

Financial Conflict of Interest (FCOI) Policy **Effective June 2024**

1. Background

The University of Hartford (University) encourages faculty and staff to seek out and participate in sponsored research and other activities. While the University recognizes the benefit of such activities, it is also committed to ensuring proper and consistent conduct, and so the University has formulated the following Financial Conflict of Interest Policy, which is available in the Faculty Policy Manual, the Employee Manual, and the University's website. Policies and procedures have been developed to increase awareness of university employees about the potential for financial conflicts of interest, protect the University and the integrity of funded research from potential financial conflicts of interest on the part of Investigators, and establish procedures whereby such conflicts may be avoided or properly managed.

This FCOI policy was revised in May 2024 to improve institutional procedures and reflect regulations and requirements, particularly the federal Public Health Service (PHS) regulations 42 CFR Part 50 and 45 CFR Part 94 on *Promoting Objectivity in Research*, which describe the actions an individual and an institution must take in order to promote objectivity in research.

This FCOI policy supports the University's mission and equity and inclusion efforts through its application to and equal treatment of all university employees participating in sponsored research and its aim to eliminate bias in research resulting from conflicting financial interests.

2. Definitions

Business Entity is defined for the purposes of this policy as a business that has a relationship with the University for the sale of goods and/or services.

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

Human Subject (PHS regulations "Protection of Human Subjects" 45 CFR Part 46, as administered by the Office of Human Research Protections (OHRP) means a living individual about whom an Investigator conducting research obtains data through intervention or interaction with the individual, or identifiable private information.

Investigator means the project director/principal investigator (PD/PI) and any other person (regardless of title or position) who is responsible for the design, conduct or reporting of research or other funded activities, which may include faculty, staff, visiting scientists, technicians, graduate students, other collaborators, and consultants.

Immediate Family means the Investigator's spouse/domestic partner and dependent children.

Institutional Responsibilities means an Investigator's professional responsibilities on behalf of the Institution, which may include: research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

Senior/Key Personnel means the project director/principal investigator (PD/PI) and any other person identified as senior/key personnel by the University in the grant application, progress report, or any other report submitted to the funding agency by the University as required by the regulation. The term is defined as it relates to the "public accessibility" requirements of identified

FCOIs as described below (H. Public Accessibility) and is not related to disclosure requirements of Investigator's significant financial interests.

Significant financial interest (SFI) means a financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse/domestic partner and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

For U.S. Department of Energy (DOE), Public Health Services (PHS) and all sponsors that follow the 2011 PHS FCOI Regulations

For National Science Foundation (NSF) and all other sponsors:

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; or

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 (or the Investigator's Immediate Family) holds any equity interest (e.g., stock, stock option, or other ownership interest); or

With regard to intellectual property rights and interests (e.g., patents, copyrights), an SFI exists upon receipt of income of greater than \$5,000 related to such rights and interests; or

Any reimbursed or sponsored travel (reimbursed or paid on behalf of the Investigator related to the Investigator's responsibilities, if the cost or value received from a single entity exceeds \$5,000 for the preceding twelve months. This disclosure does not apply to travel that is reimbursed or sponsored by a United States federal, state, or local government agency, or a United States institution of higher education as defined by 20 U.S.C. § 1001(a). Investigators must submit an updated disclosure of reimbursed or sponsored travel within 30 days of each occurrence. Disclosure of SFIs is as follows:

- At the time of application
- On an annual basis as prescribed by the institution
- Within 30 days of discovering or acquiring a new SFI for other types of SFIs other than travel.

Travel disclosure is as follows:

- At the time of application and
- Within 30 days of each occurrence after the initial disclosure.

An equity interest that when aggregated for the Investigator and the Investigator's Immediate Family exceeded \$5,000 over the last 12 months, and/or is expected to exceed \$5,000 in value over the next 12 months as determined through reference to public prices or other reasonable measures of fair market value; or when the Investigator (or the Investigator's Immediate Family) holds a 5% or greater equity interest (e.g., partnership, ownership, stock, stock option, or other ownership interest) in a single publicly traded entity or holds any equity interest in a non-publicly traded entity; or

Salary, royalties or other payments not from the University for services (e.g., consulting fees or honoraria) that when aggregated for the Investigator and the Immediate Family over the last 12 months exceeded \$5,000 or are expected to exceed \$5,000 over the next 12 months.

The term significant financial interest does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization; income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles; income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency located in the United States, a United States Institution of higher education, 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, a United States Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a United States Institution of higher education.

3. Procedures

a) Notification

A copy of this policy will be provided to all current and new Investigators. The policy is also available on the University's website.

b) Training

All Investigators must complete training prior to engaging in federally funded research.

