

Financial Conflict of Interest Policy

Policy Category:	Compliance
Effective Date:	May 15, 2023
Date Last Revised:	September 21, 2023
Responsible Policy Administrator:	Chief Financial Officer

Reason for Policy

Sanford Laboratories for Innovative Medicines (“Sanford Labs”) has an institutional responsibility to establish and maintain policies that strengthen accountability and transparency, promote research integrity, and ensure prudent stewardship of public funds. This policy implements Federal disclosure regulations and requirements pertaining to the objectivity in research issued by the Public Health Service (PHS) in 42 CFR Part 50, Subpart F, and 45 CFR Part 94. The Financial Conflict of Interest (FCOI) regulations establish the standards that must be followed by institutions that apply for or receive research funding from PHS awarding components, including the National Institutes of Health (NIH), for all grants, cooperative agreements, and research contracts.

Who is Affected by This Policy

- All Sanford Labs employees who fit the definition of ‘Investigator’ as described in the Definitions section below.

Definitions

Term	Definition
COI Committee	A committee comprising members of Sanford Labs and an external member will review FCOI disclosures that have a disclosed Significant Financial Interest (SFI) to determine whether an FCOI exists.
Director of Compliance	The person with the job title Director of Compliance, or the person appointed by the President of Sanford Labs to fulfill the role, or if there is no one holding the job title or no one has been appointed by the President, the Chief Financial Officer will act as Director of Compliance.
Entity	Any domestic or foreign, public or private, organization (excluding a federal agency) from which an Investigator (and/or spouse and dependent children) receive remuneration or in which they have an ownership or equity interest.
Financial Conflict of Interest (FCOI)	A SFI that could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.
Institution	Any domestic or foreign, public or private, entity or organization (excluding a federal agency) that is applying for or that receives NIH funding, such as Sanford Labs.
Institutional Responsibilities	An Investigator’s professional responsibilities on behalf of Sanford Labs that include, but are not limited to, activities such as research, research consultation, teaching, institutional committee memberships, and service on panels such as Institutional Review Boards (IRB), Data and Safety Monitoring Boards, and Scientific Advisory Boards (SAB).
Investigator	The Principal Investigator or Project Director (PI/PD) and any other person, regardless of title or position, who is eligible to submit grant applications on

	behalf of Sanford Labs or who will be responsible for the design, conduct, or reporting of research or educational activities funded or proposed for funding by the PHS.
Investigator's spouse and children	The terms "spouse" and "marriage" include legally recognized same-sex spouses/marriages. The term "children" applies to the dependent children of the Investigator.
Management Plan	A plan that is developed by the Director of Compliance and approved by the COI Committee that will specify the actions that have been taken or will be taken to manage an identified FCOI.
Private Entity	An Entity whose stock is not traded publicly.
Public Entity	A company whose ownership is dispersed among the general public in shares of stock, which are freely traded on a stock exchange or in over-the-counter markets.
Remuneration	Money paid for work or service from an Entity other than Sanford Labs, as well as any payment directly to the Investigator from intellectual property rights such as patents, copyrights, and royalties not owned by Sanford Labs and not paid pursuant to Sanford Labs' Intellectual Property Agreement.
Senior/Key Personnel	The Project Director/Principal Investigator (PD/PI) and any other person identified as senior/key personnel by Sanford Labs in a grant application, progress report, or any other report submitted to the NIH by Sanford Labs.
Significant Financial Interest (SFI)	A financial interest described in Policy & Procedures, section A of the Investigator and/or of the Investigator's spouse and dependent children that reasonably appears to be related to the Investigator's Institutional Responsibilities.
Subrecipients	A relationship when federal funds flow down from or through an awardee institution to another individual or entity where the subrecipient will be conducting a substantive portion of the PHS-funded research project and who will be accountable to the awardee institution for programmatic outcomes and compliance matters. This may also include subgrantees, consortium participants, collaborators, and/or consultants.

