

POL-004 NIH FCOI POLICY

| TRAINING REQUIREMENTS | Training Type | | | | |
|--|----------------|---------------------|----------------|-----------------|-----|
| | A Read Only | B Read & Discuss | C Classroom | D On-the-Job | N/A |
| For current version | X | | | | |
| For initial version & employees not trained previously on this procedure | X | | | | |

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1 SCOPE

This policy applies to Investigators participating in, or planning to participate in the design, conduct, reporting or proposing research. This policy does not apply to applications and awards supported under the Small Business Innovation Research Phase I Program or the Small Business Technology Transfer Phase I program. If a research project involves subcontractors, subgrantees, or subawardees (collectively subrecipients), the subrecipient institution must provide written assurance that a financial conflict of interest in research policy is in effect at that institution and compliant with all applicable federal regulations. Should Public Health Service (PHS) or National Science Foundation (NSF) funds be subcontracted by Selux to a subrecipient institution without a conflict of interest in research policy, a written agreement must state that this policy shall apply to the subrecipient.

2 PURPOSE

The purpose of this policy is to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, or reporting of funded research, grants or cooperative agreements will be free from bias resulting from Investigator's financial conflicts of interest (and/or of the Investigator's spouse and/or dependent children). This policy complies with the following federal regulations:

- Title 42 Code of Federal Regulations (CFR), Part 50, Subpart F, Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought
- Title 45 Code of Federal Regulations (CFR), Part 94, Responsible Prospective Contractors
- National Science Foundation 05-131 Chapter V, 510, Conflict of Interest Policies

3 DEFINITIONS

- 3.1 **Conflict of Interest Management Plan:** the document specifying the actions to be taken to manage a Financial Conflict of Interest. This could include any or all of the following: public disclosure of significant financial interests (e.g., when presenting or publishing the research), modification of research plan, change of personnel or personnel responsibilities or disqualification from participation in all or a portion of the research, reduction or elimination of the financial interest (e.g., sale of an equity interest), or severance of relationships that create the actual or potential conflict of interest.

- 3.2 **Entity:** any domestic or foreign, public or private, entity or organization (excluding a Federal agency) from which an Investigator (and/or the Investigator's spouse and/or dependent children) receives remuneration, or in which any person has an ownership or equity interest.
- 3.3 **External Partner:** a consultant, subcontractor, or sub-recipient performing work under a Government Award who is not employed by Selux.
- 3.4 **Government Award:** government grants and cost reimbursement contracts including research grants or contracts, and other types of government financial assistance (e.g., cooperative agreements, loans, loan guarantees, property, donated supplies, and direct appropriations) that Selux receives directly from government agencies or indirectly from pass through entities. (At Selux, Government Awards are commonly referred to as "Sponsored Projects.") Government Awards do not include procurement contracts, payments for health care services provided under government health care programs (e.g., Medicare, Medicaid) or Medical Education and Research Costs (MERC)).
- 3.5 **Financial Conflict of Interest (FCOI):** a significant financial interest that could directly and significantly affect the design, conduct, or reporting of a research study or other government funded project.
- 3.6 **Immediate Family Member:** a spouse, domestic partner, and dependent children.
- 3.7 **Investigator:**
- (1) For PHS-funded research: the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants.
- (2) For other Government Awards: project staff directly involved in management of the project or who hold key responsibilities on the Government Award. Typically, these would be individuals specifically named to a Government Award or whose participation is key to the success of the project.

- 3.8 **Institution:** any domestic or foreign, public or private, entity or organization (excluding a Federal Agency) that is applying for, or receives, PHS or NSF research funding.
- 3.9 **Institutional Responsibilities:** An Investigator's professional responsibilities on behalf of Selux, which may include, but is not limited to research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.
- 3.10 **Public Health Service (PHS):** a division of the Department of Health and Human Services, consisting of the following agencies: Agency for Healthcare Research and Quality (AHRQ), Agency for Toxic Substances and Disease Registry (ATSDR), Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), Health Resources and Services Administration (HRSA), Indian Health Service (IHS), National Institutes of Health (NIH), and Substance Abuse and Mental Health Services Administration (SAMHSA).
- 3.11 **Research:** 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.
- 3.12 **Remuneration:** salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorships).
- 3.13 **Significant Financial Interest (SFI):**
- (1) A financial interest consisting of one or more of the following interests of the Investigator or their Immediate Family Member that reasonably appears to be related to the Investigator's Institutional Responsibilities:
- a. the value of any remuneration received from a public 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; or
 - b. the value of any remuneration received from a non-publicly traded entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or their immediate family) 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 greater than \$5,000.