- All Investigators on National Institute of Health-funded (NIH) projects (including subrecipients) must complete NIH FCOI training, using [NIH's FCOI Training Module](#).
- All Investigators on other federally-funded projects must complete the Collaborative Institutional Training Initiative (CITI Program) course, "COI – Other Federal Sponsors."
- The University's Office of Sponsored Programs (OSP) will provide additional information to Investigators about the University's policy and their disclosure responsibilities.

All Investigators must complete required FCOI training at least every four years thereafter as well as under the following circumstances:

- a. The University's Financial Conflict of Interest policy changes in a manner that affects Investigator requirements;
- b. An Investigator is new to the University;
- c. The University finds that an Investigator is not compliant with the established policy or a management plan, as applicable.

Upon completion of required training, Investigators should forward certificates of completion (from the NIH FCOI Training Module or the CITI Program, as applicable) to the Office of Sponsored Programs (OSP): ospgrants@hartford.edu.

c) Subrecipient Requirements

For subrecipients on PHS prime awards, the University will establish whether its FCOI policy or that of the subrecipient applies to the subrecipient's investigator(s). If the subrecipient relies on its own FCOI policy, the subrecipient shall certify as part of the subrecipient agreement that its policy complies with 42 CFR Part 50 and 45 CFR Part 94, as appropriate. In either case, the subrecipient agreement will include time periods to meet the disclosure and/or FCOI reporting requirements of the University of Hartford, and the subrecipient must report identified FCOIs to the University in sufficient time to allow for reporting obligations to PHS.

d) Disclosure

When Investigators are submitting proposals/applications for grants, contracts, and subcontracts to external agencies, they must familiarize themselves with the University's Financial Conflict of Interest Policy, and all Investigators must complete and submit a disclosure form for all SFIs that are related to their institutional responsibilities (e.g., research, research consultation, teaching, etc.) (blank form appended) for themselves, their spouses/domestic partners, and their dependent children as defined above. Furthermore, it is the Investigator's responsibility to submit a disclosure update form (blank form appended) at any time during the proposal pending stage, or, if funded, within thirty (30) days of acquiring or discovering a new SFI or an SFI that was not disclosed in a timely manner.

Investigators must disclose all foreign financial interests (which include but are not limited to 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 and foreign governments (which includes local, provincial, or equivalent governments of another country) when such income meets the threshold for disclosure.

Disclosure forms/statements are to be reviewed by the appropriate dean or director and the Provost or relevant cabinet member. Each disclosure form is reviewed (E. Review Process) to distinguish between negative disclosure (disclosures that reveal no financial conflict) and positive disclosure (disclosures that require additional review). Disclosure forms/statements are filed with the request for external funding and maintained by the Office of Sponsored Programs (OSP).

Investigators carrying out research or other activities supported by PHS or supported by another sponsor that mandates compliance with the PHS regulation must comply with 42 CFR Part 50 and 45 CFR Part 94 on Promoting Objectivity in Research. Such Investigators must submit an updated disclosure of SFI at least annually (by July 1) during the period of award, must update information regarding any previously disclosed SFI, and must submit an updated disclosure of SFI within thirty (30) days of discovering or acquiring a new SFI. Travel disclosures must be updated within thirty (30) days of each occurrence and should include the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.

Human Subjects Research

For research involving human subjects, the Investigator must disclose FCOIs to the Institutional Review Board (IRB) with every submission of protocols. If an Investigator has an FCOI, but a management plan is not on file, the IRB will contact the Office of the Provost or office of the relevant cabinet member and hold approval of the protocol until a determination is made. For projects involving human subjects research, FCOIs will be disclosed directly to participants.

Confidentiality

All information disclosed by a faculty or staff member for the purpose of disclosure and management, and all official records of disclosure and management, shall be considered a part of the request for external funding and shall be deemed confidential. Any information disclosed by a faculty or staff member as required by this policy shall be used solely for the purpose of administering this policy and may not be used for any other purpose unless required by law. Unauthorized disclosure of any such information by a faculty or staff member shall be subject to appropriate disciplinary action.

e) Review Processes

A committee (which will include, at minimum, the appropriate Dean and/or Director and the

Provost or relevant cabinet member) will determine whether the Investigator's SFI is related to the funded research and, if so, whether the SFI is a FCOI. An Investigator's SFI is related to funded research when the Committee reasonably determines that the SFI could be affected by the funded research, or is in an entity whose financial interest could be affected by the research. A FCOI exists when the Committee reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the funded research.

