**THE HOPE FOUNDATION**
Standard Practice Guide

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| Federal Policy Number | FP #5 |
| Subject | Financial Conflict of Interest in PHS-Funded Research (42 CFR Part 50, Subpart F) |
| Departments Affected | All; applies to every Investigator, as defined in Section III, on research funded or proposed for funding by the Public Health Service |
| Policy Owner | Chief Financial Officer, as Designated Institutional Official |
| Approved By | Board of Directors |
| Original Release Date | October 2026 |
| Revision Date | Not applicable (initial release) |
| Supersedes | Reliance on SPG #38 for PHS financial conflict of interest compliance |
| Related Documents | SPG #38 (Conflict of Interest, general); Form FCOI-1, Significant Financial Interest Disclosure; Form FCOI-2, Management Plan; Subrecipient Monitoring Policy and Procedures; Federal Grants Compliance Training Policy; SPG #41 (Records Retention) and its federal addendum |

## I. PURPOSE AND REGULATORY BASIS

This policy establishes the written, enforced administrative process by which The Hope Foundation (THF) identifies, reviews, manages, reports, and maintains records of financial conflicts of interest of Investigators engaged in research funded by the Public Health Service (PHS), including the National Institutes of Health (NIH) and the National Cancer Institute (NCI). Its purpose is to provide a reasonable expectation that the design, conduct, and reporting of PHS-funded research will be free from bias resulting from any Investigator financial conflict of interest, as required by 42 CFR 50.601.

This policy is written to satisfy each institutional responsibility in 42 CFR 50.604 and each management and reporting requirement in 42 CFR 50.605 and 50.606, as amended at 89 FR 80064 (October 2, 2024). It is supported by NIH Grants Policy Statement (GPS) Section 4.1.10 and the NIH Checklist for Policy Development Related to the FCOI Regulation (revised June 29, 2026). Where THF elects a standard more stringent than the regulation, THF adheres to its own standard and reports to NIH within the regulatory time frames, consistent with 42 CFR 50.604(a).

By signing each application for PHS funding, THF's Authorized Organizational Representative certifies, under 42 CFR 50.604(k), that THF has this policy in effect, promotes and enforces

Investigator compliance, manages financial conflicts of interest and reports them to the PHS Awarding Component, will make disclosure and review information available to HHS promptly upon request, and will fully comply with 42 CFR Part 50, Subpart F.

## II. SCOPE AND APPLICABILITY

### A. Awards Covered

This policy applies to every grant and cooperative agreement for research for which THF applies to, or receives funding from, a PHS Awarding Component, whether THF is the direct recipient or a subrecipient of another institution (42 CFR 50.602). It does not apply to Phase I SBIR or STTR applications and awards. THF applies the same disclosure, review, and management standards to research funded by non-PHS sponsors when the sponsor's terms require it or when the President and Chief Executive Officer directs.

### B. Persons Covered

This policy applies to each Investigator, as defined in Section III, who is planning to participate in, or is participating in, PHS-funded research, regardless of whether the individual is a THF employee, officer, director, consultant, contractor, or an individual working under a subaward from THF. Section XI governs how the policy reaches Investigators at subrecipient organizations.

### C. Relationship to Other THF Policies

SPG #38 governs conflicts of interest of directors, officers, and staff in THF's business and governance matters, and the disclosure of organizational conflicts to NIH under 2 CFR 200.112. SPG #38 does not substitute for this policy. Where an individual is subject to both, each policy applies according to its own terms and the more stringent requirement controls. A disclosure made under SPG #38 or under any other organization's conflict of interest policy does not satisfy this policy unless it contains every element required by Section VI and is submitted to the Designated Institutional Official on Form FCOI-1.

Conflicts of interest in the selection of contractors under THF's Procurement Policy are governed by 2 CFR 200.318(c)(1) and are outside the scope of this policy.

## III. DEFINITIONS

The following definitions are taken from 42 CFR 50.603. Where THF has added an institutional interpretation, the addition is identified.

**Designated Institutional Official (DIO).** The THF official designated under 42 CFR 50.604(d) to solicit and review Investigator disclosures of significant financial interests, make relatedness and conflict determinations, and administer this policy. Section IV identifies the DIO and the alternate.

**Financial Conflict of Interest (FCOI).** A significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research. "Significantly" means the interest would have a material effect on the research (76 FR 53256, 53261).

**Financial Interest.** Anything of monetary value, whether or not the value is readily ascertainable.

**FCOI Report.** THF's report of a financial conflict of interest to a PHS Awarding Component, submitted through the eRA Commons FCOI Module.

