

Policy on Financial Conflicts of Interest in Research

Responsible Office(s): Office of the Vice Provost of Research and Innovation; Office of Research Integrity & Compliance
Effective Date: March 13th, 2024

I. Purpose of this Policy

This Policy contains guidelines aimed to ensure research objectivity and proper stewardship of research funding; the Policy provides for the disclosure, assessment, and reporting of financial interests, consistent with requirements of external sponsors, including U.S. federal sponsors. Through this Policy, Stevens Institute of Technology (“Stevens” or the “university”) promotes objectivity in research and requires that the design, conduct, and reporting of research be free from bias resulting from conflicts.

The Policy applies to “Investigators” at Stevens, which encompasses all individuals, regardless of position, who are responsible for designing, conducting, or reporting sponsored research. Stevens’ Investigators include faculty, staff, and students explicitly named in sponsored research applications, proposals, and budgets, and also includes key personnel identified in progress reports that Stevens submits to sponsors.

Financial conflicts of interest, or FCOIs, arise when the financial interests of Investigators or their spouses/domestic partners or dependent children could affect the design, conduct, or reporting of Stevens’ research. Such conflicts have the potential to exert undue influence on various aspects of research, spanning study design, data collection, analysis, and reporting, as well as the involvement of individuals and entities in the research.

This Policy is specific to the Stevens research community and is administered by the Office of Research Integrity and Compliance within Stevens’ Office of Research and Innovation. This Policy operates in addition to Stevens’ university-wide Conflict of Interest Policy (located in the [Policy Library](#)) and does not replace or supersede the university-wide Conflict of Interest Policy or any other process at Stevens. Stevens Investigators must comply with this Policy in addition to the university-wide Conflict of Interest Policy.

II. Policy

This Policy requires the disclosure of significant financial interests (as further defined below, “SFI”) by Stevens’ Investigators who are involved in the design, conduct, or reporting of research at Stevens. Stevens’ Financial Conflicts of Interest Committee (the “Committee”) will evaluate and determine if a reported SFI constitutes a financial conflict of interest (“FCOI”) as described below and as consistent with applicable sponsor policies and requirements.

A. Financial Conflicts of Interest

A Financial Conflict of Interest (“FCOI”) arises when Stevens determines that a Significant Financial Interest (“SFI”) has the potential to directly and significantly affect the design, conduct, or reporting of the Investigator’s research.

It is the responsibility of the project principal investigator or project director for each research project to ensure that each Investigator under a project has made all required SFI disclosures.

SFIs that give rise to financial conflicts of interest may arise from (for example) an Investigator's professional interactions outside their work for the university or from the personal financial interests of the Investigator or the Investigator's spouse/domestic partner, or dependent children. Some such outside activities and interests that are governed by the Faculty Handbook and the university-wide Conflict of Interest Policy may be permitted under those policies but present a conflict of interest under this Policy. The existence of a potential financial conflict of interest does not imply wrongdoing. However, when financial conflicts of interest arise in research, the university must manage, reduce, or eliminate the conflict to assure objectivity in the design, conduct, and reporting of research at Stevens.

B. Definitions

Institutional Responsibilities refers to an Investigator's professional duties on behalf of the university, or associated with an Investigator's Stevens appointment or position, encompassing activities such as teaching, administration, research, and clinical care. Examples of Institutional Responsibilities at Stevens include:

- Externally sponsored research and scholarly activities (e.g., proposing, conducting, and analyzing research and disseminating results);
- Departmental/university research (e.g., participation in study sections, peer review of manuscripts and effort on non-sponsored research);
- Instruction/university supported academic activities (including preparation for and presentations of formal and informal courses to students/trainee groups, mentoring students and trainees, and participation in resident training);
- Administrative activities including serving as department chair, program director, and service on institutional committees, participation in department activities and faculty advisory boards, etc.;
- or
- Special service activities on behalf of the university, including institutional community service.

Institutional Responsibilities typically do not include volunteer community or public service activities unrelated to one's profession or university responsibilities.

Investigator¹ refers to the project director or principal investigator and any other person, regardless of title or position, responsible for the design, conduct, or reporting of research, including research proposed for funding. Investigators may include students, consultants, and contractors. Stevens' Investigators include faculty, staff, and students explicitly named in sponsored research applications, proposals, and budgets, and also includes key personnel identified in progress reports that Stevens submits to sponsors.

