

**INSTITUTE FOR SYSTEMS BIOLOGY
INVESTIGATOR CONFLICT OF INTEREST POLICY**

Promoting Objectivity in Research

PURPOSE

The Institute will maintain an up-to-date, written, enforced policy on financial conflicts of interest (this "**Policy**") that complies with 42 CFR 50 Subpart F, 45 CFR 94, and the National Science Foundation's Grantee Standards NSF 05-131. This Policy applies to all research, regardless of funding source. This Policy will be made publicly available via the Institute's public-facing website.

This Policy promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research will be free of bias. In addition to meeting federal regulations and funding requirements, this Policy strives to protect the interests and reputation of the Institute while ensuring public trust in our work.

There are certain cases in which the appearance of a Conflict of Interest (COI) is present even when no actual conflict exists. Such perceived conflicts can be as harmful as actual conflicts, undermining the credibility of research and calling into question the integrity of the Institute's work. For this reason, it is important for Institute personnel, in evaluating a potential conflict of interest, to consider how it might be perceived by others.

This Policy provides guidelines for identifying, resolving or managing potential or actual Financial Conflicts of Interest (FCOI) that could directly and significantly affect the design, conduct or reporting of the results of research and/or affect an Investigator's Institutional Responsibilities.

APPLICABILITY

This Policy applies to all persons, paid or unpaid, employed on a full or part time basis, or who work in any capacity on behalf of the Institute, including without limitation, all Institute employees, faculty members, visiting scholars, temporary employees, collaborators, academic subcontractors, graduate students, interns, volunteers, and appointed affiliate faculty members *who could directly and significantly affect the design, conduct or reporting of the results of research*. Such persons will be referred to as "Investigators" throughout this Policy, in accordance with 42 CFR 50, Subpart F and 45 CFR 94.

In addition to this Policy, Officers and Board Members must comply with the Institute's Fiduciary Conflict of Interest Policy.

DEFINITIONS

Conflict of Interest Committee (COI Committee) means the group to which the Institute delegates its authority to determine if a FCOI exists, and if a FCOI exists, to create a management plan designed to eliminate or mitigate the FCOI, and conduct retrospective reviews of existing projects to the extent potential FCOI are identified. The COI Committee will conduct its business in light of the Institute's mission to make available to the public the benefits

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of its research and recognize that COI are a common occurrence in fulfilling this mission. Its charge is to establish appropriate oversight procedures designed to ensure that the conduct of Funded Research is not influenced by FCOI and that all FCOI are disclosed and when appropriate, managed.

Designated Institutional Official (DIO) means the individual responsible for reviewing all Significant Financial Interest (SFI) disclosures, determining whether a FCOI potentially exists, and sending potential FCOIs to the COI Committee for review.

Financial Conflict of Interest (FCOI) means a SFI that could directly and significantly affect the design, conduct or reporting the results of the Funded Research.

Financial Interest means anything of monetary value, whether or not the value is readily ascertainable.

Funded Research means all funded research, including grants, contracts, and cooperative agreements. External sponsors 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 means the spouse, domestic partner, or a dependent child of an Investigator.

Institute means the Institute for Systems Biology.

Institutional Responsibilities means an Investigator's professional responsibilities on behalf of the Institute, which may include, but are not limited to, 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 Use and Care Committee.

Investigator means a project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of proposed or funded research. The term "Investigator" includes subrecipients, collaborators, consultants, and all Senior/Key Personnel on a project, regardless of funding.

PD/PI means a Project Director or Principal Investigator of a research project. In Funded Research, the PD/PI is included in the definitions of Senior/Key Personnel and Investigator.

PHS-funded Research means all research which is sponsored by the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including but not limited to, 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).

Senior/Key Personnel means the PD/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.