(2) Investigators must disclose the occurrence of any reimbursed or sponsored travel greater than \$5,000 related to their Institutional Responsibilities. The disclosure will include, at a minimum, the following details: (i) the purpose of the trip; (ii) the identity of the sponsor/organizer; (iii) the destination; and (iv) the trip duration. (This disclosure requirement does not apply to travel that is reimbursed or sponsored by a domestic federal, state, or local government agency, a domestic Institution of higher education, a domestic academic teaching hospital, a domestic medical center, or a research institute that is affiliated with a domestic Institution of higher education.)

(3) A significant financial interest does not include the following:

- a. Salary, royalties, or other remuneration paid by Selux to the Investigator if the Investigator is currently employed or otherwise appointed by Selux including intellectual property rights assigned to Selux and agreements to share in royalties related to such rights; income from investment vehicles, such as mutual funds and retirement accounts, if the Investigator does not directly control the investment decisions made in these vehicles.
- b. Income from seminars, lectures, or teaching engagements sponsored by a domestic federal, state, or local agency, a domestic Institution of higher education, a domestic academic teaching hospital, a domestic medical center, or a research institute that is affiliated with a domestic Institution of higher education.
- c. Income from service on advisory committees or review panels for a federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.
- d. Travel by a PHS-funded Investigator that is reimbursed or sponsored by a federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

3.14 Small Business Innovation Research (SBIR) Program - the extramural research program for small businesses established by the awarding components of certain Federal agencies under Public Law 97-219, the Small Business Innovation Development Act, as amended. The term SBIR Program includes the Small

Business Technology Transfer (STTR) Program, which was established by Public law 102-564.

4 POLICY

4.1 Investigator Responsibilities: Investigators are responsible for:

1. Disclosing all significant financial interests
2. Providing updates to disclosed information as needed
3. If acting as the PI/PD, providing a list of individuals who meet the definition of “investigator” (see Section 3) within the required disclosure timeline
4. Completing all required training and education
5. Completing the annual disclosure form even if they have no financial interests to report.
6. Ensuring that an updated FCOI in Research Disclosure is on file at the time of Institutional Review Board (IRB) or the Institutional Animal Care and Use Committee (IACUC) approval for any new research proposals.

4.2 Financial Conflicts of Interest - A financial conflict of interest (FCOI) means a significant financial interest that could directly and significantly affect the design, conduct or reporting of Public Health Services (PHS) or NIH-supported research Excluding the following:

1. salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by Selux;
2. intellectual property rights assigned to Selux and agreements to share in royalties related to such rights
3. any ownership interests in Selux held by the Investigator, if the Institution is a commercial or for-profit organization
4. 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;
5. income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an Institution of higher education as defined in 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education;
6. income from service on advisory committees or review panels for a federal, state, or local government agency, or an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

This policy addresses individual financial conflicts of interest; however, Selux may also have conflicts of interest in research whenever the financial interests of Selux, or of a Selux official acting within his or her authority on behalf of Selux, might affect—or reasonably appear to affect—Selux processes for the conduct, review, or oversight of research. If institutional conflicts of interest are identified via the process described below, they will normally be addressed in a manner that is consistent with this policy.

