



Policy Name:	Investigator Conflict of Interest (COI) Policy		
Approval Authority:	COI Committee	Adopted:	February 2018, revised 11/16/20
Responsible Office:	Sponsored Projects	Contact:	Director of Sponsored Projects

1. Executive Summary

The Institute for Systems Biology (hereby referred to as “the Institute”) is committed to promoting objectivity in its research activities. In compliance with the U.S. Department of Health and Human Services (HHS) regulations and the National Science Foundation’s (NSF) Investigator Financial Disclosure Policy, this policy establishes the responsibilities of the Institute, its faculty, and staff necessary to ensure research activities are free from bias.

2. Scope

This policy applies to all Investigators (as defined in this Policy) who participate in Funded Research regardless of funding source. In addition to this Policy, Investigators who are also Institute Directors or Officers must comply with the Institute's Fiduciary Conflict of Interest Policy.

3. The Policy

No research, scholarly, or creative activities occurring at, on behalf of, or through the Institute will be adversely affected by financial conflicts of interests of persons involved in carrying out those activities.

A. Investigator Responsibilities

Investigators are required to:

1. Complete FCOI training in a timely manner;
 - a. Upon joining the Institute;
 - b. If mandated by the COI Committee, upon determination of non-compliance with this policy or any applicable Management Plan;
 - c. When the Institute revises this policy in a manner that affects Investigator obligations and responsibilities;
 - d. At least every four (4) years;
 - e. As otherwise required by the Institute.
2. Submit complete SFI disclosures in a timely manner and in accordance to Institute procedures:
 - a. Upon joining the Institute;
 - b. Prior to submitting an application for research funding or engaging in research activities related to an existing Funded Research project;
 - c. Within 30 days of discovering or acquiring a new SFI. In the case of Sponsored or Reimbursed Travel, the disclosure must be made within 30 days of the trip end;

- d. Annually as a SFI disclosure update;
 - e. As directed by the DIO or the COI Committee.
3. If subject to a Management Plan, submit a Management Plan Compliance Report upon request.
 4. If investigator is ISB faculty, disclose any SFI that has the potential to constitute an FCOI, in writing, to their direct reports and/or research lab members, including students and trainees, and to new incoming research lab members. All other investigators, disclose any FCOIs to their research lab members. Individuals must acknowledge receipt of the disclosure via signed statements or verbal acknowledgement during an in-person or virtual meeting.

B. Principal Investigator Responsibilities

In addition to the responsibilities outlined for Investigators, Principal Investigators are required to:

1. Ensure all Investigators involved in a Funded Research project, including newly hired Investigators:
 - a. Complete FCOI training under this Policy;
 - b. Submit required SFI Disclosures.
2. Identify Senior/Key Personnel who are also Investigators on an application for research funding and throughout the life of an existing Funded Research project prior to their participation in the project.

C. Institute Responsibilities

The Institute shall be responsible for:

1. Review of Investigator SFI Disclosures
 - a. The DIO shall review all SFI disclosures to determine whether any SFI relates to Funded Research and constitutes an actual or potential FCOI. If necessary, the Investigator may be required to provide additional information to understand the SFI, how it relates to the Funded Research and how it relates to the Investigator's Institutional Responsibilities.
 - b. All actual or potential FCOIs shall be referred to the COI Committee for further review.
 - c. The COI Committee may postpone its review of an actual or potential FCOI related to a Funded Research proposal until after the proposal is funded.
2. Management of FCOI
 - a. If the COI Committee determines that a SFI constitutes a FCOI related to a specific Funded Research project, it shall develop and implement a Management Plan (MP). The COI Committee may conduct factual inquiries and consult and request recommendations from such persons as it deems necessary and appropriate to develop such MP.
 - b. MPs shall consist of measures the COI Committee deems reasonable and appropriate in order to reduce, eliminate or manage the FCOI.
 - c. The COI Committee may implement interim measures with regard to an Investigator's participation in a Funded Research project between the date of the SFI Disclosure and the completion of its review of the SFI.
 - d. No Investigator having an FCOI may participate in a related Funded Research project

without an executed MP.

- e. For PHS-Funded research projects, the COI Committee shall complete the actions detailed in 1 and 2 above prior to the expenditure of any research funds and within 60 days of any subsequently identified SFI disclosed by an existing or new Investigator on the Funded Research project.