Significant Financial Interest (SFI) means a financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's Family Members) that reasonably appears to be related to the Investigator's Institutional Responsibilities:

- With regard to any publicly traded entity, a SFI exists if the value of the remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity 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**. 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.
- With regard to any non-publicly traded entity, a SFI exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds **\$5,000**, or when the Investigator (or the Investigator's Family Member) holds any equity interest (e.g. stock, stock option, or other ownership interest); or intellectual property rights and interest (e.g. patents, copyrights), upon receipt of income related to such rights and interest.
- Investigators must also disclose the occurrence of reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator) valued at **\$5,000** or more, in aggregate, over the course of the year from the same source, and that is related to the Investigator's Institutional Responsibilities. Exceptions include travel that is reimbursed or sponsored by a U.S. federal, state, or local government agency; a U.S. institution of higher education (as defined at 20 USC 1001(a)); a U.S. academic teaching hospital; a U.S. medical center; or a domestic research institute that is affiliated with a U.S. institution of higher education. Exceptions may also be made for Investigators who regularly receive travel compensation from varied sources which in the judgment of the COI Committee are not reasonably likely to directly and significantly affect the design, conduct or reporting of the Funded Research. When exact monetary values are not known, estimates are acceptable.

I. INVESTIGATOR DISCLOSURE REQUIREMENTS

Initial Disclosures. Each Investigator is required to disclose his or her SFI – and those of his or her Family Members – prior to submitting an application for Funded Research or prior to engaging in such Research. Disclosing SFI allows the DIO to identify potential FCOI, in turn allowing the COI Committee to determine whether an FCOI exists.

Investigators who are new to the Institute must disclose SFI upon hiring if the Investigator transfers any research to the Institute, and before engaging in any Funded Research activities at the Institute.

SFI disclosures must be made, in writing, to the DIO or COI Committee Chair in accordance with published Investigator COI Disclosure form(s), regardless of funding.

Subsequent Disclosures. Each Investigator who participates in Funded Research must submit an updated SFI disclosure at least once per year during the period of the award or project, to determine whether the interest, if any, is a FCOI.

The disclosure must include any information that was not initially disclosed to the Institute, and shall also include updated information on any previously disclosed SFI (e.g., updated value of a previously disclosed equity interest).

Additionally, Investigators must submit an updated SFI disclosure within 30 days of discovering or acquiring (through purchase, marriage, inheritance, etc.) a new SFI.

II. RESPONSIBILITIES OF THE INSTITUTE

Review. The COI Committee shall review potential FCOI identified by the DIO. If a FCOI is determined to exist, then the COI Committee shall prepare an appropriate management plan designed to eliminate or mitigate the FCOI. The COI Committee shall conduct retrospective reviews of existing projects to the extent potential FCOI are identified.

Notice and Acknowledgement. The Institute is responsible for informing each Investigator of this Policy, relevant regulations, and the Investigator's responsibility to disclose SFIs. Investigators are required to complete training on this Policy and the associated regulations before engaging in research, and at least once every four years.

In addition, Investigators will be provided notice about the Policy immediately when:

- The Institute revises this Policy in any manner that affects the requirements of Investigators;
- An Investigator is new to the Institute; or
- The Institute finds that an Investigator is not in compliance with this Policy or management plan(s).

Reporting. DIO will report to external funders all FCOI related to the funded project in accordance with the funders' rules and expectations.

PHS-funded Research. The Institute is obligated under 42 CFR 50 Subpart F and 45 CFR 94 to report to the PHS Awarding Component all related SFI that are deemed FCOI, as defined in this Policy, prior to the expenditure of funds and within 60 days of any subsequently identified FCOI. The Institute delegates its responsibility to review, manage, mitigate, report, and when appropriate, conduct retrospective reviews of potentially conflicted projects as described in this Policy to the COI Committee.

Management of Subrecipients. When the Institute carries out research through an academic subrecipient (e.g. subcontractors or consortium members), the Institute must take reasonable steps to ensure that the subrecipient Investigator(s) will comply with either this Policy or the subrecipient's conflict of interest policy.

Special Provisions for PHS-funded Subrecipients: When the Institute carries out PHS-funded Research through an academic subrecipient (e.g. subcontractors or consortium members), the Institute must take reasonable steps to ensure that the subrecipient Investigator(s) will comply with 42 CFR 50 Subpart F and 45 CFR 94 by incorporating one of the following into the subcontract agreement:

- Statement that the academic subrecipient will comply with their own financial conflict of interest policy which complies with 42 CFR 50 Subpart F and 45 CFR 94. The agreement will specify the time periods for the subrecipient to report all identified FCOI to the awardee institution (the Institute). Time periods for reporting to the Institute must be sufficient to allow the Institute to complete the review, management, and reporting of

subrecipient FCOI which are related to PHS-funded Research.