Policy & Procedures

Sanford Labs has the responsibility to manage Financial Conflicts of Interest between an Investigator's (and his/her spouse and dependent children) personal financial interests and his/her Institutional Responsibilities. Sanford Labs and its Investigators must identify and then manage, reduce, or eliminate Financial Conflicts of Interest (FCOI) to strengthen accountability and transparency, promote research integrity, maintain the integrity of research findings, and ensure prudent stewardship of public funds. By implementing this policy, Sanford Labs certifies it:

- Has in effect an up-to-date written and enforced administrative process to identify and manage financial conflicts of interest with respect to all research projects for which funding is sought or received from the PHS;
- Shall promote and enforce Investigator compliance with requirements pertaining to the disclosure of significant financial interests;
- Shall manage financial conflicts of interest and provide initial and ongoing FCOI reports to the PHS Awarding Component consistent with this policy;
- Agrees to make information available, promptly upon request, to the PHS relating to any Investigator disclosure of financial interests and Sanford Labs' review of, and response to, such disclosure, whether or not the disclosure resulted in Sanford Labs' determination of a financial conflict of interest; and,
- Shall fully comply with the requirements of this policy.

A. What Constitutes a Significant Financial Interest (SFI)?

An SFI is a financial interest consisting of one or more of the following interests of the Investigator (and/or those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's Sanford Labs Responsibilities.

1. Publicly Traded Entity: An SFI exists if the value of any remuneration received from the entity in the twelve (12) months preceding the disclosure and the value of any equity interest in the entity as of the date of the 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 ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.
2. Non-Publicly Traded Entity, also known as Private Entity: A SFI exists if the value of any remuneration received from the entity in the twelve (12) 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). The Investigator must fully describe the nature of the equity interests (including the number of shares owned, voting rights, etc.) if at the time of disclosure, there is no reasonable basis for assessing the fair market value or percentage interest in the non-publicly traded entity.
3. Intellectual Property Rights: Receipt of income related to such rights and interests (e.g., patents, copyrights, etc.).

Travel Disclosures

Investigators must disclose the occurrence of any reimbursed travel or sponsored travel (i.e., travel paid on behalf of the Investigator and not reimbursed to the Investigator, so the exact monetary value may not be readily ascertainable) related to their Sanford Labs Responsibilities. The disclosure must include the following details:

- Purpose of the travel
- Identity of sponsor/organizer
- Destination of the travel
- Time duration of travel

Sanford Labs will determine if the travel requires further investigation, including determining or disclosing the monetary value to determine whether the travel constitutes an FCOI.

This travel disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an institution of higher education as defined at 20 USC 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

Significant Financial Interests do not include the following:

1. Salary, royalties, or other remuneration received from Sanford Labs if the Investigator is currently employed or appointed by Sanford Labs.
2. 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.
3. Income from seminars, lectures, or teaching engagements sponsored by a United States (a) federal, state, or local government agency; (b) institution of higher education (as defined by 20 USC 1001(a)); (c) academic teaching hospital; (d) medical center; or (e) research institute that is affiliated with an institution of higher education.
4. Income from service on advisory committees or review panels for Sanford Labs or the United States (a) federal, state, or local government agency; (b) institution of higher education (as defined by 20

USC 1001(a)); (c) academic teaching hospital; (d) medical center; or (e) research institute that is affiliated with an institution of higher education.

5. Travel expenses that are reimbursed or sponsored by Sanford Labs or a United States (a) federal, state, or local government agency; (b) institution of higher education (as defined by 20 USC 1001(a)); (c) academic teaching hospital; (d) medical center; or (e) research institute that is affiliated with an institution of higher education.
6. Intellectual property rights assigned to Sanford Labs and unlicensed intellectual property that does not generate income.
7. Agreements with Sanford Labs to share in royalties related to such rights.

B. Disclosure: Initial, Annual, and Updates

All individuals who meet the definition of Investigator will receive Sanford Labs' FCOI policy that describes the Investigator's responsibilities regarding disclosure of significant financial interests and Federal regulations. Each Investigator (and those of the Investigator's spouse and dependent children) must submit an SFI disclosure form at the time of hire and annually thereafter [42 CFR 50.603 and 42 CFR 604(b)].

Sanford Labs will solicit and review SFI disclosure forms submitted by Investigators (and those of the Investigators' spouse and dependent children) who are planning to participate in or is participating in, the PHS-funded research [42 CFR 50.604(d)]

In addition, Investigators have an ongoing obligation to promptly update their SFI disclosure form to accurately reflect any significant change in their external activities and SFIs as follows [42 CFR 50.604(e)(1)-(3)]:

- At the time of application for funded research
- Prior to expenditure of funds on any PHS award
- Within 30 days of determining or acquiring a new SFI

All Investigators are required to disclose both existing and new SFIs (e.g., information not initially disclosed, including but not limited to any financial conflict of interest identified on a PHS-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). SFI disclosure forms collected annually must be submitted by the deadline.