Significant Financial Interest or SFI means:

- (1) A financial interest consisting of one or more of the following interests of the Investigator (including those of the Investigator's spouse/domestic partner and dependent children) that reasonably appear to be related to the Investigator's Institutional Responsibilities:
 - (i) Regarding any foreign or domestic publicly traded entity, a Significant Financial Interest exists if the aggregated value of remuneration received from the entity in the twelve months

¹ Department of Energy (DOE) program offices have the discretion to expand the definition to include any person who participates in the purpose, design, conduct, or reporting of a project funded by DOE or proposed for funding by DOE. Such expansion will be specified in the applicable funding opportunity announcement and/or terms and conditions of the financial assistance award.

preceding the disclosure, plus the value of any equity interest in the entity or venture or other capital financing from the entity as of the disclosure date, exceeds \$5,000. Remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); an equity interest includes any stock, stock option, or other ownership interest, determined through reference to public prices or other reasonable measures of fair market value.

- (ii) Regarding any foreign or domestic non-publicly traded entity, a Significant Financial Interest exists if the aggregated value of any remuneration or venture or other capital financing received from the entity in the twelve months preceding the disclosure exceeds \$5,000, or when the Investigator (or the Investigator's spouse/domestic partner or dependent children) holds any equity interest (e.g., stock, stock option, private equity, or other ownership interest) regardless of value.
 - (iii) Income derived from intellectual property rights and interests (e.g., patents, copyrights, and royalties from such rights), upon receipt of income related to such rights and interests, regardless of value, in the 12 months preceding the disclosure.
- (2) Any reimbursed or sponsored travel (i.e., reimbursed to or paid on behalf of the Investigator, the Investigator's spouse/domestic partner, or dependent children) related to the Investigator's Institutional Responsibilities, regardless of value received from a single entity in the preceding twelve months. Note: A SFI includes reimbursement or sponsored travel from non-U.S. governments, non-U.S. universities, or other non-U.S. entities where the cost or value received from such entity exceeds \$5,000 in the preceding twelve months.

However, the following is not considered a SFI: travel reimbursed or sponsored by a U.S. federal, state, or local government agency, a U.S. institution of higher education as defined at 20 U.S.C. § 1001(a), a U.S. academic teaching hospital, a U.S. medical center, or a U.S. research institute affiliated with a U.S. institution of higher education.

The details of disclosure for reimbursed or sponsored travel will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.

- (3) The term Significant Financial Interest excludes the following types of financial interests:
- (i) Salary, royalties, and other remuneration paid by the university to the Investigator if the Investigator is currently employed or otherwise appointed by the university, including intellectual property rights assigned to the university and agreements to share in royalties related to such rights.
 - (ii) 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.
 - (iii) Income from seminars, lectures, and teaching engagements sponsored by a U.S. federal, state, or local government agency, a U.S. institution of higher education as defined at 20 U.S.C. 1001(a), a U.S. academic teaching hospital, a U.S. medical center, or a U.S. research institute that is affiliated with a U.S. institution of higher education.
 - (iv) Income from service on advisory committees and review panels for a U.S. federal, state, or local government agency, a U.S. institution of higher education as defined at 20 U.S.C.

1001(a), a U.S. academic teaching hospital, a U.S. medical center, or a U.S. research institute that is affiliated with a U.S. institution of higher education.

III. Disclosure

Before submitting an application to a research sponsor, each Investigator must disclose their Significant Financial Interests (including those of their spouse/domestic partner, and dependent children) to the Office of Research Integrity and Compliance² via the disclosure form provided in Workday. Submission of a disclosure form serves as a certification of the truthfulness of the SFI disclosures and acknowledgement of the responsibility to update disclosures during the award period should circumstances change which affect previous disclosures. If a new Investigator intends to join the project after the submission of the funding application or during the research project, the Investigator must promptly disclose any SFI to the Office of Research Integrity and Compliance via the disclosure form before participating in research.

Investigators participating in Stevens' research must provide updated disclosures of their SFIs at least annually. These disclosures must cover any information not initially disclosed to Stevens in accordance with this Policy or in subsequent SFI disclosures (e.g., any SFI subsequently acquired) and updated information on previously disclosed SFIs, such as the revised value of an equity interest, must also be included.

Furthermore, all Investigators participating in Stevens' research must promptly submit an updated disclosure of SFIs within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI.

IV. Subrecipient Requirements

If Stevens' research includes a subrecipient, Stevens will take steps to ensure that a subrecipient Investigator complies with sponsor requirements. Where required, Stevens will provide FCOI reports to the sponsor regarding all subrecipient FCOIs.