OR

- Statement that the academic subrecipient will comply with this Policy which complies with 42 CFR 50 Subpart F and 45 CFR 94. The agreement will specify the time periods for the subrecipient to report all Investigator disclosures of SFI to the awardee institution (the Institute). Time periods for reporting to the Institute must be sufficient to allow the Institute to complete the review, management, and reporting of subrecipient FCOI which are related to PHS-funded Research.

III. PHS FUNDING APPLICATION CERTIFICATION

In accordance with 42 CFR 50 Subpart F and 45 CFR 94, the Department of Sponsored Projects will meet the following PHS expectations when applying for PHS-funding:

Certification. The Institute must certify, in each grant application for PHS-funded Research, that the Institute:

- Has in effect an up-to-date, written, and enforced administrative process to identify and manage FCOI with respect to all research projects for which funding is sought or received from the PHS;
- Shall promote and enforce Investigator compliance with the requirements under 42 CFR 50 Subpart F and 45 CFR 94 (as applicable), including those pertaining to disclosure of SFI;
- Shall manage FCOI and provide initial and ongoing FCOI reports to the PHS Awarding Component;
- Agrees to make information available, promptly upon request, to the HHS relating to any Investigator SFI disclosure and the Institute's review of, and response to, such disclosure, whether or not the disclosure resulted in the Institute's determination of a FCOI; and
- Shall fully comply with the requirements of 42 CFR 50 Subpart F and 45 CFR 94.

IV. REVIEW AND MANAGEMENT OF SFI/COI

Prior to the Investigator's involvement in Funded Research, and prior to the Institution's expenditure of any funds under a Funded Research project, the DIO shall review all Investigator SFI Disclosures; determine whether any SFIs might relate to the Funded Research; and if so, work with the COI Committee to determine whether an FCOI exists. When an FCOI exists, the COI Committee will develop and implement a management plan that shall specify the actions that have been, and will be, taken to manage the FCOI. This process must be completed prior to expenditure of any funds whatsoever on the Funded Research.

Designated Institutional Official

The Director of Sponsored Projects shall serve as ISB's Designated Institutional Official (DIO) and submit FCOI reports to the appropriate funding agencies as applicable. The COI Committee

Chair shall serve as the Alternate DIO. The DIO is responsible for soliciting and reviewing SFI disclosures from each Investigator who is planning to participate in, or is participating in, Funded Research. Disclosures must be made, in writing, to the Department of Sponsored Projects prior to the submission of each application for funding, or prior to engaging in Funded Research, in accordance with the Institute's published Investigator COI Disclosure form(s). The DIO will provide initial and ongoing FCOI reports to appropriate funding agencies in accordance with the funding agency's policies.

The Institute will provide guidelines consistent with 42 CFR 50 Subpart F and 45 CFR 94 (the "**Guidelines**") for the COI Committee to determine whether an Investigator's SFI is related to the Funded Research, and if so, whether the SFI constitutes an FCOI. A potential FCOI is presented when the DIO reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the Funded Research. The DIO shall submit the potential FCOI to the COI Committee to determine, based on the Guidelines, whether there is an FCOI, and if so, how to manage, mitigate, or remove the financial conflicts of interest sufficient to ensure objectivity in the research. The COI Committee may, however, request information and feedback from the Investigator regarding how the SFI relates to the Funded Research and/or the Investigator's Institutional Responsibilities.

Conflict of Interest Committee

The DIO shall forward all potential FCOI to the COI Committee. A quorum of the COI Committee shall consist of a majority of members, either in-person or telephonically. Certain decisions may be made via unanimous electronic voting, however a convened meeting will be called following an electronic vote when: a) it is determined that an FCOI exists and a management plan must be considered or implemented, b) a COI Committee member requests a convened meeting, or c) the COI Committee Chair does not receive unanimous electronic votes in a timely manner.

The COI Committee shall consist of at least seven (7) members, at least two of whom do not engage in research. The Chief Operating Officer, the Associate Director of Compliance, the Director of Human Resources, the Director of Sponsored Projects, and the Director of Finance shall be standing members of the COI Committee. The Associate Director of Compliance shall serve as the Chair of the COI Committee. The Chief Compliance Officer shall be an ex-officio member. In addition, the Committee shall include one (1) Faculty Member or Principal Scientist and one (1) Senior Research Scientist or equivalent, as appointed by the standing members of the COI Committee. These rotating members shall serve for a one (1) year term only and then rotate off. Rotating members may not serve consecutive terms, but may rotate back onto the COI Committee the following year. Additional members may be appointed and non-voting consultants may be utilized at the COI Committee's discretion.