4.3 Review of FCOIs

The designated Research Administration staff member (Designee) conducts an initial review of all disclosures. If necessary, the Designee obtains additional information from the investigator and other individuals to help determine whether the SFI disclosed is related to a proposed or existing sponsored project or program. The Designee then formally identifies cases that require further review and refers such cases to Selux CEO for review. The committee will review the collected information to determine whether a financial conflict of interest exists or if the SFI could directly and significantly affect the design, conduct or reporting of the PHS funded research by considering the following:

1. Impact on integrity of research data
2. Risks to rights and safety of animal and/or human research subjects;
3. Risks to the rights of students and trainees participating in research;
4. Appearance of conflicts of interest

If a financial conflict of interest is identified, the committee will determine whether the research can be undertaken with appropriate management.

4.4 Management of FCOIs

For cases that require management, a Management Plan will be developed by the Designee and committee. The Management Plan will be developed collaboratively and examples of conditions or restrictions that may be employed to manage conflicts include:

1. Public disclosure of significant financial interests (e.g., when presenting or publishing the research to research personnel working on the study, to the Institution Review Board and Institutional Animal Care and Use Committee, as applicable), if appropriate;
2. Disclosure of significant financial interests directly to subjects involved in human research;

3. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of research;
4. Modification of research plan;
5. Change of personnel or personnel responsibilities or disqualification from participation in all or a portion of the research;
6. Reduction or elimination of the financial interest (e.g., sale of an equity interest).
7. Severance of relationships that create the actual or potential conflict of interest;
8. A draft Management Plan will be provided to the Investigator for review and comment before it is finalized. The Investigator and their immediate supervisor must sign the final plan to acknowledge their agreement to comply. If the Institution identifies a SFI that was not disclosed or reviewed in a timely manner it will initiate the review process and an interim management plan will be implemented when necessary.

4.5 **Monitoring** - Investigator compliance with Management Plans will be monitored by the designated Research Administration staff member. The frequency of monitoring will be dictated by sponsor/agency requirements and Management Plan provisions.

4.6 **Appeals** - Investigators may appeal committee decisions in writing within 15 days of receipt of the finalized management plan or other decision of the committee. The written appeal should include details regarding circumstances which support the request for a proposed revision to a committee decision. An Appeals committee will be formed for purposes of investigating the appeal and making a final decision. A meeting of the Appeals Committee will be convened to review the SFI information, the Management and Monitoring Plan, and previous meeting minutes to decide. The Investigator may be invited to describe reasons for the appeal and to address further questions. The appeals process will take no more than 60 days from the date requested by the Investigator. The decision of the Appeals Committee is final and binding.

4.7 **Confidentiality** - Financial and other information disclosed in compliance with this policy will be kept confidential and disclosed only on a need-to-know basis as required to perform appropriate review and evaluation required by the policy, except in the case of required public accessibility of identified financial conflicts of interest held by senior/key personnel.

- 4.8 **Enforcement** - Failure on the part of an Investigator to comply with this policy will result in disciplinary action and/or sanctions which may include formal reprimand, non-renewal/termination of appointment or affiliation, additional training requirements, additional supervision, closing existing research or denying future research by the Investigator, and/or any other enforcement action mandated by the applicable funding agency or Selux.
- 4.9 **Policy Revision** - Selux may modify this policy to conform to organizational changes and circumstances including revisions to federal or state law or regulations. The committee will have five business days to review and comment on any proposed revisions.
- 4.10 **Additional Requirements** - The following additional requirements also apply to all research funded by the PHS of the U.S. Department of Health and Human Services and any PHS Awarding Component including the NIH.
- 4.11 **Reporting** - Selux will provide to the PHS Awarding Component a FCOI report as outlined in the regulations.

Initial Report: Prior to expenditure of any funds under the NIH-funded research project, the Institution will provide a FCOI report regarding any SFI found to be a FCOI. Selux will also provide a FCOI report within 60 calendar days from the date of a new SFI disclosure determined to be a FCOI, a new Investigator with an identified FCOI becomes engaged in the project or when the Institution identifies a FCOI not previously disclosed. This report will include the following information:

- a. Grant/Contract Number
- b. PD/PI
- c. Name of Investigator with FCOI
- d. Nature of the FCOI (equity, consulting, fee, travel reimbursement, etc.)
- e. Value of the financial interest or statant that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value
- f. Description of how FCOI relates to the PHS funded research and the basis for determination that the financial interest conflicts with research
- g. Key elements of Management Plan