3. Management of Other Interests

If the COI Committee determines that a SFI or other interest does not constitute a FCOI, it may nonetheless determine some type of management or oversight of the interest is appropriate. In those cases, the COI Committee may develop procedures or guidance regarding the management or oversight these interests.

4. Subrecipient Compliance

a. Research

i. Non-PHS-Funded Research

1. Institute subrecipients shall provide appropriate assurances that policies and procedures no less stringent than this Policy are in place and enforced in connection with subcontracts or sub-award agreements.
2. Subrecipients shall confirm that Investigators employed by subrecipients including sub-grantees, contractors, subcontractors, and collaborators are subject to conflict of interest rules and procedures that are no less stringent than this Policy.

ii. PHS-Funded Research

PHS-Funded subrecipients shall provide appropriate assurances that they comply with this Policy or their conflict of interest policy if such policy complies with all applicable PHS and federal FCOI rules and requirements.

b. Agreements

Written agreements with subrecipients shall specify periods for reporting FCOIs to the Institute, which are sufficient to allow the Institute to perform the review, management and reporting required by this Policy.

5. Reporting

a. The Institute shall submit FCOI reports:

- i. for PHS-Funded research, to the PHS Awarding Component according to the PHS Awarding Component's policies:
 1. prior to the expenditure of funds;
 2. **within 60 days** of any subsequently identified FCOI and prior to a project period end date;
 3. annually for any FCOI previously reported and related to ongoing PHS-Funded Research for the duration of the research project. The report shall specify the status of the FCOI and if appropriate any changes to the MP. If the FCOI no longer exists, the report will include an explanation of why that is the case.
- ii. to external funders in accordance with the funder's rules and expectations, as applicable.

- b. For research funded by NSF, the Institute shall notify NSF of any FCOI the COI Committee determines the Institute cannot manage satisfactorily.

- c. FCOI reports submitted to PHS Awarding Components shall include information required by 42 CFR 50 Subpart F and sufficient additional information to understand the nature and extent of the FCOI and assess the appropriateness of the Institute's MP.

6. Retrospective Review

If a FCOI is not identified or managed in a timely manner due to Investigator non-compliance (such as failure to submit a SFI disclosure or comply with a MP) or Institute non-compliance (such as failure to review or manage a FCOI), the Institute shall:

- a. Complete a retrospective review of the Investigator's activities and the Funded Research project to determine whether there was any bias in the design, conduct or reporting of the Funded Research resulting from the FCOI;
- b. Document all retrospective reviews to include all elements as specified by 42 CFR Part 50 Subpart F; and
- c. If bias is found,
 - i. Notify the funder promptly and submit an updated FCOI Report;
 - ii. Develop a mitigation plan that includes, at a minimum, the key elements documented in the retrospective review, a description of any impact of the bias on the Funded Research, and the Institute's plan to mitigate the effect of the bias; and
 - iii. For PHS-Funded Research, submit the mitigation plan to the PHS Awarding Component and annual FCOI reports thereafter addressing the status of the identified FCOI and any changes to the mitigation plan for the duration of the PHS-Funded research. For clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, the mitigation plan will require the Investigator to disclose the FCOI in each public presentation of the research results and request an addendum to previously published presentations.
 - iv. The Institute will complete the actions detailed in a through c above **within one-hundred twenty (120) days** from the date the non-compliance is identified.

7. Auditing and Monitoring

The COI Committee shall take such actions as it deems appropriate to audit and/or monitor compliance with a MP until the completion of the related Funded Research project or the MP is no longer needed, whichever comes first. Such actions may include obtaining regular compliance reports from individuals and committees charged with oversight responsibilities specified in applicable MPs.

D. Appeals

An Investigator who disagrees with a COI Committee decision may submit a written appeal to the COI Committee within ten (10) calendar days of the receipt of the COI Committee decision. If the COI Committee grants the Investigator's appeal, the MP will be adjusted to reflect the COI Committee's decision.

If the COI Committee denies the Investigator's appeal, the President shall make the final decision. If the President, as an Investigator, submits the appeal on their own behalf, the Board Chair will make the final decision. The Investigator will be notified of the final decision within thirty (30) days of receipt of the appeal.

