

Financial Conflict of Interest Policy (FCOI)



August 7, 2024

Purpose:

Introduction: The federal Department of Health and Human Services has developed regulations (42 CFR Part 50 Subpart F and 45 CFR Part 94) on Promoting Objectivity in Research. The regulations were first developed in 1995, and in 2011, the regulations were revised. These regulations describe the actions an individual and an organization must take to promote objectivity in Public Health Service (PHS)-funded research. The regulations apply to all PHS (e.g., National Institutes of Health [NIH])-funded grants, cooperative agreements, and research contracts. This policy implements the regulatory requirements for HER FOUNDATION.

Scope: This policy applies to all personnel, including all Members and full-time, part-time, temporary, consulting, Board Officers, and contract employees of HER FOUNDATION who are participating in, or planning to participate in, the design, conduct, or reporting of Public Health Service (“PHS”) funded research and research proposals.

For federally-supported research projects involving subawardees or contractors (collectively “subrecipients”), the subrecipient HER FOUNDATIONS are required to provide written assurance that a FCOI policy is in effect that is compliant with all applicable federal regulations, or that the subrecipient will conform to and abide by HER FOUNDATION FCOI policy and procedures. Consistent with PHS regulations, this policy will be made available via a publicly accessible website. All HER FOUNDATION Investigators (that is, individuals who, regardless of position or title, are responsible for the design, conduct or reporting of PHS supported research, and Investigators seeking PHS research support) shall be informed where this policy and relevant reporting requirements may be accessed via the web. The purpose of this policy is to prevent potential bias resulting from any Financial Conflict of Interest (FCOI) by individuals who have influence in the allocations and use of



public funding in the conduct of research. This policy applies to research and initiatives funded by US Public Health Service (PHS) grants wherein HER FOUNDATION is the recipient of such funds. This policy aligns to the requirements within regulation 42 CFR Part 50-Subpart F (FCOI regulation) with the goal of promoting objectivity and transparency in research.

Responsible Parties:

The FCOI Manager will solicit and review Investigator disclosures to determine whether an Investigator's SFI related to an Investigator's institutional responsibilities is an FCOI.

The Authorized Organization Representative (AOR), when submitting a grant application, will certify the applicant HER FOUNDATION's compliance with the requirements of the FCOI Regulations.

This policy will be reviewed every 2 years.

Policy Statement:

NIH requires applicant and recipient institutions (except Phase I SBIR/STTR applicants and recipients) to comply with the requirements of 42 CFR Part 50, Subpart F, "Promoting Objectivity in Research" for which PHS funding is sought, as implemented in the 2011 Final Rule for grants and cooperative agreements.

This Financial Conflict of Interest policy (FCOI Policy) has been established to align with standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under the Public Health Service (PHS) grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest (FCOI).

This FCOI policy defines the requirements and processes for HER FOUNDATION to identify and properly manage any FCOIs. In addition, it outlines activities related to management, enforcement, and remedies for noncompliance.

DEFINITIONS

Investigator(s) include the Principal Investigator (PI)/Project Director and any other individuals, regardless of title or position, who is responsible for the design, conduct, or reporting of PHS/NIH-funded research, or proposed for such funding, and which may include for example, collaborators or consultants. This definition is not limited to titles such as senior/key personnel, PHDs, MDs, etc.

Senior/key personnel means the PD/PI and any other person identified as senior/key personnel by the HER FOUNDATION in the grant application, progress report, or any other



report submitted to the PHS/NIH by the HER FOUNDATION. This term is defined only as it relates to the public accessibility requirements described under the section labeled “PUBLIC ACCESSIBILITY REQUIREMENTS” explained below.

Research means a systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social sciences research. The term encompasses basic and applied research (e.g., a published article, book, or book chapter) and product development (e.g., a diagnostic test or drug). For PHS-Funded Research, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant, cooperative agreement, or contract, whether authorized under the PHS Act or other statutory authority.

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).

NIH means the biomedical research agency of the PHS.

Institutional responsibilities mean an Investigator's professional responsibilities on behalf of the HER FOUNDATION, and as defined by the HER FOUNDATION, including but not limited to, activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards for PHS funded research.

Financial interest means anything which has monetary value, and if the value is readily ascertainable.

A Financial Conflict of Interest (FCOI) exists when the HER FOUNDATION, through its designated official(s), reasonably determines that an Investigator's Significant Financial Interest (SFI) is related to an NIH-funded research project (i.e., the SFI could be affected by the research or the SFI is in an entity whose financial interest could be affected by the research) and could directly and significantly affect the design, conduct or reporting of the NIH-funded research.

