

Fairfield University

Financial Conflict of Interest in Research Policy

Introduction

Fairfield University has developed the following policy on Financial Conflict of Interest in Research (FCOI) for all investigators, including those applying to or holding grants from federal sponsors, including but not limited to, the National Institutes for Health and the National Science Foundation. This Policy provides guidelines to promote objectivity in research and establishes standards to ensure that the design, conduct, and reporting of research funded by external agencies will not be biased by any conflicting financial interest of an Investigator. The University encourages Investigators to engage in appropriate outside relationships, but significant financial interests related to these relationships need to be disclosed, reviewed, and managed in accordance with this Policy.

Overview

This policy requires that Investigators disclose significant financial interests (SFI) received or held by themselves, their spouse and/or their dependent children that are related to the Investigator's institutional responsibilities.

A financial conflict of interest (FCOI) exists when the university's designated official(s) reasonably determines that an investigator's significant financial interest (SFI) could be affected by the research or 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 externally-funded research.

Conflicts of interest frequently are matters of degree and judgment, and Fairfield University expects faculty and staff to be alert to the possible effect of outside activities on the integrity of decisions and on the ability to fulfill obligations to the institution or to funding agencies.

When is a Disclosure Required?

Investigator disclosures must be made **prior** to the submission of a proposal for funding and updated **annually** throughout the award period. Should the university determine that a financial conflict of interest exists, the university must ensure that the conflict will be satisfactorily managed, reduced, or eliminated prior to the expenditure of any funds on an award.

If a new significant financial interest (SFI) is discovered or acquired at any time during the period after the submission of the proposal through the period of the award, the investigator must submit a new disclosure **within 30 days** of discovering or acquiring a new SFI.

Definitions

Conflict of Interest: A conflict of interest may take various forms, but a financial conflict of interest (FCOI) arises when a significant financial interest (SFI) is determined to be related to the Public Health Service (e.g., NIH) – funded research and may directly and significantly affect the design, conduct, or reporting of externally-funded research. Other types of conflicts of interest may occur when an Investigator is or may be in a position to influence the business of the college, research, or other decisions in ways that could lead to any form of personal gain for the Investigator, or for any member of the Investigator's family (spouse and/or dependent child).

Investigator: The Principal Investigator or Project Director and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded or proposed for funding by an external agency.

Significant Financial Interest (SFI): A financial interest consisting of one or more of the following interests of the Investigator (and those of Investigator's spouse and dependent children) that reasonably appear to be related to the investigator's institutional responsibilities:

- **For any publicly traded entity**, a significant financial interest exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure **and** the value of any equity interest as of the date of disclosure, when aggregated, **exceeds \$5,000**. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary; equity interest includes any stock, stock option or other ownership interest as determined through reference to public prices or other reasonable measures of fair market value;
- **For any non-publicly traded entity**, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, **exceeds \$5,000**, or when the Investigator (or the Investigator's spouse or dependent children) holds **any** equity interest (e.g. stock, stock option, or other ownership interest); or
- **Intellectual property rights and interests** (e.g. patents, copyrights) upon receipt of income that **exceeds \$5,000** related to such rights and interest.

Reimbursed or sponsored travel: Investigators must also disclose any reimbursed or sponsored travel (i.e., paid on behalf of the Investigator) received in the preceding twelve months that **exceeds \$5,000** related to their institutional responsibilities. This includes all travel sponsored by **foreign** entities but does not include travel that is reimbursed or sponsored by a U.S. public agency or U.S. academic institution (i.e. a United States federal, state or local government agency, a United States institution of higher education, an academic teaching hospital, a medical center, or a research institute affiliated with a United States institution of higher education). This disclosure should include the purpose of the trip, the name of the sponsor/organizer, the destination, and the duration.

Significant Financial Interest (SFI) does **not** include:

- Salaries, royalties or other remuneration paid to the Investigator by the University;
- Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control their investment decisions;
- Income from seminars, lectures, or teaching engagements sponsored by a U.S. public agency or academic institution (i.e. a United States federal, state or local government agency, a U.S. institution of higher education, an academic teaching hospital, a medical center, or a research institute affiliated with a U.S. institution of higher education);
- Income from service on advisory committees or review panels for a U.S. public agency or U.S. academic institution (i.e. a United States federal, state or local government agency, a United States institution of higher education, an academic teaching hospital, a medical center, or a research institute affiliated with a United States institution of higher education).