**Institutional Responsibilities.** An Investigator's professional responsibilities on behalf of THF. THF defines these to include research, research consultation, protocol development and leadership, statistical and data management, study reporting and publication, service on THF committees, service on institutional review boards or data and safety monitoring committees, administration of THF-funded research, and professional practice performed under THF's auspices (complies with 42 CFR 50.603)

**Investigator.** The project director or principal investigator (PD/PI) and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS or proposed for such funding. The term includes collaborators and consultants. THF interpretation: at THF and its subrecipients, the term includes the PD/PI, all senior/key personnel named in the application or progress report, protocol chairs and co-chairs, study statisticians, and any individual with authority over protocol design, eligibility determinations, response or toxicity assessment, data analysis, or the content of study reports. An individual whose role is limited to enrolling participants, delivering protocol-specified treatment, or collecting data as directed by an approved protocol is not an Investigator unless the DIO determines otherwise on the facts of the project.

**Manage.** Taking action to address a financial conflict of interest, which can include reducing or eliminating it, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

**PHS.** The Public Health Service of the U.S. Department of Health and Human Services and any component to which authority has been delegated, including NIH and NCI.

**PHS Awarding Component.** The organizational unit of the PHS that funds the research (for THF's NCORP and NCTN awards, the NCI).

**Research.** 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, basic and applied research, and product development, for which funding is available from a PHS Awarding Component through a grant or cooperative agreement.

**Senior/Key Personnel.** The PD/PI and any other person identified as senior/key personnel by THF in the grant application, progress report, or any other report submitted to the PHS under 42 CFR Part 50, Subpart F.

**Significant Financial Interest (SFI).** A financial interest consisting of one or more of the following interests of the Investigator, and of the Investigator's spouse and dependent children, that reasonably appears to be related to the Investigator's Institutional Responsibilities:

1. With regard to any publicly traded entity, an SFI 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. Remuneration includes salary and any payment for services not otherwise

identified as salary, such as consulting fees, honoraria, and paid authorship. Equity interest includes any stock, stock option, or other ownership interest, valued by reference to public prices or other reasonable measures of fair market value (42 CFR 50.603, SFI paragraph (1)(i)).

2. With regard to any non-publicly traded entity, an SFI 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, spouse, or dependent child holds any equity interest, of any value, in the entity (SFI paragraph (1)(ii)).
3. Intellectual property rights and interests, such as patents and copyrights, upon receipt of income related to such rights and interests. THF applies A $5,0000 dollar threshold to this category (SFI paragraph (1)(iii)).
4. Reimbursed or sponsored travel related to the Investigator's Institutional Responsibilities, as described in Section VI.C (SFI paragraph (2)).

The term SFI applies to domestic and foreign interests alike. Remuneration, travel, or other financial interests received from a foreign entity, including a foreign institution of higher education or the government of another country at any level, are not excluded and must be disclosed when they meet the thresholds above (NIH Guide Notices NOT-OD-18-160 and NOT-OD-22-210).

The term SFI does not include (SFI paragraph (3)):

- Salary, royalties, or other remuneration paid by THF to the Investigator while the Investigator is employed by or appointed at THF, including intellectual property rights assigned to THF 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 those vehicles;
- Income from seminars, lectures, or teaching engagements sponsored by a United States 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 an institution of higher education; or
- Income from service on advisory committees or review panels for any of the entities listed in the preceding bullet.

Because 20 U.S.C. 1001(a) refers only to institutions of higher education located in the United States, the exclusions above do not extend to foreign institutions of higher education or foreign governments.

**Subrecipient.** An entity that receives a subaward from THF to carry out part of the PHS-funded research, including NCORP sub-sites and NCTN consortium members, whether the subaward is cost-reimbursement or per-case reimbursement.

## IV. ROLES AND RESPONSIBILITIES

### A. Designated Institutional Official

The Chief Financial Officer is the Designated Institutional Official under 42 CFR 50.604(d). The DIO solicits and reviews all Investigator disclosures, makes relatedness and FCOI determinations using the guidelines in Section VII, develops and monitors management plans, prepares and submits FCOI reports, conducts retrospective reviews, maintains records, and reports annually to the Board of Directors on the operation of this policy.

The President and Chief Executive Officer serves as alternate DIO whenever the CFO is an Investigator on the project under review, has disclosed an SFI under review, or is otherwise unavailable. If both officials are conflicted or unavailable, the Chair of the Board's [Finance and Audit] Committee, or a Board designee with no interest in the project, acts as DIO for that matter. The DIO may obtain scientific or clinical input from an independent physician or statistician, or legal input from outside counsel, but the determinations required by this policy remain THF's and are made and signed by the DIO.