FCOI Manager is the grant recipient's designated official for managing the FCOI process related to a specific PHS grant, reviewing SFI disclosures, making determinations of FCOI, and developing management plans. The FCOI Manager, or designee, may be assigned to submit FCOI reports to the NIH. The current FCOI Manager for HER FOUNDATION is Aimee Brecht-Doscher, MD.



Significant Financial Interest (SFI) is a financial interest consisting 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 (e.g., research, research consultation, administrative, etc.):

1) Regarding any publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.

2) Regarding 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

3) With regard to Intellectual property rights and interests (e.g., patents, copyrights), a significant financial interest exists upon receipt of income greater than \$5,000 related to such rights and interest;

4) Investigators must disclose the occurrence of any reimbursed or sponsored travel that exceeds \$5,000 (*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. The initial disclosure of reimbursed or sponsored travel must include income received over the previous twelve (12) months. The disclosure requirement does not apply to travel that is reimbursed or sponsored by:

- a Federal, state, or local government agency located in the United States
- a United States 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 a United States Institution of higher education.



The disclosure will include, at a minimum:

- the purpose of the trip,
- the identity of the sponsor/organizer,
- the destination, and
- the duration.

In accordance with this FCOI policy, the institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, 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 HER FOUNDATION to the Investigator if the Investigator is currently employed or otherwise appointed by the HER FOUNDATION, including intellectual property rights assigned to the HER FOUNDATION and agreements to share in royalties related to such rights.
- any ownership interest in the HER FOUNDATION held by the Investigator, if the HER FOUNDATION is a commercial or for-profit organization.
- income from investment vehicles, such as mutual funds and retirement accounts, if the Investigator does not directly control the investment decisions made in these vehicles.
- income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency located in the United States, a United States 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 a United States Institution of higher education; or
- income from service on advisory committees or review panels for a Federal, state, or local government agency located in the United States, an United States 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 a United States Institution of higher education.

Foreign Financial Interests and Foreign SFIs Related to the Exclusions above:

- Investigators must disclose all foreign financial interests (which includes income from seminars, lectures, or teaching engagements, income from service on advisory committees or review panels, and reimbursed or sponsored travel) received from any foreign entity, including foreign Institutions of higher education or a foreign



government (which includes local, provincial, or equivalent governments of another country) when such income meets the threshold for disclosure (e.g., income in excess of \$5,000).

Subrecipient is a subcontractor or consortium participant who may indirectly receive grant funding via the HER FOUNDATION that holds the prime contract with the US Government.

FCOI TRAINING

In compliance with federal regulations, all HER FOUNDATION Investigators who are planning to participate in or are participating in Public Health Service (PHS) funded research are required to:

- Review the HER FOUNDATION FCOI policy, which is compliant with federal regulations.
- Complete the NIH's online FCOI Training module:

https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html

- Prior to engaging in research related to any PHS/NIH-funded grant
- At least every four (4) years
- Immediately, if:
 - HER FOUNDATION revises its FCOI policy that affects requirements of investigators.
 - An Investigator is new to the HER FOUNDATION.
 - An Investigator is not in compliance with the policy or management plan.
- Understand the disclosure responsibilities of all foreign and domestic significant financial interests (SFI) per this policy.

Upon completion of the training, a certificate of completion must be sent to the FCOI Manager. Investigators should also retain a copy for their records.

DISCLOSURE, REVIEW AND MONITORING REQUIREMENTS

Disclosure

The Principal Investigator of a research project and all other individuals who meet the definition of *Investigator* must disclose their SFIs that are related to the responsibilities performed on behalf of HER FOUNDATION to the FCOI Manager. The FCOI Manager is responsible for collecting these disclosures for all Investigators:

- Not later than at the time of application for PHS-funded research



- At least annually (June 1st) during the period of award, and
- Within 30 days of discovering or acquiring a new SFI
- Within 30 days of each occurrence for reimbursed or sponsored travel

Review

HER FOUNDATION will designate an FCOI manager. Prior to expenditure of funds, the FCOI Manager will solicit and review Investigator disclosures to determine whether an SFI is related to the research and is a FCOI per the regulatory criteria explained below.

Criteria for Determining FCOI Relatedness:

An Investigator's significant financial interest is related to PHS-funded research when the FCOI Manager reasonably determines that the significant financial interest:

- could be affected by the PHS-funded research (e.g. R13 for conference funding);
or
- is in an entity whose financial interest could be affected by the research.