Any COI Committee member who is determined to have a SFI shall recuse himself/herself from the deliberation and vote.

The COI Committee Chair will appoint a COI Committee member to take minutes at each convened meeting. The COI Chair will keep records of all reviews conducted remotely and maintain all Minutes from convened meetings. Investigator feedback to the COI Committee is encouraged.

If the COI Committee determines that an FCOI involves the President and/or Chief Operating Officer of ISB, the Chief Compliance Officer will take the FCOI to the Chairman of the Board and

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the Audit and Compliance Committee. Simultaneously, the COI Committee Chair shall complete an FCOI Report as applicable.

Examples of conditions or restrictions that may be imposed to manage a FCOI include, but are not limited to:

- Public disclosures of FCOI, such as when the Investigator presents or publishes Funded Research results;
- Appointment of an independent monitor capable of taking measure to protect the design, conduct, and reporting of the Funded Research against bias resulting from the FCOI;
- Modification of the Funded Research plan (e.g. removing conflicted Investigator from data analyses);
- Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or part of the Funded Research;
- Reduction or elimination of the financial interest;
- Severance of relationships that create financial conflicts;
- For research projects involving human subjects research, disclosure of FCOI directly to participants, when applicable. Office for Human Research Protections (OHRP) and Department of Health and Human Services (DHHS) requirements relating to conflicts and human subjects must be met in accordance with 45 CFR 46 and local IRB policies.

Whenever a FCOI management plan is implemented, the COI Committee shall appoint an appropriate individual, on a case-by-case basis, to monitor Investigator compliance with the management plan on an ongoing basis, until the completion of the research project.

The Investigator shall be notified of all COI Committee management, mitigation, and retrospective review plans. If the COI Committee determines that no FCOI exists, the COI Committee shall notify the Investigator that the COI Committee found no FCOI requiring management or mitigation.

Appeals

Any Investigator, other than the Institute's President or Chief Operating Officer, who disagrees with a final decision of the COI Committee may appeal in writing to the Committee or to the Institute's Chief Compliance Officer within ten (10) calendar days of a final decision.

Should the FCOI involve the Institute's President or Chief Operating Officer and they disagree with a COI Committee decision, the appeal will be submitted to the Chief Compliance Officer and the Chairman of the Board. If the COI Committee does not accept an Investigator's appeal, the Institute's Chief Compliance Officer or Chairman of the Board shall review the COI Committee's findings and recommended actions and issue a decision. The Chief Compliance Officer or Chairman of the Board's decision regarding the COI Committee's findings and recommended actions shall be final and unappealable.

New Investigators and/or Subsequent Disclosures

Whenever, in the course of an ongoing Funded Research project, an Investigator who is new to the project discloses a SFI, the DIO shall within 60 days:

- Review the disclosure;
- Determine whether the SFI appears to be related to the Funded Research;
- Determine, through the COI Committee, whether a FCOI exists, and if so;
- Implement, at least on an interim basis, a management plan that shall specify the actions that have been, or will be, taken to manage the FCOI.

Interim Measures: Depending on the nature of a SFI, the COI Committee may determine that additional "interim measures" are necessary with regard to an Investigator's participation in the Funded Research between the date of the disclosure and the completion of the COI Committees' review.

Retrospective Reviews

In addition, whenever a FCOI was not identified or managed in a timely manner due to Investigator failure to disclose the FCOI, failure of the COI Committee to review or manage the FCOI, or failure by the Investigator to comply with a FCOI management plan, the DIO shall, within 120 days:

- Review the disclosure;
- Determine whether the SFI is related to the Funded Research;
- Determine, through the COI Committee, whether a FCOI exists, and if so:
- The COI Committee will, on a case-by-case basis, appoint appropriate individual(s) to complete a retrospective review of the Investigator's activities and the Funded Research project. The retrospective reviewer and the COI Committee will determine whether any research conducted during the period of noncompliance was biased in the design, conduct, or reporting of such Funded Research;
- The Institute is required to document the retrospective review as specified in the section of this Policy titled, "Maintenance of Records."