### B. Investigators

Each Investigator is responsible for completing the training required by Section V, submitting complete and timely disclosures under Section VI, cooperating in the review of those disclosures, complying with any management plan, and disclosing to the DIO any change in circumstances that affects a prior disclosure or an existing management plan.

### C. Project Director / Principal Investigator

The PD/PI of each PHS-funded project identifies to the DIO every individual who meets the definition of Investigator for that project, at the time of application, at each progress report, and whenever a new Investigator joins the project, and confirms that each has completed training and disclosure before the individual begins work on the project.

### D. Authorized Organizational Representative

The President and Chief Executive Officer, as Authorized Organizational Representative, makes the certification required by 42 CFR 50.604(k) in each application, relies on the DIO's written confirmation that all Investigator disclosures have been reviewed before that certification is made, and approves each management plan before it is implemented.

### E. Grants Administration Staff

The NCORP Grants Administrator (or, until that position is filled, the senior accountant assigned to federal awards) maintains the Investigator roster for each project, tracks training and disclosure due dates, prepares subaward FCOI terms under Section XI, drafts FCOI reports for DIO review, and maintains the records required by Section XIII.

### F. Board of Directors

The Board of Directors approves this policy and material revisions, receives the DIO's annual report, and is informed of any FCOI involving an officer or director and any retrospective review that identifies bias.

## V. TRAINING

Under 42 CFR 50.604(b), THF informs each Investigator of this policy, the Investigator's disclosure responsibilities, and the requirements of 42 CFR Part 50, Subpart F, and requires each Investigator to complete FCOI training:

1. Before engaging in research related to any PHS-funded grant or cooperative agreement;
2. At least every four years thereafter; and
3. Immediately when any of the following occurs: THF revises this policy or its procedures in any manner that affects the requirements of Investigators; an Investigator is new to THF; or THF finds that an Investigator is not in compliance with this policy or with a management plan.

THF uses the NIH FCOI training module available on the NIH FCOI Training webpage (grants.nih.gov/policy-and-compliance/policy-topics/fcoi/fcoi-training) as its standard curriculum, supplemented by a copy of this policy and a briefing on THF-specific disclosure procedures. An Investigator who completed the NIH module at another institution within the preceding four years may submit that certificate, but must still receive this policy and the THF briefing before beginning work. The DIO retains each certificate of completion and the date of each briefing. Training completion is tracked under the Federal Grants Compliance Training Policy and is a condition of charging an individual's effort to a PHS award.

## VI. DISCLOSURE OF SIGNIFICANT FINANCIAL INTERESTS

### A. When Disclosure Is Required

Each Investigator discloses to the DIO, on Form FCOI-1, the Investigator's SFIs and those of the Investigator's spouse and dependent children:

1. No later than the time of application for PHS-funded research, and in any event before THF submits the application (42 CFR 50.604(e)(1));
2. At least annually during the period of the award, on or before [August 1] of each year, or on the anniversary of the Investigator's initial disclosure if the DIO so directs. The annual disclosure must include any information not previously disclosed and updated information on each previously disclosed SFI, including the current value of any equity interest (42 CFR 50.604(e)(2));
3. Within 30 days of discovering or acquiring a new SFI, whether through purchase, marriage, inheritance, a new consulting or employment relationship, or any other means (42 CFR 50.604(e)(3)); and
4. Within 30 days after the end of each occurrence of reimbursed or sponsored travel that meets the criteria in Section VI.C.

A new Investigator joining an ongoing PHS-funded project discloses before beginning work on the project. An Investigator with no SFI to report submits Form FCOI-1 certifying that fact; a blank or missing form is not a disclosure.

### B. Content of Disclosure

Each disclosure identifies, for each SFI: the name of the entity; whether the entity is publicly traded, non-publicly traded, or a foreign institution or government; the nature of the interest (remuneration, equity, intellectual property income, travel, or other); the value of remuneration received in the preceding twelve months and the value of any equity interest as of the date of disclosure, or a statement that the value cannot be readily determined; the relationship of the entity, if any, to any PHS-funded project on which the Investigator participates; and the Investigator's own assessment of whether the interest could relate to that research. The DIO may require any additional information reasonably needed to complete the review.

### C. Reimbursed and Sponsored Travel

Each Investigator discloses the occurrence of any reimbursed or sponsored travel related to the Investigator's Institutional Responsibilities that is paid on the Investigator's behalf or reimbursed to the Investigator by any entity other than THF, a United States federal, state, or local government agency, 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 affiliated with a United States institution of higher education. Travel paid by a foreign institution of higher education or a foreign government at any level must be disclosed. THF applies no minimum dollar threshold to travel disclosure.