To determine if the Investigator's SFI is related to the funded research and, if so, whether or not it creates a FCOI, they will consider the role of the Investigator and the opportunity to bias the results, the nature of the research proposed, and the value of the SFI in relation to the size and value of the entity. They may also consider other factors, including:

- Whether the research is of a basic or fundamental nature directed at understanding basic scientific processes; or
- Whether the degree of replication and verification of research results is such that immediate commercialization or clinical application is not likely; or
- Whether the goal of the research is to evaluate an invention linked to the SFI (such as where the SFI is a patent, or an interest in a company that has licensed the invention); or
- Where the research involves human subjects, whether there are double blind conditions or the involvement of a data and safety monitoring board; or
- Where the SFI is in a privately held company, whether the researcher's SFI could result in the researcher having influence over company decisions, or whether the research could have a significant impact on the company's business or financial outlook (excluding Phase I Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) requests); or
- The magnitude of the SFIs (e.g., the amount of consulting, or the percentage or value of equity); or
- Where the SFI is in the sponsor of the research, and the sponsor is a licensee of the Investigator's technology, the amount of commercialization payments received by the faculty member or staff member from that technology, both currently or in the future; or
- The number and nature of the relationships an Investigator has within an entity. Multiple entanglements can create a relationship with an outside entity that is stronger than the sum of the parts; or
- Whether the goal of the research is to validate or invalidate a particular approach or methodology that could affect the value of the SFI; or
- Whether other scientific groups are independently pursuing similar questions; or
- Whether sufficient external review of the research conducted and the reporting of research results exist to mitigate undue bias; or
- Whether the goal of the project is a comparative evaluation of a technology in which an Investigator has an SFI; or
- Whether the project involves a subaward to an entity in which the Disclosure has a SFI.

The Provost or relevant Cabinet member in consultation with the President will ultimately make recommendations for how the FCOI will be managed. Criteria will be developed for deciding what is allowable and what can be conditionally allowed in accordance with university policy and experience. Criteria will include elements such as the extent and nature of the involvement, the openness of the activity, the freedom of communication about the activity, the control of intellectual property arising from the activity, and the use of university resources including the

involvement of students. These questions include:

- Will the negotiation of relevant research affiliations or other contracts be handled by truly disinterested representatives of the institution?
- Will the research work plan receive independent peer review prior to its initiation?
- Are there mechanisms in place to prevent the introduction of bias into research products (e.g., is the protocol double-blinded? Are research subjects randomly selected?)?
- Will the project be supervised by someone with authority and no conflicting interests?
- Are there means to verify research results (e.g., independent corroboration in another lab, Food and Drug Administration review)?
- Will data and materials be shared openly with independent researchers? If not, who determines accessibility to such resources?
- Will the product of collaborative effort with an outside party be published in peer-reviewed scientific literature?
- Will the sponsorship and relevant interests receive acknowledgement in public presentations of the research results?

f) Recommendation and Decisions

A FCOI exists when the University, through its designated officials, reasonably determines that an Investigator's SFI is related to a 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 funded research.

If an FCOI is determined, it will be communicated to the Investigator, to the relevant Primary Investigator/Project Director, and the appropriate dean or director, and it will be resolved by elimination, mitigation, or the creation of a management plan. In cases in which the nature of the outside activity or relationship is such that it will not be possible to ensure the integrity of the science or the University, the outside relationship or activity should be eliminated before research can proceed.

In instances in which a management plan can be implemented to manage the FCOI and promote objectivity in the funded research, carefully monitoring and reporting will be crucial to ensuring that the objectivity of the science and the integrity of the University are protected. As appropriate, certain measures may be required including: public disclosure of significant financial interests (e.g., requiring the Investigator to publicly disclose the SFI in presentations and publications; to research personnel working on the project; and to the Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC), and Data and Safety Monitoring Board, as applicable); monitoring of the research by independent reviewers; modification of the research plan; disqualification from participation in the portion of the externally funded research that would be affected by the significant financial interest; or divestiture of significant financial interests.

In those instances, in which the University finds itself unable to satisfactorily manage a conflict of interest, OSP will notify the relevant funding agency of the matter to seek assistance in its resolution. The University is committed to keeping the relevant funding agencies, through their respective Awarding Component (e.g., NIH Program Official, Grants Manager, etc.), informed of any developments regarding these cases.

No expenditures on federal awards will be permitted until the Investigator has complied with the disclosure requirements of this policy and has agreed to, in writing, to comply with any plans determined by the review committee necessary to manage the FCOI.

Opportunity to Appeal

There are no opportunities to appeal a decision rendered by the Provost or relevant Cabinet member on FCOIs.

g) Noncompliance

Whenever the University identifies a SFI that was not disclosed in a timely manner by an Investigator or previously reviewed by the University during an ongoing PHS-funded project, the review committee shall within sixty days review the SFI, determine whether it is related to PHS-funded research, and determine whether a FCOI exists. If so, it will implement, on at least an interim basis, a management plan that shall specify the actions that have been and will be taken to manage the FCOI.