Sanford Labs may not submit any new grant applications to a Federal agency for research projects and may not spend any Federal funds in connection with award notices for new or continuing Federally funded research projects, until all Investigators identified to work on such projects have completed training and submitted their disclosures as required by this policy.

C. Review of SFI Disclosures

The Chief Financial Officer will initially review the SFI disclosure forms and may request further information or clarification. The Director of Compliance will make a preliminary determination of whether an SFI appears to relate to funded research. If so, the matter will be referred to the COI Committee for further review. The COI Committee will be comprised of approximately eight members from the following:

- Director of Compliance
- Group Leaders
- Executive Leadership
- Finance
- Scientific Planning and Strategy
- Sponsored Research Office
- External Community Member

The COI Committee will review all SFIs that appear to be related to funded research to determine whether the SFI may be a FCOI. The COI Committee reviews and analyzes the specific circumstances of an SFI by considering such factors as the nature of the Investigator's relationship to the entity, the dollar value of that relationship, and the degree and nature of any overlap between that relationship and the Investigator's research. The COI Committee may, if warranted, involve the Investigator and/or other researchers or advisors in determining whether an SFI is related to the research. An FCOI will be deemed to exist when the majority of the COI Committee reasonably determines that an SFI disclosed by an Investigator could directly and significantly affect the design, conduct, or reporting of the Investigator's research [42 CFR 50.604(f)].

The steps set forth below must be completed promptly following the determination of a FCOI. Any FCOI must be reported to the federal funding agency within sixty (60) days as set forth in the FCOI Regulations. Where a documented SFI is deemed NOT to be FCOI, the COI Committee nevertheless may decide to manage the SFI and may institute guidelines for the Investigator to follow as an internal measure.

D. Management Plan

If an FCOI is identified by the COI Committee, the Director of Compliance will develop a Management Plan to manage, reduce, or eliminate the conflict. The COI Committee will review and approve the Management Plan. The Management Plan will be outlined in a written document and may require the Investigator to take certain steps and follow guidelines approved by the COI Committee.

The Management Plan shall specify the actions that have been or will be taken to manage, reduce, or eliminate the FCOI. Examples of conditions or restrictions that might be imposed include, but are not limited to [42 CFR 50.605(a)(1)]:

- Disclosure of the FCOI to lab personnel and collaborators
- Disclosure of the FCOI in publications, journals, and posters
- Monitoring of research by independent reviewers
- Modification of research plan
- Removal of Investigator from participating in all or a portion of the project funded by the entity
- Divestiture of an SFI by the affected Investigator
- Severance of relationship(s) that created the conflict
- For research projects involving human subjects research, disclosure of financial conflicts of interests directly to participants

As appropriate, the COI Committee may meet with the Investigator during the design and development of the Management Plan to develop oversight mechanisms appropriate for the specific situation. The Management Plan will contain all elements required by the FCOI Regulations, which may include the role and principle duties of the conflicted Investigator in the research project; terms and conditions; how the Management Plan is designed to safeguard objectivity in the research; confirmation of the Investigator's agreement to the Management Plan; how the Management Plan will be monitored; and other information as needed.

A copy of the Management Plan will be provided to the Investigator. The Investigator may appeal the COI Committee's proposed Management Plan or the findings on which the plan is based to the President within ten (10) calendar days of the date of receipt of the Management Plan. Once finalized, the Investigator will review and sign the Management Plan to acknowledge his or her commitment to compliance.

E. Reporting Financial Conflicts of Interest to PHS

Sanford Labs must report to PHS any SFI that meets the following three criteria: (1) The SFI is still held by the senior/key personnel as defined by this policy. (2) Sanford Labs determines that the SFI is related

to the PHS-funded research. (3) Sanford Labs determines that the SFI is a FCOI.

New PHS Funded Research: Prior to Sanford Labs' expenditure of any funds on a PHS-funded research project for which the FCOI has been determined, the Director of Compliance, within sixty (60) days, will provide to the PHS a FCOI report. All FCOI reports will be submitted through the eRA Commons FCOI Module. If a FCOI is able to be reduced or eliminated prior to the expenditure of funds, a report to the PHS is not required. [42 CFR 50.604(h) and 42 CFR 50.605(b)]

The report will contain all elements required by the FCOI Regulations, which may include: (i) Project number; (ii) project title; (iii) PD/PI or contact PD/PI; (iv) name of the Investigator with the FCOI; (v) name of the entity with which the Investigator has an FCOI; (vi) nature of the financial interest; (vii) value of the financial interest, 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; (viii) a description of how the financial interest relates to the PHS-funded research and the basis for Sanford Labs' determination that the financial interest conflicts with such research; and (ix) a description of the critical elements of Sanford Labs' Management Plan, including: role and principle 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.