Each travel disclosure states, at a minimum, the purpose of the trip, the identity of the sponsor or organizer, the destination, and the duration (42 CFR 50.603, SFI paragraph (2)). The DIO determines whether further information, including the monetary value of the travel, is needed to decide whether the travel constitutes an FCOI and may require the Investigator to supply it within 10 business days of the request.

### D. Confidentiality

Disclosures and the DIO's review files are confidential to the extent permitted by law and are shared only with those who need the information to administer this policy, with the PHS Awarding Component and HHS on request, and as required by Section XII.

## VII. REVIEW AND DETERMINATION

### A. Guidelines for the Designated Institutional Official

These guidelines are provided under 42 CFR 50.604(f). The DIO applies them, and documents the result on the review record, for every disclosure that reports an SFI. The determination proceeds in two steps.

**Step 1, Relatedness.** An SFI is related to PHS-funded research when the DIO reasonably determines that the SFI could be affected by the research, or that the SFI is in an entity whose financial interest could be affected by the research. Indicators of relatedness include, without limitation: the entity supplies a drug, device, agent, assay, or technology under study; the entity is a sponsor, co-sponsor, or funder of the study or of a correlative study; the entity markets or is developing a product that competes with a product under study; the entity has licensed, or has an option on, intellectual property arising from the research; or the research results could

reasonably affect the entity's revenue, valuation, or regulatory position. The DIO may involve the Investigator in this step.

**Step 2, Conflict.** A related SFI is an FCOI when the DIO reasonably determines that it could directly and significantly affect the design, conduct, or reporting of the research, meaning that it would have a material effect on the research. Factors the DIO weighs include: the nature and value of the interest; the Investigator's role and degree of independent authority over design, eligibility, treatment decisions, response and toxicity assessment, data analysis, and reporting; whether the research involves human subjects and whether it evaluates the safety or effectiveness of a drug, device, or treatment; whether the study is blinded or has independent statistical oversight; the presence of independent monitoring, such as a data and safety monitoring committee or NCI Central Institutional Review Board oversight; and whether the interest is contingent on the outcome of the research. An interest whose value is contingent on the outcome of the research is always an FCOI.

A related SFI that is not an FCOI is documented as such with the reasons. The DIO may impose conditions on an SFI that is not an FCOI when doing so protects the objectivity of the research (42 CFR 50.605(a)(6)).

### B. Timing of Review

1. **Before expenditure of funds.** Before THF expends any funds under a PHS-funded research project, including drawdown of an initial award or a competing or noncompeting continuation that adds Investigators, the DIO reviews every Investigator disclosure for that project, determines relatedness and conflict, and, where an FCOI exists, develops and implements a management plan (42 CFR 50.605(a)(1)). The DIO documents this review in writing, and the Authorized Organizational Representative does not authorize expenditure until it is complete.
2. **New Investigator or new SFI during an ongoing project.** Within 60 days after an Investigator who is new to the project discloses an SFI, or an existing Investigator discloses a new SFI, the DIO reviews the disclosure, determines relatedness and conflict, and, where an FCOI exists, implements a management plan on at least an interim basis (42 CFR 50.605(a)(2)). The DIO may impose interim restrictions on the Investigator's participation between the date of disclosure and completion of the review.
3. **SFI not timely disclosed or not previously reviewed.** Within 60 days after THF identifies an SFI that was not disclosed timely by an Investigator or, for any reason, was not previously reviewed (including an SFI not timely reviewed or reported by a subrecipient), the DIO completes the same review and, where an FCOI exists, implements an interim management plan going forward and initiates the retrospective review required by Section X (42 CFR 50.605(a)(3)).

### C. Determination Record

For every reviewed disclosure the DIO records the date received, the date reviewed, the relatedness determination and its basis, the FCOI determination and its basis, any conditions or management plan imposed, and the DIO's signature. The record is retained under Section XIII whether or not an FCOI was found.

## VIII. MANAGEMENT PLANS

When the DIO determines that an FCOI exists, the DIO develops a written management plan on Form FCOI-2 that specifies the actions that have been and will be taken to manage the conflict. Conditions or restrictions that may be imposed include, but are not limited to (42 CFR 50.605(a)(1)(i) through (vii)):

- Public disclosure of the FCOI, including when presenting or publishing the research;
- For research involving human subjects, disclosure of the FCOI directly to participants, including 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;
- Modification of the research plan;
- Change of personnel or personnel responsibilities, or disqualification of the Investigator from all or a portion of the research, such as removal from eligibility determinations, response or toxicity assessment, or statistical analysis;
- Reduction or elimination of the financial interest, such as sale of an equity interest;
- Severance of the relationship that creates the conflict;
- Independent review of the protocol, analysis, or manuscript by the NCI, a data and safety monitoring committee, or another independent reviewer; and
- Any other condition the DIO determines is necessary to safeguard objectivity.