As part of the subaward agreement, subrecipients will be required to certify that their policy complies with the sponsor's FCOI policy and that their policy is publicly available, and the subaward agreement will include a specific time period in which the subrecipient must report all identified FCOIs to Stevens. If the subrecipient cannot certify that its policy complies with the sponsor's FCOI requirements, the subaward agreement will state that the subrecipient will comply with this Policy on Financial Conflicts of Interest in Research.

V. Review by the Financial Conflicts of Interest Committee

A. Overview; Composition

The Financial Conflicts of Interest Committee (the "Committee") is composed of the Institutional Official, the Vice Provost for Research and Innovation ("VPR"), the Associate Provost, the Associate Dean for Research in the School of Engineering and Science, the Chief Compliance Officer, and a member of Internal Audit. The Committee will manage, mitigate, reduce or eliminate SFIs.

² The Provost has designated the Director of the Office of Research Integrity and Compliance as the Institutional Official who will solicit and review disclosures of significant financial interests from each Investigator who is planning to participate in, or is participating in, research.

B. Guidelines for Determining Conflicts of Interest

The Committee will assess SFI disclosures to determine whether an SFI is related to the Investigator's research activity and, if so, whether the SFI gives rise to a FCOI in connection with that research activity. An Investigator's SFI is considered related to the Investigator's research activity when the Committee reasonably determines that the SFI could be affected by the Investigator's research activity or is in an entity whose financial interest could be affected by the Investigator's research activity.

A FCOI exists when the Committee determines that the SFI could directly and significantly affect the design, conduct, or reporting of the Investigator's research activity. Factors to be considered in determining that an FCOI exists include the Investigator's role and the potential for bias in the results of the research, the nature of the proposed research, funding from an entity in which the Investigator holds an SFI, and an evaluation of the SFI's.

The Committee will determine the appropriate management or mitigation plan for any FCOI and communicate its decision to the relevant Investigator and the Provost. The Committee may call upon subject-matter experts as needed with respect to any particular project, or upon the Investigator, to inform the Committee's decisions.

C. Management of Financial Conflicts of Interest (FCOI)

Examples of mechanisms that the Committee may use to avoid or manage conflicts include requiring the Investigator to recuse themselves from decisions involving the conflicting entity, abstain from certain activity, modify an activity, publicly disclose the significant financial interest, divest the significant financial interest, and/or be subject to independent monitoring. The necessity of the Investigator's ongoing role in advancing the research, considering their expertise, will also be weighed.

If the Investigator disagrees with the Committee's decision, a written request may be submitted to the Committee which will refer the matter to the Provost for a decision. The Provost's decision will be conclusive, and failure to comply with the Provost's decision may result in disciplinary action up to and including termination.

Expenditures on sponsored awards will not be authorized until the Investigator adheres to the disclosure requirements outlined in this Policy and agrees in writing to comply with any plans established by the Committee to manage a conflict of interest.

VI. Record Keeping

The Office of Research Integrity and Compliance will maintain records of Investigator disclosures of Significant Financial Interests and the Committee's review and response to such disclosures, as well as all actions taken under this Policy. These records will be preserved for three years from the date of the final expenditures report for grants, three years from the date of the final payment for contracts or, if applicable, for such other time periods required by applicable law.

VII. Public Accessibility Specific to PHS and DOE Funded Awards

Before expenditure of any funds for a Public Health Service (PHS)³ or US Department of Energy (DOE) funded research project, Stevens will ensure that information about those Significant Financial Interests which meet the criteria set forth below and have been disclosed to Stevens is publicly accessible upon request, according to agency-specific requirements. The criteria include:

- (i) The SFI was disclosed and is still held by Investigators identified in the grant application or progress reports submitted to PHS or DOE by the university;
- (ii) Stevens has determined that the SFI is related to the PHS or DOE funded research; and
- (iii) Stevens has determined that the SFI is a Financial Conflict of Interest.

The information made publicly available will, at a minimum, include:

- (i) Investigator's name
- (ii) Investigator's title and role in the research project
- (iii) Name of the entity in which the SFI is held
- (iv) Nature of the SFI
- (v) Approximate dollar value of the SFI in specified 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 indicating that the value of the interest cannot be easily determined through reference to public prices or other reasonable measures of fair market value.

Public accessibility will be consistent with all sponsor requirements.

VIII. Reporting to Sponsors

Where required, Stevens will notify research sponsors about identified FCOIs and management plans that address the FCOI. Investigators are required to cooperate with Stevens to fulfill all reporting obligations to research sponsors.

Prior to expenditure of any funds for a sponsored project, Stevens will also confirm that the Investigator has accepted and implemented any corresponding management plan. Throughout the duration of a sponsored award, including any extensions, and where required by the sponsor, Stevens will furnish the sponsor with an annual FCOI report, detailing the status of the financial conflict of interest and any adjustments made to the management plan.

