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**Responsible Department**  
**Sponsored Research Office**

**Responsible Policy Administrator**  
Chief Financial Officer

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## **Policy Statement**

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### **Section 1: Purpose**

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 and 45 CFR Part 94](#). The Conflict of Interest (COI) Regulations establish new standards and clarify previously established standards to be followed by institutions that apply or receive research funding from PHS awarding components, including National Institutes of Health, for all grants, cooperative agreements, and research contracts.

The Sanford Burnham Prebys Medical Discovery Institute (Institute), has the responsibility under the COI Regulations to manage Financial Conflicts of Interest between an Investigator's (and his/her spouse and dependent children) personal financial interest and his/her Institutional Responsibilities. The Institute 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 implementation of this policy the Institute certifies each application for which PHS funding is sought. Further, the Institution certifies it:

- Has in effect at that Institution 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 this requirement including those pertaining to disclosure of significant financial interests;
- Shall manage financial conflicts of interest and provide initial and ongoing FCOI reports to the PHS Awarding Component consistent this policy;
- Agrees to make information available, promptly upon request, to the HHS relating to any Investigator disclosure of financial interests and the Institution's review of, and response to, such disclosure, whether or not the disclosure resulted in the Institution's determination of a financial conflict of interest; and,
- Shall fully comply with the requirements of this policy.

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## Entities Affected By This Policy

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### Section 2: Applicability

The Conflict of Interest Policy (COI Policy) applies to all individuals who fit the definition of Investigator as described in the Definitions section below, including, without limitation, faculty, post-doctoral fellows, non-faculty researchers, as well as individuals identified by the Institute as senior/key personnel in a grant application, progress report or any other report submitted to a PHS funding agency. Subrecipients, collaborators, visiting researchers, consortium members, or consultants may also be subject to this policy if they are responsible for the design, conduct or reporting of federally funded research or research that is proposed for federal funding.

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## Definitions

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### Section 3: Definitions

1. **Financial Conflict of Interest (FCOI):** A significant financial interest (SFI) that could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.
2. **Significant Financial Interest (SFI):** A financial interest consisting of one or more of the following interests of the Investigator and those of the Investigator's spouse and dependent children that reasonably appears to be related to the Investigator's Institutional Responsibilities:
  - **Publicly Traded Entity:** A 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.
  - **Non-Publicly Traded 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

equity interest (e.g., stock, stock option, or other ownership interest); or other ownership interests (including equity in a non-publicly traded company. 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.

- Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
3. ***Investigators' Institutional Responsibilities:*** An Investigator's professional responsibilities on behalf of the Institute 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, Scientific Advisory Boards (SAB).
  4. ***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 the Institute or who will be responsible for the design, conduct, or reporting of research or educational activities funded or proposed for funding by the PHS.
  5. ***COI Committee:*** A committee comprised of members of the Institute that will review COI disclosures to determine whether a FCOI exists, if so, develop a Management Plan for the Investigator to manage, reduce or eliminate the FCOI.
  6. ***Management Plan:*** A plan that is created by the COI Committee that will specify the actions that have been taken or will be taken to manage an identified FCOI.
  7. ***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.
  8. ***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.

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## Policy Statement (continued)

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### **Section 4: What Constitutes a Significant Financial Interest**

A 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 Institutional Responsibilities.

1. ***Publicly Traded Entity:*** A 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:*** 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 equity interest (e.g., stock, stock option, or other ownership interest); or other ownership interests including equity in a non-publicly traded company. 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. **Remuneration:** Payment directly to the Investigator from intellectual property rights such as patents, copyrights and royalties not owned by the Institute.
4. **Travel:** Investigators must disclose the occurrence of any reimbursed or sponsored travel if in aggregate the travel exceeds \$5,000.00 per entity (i.e., travel that is paid on behalf of the Investigator and not reimbursed to the Investigator so the exact monetary value may not be readily ascertainable) that is related to their Institutional Responsibilities and reimbursed or sponsored by an entity *other than* the Institute or a United States (a) federal, state, or local government agency; (b) institution of higher education; (c) academic teaching hospital; (d) medical center; or (e) research institute that is affiliated with an institution of higher education. The disclosure must include the following details:
  - Purpose of the travel
  - Destination of the travel
  - Identity of sponsor/organization
  - Time duration of travel

The Institute will then determine if any travel requires further investigation, including determination or disclosure of the monetary value to determine whether the travel constitutes a FCOI.