Training and Support

It is Fairfield University's responsibility to inform Investigators about this policy and provide training on their obligations to disclose SFIs related their institutional responsibilities (e.g. research, research consultation, teaching, clinical, etc.)

An online training course on "Conflict of Interest (COI)" available from the NIH (<https://grants.nih.gov/grants/policy/coi/fcoi-training.htm>) will serve as the primary training mechanism for PHS-funded Investigators. Additional online training is available at CITI Program (www.citiprogram.org) for non-PHS funded Investigators. All externally-funded Investigators must complete the relevant training **prior** to engaging in externally-funded research and at least **every four years** thereafter. Investigators should submit their certificate of completion to the Office of Research and Grants (ORG). Additional in-person training may be offered at the university's discretion.

Any Investigator that is new to the University must also complete training prior to engaging in externally-funded research. Further training may be required should the university find that an Investigator is not in compliance with the Policy or a management plan, as applicable.

Disclosure and Mitigation Procedures

1. All investigators must disclose their significant financial interests utilizing the Conflict of Interest Form and attaching all required supporting documentation. The completed form must be submitted to the Office of Research and Grants (ORG). This form requires individual faculty members to certify that they have read and understood this Conflict of Interest in Research Policy, that they have made all required disclosures, and that they agree to comply with any conditions or restrictions imposed by Fairfield University to manage a conflict of interest. In accordance with Federal regulations, a complete disclosure must be made by investigator(s) **prior** to submission of the proposal and updated **annually** and/or **within 30 days** of any newly acquired or discovered SFIs.
2. The Associate Vice Provost for Research and Scholarship, the Director of the Office of Research and Grants, or the Director of Foundation Relations shall perform an initial review of all financial disclosures by an investigator if they, their spouse or dependent children receive or hold a significant financial interest that is related to the Investigator's institutional responsibilities. A conflict of interest exists when this review reasonably determines that the financial interest could be affected by the research or is in an entity whose financial interest could be affected by the research and is determined to directly and significantly affect the design, conduct, or reporting of the proposed sponsored project. If the initial determination is made that a financial conflict of interest exists, the disclosure package will be referred to the Provost. The Provost shall determine what conditions or restrictions, if any, must be imposed by the institution to manage the financial conflict of interest arising from the disclosed significant financial interests.
3. Prior to consideration by the Provost, the investigator, in cooperation with the Associate Vice Provost for Research and Scholarship and the school dean, shall develop and present a Conflict of Interest Resolution Plan that details proposed steps that will be taken to manage, reduce, or eliminate any conflict of interest presented by a significant financial interest. At a minimum the resolution plan shall address such issues as:
 - a. Public disclosure of financial conflicts of interests (e.g., when presenting or publishing the research; to staff members working on the project; to the Institution's Institutional Review Board(s), Institutional Animal Care and Use Committee(s), etc;

- b. For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
- c. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the Financial Conflict of Interest;

The Provost shall review the resolution plan and approve it and add conditions or restrictions which may include any of the following:

- a. Modification of the research plan;
 - b. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research funded;
 - c. Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
 - d. Severance of relationships that create actual financial conflicts.
4. An approved resolution plan shall be incorporated into a Memorandum of Understanding (MOU) between Fairfield University and the Investigator that details the conditions or restrictions imposed upon the Investigator in the conduct of the project or in the relationship with the business or entity. The MOU shall be signed by the Investigator, department chair or program director, school dean, and the Provost.
 5. The Associate Vice Provost for Research and Scholarship will certify that conflicts of interests will be satisfactorily managed, reduced, or eliminated in accordance with these guidelines prior to expending any funds from the applicable federal award, or they will be disclosed to the sponsored agency for action.
 6. Resolutions to financial conflicts of interest must be articulated in writing and signed prior to expenditure of any award funds and **within 60 days** of identifying a financial conflict of interest during the period of an award.
 7. Any financial conflicts of interest that were not eliminated prior to award start must be reported to the funding agency **prior** to the expenditure of award funds or **within 60 days** of identification of the financial conflict of interest. Annual FCOI updates shall be provided to the funding agency if required for the duration of the award period. See **Appendix A** for details on FCOI reporting requirements.
 8. In any case where a financial conflict of interest was not identified or managed by the university on a timely basis for whatever reason, the university must **within 120 days** of determination of non-compliance, complete a retrospective review of the investigator's activities and the externally-funded research project to determine whether any bias occurred in the design, conduct, or reporting of such research and document the review and any findings with notification to the funding agency if bias is found. See **Appendix B** for full retrospective review requirements.
 9. **Non-Compliance:** If an Investigator violates this policy, his or her dean will recommend to the Provost sanctions which range from additional training for minor oversights to a public letter of reprimand up to and including dismissal. The Provost will make the final decision as to the sanctions to be invoked. In addition, the University will follow Federal regulations regarding the notification of the sponsoring agency in the event an Investigator has failed to comply with this policy. The sponsor may take its own action as it deems appropriate.