Based on the results of the retrospective review, if appropriate, the DIO shall update the previously submitted FCOI report to the appropriate funding agency. For PHS-funded Research, the updated FCOI report must include the actions that will be taken to manage the FCOI going forward.

If bias is found in any Funded Research project, the DIO shall notify the funder promptly, as applicable. See "Mitigation" section below for additional requirements relating to PHS-funded Research in which bias has been found.

Mitigation

For PHS-funded Research, the Institute must notify the PHS Awarding Component promptly

and submit a mitigation report to the PHS Awarding Component. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above, and a description of the impact of the bias on the research project, as well as the Institute's plan of action to eliminate or mitigate the effect of the bias. Thereafter, the Institute shall submit FCOI reports to the PHS Awarding Component annually. Depending on the nature of the FCOI, the Institute may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded Research project between the date that the FCOI or noncompliance is determined, and the completion of the Institute's retrospective review. The COI Committee will be responsible for generating all appropriate documentation, including when the retrospective review finds no bias, and the basis for such a finding.

V. COMPLIANCE, NON-COMPLIANCE AND INSTITUTIONAL ENFORCEMENT

All persons subject to this Policy are expected to comply fully and promptly. An Investigator who submits a complete and accurate COI Disclosure and complies with conditions required by the COI Committee shall be deemed to be in compliance with this Policy. Failure to fully and accurately disclose a SFI or failure to comply with conditions or management plans imposed by the COI Committee shall constitute non-compliance with this Policy.

The Institute encourages Investigators who are aware of an unreported SFI to bring the SFI to the attention of the Associate Director of Compliance, the COI Committee, a member of the management team, or the Whistleblower Hotline (206) 732-1300.

Enforcement. All allegations and instances of non-compliance with this Policy shall be reported to the COI Committee Chair who shall consult with the COI Committee regarding possible enforcement actions to be taken. If the COI Committee determines that an Investigator has failed to comply with any aspect of this Policy, the COI Committee shall submit a report in writing to the Chief Operating Officer and Chief Compliance Officer. The report shall include all material facts and recommendations for enforcement actions, if any.

The Chief Operating Officer, in consultation with the Chairman of the Board, shall make final decisions regarding enforcement actions, up to and including termination of employment or legal action.

Examples of possible enforcement actions:

- Halting direct deposit (paychecks)
- Cutting off funding
- Installing mentors and/or independent monitors
- Change in employment status
- Change in research roles
- Termination

In instances of non-compliance by the President or Chief Operating Officer, the COI Committee shall submit its recommendations to the Chairman of the Board and the Audit and Compliance Committee (ACC) of the Board of Directors and will conduct a retrospective review in

accordance with 42 CFR 50. If bias is found, the BOD Chair will work with the COI Committee to create a Mitigation Plan. The implementation of the Mitigation Plan shall be monitored by the Chief Operating Officer and the Chief Compliance Officer. In PHS-funded research, the DIO will update the previously submitted FCOI Report to the appropriate funding agency and/or report the Mitigation Plan in accordance with 42 CFR 50. The BOD Chair will inform the President/COO of the action. The BOD Chair, ACC, and Chief Compliance Officer will monitor the implementation of the Investigator COI Management/Mitigation Plan on an ongoing basis.

VI. PUBLIC ACCESSIBILITY

Prior to the expenditure of any funds under any Funded Research projects, and prior to the Investigator's participation in Funded Research, the Institute will ensure public accessibility of information concerning any FCOI disclosed to the Institute. The Institute will ensure such accessibility by responding to any requesters within five (5) business days of a request, or posting on the Institute's external website, when the following criteria are met:

- A SFI was disclosed and is still held by the Senior/Key Personnel as defined in 45 CFR 94 and 42 CFR 50 and;
- The DIO and/or COI Committee has determined that the SFI is related to the Funded Research and;
- The COI Committee determines that the SFI is a FCOI.

The information that the Institute must make publicly available includes, at a minimum:

- Investigator's name
- Investigator's title and role with respect to the Funded Research project
- The name of the entity with which the SFI is held
- The nature of the SFI
- The approximate value of the SFI (dollar ranges are permissible as follows: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 in increments of \$20,000; amounts above \$100,000 in increments of \$50,000)
- When the value of a SFI cannot be readily determined through reference to public prices or other reasonable measure of fair market value, a statement stating so.
- A statement that the information is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within 60 days of the Institution's identification of a new FCOI, which should be requested subsequently by the requester.