Each management plan states the Investigator's role and principal duties on the project, the conditions imposed, how the plan safeguards objectivity, how compliance will be monitored, and the Investigator's written agreement to the plan. The plan is signed by the Investigator, the DIO, and the President and Chief Executive Officer. The DIO monitors Investigator compliance with each management plan on an ongoing basis until completion of the PHS-funded research project (42 CFR 50.605(a)(4)), reviews each plan at least annually and at each annual disclosure, and documents each monitoring contact. The Investigator reports to the DIO any change that affects the plan within 30 days.

## IX. REPORTING TO THE PHS AWARDING COMPONENT

### A. Reports Required

The DIO submits FCOI reports to the PHS Awarding Component through the eRA Commons FCOI Module (or, for research contracts, to the Contracting Officer) as follows (42 CFR 50.604(h) and 50.605(b)):

1. **Initial report.** Before THF expends any funds under a PHS-funded research project, an FCOI report for each Investigator SFI found to be conflicting, with confirmation that a management plan has been implemented (42 CFR 50.605(b)(1)). No report is submitted for an FCOI that THF eliminates before expenditure of PHS funds.
2. **Sixty-day report.** Within 60 days after THF identifies an FCOI during an ongoing project, including an FCOI of a new Investigator, a newly disclosed SFI of an existing Investigator, or an SFI not timely disclosed or reviewed, an FCOI report with confirmation that a management plan has been implemented (42 CFR 50.605(b)(2)).

3. **Annual report.** For each previously reported FCOI, an annual FCOI report addressing the status of the conflict and any change to the management plan, stating whether the conflict is still being managed or explaining why it no longer exists, submitted for the duration of the project period, including extensions with or without funds, at the time the annual progress report or multi-year progress report is due or at the time of extension (42 CFR 50.605(b)(4)).
4. **Revised report and mitigation report.** An updated FCOI report following a retrospective review, and a mitigation report whenever bias is found, as provided in Section X (42 CFR 50.605(a)(3)(iii)).
5. **Subrecipient FCOIs.** Reports for all FCOIs of subrecipient Investigators on the same schedule (42 CFR 50.604(c)(2)).

### B. Content of FCOI Reports

Each initial and sixty-day FCOI report includes (42 CFR 50.605(b)(3)): the project number; the PD/PI or contact PD/PI; the name of the Investigator with the FCOI; the name of the entity with which the Investigator has the FCOI; the nature of the financial interest; the value of the financial interest, stated in the dollar ranges permitted by the regulation or as one whose value cannot be readily determined; a description of how the financial interest relates to the research and the basis for THF's determination that it conflicts with the research; and the key elements of the management plan, including the Investigator's role and principal duties, the conditions of the plan, how the plan safeguards objectivity, confirmation of the Investigator's agreement, how compliance will be monitored, and any other information needed.

### C. When THF Is a Subrecipient

For PHS-funded research on which THF is a subrecipient of another institution, THF's Investigators comply with this policy unless the subaward agreement specifies that the pass-through entity's policy applies. THF certifies to the pass-through entity that this policy complies with 42 CFR Part 50, Subpart F, and the DIO reports each identified FCOI to the pass-through entity within the period specified in the subaward, and in any event within 30 days of THF's determination, so that the pass-through entity can meet its own reporting deadline.

## X. NONCOMPLIANCE, RETROSPECTIVE REVIEW, AND MITIGATION

### A. Events Requiring Retrospective Review

Whenever an FCOI is not identified or managed in a timely manner, including failure by an Investigator to disclose an SFI that THF determines to be an FCOI, failure by THF to review or manage such an FCOI, or failure by an Investigator to comply with a management plan, the DIO completes a retrospective review within 120 days of THF's determination of noncompliance to decide whether any PHS-funded research, or portion of it, conducted during the period of noncompliance was biased in its design, conduct, or reporting (42 CFR 50.605(a)(3)(ii)(A)). The DIO may impose interim restrictions on the Investigator's participation pending completion of the review.

### B. Documentation of Retrospective Review

The DIO documents each retrospective review with at least the following elements (42 CFR 50.605(a)(3)(ii)(B)): project number; project title; PD/PI or contact PD/PI; name of the Investigator with the FCOI; name of the entity with which the Investigator has the FCOI; reasons for the retrospective review; detailed methodology, including the review process, the composition of the review panel, and the documents reviewed; findings; and conclusions.