Subrecipients

Fairfield University is responsible for monitoring subrecipients for compliance with the Financial Conflict of Interest regulation, management plans, and for reporting all identified financial conflicts of interest to the NIH or other funding agency.

Any institution proposed as a subrecipient must provide the following **prior** to proposal submission:

- signed certification that their institutions are in compliance with federal policies regarding Significant Financial Interest disclosure and that their portion of the project is in compliance with their institutional policies; or
- if they cannot provide this certification, then the subrecipient's investigators must agree to be subject to Fairfield University's Financial Conflicts of Interest in Research Policy.

Upon award of external funding, the university will establish a written agreement with the subrecipient that confirms whether the Financial Conflict of Interest policy of Fairfield University or that of the subrecipient will apply to subrecipient Investigators and providing sufficient time to meet disclosure and/or Financial Conflict of Interest reporting requirements.

Subrecipient Institutions who rely on their own Financial Conflict of Interest policy must report identified financial conflicts of interests to Fairfield in sufficient time to allow the university to report the Financial Conflict of Interest to the NIH or other funding agency to meet its reporting obligations.

Subrecipient institutions that agree to comply with Fairfield University's policy must submit all Investigator disclosures of Significant Financial Interests to the university in sufficient time to allow Fairfield to review, manage and report identified FCOIs to the NIH or other funding agency.

Reporting Requirements

Financial conflicts of interest must be reported prior to the expenditure of project funds to the external funding agency per their specific guidelines. See **Appendix A** for NIH FCOI reporting requirements and procedures.

For awards funded by the National Science Foundation (NSF), the university must keep the Office of the General Counsel (OGC) appropriately informed if the university finds that it is unable to satisfactorily manage a conflict of interest and if the university finds that research will proceed without the imposition of conditions or restrictions when a conflict of interest exists.

Recordkeeping and Public Accessibility

The university must maintain records relating to all Investigator disclosures of financial interests and the university's review of, and response to, such disclosures (whether or not a disclosure resulted in a determination of a financial conflict of interest) and all actions under the university's policy or retrospective review, if applicable. These records shall be retained by the Office of Research and Grants (ORG) until at least **three (3) years** after the date of submission of the final expenditures report for the award to which they relate, or the resolution of any government action involving those records, whichever comes later.

The university's Financial Conflict of Interest in Research Policy is available on the university's public website. Any written requests for information on an investigator's identified financial conflict of interest will be answered within **five business days** of receipt of such request and

available for **at least three years** from the most recent update to the conflict of interest. This information shall include, at a minimum, the following:

- a. Investigator's name;
- b. Investigator's title and role with respect to the research project;
- c. Name of the entity in which the Significant Financial Interest is held;
- d. Nature of the Significant Financial Interest; and
- e. Approximate dollar value of the Significant Financial Interest (by range: \$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.

Additional Resources

Public Health Service (PHS)

<https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-50/subpart-F>

<https://grants.nih.gov/grants/policy/coi/index.htm>

<https://grants.nih.gov/grants/policy/coi/fcoi-training.htm>

National Science Foundation (NSF) PAPPG Chapter IX.A

<https://new.nsf.gov/policies/pappg/24-1/ch-9-recipient-standards#a-conflict-of-interest-policies-28e>

Department of Energy (DOE) Interim Conflict of Interest Policy

<https://www.energy.gov/sites/default/files/2022-10/Department%20of%20Energy%20Interim%20Conflict%20of%20Interest%20Policy.pdf>

National Aeronautics and Space Administration (NASA) Grant and Cooperative Agreement Manual (GCAM), Section 3.3

<https://www.nasa.gov/general/grants-policy-and-compliance-team/>

Appendix A – FCOI Reporting Requirements and Procedure

Initial Reports:

Prior to the university's expenditure of any funds under an externally-funded research project, the university must provide to the funding agency an FCOI report regarding any Investigator's Significant Financial Interest found to be a Financial Conflict of Interest in accordance with this policy. The university must also provide an FCOI report whenever an Investigator does not timely disclose a Significant Financial Interest or whenever the university, for whatever reason, does not review a disclosed Significant Financial Interest and subsequently determines that a Financial Conflict of Interest exists.