**A SFI does not include the following types of financial interests:**

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

5. An equity interest that when aggregated for the Investigator and the immediate family, meets both of the following tests:
  - a. Does not exceed \$5,000 in value as determined through reference to public prices or other reasonable measures of fair market value.
  - b. Does not represent more than five (5) percent ownership interest in any single entity.
6. Salary, royalties or other payments that when aggregated for the Investigator and the immediate family over the next twelve (12) months are not expected to exceed \$5,000.
7. Intellectual property rights assigned to the Institute and unlicensed intellectual property that does not generate income.
8. Agreements with the Institute to share in royalties related to such rights.
9. 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

## **Section 5: Annual Disclosure: Submission and Updates**

### **Submission and Updates**

All individuals who meet the definition of Investigator will receive the Institute's policy on FCOI as well as the Investigator's responsibilities regarding disclosure of significant financial interest. Each Investigator must submit an Annual Disclosure form at time of hire and each subsequent year thereafter. All Investigators are required to complete an Annual Disclosure form that identifies and describes both existing and new SFIs (e.g., information not disclosed initially to the Institute or in a subsequent disclosure of significant financial interest. 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). Disclosure forms must be submitted to the COI Committee coordinator by the annual deadline. In addition, Investigators have an ongoing obligation to promptly update their Annual Disclosure form to accurately reflect any significant change in their external activities and SFIs as follows:

- At time of hire (including PI transfers)
- On an annual basis (October)
- 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

The Institute 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 required by this policy. [42CFR50.604\(2\)](#)

## **Section 6: Annual Disclosure: Committee Review**

### **Committee Review**

The Institute's COI Committee coordinator will initially review the Annual Disclosure forms and may request further information or clarification about a SFI. The COI coordinator will review all disclosures of SFIs and make a preliminary determination whether an SFI appears to relate to funded research. If so the matter will be immediately referred to the COI Committee for further review. The COI Committee will be comprised of approximately 3 or 4 members from the following:

- Faculty
- Executive Leadership

- Finance
- Office of Intellectual Property & Legal Affairs
- Sponsored Research Office
- Additional members as necessary

The members of the COI Committee will initially review all disclosed SFIs to determine whether any are related to the Investigators research and, if so, whether the SFI may be a FCOI. The COI Committee reviews and analyzes the specific circumstances of a SFI by taking into account such factors as the nature of the Investigator's relationship to an outside entity, the dollar value of that relationship, and the degree and nature of any overlap between that relationship and the Investigator's research. The administrative members of the COI Committee may, if warranted, involve the Investigator and/or other faculty members or advisors in determining whether a SFI is related to the research in question. An FCOI will be deemed to exist when the full 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.

The steps set forth below must be completed promptly following disclosure of a SFI in order to enable any FCOIs to be reported to the federal funding agency within the sixty (60) day deadline set forth in the COI 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. [42CFR 50.604\(d\)](#)

### **Section 7: Management Plan**

If an FCOI is identified by the COI Committee, the COI Committee will develop a Management Plan to manage, reduce or eliminate the conflict. The Management Plan will be set forth 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:

- 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 that will include mechanisms appropriate for the specific situation. A copy of the Management Plan will be provided to the Investigator and to the Institute's President. The President will have final authority to determine whether or not a FCOI exists and the appropriate plan for managing the FCOI. 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.

The Institute's Management Plan will contain all elements required by the COI Regulations, which may include: 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 Investigators agreement to the Management Plan; how the Management Plan will be monitored; and other information as needed. [42CFR50.605\(b\)\(1\)](#)

### **Section 8: Reporting Financial Conflicts of Interest to PHS**

The Institute will report any significant financial interest disclosed that meet the following three criteria: 1) The significant financial interest was disclosed and is still held by the senior/key personnel as defined by this policy; 2) The Institution determines that the significant financial interest is related to the PH-funded research; and 3) The Institution determines that the significant financial interest is a financial conflict of interest.