In the event that Steven deems an SFI to be a conflict of interest after the initial FCOI report to the sponsor and while an ongoing research project is underway (e.g., with the involvement of a new Investigator),

³ The following agencies are a part of PHS: Agency for Health Care Research & Quality (AHRQ), Agency for Toxic Substances and Disease Registry (ATSDR), Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), Health Resources and Services Administration (HRSA), Indian Health Service (IHS), National Institutes of Health (NIH), and Substance Abuse and Mental Health Services Administration (SAMHSA). The following U.S. Department of Health and Human Services units typically follow PHS regulations on financial conflicts of interest in research: Office of Global Affairs (OG), Office of the Assistant Secretary for Health (OASH), Office of the Assistant Secretary for Planning and Evaluation (OASPE), Office of the Assistant Secretary for Preparedness and Response (ASPR), and Office of Public Health and Science (OPHS).

Stevens will deliver a FCOI report to the sponsor within sixty days. This report will outline the financial conflict of interest, the implemented management plan, and confirmation that the Investigator has agreed to adhere to the management plan.

IX. Training Requirements

Stevens' Office of Research Integrity and Compliance will oversee and monitor specific training requirements for Investigators. Investigators engaged in research must complete conflict of interest training in accordance with sponsor-specific requirements before commencing work related to the funded award.

In all cases, Investigators must participate in training about this Policy and sponsor requirements before engaging in research activity and at least every four years thereafter, and immediately when any of the following circumstances apply:

1. Stevens revises this Policy or procedures related to this Policy in any manner affecting the requirements of Investigators;
2. When an Investigator is new to Stevens, training must be completed within 30 days; and
3. If Stevens determines that an Investigator is not in compliance with this Policy or a management plan issued under this Policy, training must be completed within 30 days.

The required training is accessible online through the [Collaborative Institutional Training Initiative \(CITI\)](#). On the CITI website, you must complete the four modules under Conflicts of Interest:

- Financial Conflicts of Interest: Overview, Investigator Responsibilities, and COI Rules (COI-Basic) (ID: 15070)
- Institutional Responsibilities as They Affect Investigators (COI-Basic) (ID: 15072)
- Conflicts of Commitment and Conscience (COI-Basic) (ID: 15073)
- Conflicts of Interest Institution-Specific Policies (ID: 15246)

If you are new to CITI, please refer to the article on the CITI website relating to "[Guide to Getting Started](#)". Please remember to affiliate your training with Stevens to ensure Stevens receives notification upon completion.

X. Failure to Comply with Stevens' Policy on Financial Conflicts of Interest in Research

If an FCOI is not identified or managed promptly for any reason including without limitation delayed disclosure of the Significant Financial Interest by an Investigator, untimely review or reporting of an FCOI by a subrecipient or by Stevens, or non-compliance with a management plan by an Investigator, Stevens will follow sponsor requirements, including any requirements for a retrospective review.

The purpose of any retrospective review (if required by a sponsor) will be to assess whether any research or a portion thereof conducted during the period of noncompliance exhibited bias in its purpose, design, conduct, or reporting. The VPRI will appoint one or more individuals to conduct the review. If bias is identified, Stevens will develop and implement a plan to mitigate it. The Institutional Official will provide prompt notification to the sponsor, and a mitigation report will be submitted within 120 days of determining noncompliance. Future expenditures of funds on the relevant award(s) will only be allowed if the Investigator has complied with the disclosure requirements of this Policy and has agreed in writing to adhere to any Committee-approved FCOI management plan.

Any failure by an individual to comply with this Policy may result in disciplinary action up to and including termination.

XI. Sponsor-Specific Requirements

Stevens will comply with all applicable sponsor requirements, which may modify or supplement the requirements of this Policy. Please contact the Office of Research Integrity and Compliance to address any sponsor-specific requirements.

XII. Malign Foreign Talent Recruitment Programs

[Federal law](#) and Stevens prohibit Investigator participation in a malign foreign talent recruitment program (“MFTRP”). An Investigator’s submission of, or inclusion in, a research proposal is the Investigator’s certification that they are not party to a MFTRP. Please contact the Office of Research Integrity and Compliance with questions.

XIII. Current and Pending Support

Current and Pending/Other Support disclosure requirements are distinct from the principles in this Policy. Some information disclosed for Current and Pending/Other Support may overlap with information disclosed for purposes of this Policy but require separate and distinct submissions. Please contact the Office of Research Integrity and Compliance with questions.