### C. Updated Report and Mitigation Report

Based on the results of the retrospective review, the DIO updates the previously submitted FCOI report where appropriate, specifying the actions that will be taken to manage the FCOI going forward. If bias is found, THF notifies the PHS Awarding Component promptly and submits a mitigation report that includes the key elements of the retrospective review, a description of the impact of the bias on the research project, including the extent of harm and any qualitative and quantitative data supporting actual or future harm and an analysis of whether the project is salvageable, and THF's plan of action or actions taken to eliminate or mitigate the effect of the bias (42 CFR 50.605(a)(3)(iii)). THF then submits annual FCOI reports as provided in Section IX.

### D. Notification of Corrective Action

If an Investigator's failure to comply with this policy or a management plan appears to have biased the design, conduct, or reporting of PHS-funded research, THF promptly notifies the PHS Awarding Component of the corrective action taken or to be taken (42 CFR 50.606(a)). THF submits, or permits on-site review of, all records pertinent to compliance with 42 CFR Part 50, Subpart F, whenever the PHS Awarding Component or HHS requests them (42 CFR 50.606(b)).

### E. Clinical Research Disclosure Requirement

If HHS 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 was designed, conducted, or reported by an Investigator with an FCOI that THF did not manage or report as required, THF requires the Investigator to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations (42 CFR 50.606(c)).

### F. Enforcement and Sanctions

Under 42 CFR 50.604(j), an Investigator who fails to complete training, fails to disclose an SFI when required, submits a disclosure that is incomplete or inaccurate, or fails to comply with a management plan is subject to sanctions determined by the President and Chief Executive Officer on the DIO's recommendation, including any of the following: written reprimand; required additional training; suspension of authority to charge effort to PHS awards; removal from the project or from a leadership role on it; restrictions on authorship; disqualification from future THF-administered PHS research; and, for employees, disciplinary action up to and including termination under THF personnel policies. For consultants and subrecipient personnel, sanctions include suspension or termination of the consulting agreement or subaward. THF also

complies with any specific conditions imposed by the PHS Awarding Component under 2 CFR 200.208 and any enforcement action under 2 CFR 200.339.

### G. Appeals

An Investigator who disagrees with a determination of the DIO may request, in writing within 10 business days, review by the President and Chief Executive Officer, or by the Chair of the Board's [Finance and Audit] Committee if the President and Chief Executive Officer acted as DIO. The reviewing official's decision is final within THF. An appeal does not suspend an interim management plan or any reporting deadline.

## XI. SUBRECIPIENTS

When THF carries out PHS-funded research through a subrecipient, THF takes reasonable steps to ensure that each subrecipient Investigator complies with 42 CFR Part 50, Subpart F (42 CFR 50.604(c); NIH GPS Section 15.2.1). Each subaward agreement, including each NCORP sub-site agreement and each NCTN consortium agreement, includes written terms that:

1. Establish whether THF's policy or the subrecipient's policy applies to the subrecipient's Investigators (42 CFR 50.604(c)(1));
2. Where the subrecipient's policy applies, contain the subrecipient's certification that its policy complies with 42 CFR Part 50, Subpart F, and require the subrecipient to report each identified FCOI of its Investigators to THF within 30 days of the subrecipient's determination, and in no event later than 45 days after the subrecipient's identification of the SFI, so that THF can report to the PHS Awarding Component within 60 days (42 CFR 50.604(c)(1)(i) and (ii));
3. Where the subrecipient cannot certify, or where THF elects to apply this policy, state that the subrecipient's Investigators are subject to this policy for disclosure of SFIs directly related to the subrecipient's work for THF, and require the subrecipient to submit each Investigator's disclosure to the DIO before the subrecipient begins work, annually thereafter, and within 30 days of any new SFI or travel occurrence (42 CFR 50.604(c)(1)(iii));
4. Require the subrecipient to identify its Investigators on the project and to certify that each has completed FCOI training; and
5. Require the subrecipient to provide, on request, records of its Investigator disclosures, reviews, and management plans, and to cooperate in any retrospective review.

The Subrecipient Commitment Form and the Subrecipient Risk Assessment Tool collect the subrecipient's FCOI certification and policy at intake, and the Subrecipient Monitoring Policy and Procedures verify FCOI compliance during the award. THF reports all subrecipient Investigator FCOIs to the PHS Awarding Component on the schedule in Section IX (42 CFR 50.604(c)(2)) and manages any subrecipient FCOI that the subrecipient has not managed (42 CFR 50.604(g)).