The FCOI Manager may involve the Investigator in making the determination of whether the SFI is related to the NIH-funded research.

Criteria for Determining if the Related SFI is an FCOI:

An Investigator's SFI is an FCOI if the SFI is related to the research *and* the FCOI Manager determines the SFI could directly and significantly affect the design, conduct or reporting of the PHS/NIH-funded research ("significantly" means that the financial interest could have a material effect on the research).

If it is determined that there is a financial conflict of interest, steps will be taken to manage the FCOI to promote objectivity regarding the design, conduct or reporting of research. The FCOI manager will develop an FCOI management plan to manage the FCOI. The plan may outline terms, conditions, and restrictions, if any, to manage the conflict.

Investigators must formally agree to the proposed management strategies. All management plans are required to be signed by the Investigator. Compliance of the management plan will be monitored by the FCOI Manager.

If the FCOI Manager determines that a conflict exists, it will communicate its determination and the means it has developed for managing the FCOI in writing to the individual, to the relevant Principal Investigator/Project Director, and to the appropriate direct supervisor. Examples of conditions or management strategies that might be imposed to manage a financial conflict of interest include, but are not limited to:



- Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research, to research personnel working on the study, to the HER FOUNDATION's Institutional Review Board, Institutional Animal Care and Use Committee, Data Safety and Monitoring Board, etc.)
- For research projects involving human subjects research, disclosure of financial conflicts of interest directly to human participants in the informed consent document
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest
- Modification of the research plan
- Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research
- Reduction or elimination of the financial interest (e.g., sale of an equity interest);
- Severance of relationships that create financial conflicts

No expenditures on an NIH award will be permitted until the Investigator has complied with the Disclosure requirements of this policy and has agreed, in writing, to comply with any plans determined by the FCOI Manager necessary to manage the Financial Conflict of Interest.

REPORTING REQUIREMENTS:

When an FCOI is identified during the period of an NIH-funded award, the assigned FCOI SO will submit an Original Report (initial report) to the NIH via the eRA Commons FCOI Module (FCOI Module).

The FCOI Manager or assigned FCOI SO in the FCOI Module is responsible for the reporting the identified FCOI to the NIH. The FCOI reports include an initial report, annual report to report on the status of the FCOI (e.g., is the FCOI being managed or does it no longer exist) (i.e., ongoing) and revised FCOI reports following a retrospective review, if applicable. The following reporting times are required:

- Prior to the expenditure of funds under a new award
- Within sixty (60) days of identifying an FCOI for an Investigator who is newly participating in the project
- Within sixty (60) days for newly identified FCOIs, for existing Investigators
- At least annually (at the same time as when the HER FOUNDATION is required to submit the annual progress report, multi-year progress report, if applicable, or at time of extension)



- A user any retrospective review, to update a previously submitted report, if new information is discovered following completion of the review, including a Mitigation report if bias is found following completion of a retrospective review.

NIH is to be notified promptly if:

- an Investigator fails to comply with this FCOI policy.
- noncompliance with an FCOI management plan appears to have biased the design, conduct, or reporting of the PHS/NIH-funded research.

MAINTENANCE OF RECORDS

Records of Investigator SFI Disclosure forms, the HER FOUNDATION's review of, or response to, such disclosure (whether or not a disclosure resulted in the HER FOUNDATION's determination of a Financial Conflict of Interest), and of actions taken to manage actual or potential FCOI, shall be retained by the FCOI Manager for

- three (3) years from the date the final expenditure report or
- where applicable, from other dates specified in 45 CFR 75.361 for different situations.

ENFORCEMENT MECHANISMS AND REMEDIES AND NONCOMPLIANCE:

Investigators are expected to comply fully and promptly with this policy. Whenever a person has violated this policy, including failure to make a required disclosure of financial interests or failure to comply with a requirement of the management plan, disciplinary proceedings may be taken against the violating individual (e.g., letters of reprimand restriction on the use of funds, etc.).

RETROSPECTIVE REVIEW REQUIREMENTS:

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 the HER FOUNDATION to constitute a Financial Conflict of Interest;
- Failure by the HER FOUNDATION to review or manage such a Financial Conflict of Interest; or
- Failure by the Investigator to comply with a Financial Conflict of Interest management plan;

the HER FOUNDATION shall, within 120 days of the HER FOUNDATION's determination of noncompliance, complete a "retrospective review" of the Investigator's activities and the NIH-funded research project to determine whether any NIH-funded research, or portion



thereof, conducted during the time period of the noncompliance was biased in the design, conduct, or reporting of such research.

