

# SEWANEE

THE UNIVERSITY OF THE SOUTH

## Financial Conflict of Interest Policy

### Purpose

The purpose of this policy is to comply with the federal regulations concerning objectivity in research (42 CFR Part 50 Subpart F and 45 CFR Part 94). The federal regulations and the University's policy promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of PHS- and NSF-funded research will be free from bias resulting from Investigator financial conflicts of interest.

The University encourages its faculty and staff to engage in research activities using the highest ethical standards and preventing the introduction of bias into their research.

### Scope

This policy applies to all Investigators employed by the University of the South who intend to pursue research funding (including contracts, cooperative agreements, grants and fellowships) from the U.S. Public Health Service (PHS), which encompasses the National Institutes of Health (NIH), or the National Science Foundation (NSF).

### Responsible Party

The Sponsored Research Office is responsible for maintaining this policy and may be contacted with any questions.

### Definitions

Term	Definition
<b>Financial Conflict of Interest (FCOI)</b>	A significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS- or NSF-funded research.
<b>Financial Interest</b>	Anything of monetary value, whether the value is readily ascertainable, received or held by the Investigator, his/her spouse, or dependent children.
<b>Institutional Responsibilities</b>	An Investigator's professional responsibilities on behalf of the University, and as defined by the University in its policy on financial conflicts of interest, which may include activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards.

<b>Investigator</b>	The project director or principal investigator and any other person, regardless of title or position, who is responsible for any part of the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include collaborators or consultants.
<b>Research</b>	A systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social- sciences research. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug).
<b>Significant Financial Interest</b>	<p>(1) A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities: (a) if the value of any remuneration received from any publicly traded 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. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); 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; (b) if the value of any remuneration received from any non-publicly traded 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 (c) intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.</p> <p>(2) Investigators also must disclose the occurrence of any reimbursed or sponsored travel (<i>i.e.</i>, that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities. This disclosure requirement <u>excludes</u> travel that is reimbursed or sponsored by Federal, state, or local government agencies, U.S. institutions of higher education, research institutes affiliated with higher education institutions, academic teaching hospitals, and medical centers.</p> <p>(3) The term <i>significant financial interest</i> <u>does not</u> include: salary, royalties, or other remuneration paid by the University; intellectual property rights assigned to the University and agreements to share in royalties related to such rights; income from investment vehicles, such as mutual funds, retirement accounts, or 529 funds and other college savings funds, as long as the Investigator does not directly control the investment decisions made in these vehicles; and income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, U.S. institutions of higher education, research institutes affiliated with higher education institutions, academic teaching hospitals, and medical centers; or income from service on advisory committees or review panels for a Federal, state, or local government agency U.S. institutions of higher education, research institutes affiliated with higher education institutions, academic teaching hospitals, and medical centers.</p>

## **Policy**

### **Disclosure**

Each Investigator who is planning to participate in PHS- or NSF-funded research must disclose to the University's Sponsored Research Officer the Investigator's significant financial interests (and those of the Investigator's spouse and dependent children) no later than the time of application for PHS- or NSF- funded research.

Each Investigator who is participating in PHS- or NSF-funded research must submit an updated disclosure of significant financial interests at least annually, in accordance with the specific time period prescribed by the Institution, during the period of the award. Such disclosure shall include any information that was not disclosed initially to the University or in a subsequent disclosure of significant financial interests (e.g., any financial conflict of interest identified on a PHS- or NSF-funded project that was transferred from another Institution), and shall include updated information regarding any previously disclosed significant financial interest (e.g., the updated value of a previously disclosed equity interest).

Each Investigator who is participating in PHS- or NSF-funded research must submit an updated disclosure of significant financial interests within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest.

### **Review Process**

Completed FCOI Disclosure Forms will be reviewed by the University's Provost's Office to determine whether an Investigator's significant financial interest constitutes a FCOI. The Investigator's significant financial interest will be considered to be a FCOI if the Provost's Office reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS- or NSF-funded research, or is in an entity whose financial interest could be affected by the research.

### **Management and Reporting of Financial Conflicts of Interest to PHS**

Upon determination that a significant FCOI related to PHS- or NSF-funded research exists, the Provost's Office will develop and implement a written management plan that will specify the actions that have been, and shall be, taken to manage such FCOI. Management plans may include one or more of the following conditions or restrictions: public disclosure of FCOI (for example, when presenting or publishing the research); for research projects involving human subjects research, disclosure of FCOI directly to participants; appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the FCOI; modification of the research plan; change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research; reduction or elimination of the financial interest; and severance of relationships that create financial conflicts. The Investigator must agree to the management plan by signing it before performing any PHS- or NSF-funded research.

When the University identifies a significant financial interest that was not disclosed in a timely manner for whatever reason, within 60 days the Provost's Office will review the significant financial interest; determine whether it is related to PHS- or NSF-funded research; determine whether a FCOI exists;

and, if so, implement a management plan for the FCOI. Furthermore, whenever a FCOI is not identified or managed in a timely manner, the University will complete a retrospective review of the Investigator's activities and the PHS- or NSF-funded research project to determine whether any portion of the PHS- funded research conducted during the noncompliance time period was biased in the design, conduct or reporting of such research. This review will be completed within 120 days of the noncompliance determination. The University will follow PHS and NSF regulations regarding reporting of a FCOI or non-compliance with the regulations.

### **Public Accessibility**

The University's FCOI policy will be posted on the Provost's Office and the Sponsored Research Office web pages. Prior to the expenditure of funds received under a PHS- or NSF-funded research project, the University will ensure public accessibility, via written response to a requestor within five business days of receiving the request, of information concerning any Significant Financial Interest that meets the following criteria:

(A) The significant financial interest was disclosed and is still held by the senior/key personnel as defined by this subpart;

(B) The University determines that the significant financial interest is related to the PHS-funded research; and

(C) The University determines that the significant financial interest is a financial conflict of interest.

### **Records Retention**

The designed institutional official or designee will maintain records relating to all Investigator disclosures of financial interests and the Institution's review of, and response to, such disclosures and all actions under the Institution's policy or retrospective review, if applicable, for at least three years from the date the final expenditures report is submitted to the PHS or the NSF, or, where applicable, from other dates specified in 45 CFR 75.361 for different situations.

### **Subrecipient Monitoring**

The University is responsible for ensuring that subrecipients comply with 42 CFR Part 50 Subpart F. The University will execute a written agreement with the subrecipient that establishes whether the University's FCOI policy or the FCOI policy of the subrecipient institution will be followed. If it is the latter, the agreement will specify the time period for the subrecipient to report all identified FCOI to the University.

### **Required Education on the FCOI Federal Regulations**

NIH provides online training here:

[https://grants.nih.gov/grants/policy/coi/tutorial2018/story\\_html5.html](https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html) Training must take place prior to engaging in the PHS- or NSF-funded research. Please be sure to print a certificate of completion at the end of the training session and send a copy to the Sponsored Research Office.

## **Additional Resources**

Financial Conflict of Interest (FCOI) regulation (42CFR Part 50 Subpart F – Grants):

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

Financial Conflict of Interest (FCOI) regulation (45CFR Subtitle A Subchapter A Part 94 – Responsible Prospective Contractors): <https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-94>

Frequently Asked Questions: [https://grants.nih.gov/grants/policy/coi/coi\\_faqs.htm](https://grants.nih.gov/grants/policy/coi/coi_faqs.htm)

NSF Financial Conflict of Interest: [https://www.nsf.gov/pubs/policydocs/pappg22\\_1/pappg\\_9.jsp](https://www.nsf.gov/pubs/policydocs/pappg22_1/pappg_9.jsp)