

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 financial interests held by themselves, their spouse and/or their dependent children that:

1. Would reasonably appear to be affected by the research activities funded, or proposed for funding, by an external sponsor; or
2. In an entity whose financial interest would reasonably appear to be affected by the research activities funded, or proposed for funding, by an external sponsor.

A financial conflict of interest exists when the university's designated official(s) reasonably determines that an investigator's significant financial interest (SFI) 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?

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 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 reportable significant conflict of interest arises at any time during the period after the submission of the proposal through the period of the award, the filing of a disclosure is also required **within 30 days** after new or significant financial interests are acquired.

Definitions

Conflict of Interest: A conflict of interest may take various forms, but arises when a significant financial interest (SFI) may directly and significantly affect the design, conduct, or reporting of externally-funded research, or 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 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) 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 federal, state or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute affiliated with an 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 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 an 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 federal, state or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute affiliated with an institution of higher education).

Training and Support

An online training course on "Conflict of Interest (COI)" available from CITI Program (www.citiprogram.org) will serve as the primary training mechanism for Investigators. All externally-funded Investigators must complete 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 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 the 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 conflict of interest.
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 to determine whether a conflict of interest exists. A conflict of interest exists when the review reasonably determines that a significant financial interest could directly affect the design, conduct, or reporting of the proposed sponsored project. If the initial determination is made that a conflict of interest exists, the disclosure package will be referred to the Provost. The Provost shall determine what conditions or restrictions, if any, should be imposed by the institution to manage conflicts of interest arising from 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 significant financial interests;
 - b. Review of research protocol by independent reviewers; and
 - c. Monitoring of research by independent reviewers.

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. Disqualification from participation in all or a portion of the research funded;
 - c. Divestiture of Significant Financial Interests; or
 - d. Severance of relationships that create actual or potential conflicts of interest.
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 conflicts of interest must be articulated in writing and signed prior to expenditure of any award funds and **within 60 days** of disclosure of the conflict.
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 conflict of interest. Annual FCOI updates shall be provided to the funding agency if required for the duration of the award period.
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.
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

All collaborators from other institutions paid as subrecipients of federal grant funds 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.

Recordkeeping and Public Accessibility

Records of the investigator, financial disclosures, and of actions taken to manage conflicts of interest shall be retained by the Office of Research and Grants (ORG) until **three (3) years** after the termination or date of submission of the final financial 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 will be 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.

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>

Rev 10/2017

Rev 8/24/2012

Rev 4/3/2024

<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/>