Ongoing PHS Research Projects: Whenever a new or existing Investigator participating in the research project discloses a new SFI, Sanford Labs will review the disclosure and determine whether it is related to PHS-funded research. If related, the COI Committee will determine if a FCOI exists. If a FCOI exists, Sanford Labs will complete the required reporting within sixty (60) days through the eRA Commons FCOI Module. [42 CFR 50.605(a)(2)]

For any FCOI identified after Sanford Labs' initial report during an ongoing funded research project, Sanford Labs shall implement, within sixty (60) days, on at least an interim basis, a Management Plan that will specify the actions that have been and/or will be taken to manage the FCOI. If the FCOI is able to be reduced or eliminated, a report to the PHS is not required. [42 CFR 50.605(b)(2)]

Period of Non-Compliance during an Ongoing PHS Funded Project: Sanford Labs will, within sixty (60) days of an Investigator's delayed disclosure of an SFI, determine if the SFI constitutes an FCOI. If an FCOI exists, Sanford Labs will implement, on at least an interim basis, a Management Plan that shall specify the actions that have or will be taken to reduce or eliminate the FCOI. The Director of Compliance will submit the FCOI report through the eRA Commons FCOI Module. In addition to the FCOI report, Sanford Labs will, within one-hundred-twenty (120) days of its determination of non-compliance, complete a retrospective review of the Investigator's activities and the research project to determine whether part or all of the research conducted during the period of non-compliance was biased in the design, conduct or reporting of such research. Based on the review results, the Director of Compliance will update the previously submitted FCOI report, specifying the actions that will/have been taken to reduce or eliminate the FCOI. [42 CFR 50.605(a)(3)]

Sanford Labs will document the retrospective review, including all of the following key elements: project number; project title; PD/PI or contact PD/PI; the name of the Investigator with the FCOI; the name of the entity with which the Investigator has an FCOI; the reason(s) for the retrospective review; the detailed methodology used for the retrospective review; findings of the review; and conclusions of the review. [42 CFR 50.605(a)(3)]

Sanford Labs will promptly notify the PHS Awarding Component of any corrective action taken or to be taken if an Investigator fails to comply with this policy or if a Management Plan appears to have biased the design, conduct, or reporting of the PHS-funded research. [42 CFR 50.606(a)]

To evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a financial conflict of interest that was not managed or reported by Sanford Labs as required by the COI Regulations, Sanford Labs will require the Investigator involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations. [42 CFR 50.606(c)]

Annual Reports: For any FCOI previously reported, Sanford Labs will provide an annual FCOI report that addresses the status of the FCOI and any changes to the Management Plan. The annual FCOI report will specify whether the FCOI is still being managed or explain why the FCOI no longer exists. Sanford Labs will provide annual FCOI reports to the PHS for the duration of the project period, including extensions with or without funds, at the time of submission of the annual progress report or at the time of a project extension. [42 CFR 50.605(b)(4)]

F. Public Accessibility

Sanford Labs' FCOI policy will be accessible through Sanford Labs' public website (www.Sanfordlabs.org). In addition, in compliance with the FCOI Regulations, Sanford Labs will make the following information about identified FCOIs available by written response within five (5) business days of a request: [42 CFR 50.605(a)(5)(ii)]

- Investigator's name
- Investigator's title and role concerning the research project
- Name of the entity in which the SFI is held
- Nature of the SFI (e.g., equity, consulting fees, travel reimbursement, honoraria, etc.)
- Approximate dollar value of the SFI (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. Financial Conflict of Interest Monitoring

Sanford Labs will monitor the FCOI and Investigator compliance with the Management Plan until the completion of the research project. As necessary, the COI Committee may require and develop a project-specific monitoring process, including appointing a Sanford Labs official to assist with monitoring the FCOI and Investigator compliance. The COI Committee may modify an Investigator's Management Plan at any time. [42 CFR 50.605(a)(4)]

