

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

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

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), Institutio-6.7 (i)2. (i)2(c)-2 (t)-6.6 (s)-c4 (l)2oal wimums

- 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 c t of ha on if(if the appo) Final 02 Tc 0.002 E w 0.16 T 0.03 0.01

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, ~~pre~~that

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>

~~http://www.psf.gov/po-8ics/pp (g)-11.4 (l)-7.824oi~~

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;

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