FCOIs to the NIH, as required by the regulation; or
  - iii. Alternatively, if applicable, a requirement to solicit and review subrecipient Investigator

disclosures that enable CPWR (as the awardee Institution) to identify, manage and report identified FCOIs to the NIH.

## Notification to External Sponsors

CPWR will make reports to appropriate funding partners to the extent required by and in accordance with its funding agreement with the sponsor and applicable law and regulation. As stipulated in 42 CFR 50.604(h) and 42 CFR 50.605(b), such reports will be sent:

- Prior to the expenditure of funds;
- Within 60 days of identification for a PHS-Investigator who is newly participating in a research project;
- At least annually (at the same time as when CPWR 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 an applicable conflict management plan(s), if applicable, until the completion of the project;
- Following a retrospective review to update a previously submitted report, if appropriate, pursuant to 42 CFR 50.605(a)3(iii);
- If bias is found, is found with the design, conduct or reporting of NIH-funded research and will include a *Mitigation Report* in accordance with the regulation, pursuant to 42 CFR 50.605(a)3(iii).
- If an Investigator fails to comply with this financial conflict of interest policy or if a *Conflict Management Plan* appears to have biased the design, conduct, or reporting of the NIH-funded research, pursuant to 42 CFR 50.606(a).

## Maintenance of Records

Records relating to all PHS-Investigator disclosures of financial conflicts of interests and external activities, including CPWR's review of and response to such disclosures, will be maintained for at least 3 (three) years from the date the final expenditures report is submitted to the PHS or for such longer periods as prescribed in the external agreement or applicable regulations, pursuant to 42 CFR 50.604(i) and 45 CFR 75.361.

Upon authorized request of a sponsoring agency, disclosure documents and related records pertaining to the specific sponsored project will be made available to appropriate officials.

## Enforcement Mechanisms, Remedies, and Noncompliance

All staff are made aware upon their employment that violations of this policy, whether willful or through negligence, may result in discipline up to and including termination of employment, pursuant to 42 CFR 50.604(j).

The process for determining and managing FCOIs (described in "*Management of Conflict of Interest*") will apply to complete and document a retrospective review within 120 days of CPWR's determination of noncompliance for significant financial conflicts of interest not disclosed in a timely manner or previously reviewed or whenever an FCOI is not identified or managed in a timely manner and to document the reviews consistent with the regulation, pursuant to 42 CFR 50.605(a)(3).

Although CPWR does not perform clinical research, should it do so in the future and if during the course of that research a situation arises in which the Department of Health and Human Services determines that a PHS-funded project of such clinical research has been designed, conducted, or reported by an *Investigator* with a Financial Conflict of Interest that was not managed or reported by CPWR as required by this Policy, CPWR will require that the *Investigator* 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, pursuant to 42 CFR 50.606(c).

To ensure that in any case in which the Department of Health and Human Services determines that a PHS-funded research project of clinical research has been designed, conducted, or reported by an Investigator with an FCOI that was not managed or reported by CPWR as required by the regulation, CPWR shall require the Investigator involved to:



- Disclose the FCOI in each public presentation of the results of the research, and
- To request an addendum to previously published presentations.

Agreements with consultants who either fail to file a complete disclosure or fail to comply with any conditions or restrictions imposed may be terminated.

Agreements with subrecipient organizations may be terminated if that organization fails to comply with its obligations under the PHS regulations.

## Public Disclosure of Information

CPWR shall make this financial conflict of interest policy available via CPWR's publicly accessible website, pursuant to 42 CFR 50.604(a) and NPH GPS 4.1.10.

Prior to the expenditure of any funds under a PHS-funded research project, CPWR will make available, either via a publicly accessible website or by responding within five (5) days to any written request, information concerning any significant financial interest determined by CPWR to be a financial conflict of interest held by a senior Investigator (project lead, project principal, project manager, principal Investigators, co-Investigator) or any other individual who has been identified by CPWR as key personnel on the PHS-funded project.

As per 42 CFR 50.605(a)(5)(i)-(iv), the information provided on the publicly accessible site will:

- Contain at least the minimum elements as provided in the regulation, and include:
  - a. The name of the Investigator;
  - b. The Investigator's title and role with respect to the research project;
  - c. The name of the entity in which the SFI is held;
  - d. The nature of the SFI;
  - e. The approximate dollar value of the SFI or a statement that the interest is one whose value cannot be readily determined through reference to public process or other reasonable measures of fair market value;
- Be posted on a public website or made available within 5 (five) calendar days of a written request;
- Be updated, at least annually (website only but any response to a written request should include the updated information);
- Be updated, within 60 (sixty) days of a newly identified FCOI (Website only but any response to a written request should include the updated information);
- Remain available for 3 (three) years from the date the information was most recently updated.

## Definitions Applicable to PHS-Funded Research

Definitions applicable to PHS-funded research are provided by the PHS and can be accessed here:

<https://www.ecfr.gov/cgi-bin/text-idx?SID=5b1d7295959f3a0f7903573310ccf899&mc=true&node=sp42.1.50.f&rqn=div6>