The HER FOUNDATION shall document the retrospective review which must include at least the following key elements:

- Project number;
- Project title;
- PD/PI or contact PD/PI if a multiple PD/PI model is used;
- Name of the Investigator with the FCOI;
- Name of the entity with which the Investigator has a financial conflict of interest
- Reason(s) for the retrospective review;
- Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed, etc.);
- Findings of the review; and
- Conclusions of the review

If bias is found, the HER FOUNDATION must notify NIH promptly and submit a mitigation report. If the FCOI was previously reported to the NIH, the mitigation report is submitted as a “Revised FCOI Report.” The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and the HER FOUNDATION’s plan of action or actions taken to eliminate or mitigate the effect of the bias (i.e., impact on the research project, extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). Thereafter, the HER FOUNDATION will submit FCOI reports annually as prescribed by the regulation.

When bias is not found following the completion of a Retrospective Review, the recipient should not submit a “Revised” FCOI report to notify NIH that either the Retrospective Review has been completed or that bias is not found.

CLINICAL RESEARCH REQUIREMENTS:

HER FOUNDATION will ensure compliance in any case in which the Department of Health and Human Services determines that a PHS-funded *project of clinical research* whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a financial conflict of interest that was not managed or reported by HER FOUNDATION, as required by the regulation, HER FOUNDATION will require the Investigator involved to:



- disclose the financial conflict of interest in each public presentation of the results of the PHS funded research and
- to request an addendum to previously published presentations under PHS Funded research.

SUBRECIPIENT REQUIREMENTS:

When carrying out the PHS-funded research through a subrecipient (e.g., subcontractors), HER FOUNDATION shall establish a written agreement in accordance with the NIH Grants Policy Statement Section 15.1.2 (e.g., subaward contract) which confirms that the investigators of the subrecipient institution will comply with this policy or provide certification that their organization is compliant with the Federal regulation, 2011 Revised Financial Conflict of Interest Regulation, Promoting Objectivity in Research (42 CFR part 50 subpart F).

If the subrecipient's FCOI policy will apply to subrecipient Investigators, the written agreement will include time frames for the subrecipient to report identified FCOIs to HER FOUNDATION so that HER FOUNDATION can report the identified FCOI to the NIH as required by the regulation (i.e., prior to the subrecipient's expenditure of funds and within 60 days of the subrecipient's identification of an FCOI). The information reported to HER FOUNDATION must include the same information as provided in NIH's FAQ H.5. The FCOI report information will be required prior to the subrecipient's expenditure of funds under a new subaward and within 50 or 55 days following the identification of a new FCOI during the period of an award.

If HER FOUNDATION FCOI policy applies to a subrecipient institution, HER FOUNDATION will require the submission of Investigator SFI disclosures for HER FOUNDATION review and determination of FCOI in time to meet the reporting obligations of the FCOI regulation.

PUBLIC ACCESSIBILITY REQUIREMENTS:

Prior to the expenditure of any funds under an NIH award, HER FOUNDATION will ensure public accessibility by written response to any requestor within five (5) business days of a request of information concerning any SFI disclosed that meets the following three criteria:

- The SFI was disclosed and is still held by the senior/key personnel. Senior/key personnel means the PD/PI and any other person identified as senior key personnel by HER FOUNDATION in the award application, progress report, or any other report submitted to the NIH;
- HER FOUNDATION has determined that the SFI is related to the research funded through an award; and



- HER FOUNDATION has determined that the SFI is a financial conflict of interest.

The information that HER FOUNDATION will make available via a publicly accessible Web site or in a written response to any requestor within five (5) days of request will include, at a minimum, the following:

1. The Investigator's name
2. The Investigator's title and role with respect to the research project
3. The name of the entity in which the SFI is held
4. The nature of the SFI
5. The approximate dollar value of the Significant Financial Interest in the following ranges: \$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

If HER FOUNDATION uses a publicly accessible website to comply with the public disclosure requirements of the NIH regulations, the information posted will be updated at least annually and within 60 days of receipt or identification of information concerning any additional SFI of the senior/key personnel for the NIH-funded research project that had not been previously disclosed, or upon the disclosure of a Significant Financial Interest of senior/key personnel new to the NIH-funded research project, if it is determined by the designated official that the Significant Financial Interest is related to the research and is a financial conflict of interest.

FOR ADDITIONAL GUIDANCE:

<https://grants.nih.gov/faqs#/financial-conflict-of-interest.htm>