Whenever a FCOI is not identified or managed in a timely manner, including:

- Failure by the Investigator to disclose a SFI that is determined by the University to constitute a FCOI;
- Failure by the University to review or manage such a FCOI; or
- Failure by the Investigator to comply with a FCOI management plan;

the University shall, within 120 days of the University's determination of noncompliance, complete a "retrospective review" of the Investigator's activities and the funded research project to determine whether any 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 University shall document the respective review, which will include 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 FCOI;
- 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.

The Provost or relevant Cabinet member will appoint a committee that will include related subject matter experts to determine if the research was biased. If bias is found, University of Hartford will develop and implement a plan to mitigate the bias and notify the Awarding Component promptly after retrospective review.

In any case in which the Department of Health and Human Services determines that a PHS-funded project of clinical research conducted by an Investigator with a FCOI was not managed or reported as required by PHS regulations, University of Hartford will require the Investigator to disclose the FCOI in each public presentation of research and request an addendum to previously published presentations.

Any failure by an individual to adhere to this policy may be cause for disciplinary action.

h) Public Accessibility

Prior to the expenditure of any funds under a PHS-funded research project, the University will ensure public accessibility by written response to a requestor within five business days of the request, of information concerning any SFI disclosed that meets the following criteria:

- 1) The SFI was disclosed and is still held by the senior/key personnel for the NIH-funded research project identified by the University in the grant application, progress report, or any other required report submitted to the NIH.
- 2) The University determines that the SFI is related to the NIH-funded research.
- 3) The University determines that the SFI is an FCOI.

The information the University will make available in a written response to any requestor within five days of the request, will include:

- 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 Significant Financial Interest is held;
- 4) The nature of the Significant Financial Interest; and
- 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.

i) Other Administrative Matters

Record Keeping

The University will maintain records relating to all Investigator disclosures of SFIs and the University's review of, and response to, such disclosures (whether or not a disclosure resulted in the University's determination of a FCOI) and all actions under the University's policy or retrospective review, if applicable, of at least three years from the date the final expenditures report is submitted to the funding agency or, where applicable, from other dates specified in 45 CFR 75.361 for different situations.

Notification of the Funding Agency

In submitting funding applications to public and private agencies, the University may be required to certify that: the University has implemented a written and enforced policy on conflicts of interest consistent with the funding agency's requirements; that to the best of the institutional representative's knowledge, all financial disclosures required by the conflict of interest policy have been made; and that all identified conflicts of interest will have been satisfactorily managed, reduced or eliminated prior to the University's expenditure of any funds under the award.

Prior to the expenditure of any funds under a PHS-funded project, the University will submit to the PHS Awarding Component an FCOI report compliant with PHS regulations regarding any Investigator's SFI found to be conflicting and will ensure the Investigator has agreed to and implemented the corresponding management plan. While the award is ongoing (including any extensions with or without funds), the University will provide to the PHS Awarding Component an annual FCOI report that addresses the status of the FCOI. The annual report will provide an indication whether the FCOI is being "Managed" and if there are any changes to the management plan, if applicable, or that the FCOI "no longer exists" with an explanation. Annual reports are due to NIH at the same time as when the University is required to submit the research performance progress report (e.g., 2 months or 45 days prior to the next budget period start date

or at the time of extension).

For any SFI that is identified as conflicting subsequent to an initial FCOI report during an ongoing PHS-funded project (e.g., participation of an Investigator who is new to the project), the University will provide to the PHS Awarding Component, within sixty days, an FCOI report regarding the FCOI and ensure it has implemented a management plan and the Investigator has agreed to the relevant management plan.

FCOI Reports submitted to the NIH are sent via the eRA Commons FCOI Module ([Financial Conflict of Interest \(FCOI\) | eRA \(nih.gov\)](#)). The Original (initial) FCOI reports will include the information provided in NIH's FAQ H.5. at [Frequently Asked Questions \(FAQs\) | grants.nih.gov](#).

Staff Support

OSP will support the implementation and management of this policy, except when the office itself is involved in the management of the external funds. In such instances, the Office of the Provost will assume this responsibility.

Resources:

- [PHS Subpart F - Promoting Objectivity in Research](#) (42 CFR Part 50 Subpart F)
- [NIH Financial Conflict of Interest Public Website](#)
- [NIH Grants Policy Statement](#)
- [NIH FAQs regarding the FCOI regulations](#)
- [NIH FCOI Training module](#)
- [Types of FCOI Reports Summary Chart](#)
- [FCOI Noncompliance Reporting Requirements Summary Chart](#)
- [NSF Proposal & Award Policies & Procedures Guide \(PAPPG 24-1\)](#)
- [U.S Department of Health and Human Services Organizational Chart](#)
- [AAMC Implementing the Final Rule on Financial Conflicts of Interest in Public Health Service Funded Research](#)