## XII. PUBLIC ACCESSIBILITY

### A. This Policy

THF posts the current version of this policy on its publicly accessible website (42 CFR 50.604(a)) and submits the policy, and each revision, to NIH through the eRA Commons Institutional Profile Module (NIH Guide Notice NOT-OD-21-002; NIH GPS Section 4.1.10).

### B. Financial Conflicts of Interest of Senior/Key Personnel

Before THF expends any funds under a PHS-funded research project, THF ensures public accessibility of information concerning any SFI that meets all three of the following criteria: the SFI was disclosed by and is still held by senior/key personnel; THF has determined that the SFI is related to the PHS-funded research; and THF has determined that the SFI is an FCOI (42 CFR 50.605(a)(5)(i)).

THF makes this information available by written response to any requestor within five business days of a written request addressed to the DIO at [email address]. Each response includes, for each such FCOI: the Investigator's name; the Investigator's title and role with respect to the research project; the name of the entity in which the SFI is held; the nature of the SFI; and the approximate dollar value of the SFI in the ranges permitted by 42 CFR 50.605(a)(5)(ii), or a statement that the value cannot be readily determined by reference to public prices or other reasonable measures of fair market value. Each response states that the information is current as of the date of the correspondence and is subject to update at least annually and within 60 days of THF's identification of a new FCOI, and that updates should be requested subsequently by the requestor (42 CFR 50.605(a)(5)(iii)). THF keeps this information available for at least three years from the date it was most recently updated (42 CFR 50.605(a)(5)(iv)).

If THF elects in the future to post this information on its website instead, the posting will be updated at least annually and within 60 days of THF's receipt or identification of any new FCOI of senior/key personnel, and will carry the currency statement required by 42 CFR 50.605(a)(5)(iii).

## XIII. RECORDS

The DIO maintains records of every Investigator disclosure of financial interests, THF's review of and response to each disclosure whether or not it resulted in an FCOI determination, every management plan and monitoring record, every FCOI report, and every retrospective review and mitigation report, for at least three years from the date the final expenditures report (final Federal Financial Report) for the project is submitted to the PHS or, where applicable, from the other dates specified in 2 CFR 200.334 for litigation, claims, audits, and other situations (42 CFR 50.604(i)). Training certificates and Investigator rosters are retained for the same period. These records are maintained under SPG #41 and its federal addendum and are made available promptly to HHS, the PHS Awarding Component, and THF's auditors on request (42 CFR 50.604(k)(4) and 50.606(b)).

## XIV. POLICY ADMINISTRATION

The DIO reviews this policy at least every three years, and sooner whenever 42 CFR Part 50, Subpart F, the NIH Grants Policy Statement, or NIH guidance changes, and recommends revisions to the Board of Directors. Any revision that affects the requirements of Investigators triggers immediate retraining under Section V, reposting under Section XII.A, and resubmission through the eRA Commons Institutional Profile Module. The DIO reports annually to the Board on the number of disclosures received, FCOIs identified, management plans in effect, FCOI reports submitted, and any retrospective reviews.

## XV. REFERENCES

- 42 CFR Part 50, Subpart F, Promoting Objectivity in Research, 76 FR 53283 (August 25, 2011), as amended at 81 FR 3006 (January 20, 2016) and 89 FR 80064 (October 2, 2024)
- NIH Grants Policy Statement, Sections 4.1.10 (Financial Conflict of Interest) and 15.2.1 (Written Agreement)
- NIH Checklist for Policy Development Related to the 2011 FCOI Regulation, revised June 29, 2026
- NIH Guide Notices NOT-OD-21-002 (Submission of FCOI Policy into eRA Commons IPF Module), NOT-OD-18-160 (Investigator Disclosures of Foreign Financial Interests), NOT-OD-13-004 (Reimbursed and Sponsored Travel), and NOT-OD-22-210 (FCOI and Other Support Reminders)
- 2 CFR 200.112 (Conflict of Interest), 200.208 (Specific Conditions), 200.318(c)(1) (Standards of Conduct), 200.334 (Retention Requirements for Records), and 200.339 (Remedies for Noncompliance)
- 20 U.S.C. 1001(a) (Institution of Higher Education)