(The Institute is not responsible for continually updating previous requests. The requester must make a new request to obtain updated information.)

Information concerning conflicts for which the above criteria are met must be available to written requesters for at least 3 years from the date that the information was last updated.

VII. REPORTING TO SPONSORS

Prior to the Institute's expenditure of any funds under a Funded Research project, the Department of Sponsored Projects shall provide the awarding organization all required COI documents.

Reporting to PHS Awarding Components: For PHS-funded Research, the Institute will provide the PHS Awarding Component with a FCOI report regarding any Investigator's SFI found to constitute FCOI, and to ensure that the Institute has implemented a management plan in accordance with 45 CFR 94 and 42 CFR 50.

For subsequent FCOI findings during the period of award (e.g. participation of a new Investigator), the Department of Sponsored Projects shall, within 60 days, provide the PHS Awarding Component with a FCOI report regarding the financial conflict and ensure that the Institute has implemented a management plan in accordance with 45 CFR 94 and 42 CFR 50. Where such a FCOI report involves a SFI that was not disclosed timely by the Investigator, or which was for any reason not previously reviewed or managed by the Institute, the Institute is also required to complete a retrospective review as referenced above. If bias is found, the Institute is required to notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component.

All FCOI reports to PHS Awarding Components must include sufficient information to enable the PHS to understand the nature and extent of the financial conflict, and to assess the appropriateness of the Institute's management plan. The FCOI report shall include, but is not limited to:

- Project number
- PD/PI or Contact PD/PI if multiple PD/PI model is used
- Name of Investigator with the FCOI
- Name of the entity with which the Investigator has the FCOI
- Nature of the financial interest (e.g. equity, travel reimbursement, honoraria)
- Value of the interest (ranges are allowed as cited in the Public Accessibility section of this Policy)
- A description of how the financial interest relates to the PHS-funded Research, and the basis for the Institution's determination that the interest conflicts with such Research, and
- A description of key elements of the Institution's management plan, including:
 - Role and principal duties of the conflicted Investigator in the Funded Research project,

- Conditions of the management plan,
- How the management plan is designed to safeguard objectivity in the Funded 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.

For any FCOI previously reported by the Institute with regard to an ongoing PHS-funded project, the Department of Sponsored Projects will provide the PHS Awarding Component an annual FCOI report that addresses the status of the FCOI and any changes to the management plan. This reporting shall continue throughout the period of funding in the time and manner specified by the PHS Awarding Component. The annual FCOI report shall specify whether the FCOI is still being managed, or explain why the FCOI no longer exists.

Reporting to non-PHS Awarding Components: The National Science Foundation (NSF) requires similar reporting only when the Institute finds that the conflict cannot be managed satisfactorily. In such cases, the Director of Sponsored Projects shall notify the NSF Office of General Council, as required by the NSF.

Reporting to external funders for non-PHS and non-NSF funded projects will be compliant with the funding agencies rules and expectations, as applicable.

VIII. MAINTENANCE OF RECORDS

The Institute shall maintain records regarding Investigator COI Disclosures, and the Institute's review of and response to such disclosures (whether or not the disclosure resulted in an FCOI determination) and all actions relating to elimination, management, mitigation, and retrospective reviews (if applicable) for at least **three (3) years after final payment** on any funded project to which the potential or actual FCOI relates; or three years after the resolution of any funding agency action involving those actions, whichever is longer.

IX. REGULATIONS ADDRESSED

42 CFR Part 50, Subpart F, Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought

45 CFR Part 94, Section 94.4, Institutional Responsibility Regarding Conflicting Interests of Investigators

National Science Foundation Grant Policy Manual, Chapter V

National Institutes of Health Grants Policy Statement, Part II: Terms and Conditions of NIH Grant Awards


48 CFR Chapter 1, Federal Acquisition Regulation

45 CFR Part 46 (HHS regulations governing IRB members and investigators)

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21 CFR Part 56 (FDA regulations governing IRBs)

REVIEWED AND APPROVED BY:



Julie Thatcher, Designated Institutional Official

1/29/15

Date



Mark Ashida, Chief Operating Officer

1/29/2015

Date