Submission of Initial FCOI reports during an Ongoing NIH-funded Research Project:

When an Investigator is newly participating in a project or an existing Investigator discloses a new Significant Financial Interest to the university during the period of award, the university must submit an FCOI report within **sixty (60) days** after its determination that an FCOI exists.

Whenever an Investigator does not disclose timely a previously existing Significant Financial Interest or the university fails to review a previously existing Significant Financial Interest during an ongoing externally-funded project, the university's designated official(s) shall, within **sixty (60) days**: review the Significant Financial Interest; determine whether it is related to the externally-funded research; and determine whether a Financial Conflict of Interest exists. If so, the university will implement, on at least an interim basis, a management plan that shall specify the actions that have been, or will be, taken to manage such Financial Conflict of Interest going forward and submit an FCOI report to the funding agency.

In addition to the FCOI report, the university must, **within 120 days** of the university's determination of noncompliance, complete a retrospective review of the Investigator's research activities and the externally-funded research project to determine whether any externally-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct or reporting of such research. See **Appendix B** for specific retroactive review requirements.

Based on the results of the retrospective review, if appropriate, the university will update the previously submitted FCOI report, specifying the actions that will be taken to manage the Financial Conflict of Interest going forward.

If bias is found, the university must notify the funding agency promptly and submit a mitigation report that includes the key elements documented in the retrospective review and a description of the impact of the bias on the research project and the university's plan of action or actions taken to eliminate or mitigate the effects of the bias. Thereafter the university will submit FCOI reports annually.

Annual FCOI Report:

For any Financial Conflict of Interest previously reported by the university, the university shall provide an annual FCOI report that addresses the status of the financial interest and any changes to the management plan. Annual FCOI reports shall specify whether the Financial Conflict of Interest is still being managed or explain why the Financial Conflict of Interest no

longer exists. Annual FCOI reports must be submitted to the external agency (e.g., through the eRA Commons for NIH grants and cooperative agreements) for the duration of the project period (including extensions with or without funds) at the same time as when the university is required to submit the annual progress report (i.e., **two months** prior to the start date or **45 days** prior to the start date of the noncompeting continuation award), including a multi-year funded progress report, or at the time of a project extension with or without funds.

The annual FCOI report is submitted to NIH separately through the eRA Commons FCOI Module. The annual FCOI report is not to be submitted as part of the annual progress report nor is it a grant closeout requirement.

All Original FCOI reports must include sufficient information to enable the funding agency to understand the nature and extent of the Financial Conflict of Interest and to assess the appropriateness of the university's management plan. Key elements that must be included in the Original FCOI report include but are not necessarily limited to the following:

- a. Project number;
- b. PD/PI or Contact PD/PI if a multiple PD/PI model is used;
- c. Name of the Investigator with the Financial Conflict of Interest;
- d. Name of the entity with which the Investigator has a Financial Conflict of Interest;
- e. Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
- f. Value of the financial interest (dollar ranges are permissible: \$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;
- g. A description of how the financial interest relates to the externally-funded research and why the Institution determined that the financial interest conflicts with such research;
- h. A description of the key elements of the Institution's management plan, including:
 - Role and principal duties of the conflicted Investigator in the research project;
 - Conditions of the management plan
 - How the management plan is designed to safeguard objectivity in the research project;
 - Confirmation of the Investigator's agreement to the management plan;
 - How the management plan will be monitored to ensure Investigator compliance; and
 - Other information as needed.

Appendix B – Retrospective Review Requirements

Whenever a Financial Conflict of Interest is not identified or managed in a timely manner, including:

- Failure by the Investigator to disclose a Significant Financial Interest that is determined by the university to constitute a Financial Conflict of Interest;
- Failure by the university to review or manage such a Financial Conflict of Interest; or
- Failure by the Investigator to comply with a Financial Conflict of Interest management plan;

Fairfield University shall, **within 120 days** of the university's determination of noncompliance, complete a "retrospective review" of the Investigator's activities and the federally-funded research project to determine whether any federally-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's retrospective review will include at least the following key elements:

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