Annual updates to this report will be submitted to the PHS Awarding Component for the duration of the research project. The annual report will include:

- a. Status of FCOI
- b. Changes to Management Plan
- c. Justification if FCOI no longer exists

4.12 Subrecipients - For PHS-funded research that involves subcontractors, subgrantees or subawardees (collectively subrecipients) at other Institutions, Selux will require a written agreement that includes terms that establish whether the FCOI policy of the awardee Institution or that of the subrecipient Institution will apply to subrecipient Investigators. This agreement will specifically address time periods to meet disclosure and/or financial conflict of interest reporting requirements. Subrecipient Institutions who rely on their Financial Conflict of Interest policy must report identified financial conflicts of interests to the awardee Institution in sufficient time to allow the awardee Institution to report the FCOI to the PHS Awarding component. Subrecipients who do not have such a conflict of interest policy will be required to follow the Selux FCOI policy. A subrecipient's failure to promptly comply with the Selux policy will be considered grounds for immediate termination by Selux of any applicable subcontract or subaward.

4.13 Travel Disclosure - PHS-funded Investigators must disclose the occurrence of reimbursable or sponsored travel related to their institutional responsibilities, at a total value greater than or equal to \$5,000. At a minimum the travel disclosure must include:

- a. Purpose of trip
- b. Identity of sponsor/organization
- c. Destination
- d. Trip Length
- e. Monetary value

The disclosure requirement does not apply to travel that is reimbursed or sponsored by the following domestic agencies or institutions:

- a. A federal, state, or local government agency
- b. An institution of higher education as defined in 20 U.S.C. 1001(a)

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- c. An academic teaching hospital
- d. A medical center
- e. A research institute that is affiliated with an institution of higher education

Travel disclosures will be reviewed by the Research Official and be referred to the committee as appropriate, to determine if the travel represents a FCOI with PHS-funded research. Additional information may be requested at the time of review. Disclosure of travel must occur no more than 30 days after the last day of the trip

4.14 Public Posting of Policy - This policy will be posted on Selux's publicly accessible Internet site (www.seluxdx.com). The publicly accessible information will:

- a. Include the minimum elements of the regulation
- b. Be available within five (5) business days of a written request

4.15 Training Requirements - PHS-funded Investigators must complete FCOI training prior to engaging in research related to any PHS-funded grant or contract and at least every four years thereafter. The training can be found at:

<https://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>

Training must also be completed as soon as reasonably possible under the following circumstances:

- a. This policy change in a manner that affects the investigator requirements
- b. An investigator is new to Selux and will be working on PHS funded research
- c. An investigator is found to be non-compliant with this policy or their approved management plan

4.16 Investigator/Institutional Non-Compliance - If an SFI is not disclosed or reviewed in a timely manner, Selux will review the Investigator's financial interest, and determine if it is related to PHS-funded research; determine whether a FCOI exists, and if so:

- a. Implement a Management Plan for ongoing research, at a minimum implement an interim Management Plan

- b. Complete a retrospective review of Investigator's activities and the PHS-funded research project within 120 days of a non-compliance finding to determine if bias was present in the design, conduct, or reporting of such research, if the institution failed to review the SFI disclosure, or if the investigator failed to comply with the management plan: and
- c. If bias/non-compliance is found, the Institution will promptly inform the PHS Awarding Component by submitting a mitigation report

If the retrospective review finds that the Investigator knew or should have known about the FCOI related to his/her institutional responsibilities but failed to disclose in compliance with this policy, the costs associated with the retrospective review and mitigation report could be the responsibility of the Investigator.

5 RECORDS

Selux will maintain all records related to all Investigator disclosures of financial interests and the Institution's review of, and response to such disclosures (whether or not a disclosure resulted in the Institution's determination of a financial conflict of interest) and all actions under the Institution's policy or retrospective review, if applicable for at least 3 years from the date of the final expenditure report submission to PHS.

6 CONTACT INFORMATION

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