E. Sanctions and Remedies for Non-Compliance

Failure to comply with this Policy, including providing incomplete or false information, failing to

submit required SFI Disclosures or comply with a MP, or failing to carry out the duties prescribed by this Policy, shall constitute non-compliance.

If an Investigator is non-compliant with this Policy, the COI Committee shall submit a report to the President. The report shall include all material facts and recommendations for appropriate sanctions or enforcement actions. In the event the Investigator is the President, the COI Committee shall submit the report to the Board Chair who will make final decisions regarding sanctions or enforcement actions.

Appropriate sanctions or enforcement actions may include some or all of the following: requiring mentors and/or independent monitors, freezing project funding, change of research role or employment status, withholding paychecks, termination of employment, legal action or some other appropriate sanction not specifically mentioned here. The President or Board Chair shall make final decisions regarding applying the enforcement sanctions or enforcement actions.

F. Public Accessibility

1. This Policy shall be available via the Institute's public website.
2. When the Institute receives a written request for information regarding an Investigator identified as Senior/Key Personnel who has an existing FCOI related to PHS-Funded Research, the Institute shall respond via a written response **within five (5) business days** of the receipt of the request. The written response shall consist of the minimum elements as required by 42 CFR Part 50 Subpart F and will state that the information provided is current as of the date of the correspondence and is subject to updates.
3. The Institute is not responsible for updating previous requests for information. The requester must submit a new written request to obtain updated information.

G. Record Retention

1. The Institute shall maintain records relating to:
 - a. All Investigator SFI Disclosures;
 - b. The Institute's review of and response to SFI Disclosures (whether or not the Disclosure resulted in an FCOI determination); and
 - c. All actions taken under this Policy.
2. Unless other applicable record retention law, requirement or policy requires a longer period, the records created under this Policy shall be retained by the Institute for **three (3) years**:
 - a. For PHS-Funded Research, from the date of submission of the final expenditure report to the PHS Awarding Component or as required by 45 CFR 75.361;
 - b. For all other Funded Research, from the date of submission of the final expenditure report.

4. Definitions

- **Conflict of Interest (COI)** - a situation in which an individual;
 - a) Has competing interests or loyalties, or
 - b) Is in a position to derive personal benefit from actions or decisions made in their official capacity, or
 - c) Has interests that may conflict with their commitment to scientific integrity.COIs may include financial and/or non-financial interests.

- **Conflict of Interest (COI) Committee** - a group to which the Institute has delegated the authority to maintain, administer and periodically update this Policy. The COIC is responsible for the review of actual and potential conflicts of interests and implementation of appropriate oversight procedures designed to eliminate, reduce or manage conflicts.
- **Designated Institutional Official (DIO)** - individual responsible for the review of all Significant Financial Interest (SFI) disclosures, determination of potential conflicts of interest related to Funded Research, and referral of potential conflicts to the COI Committee.
- **Entity** - domestic or foreign, public or private, organization (excluding a Federal agency) from which an Investigator (and spouse and dependent child(ren)) receives compensation or has 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 results of the Funded Research. Any SFI in a business will not constitute an FCOI if the business is an applicant under a Phase I Small Business Innovation Research Program (SBIR) or Small Business Technology Transfer (STTR) Program.
- **Financial Interest** - anything of monetary value, whether or not the value is readily ascertainable.
- **Funded Research** - research projects funded by grants, contracts, and cooperative agreements administered by the Institute. Funding sources include, but are not limited to, PHS-Awarding Components (e.g. NIH), other federal funding agencies (e.g. DoD, NSF), foundations, private companies and individuals.
- **Family Member** - an Investigator's spouse, domestic partner, or a dependent child(ren).
- **Institutional Responsibilities** - any professional activity performed by an Investigator on behalf of the Institute (e.g., research, consultation, speaking engagements, teaching, professional practice, contract negotiation, clinical activities, purchasing, institutional committee memberships, and service on panels such as the Institutional Biosafety Committee and the Institutional Animal Care and Use Committee).
- **Intellectual Property (IP)** - any direct or indirect rights in a patent, trademark, copyright, trade secret, know-how or other intellectual property right (e.g. inventorship, ownership, authorship, royalties, and license fees). This definition applies regardless of whether the intellectual property right is owned by the Institute or an external commercial or non-profit entity.
- **Investigator** - any person, regardless of title or position, who is responsible for the design, conduct, or reporting of proposed or Funded Research such as;
 - a) **Principal Investigator (PI)**: Investigator with primary responsibility for the scientific and technical conduct, reporting, fiscal and programmatic administration of a Funded Research Project.
 - b) **Senior/Key Personnel**: the PI and any other person identified as senior/key personnel by the Institution in a grant application, progress report, or any other report submitted to a funding agency.