H. Subrecipient Compliance

If Sanford Labs carries out research through a Subrecipient, Sanford Labs will take reasonable steps to ensure any Subrecipient Investigator complies with the FCOI Regulations. Sanford Labs will incorporate as part of its written consortium agreement with the Subrecipient, terms that establish whether the FCOI policy of Sanford Labs or that of the Subrecipient will apply to the Subrecipient Investigator(s). [42 CFR 50.604(c)]

If the Subrecipient can provide certification of an established FCOI policy, the written agreement will specify time periods for the Subrecipient to report all identified FCOI to Sanford Labs. Such time periods will provide Sanford Labs with sufficient time to review the reports and make timely reports to PHS as necessary. [42 CFR 50.604(c)(1)(ii)]

If the Subrecipient cannot provide certification of an established FCOI Policy, the written agreement issued by Sanford Labs will state that Subrecipient Investigators are subject to the FCOI policy of Sanford Labs for disclosing SFIs that are directly related to the performance of work. The Subrecipient agreement will also specify time periods for the Subrecipient to submit Investigator disclosures to Sanford Labs to allow sufficient time to review the disclosures and comply timely with its review, management, and reporting obligations under this Policy. [42 CFR 50.604(c)(1)(iii)]

In all cases, Sanford Labs is responsible for reporting all identified FCOIs for subrecipient Investigators to the PHS through the eRA Commons FCOI module.

I. Enforcement and Non-Compliance

Sanford Labs is required to establish adequate enforcement mechanisms and provide for employee sanctions and/or other administrative actions, where appropriate, to address any failure by an Investigator to comply with the FCOI Policy and/or Management Plan. Violations of this policy may result in disciplinary actions deemed appropriate by Sanford Labs. **[42 CFR 50.604(j)]**

An Investigator is non-compliant and in violation of the FCOI Policy if an Investigator **fails** to:

- Submit SFI disclosure forms by the deadlines established for such submissions.
- Complete required FCOI training.
- Provide the COI Committee with a written acknowledgement of a Management Plan.
- Provide the COI Committee with requested documentation regarding compliance with a Management Plan.

If an Investigator fails to comply with Sanford Labs' FCOI Policy and/or Management Plan, Sanford Labs must complete within one hundred twenty (120) days of determining non-compliance a retrospective review of the Investigator's activities and research projects, document Sanford Labs' determination as to whether the federally funded research or any portion thereof conducted prior to the identification and management of the FCOI was biased in the design, conduct or reporting of such research.

If bias is found, Sanford Labs must submit a mitigation report addressing the impact of the bias on the research project, including the extent of harm done, any qualitative and quantitative data to support any actual or future harm, an analysis of whether the project is salvageable and the actions Sanford Labs has taken or will take to eliminate or mitigate the effect of the bias. Depending on the nature of the FCOI, Sanford Labs may determine that additional interim measures are necessary regarding the Investigator's participation in the research project between the date the FCOI is identified and the completion of Sanford Labs' retrospective review.

J. Project Specific Certification

Investigators have an ongoing obligation to promptly update their SFI disclosure form should their situation change prior to the issuance of an award. The Sponsored Research Office will query all Investigators associated with the research to confirm there are no changes to their SFI disclosure on file. If there are reportable changes, an updated SFI disclosure form is required by the Investigator, which will promptly be reviewed and processed by the Director of Compliance.

K. Mandatory Training

Sanford Labs requires all Investigators to complete FCOI training prior to engaging in federally funded research and at least every four years thereafter or as directed by Sanford Labs. Training is required immediately when any of the following circumstances apply: **[42 CFR 50.604(b)]**

- Sanford Labs revises its FCOI policies and procedures in a manner that affects the requirements of Investigators.
- Investigator is new to Sanford Labs; or
- Investigator is not in compliance with Sanford Labs' FCOI Policy or a Management Plan.

L. Record Maintenance

Records relating to all Investigator SFI disclosures and Sanford Labs' review of, or response to, such disclosures, and all actions under Sanford Labs' policy or retrospective review, if applicable, will be maintained for at least three (3) years from the date the final expenditure report is submitted to the PHS or, where applicable, from other dates specified in 45 CFR 75.361 for different situations. **[42 CFR 50.604(i)]**

Responsibilities

See Policy & Procedure Details noted above.

Related Policies, Forms, and Resources

- [42 CFR Part 50, Subpart F—Promoting Objectivity in Research](#)
- [45 CFR Part 94—Responsible Prospective Contractors](#)
- Significant Financial Interest Disclosure Form

Approval



Michael Dollar
CAO/CFO

September 21, 2023
Date