## APPENDIX A. DISCLOSURE AND REVIEW TIMELINE

This table summarizes the deadlines established in this policy. Where a deadline in the body of the policy and this table differ, the body of the policy controls. (42 CFR Part 50)

| Action | Deadline | Authority |
|---|---|---|
| **Investigator FCOI training** | Before beginning work; every 4 years; immediately on policy revision, new hire, or noncompliance finding | 42 CFR 50.604(b); Section V |
| **Initial SFI disclosure** | No later than time of application | 42 CFR 50.604(e)(1); Section VI.A.1 |
| **Annual SFI disclosure** | On or before [August 1] each year during the award | 42 CFR 50.604(e)(2); Section VI.A.2 |
| **New SFI** | Within 30 days of discovery or acquisition | 42 CFR 50.604(e)(3); Section VI.A.3 |
| **Sponsored or reimbursed travel** | Within 30 days after each occurrence | 42 CFR 50.603 SFI (2); Section VI.A.4 |
| **DIO review, all disclosures** | Before expenditure of any funds | 42 CFR 50.605(a)(1); Section VII.B.1 |
| **DIO review, new Investigator or new SFI** | Within 60 days of disclosure | 42 CFR 50.605(a)(2); Section VII.B.2 |
| **DIO review, SFI not timely disclosed or reviewed** | Within 60 days of identification | 42 CFR 50.605(a)(3); Section VII.B.3 |
| **Initial FCOI report to NIH** | Before expenditure of any funds | 42 CFR 50.605(b)(1); Section IX.A.1 |
| **FCOI report, newly identified FCOI** | Within 60 days of identification | 42 CFR 50.605(b)(2); Section IX.A.2 |
| **Annual FCOI report** | With the annual progress report, multi-year progress report, or extension request | 42 CFR 50.605(b)(4); Section IX.A.3 |
| **Retrospective review** | Within 120 days of determination of noncompliance | 42 CFR 50.605(a)(3)(ii)(A); Section X.A |

| Action | Deadline | Authority |
|---|---|---|
| **Mitigation report** | Promptly after bias is found | 42 CFR 50.605(a)(3)(iii); Section X.C |
| **Subrecipient FCOI report to THF** | Within 30 days of subrecipient determination; no later than 45 days after identification of the SFI | 42 CFR 50.604(c)(1)(ii); Section XI |
| **Public FCOI information, written request** | Within 5 business days of written request | 42 CFR 50.605(a)(5)(i); Section XII.B |
| **Records retention** | 3 years from submission of the final Federal Financial Report, or the dates in 2 CFR 200.334 | 42 CFR 50.604(i); Section XIII |

## APPENDIX B. DESIGNATED INSTITUTIONAL OFFICIAL DETERMINATION RECORD

The DIO completes this record for each disclosure that reports one or more SFIs. Form FCOI-1 is attached to the completed record.

| | |
|---|---|
| Investigator; title; role on project | |
| Project number; project title; PD/PI | |
| Date disclosure received; date review completed | |
| Entity; nature of SFI; value or value range; publicly traded, non-publicly traded, or foreign | |
| Step 1. Is the SFI related to the PHS-funded research? (Could the SFI be affected by the research, or is the SFI in an entity whose financial interest could be affected by the research?) State the basis. | Related / Not related |
| Step 2. If related, could the SFI directly and significantly affect the design, conduct, or reporting of the research? | FCOI / Not an FCOI |

| | |
|---|---|
| State the basis, addressing the Investigator's role and authority, human subjects involvement, blinding and independent oversight, and whether the interest is contingent on the outcome. | |
| Conditions imposed on an SFI that is not an FCOI (42 CFR 50.605(a)(6)), if any | |
| Management plan required? Form FCOI-2 reference; date implemented; interim or final | |
| FCOI report required? Type (initial, 60-day, annual, revised); date due; date submitted; eRA Commons reference | |
| Retrospective review required? Date noncompliance determined; 120-day deadline | |
| Public accessibility: senior/key personnel? Information prepared for written-request response (Section XII.B) | |
| DIO signature and date; alternate DIO used? Reason | |

## APPENDIX C. MINIMUM CONTENT OF FORM FCOI-1

Form FCOI-1, issued separately, collects at least the following, consistent with the NIH Checklist for Policy Development (revised June 29, 2026):

- Investigator name, title, THF or subrecipient affiliation, and each PHS-funded project on which the Investigator participates;
- For the Investigator and for the Investigator's spouse and dependent children, each entity in which an SFI is held, and whether the entity is publicly traded, non-publicly traded, a foreign institution of higher education, or a foreign government;
- Nature of each SFI (salary, consulting fees, honoraria, paid authorship, equity, intellectual property income, reimbursed or sponsored travel, other);

- Value of remuneration received in the twelve months preceding the disclosure and value of each equity interest as of the date of disclosure, or a statement that the value cannot be readily determined;
- For each reimbursed or sponsored travel occurrence: purpose, sponsor or organizer, destination, and duration;
- The Investigator's statement of whether each SFI relates to any PHS-funded project and an explanation;
- A certification that the Investigator has completed FCOI training within the preceding four years, has read this policy, and that the disclosure is complete and accurate; and
- A "nothing to disclose" certification for Investigators with no SFI.