The significance of the tasks assigned to the person with regard to the design, conduct and reporting of the research and the degree of independence the person has in performing such tasks will determine if they are an Investigator. For the purposes of this Policy, unless otherwise determined by the PI, undergraduate and high school students, interns, lab assistants, lab technicians, and volunteers are not Investigators.
- **Management Plan (MP)** - plan that includes the actions that an Investigator shall take to eliminate, reduce or manage an FCOI.
- **PHS Awarding Component** - organizational unit of the Public Health Service (PHS) of the U.S. Department of Health and Human Services that funds the research and is subject to 42 CFR Part 50, Subpart F.
- **PHS-Funded Research** - research funded by the Public Health Service of the U.S. Department of Health and Human Services, or any components of the PHS delegated (e.g. The National Institutes of Health (NIH), the Center for Disease Control (CDC), the Food and Drug Administration (FDA), and the Agency for Healthcare Research and Quality (AHRQ)). PHS-Funded Research does not include Phase I Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Program applications or awards.

- **Significant Financial Interest (SFI)** - a financial interest of the Investigator and/or their Family Members that meets one or more of the following criteria and that reasonably appears to be related to the Investigator's Institutional Responsibilities:
 - **Payment from and/or equity in a publicly traded entity**, that when by itself or combined, **is more than \$5,000**. Payments include salary, consulting fees, honoraria, paid authorship, or other payments. Equity includes stock, stock options or other ownership interest. Exclusions include equity in investments where the Investigator does not have direct control over investment decisions (e.g. mutual funds or retirement accounts).
 - **Payment of more than \$5,000 from or any equity in a non-publicly traded entity**, Exclusions include:
 - Income from seminars, lectures or teaching engagements, and service on advisory committees or review panels paid or sponsored by a;
 - U.S. federal, state or local government agency;
 - U.S. institution of higher education (as defined at 20 USC 1001(a));
 - U.S. academic teaching hospital;
 - U.S. medical center; or
 - Domestic research institute affiliated with a U.S. institution of higher education.
 - Equity in investments where the Investigator does not have direct control over investment decisions (e.g. mutual funds or retirement accounts).
 - **Income of \$5000 or more from intellectual property rights and interest** (e.g. patents, copyrights, trademarks, agreements to share in royalties related to IP). Exceptions include payments paid by ISB to the Investigator.
 - **Reimbursed or sponsored travel** (i.e., paid to or on behalf of the Investigator) **valued at more than \$5,000**, in aggregate, **over a twelve (12) month period from the same entity**.
 - Exceptions include travel reimbursed or paid by a;
 - U.S. federal, state, or local government agency;
 - U.S. institution of higher education (as defined at 20 USC 1001(a));
 - U.S. academic teaching hospital;
 - U.S. medical center; or
 - Domestic research institute affiliated with a U.S. institution of higher education.
- **SFI Disclosure** – a disclosure of an Investigator's significant financial interests to an institution.

5. Related Policies and Other Resources

A. ISB Policies

- ISB Fiduciary Conflict of Interest Policy

B. Federal Regulations

- 42 CFR 50, Subpart F August 25, 2011 – PHS regulations on Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought
- 45 CFR Part 94 August 25, 2011 – PHS regulations on Responsible Prospective Contractors

- 60 FR 35820 – 35823, July 11, 1995 – National Science Foundation’s Investigator Financial Disclosure Policy

C. Processes and Instructions

- Investigator Initial COI Disclosure Form
- Investigator Update COI Disclosure Form
- Investigator Annual COI Disclosure Form
- COI Project-Specific Initial Disclosure
- COI Project-Specific PI Initial Disclosure
- COI Project Specific Active Award Disclosure
- COI Contractor Disclosure Form
- ISB COI Subrecipient Disclosure Form