1. ***New PHS Funded Research:*** Prior to the Institute's expenditure of any funds on a PHS funded research project, the COI Committee coordinator, 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. [42CFR50.605\(b\)\(1\)](#)

The report will contain all elements required by the COI Regulations, which may include: Project number; project title; PD/PI or contact PD/PI; name of the Investigator with the FCOI; name of the entity with which the Investigator has an FCOI; nature of the financial interest; 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; a description of how the financial interest relates to the PHS-funded research and the basis for the Institute's determination that the financial interest conflicts with such research; a description of the key elements of the Institute's Management Plan, including; 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 project; confirmation of the Investigator's agreement to the Management Plan; how the Management Plan will be monitored to ensure Investigator compliance; other information as needed.

2. ***Ongoing PHS Research Projects:*** Whenever a new or existing Investigator discloses a new SFI, the Institute will review the disclosure, determine whether it is related to PHS-funded research, and determine if a FCOI exists. If a FCOI exists, the Institute will within sixty (60) days complete required reporting through the eRA Commons FCOI Module. [42CFR50.605\(a\)\(2\)](#)

For any FCOI identified subsequent to the Institute's initial report during an ongoing funded research project, the Institute 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. [42CFR50.605\(b\)\(2\)](#)

3. ***Period of Non-Compliance during an Ongoing PHS Funded Project:*** The Institute will within sixty (60) days of the Investigator's delayed disclosure of an SFI, determine if the SFI constitutes a FCOI. If a FCOI exists, the Institute 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 COI Committee coordinator will submit the FCOI report through the eRA Commons FCOI Module. In addition to the FCOI report, the Institute will, within one-hundred-twenty (120) days of its determination of non-compliance, complete a retrospective review of the Investigators 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 results of the review the COI Committee coordinator will update the previously submitted FCOI report, specifying the actions that will/have been taken to reduce or eliminate the FCOI. [42CFR50.605\(a\)\(3\)](#)

The Institute will document the retrospective review, including all of the following key elements: project number; project title; PD/PI or contact PD/PI; name of the Investigator with the FCOI; name of the entity with which the Investigator has an FCOI; reason(s) for the retrospective review; detailed methodology used for the retrospective review; findings of the review; and conclusions of the review. [42CFR50.605\(a\)\(3\)](#)

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 the Institution as required by the COI Regulations, the Institute 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. [42CFR50.606\(c\)](#)

4. **Annual Reports:** For any FCOI previously reported, the Institute 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 will explain why the FCOI no longer exists. The Institute 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. [42CFR50.605\(b\)\(4\)](#)

### **Section 9: Public Accessibility**

The Institute's FCOI policy will be made accessible through the Institute's public web site ([www.sbpdiscovery.org](http://www.sbpdiscovery.org)). In addition, in compliance with the COI Regulations, the Institute will make the following information about identified FCOIs available by written response within five (5) business days of a request:

- Investigator's name
- Investigator's title and role with respect to 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. [42CFR50.605\(a\)\(5\)\(ii\)](#)

### **Section 10: Financial Conflict of Interest Monitoring**

The Institute will monitor the FCOI and Investigator compliance with the FCOI Management Plan until the completion of the research project. As necessary, the COI Committee may require and develop a project specific monitoring process, which may include appointing an Institute designated official to assist with monitoring the FCOI and Investigator compliance. The COI Committee may modify an Investigator's Management Plan at any time. [42CFR50.605\(a\)\(4\)](#)



### **Section 11: Subrecipient Compliance**

If the Institute carries out research through a Subrecipient, the Institute will take reasonable steps to ensure any Subrecipient Investigator complies with the COI Regulations. The Institute will incorporate as part of its written consortium agreement with the Subrecipient, terms that establish whether the FCOI policy of the Institute or that of the subrecipient will apply to the subrecipient Investigator(s).

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 Financial Conflicts of Interest to the Institute. Such time periods will provide SBP with sufficient time to review the reports and make timely reports to PHS, as necessary. [42CFR50.604\(c\)\(1\)\(ii\)](#)

If the Subrecipient cannot provide certification of an established FCOI Policy, the written agreement issued by SBP will state that subrecipient Investigators are subject to the FCOI policy of SBP 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 SBP to allow sufficient time to review the disclosures and comply timely with its review, management, and reporting obligations under this Policy. [42CRF50.604\(c\)\(1\)\(iii\)](#)

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

### **Section 12: Enforcement and Non-Compliance**

The Institute 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 COI Policy and/or Management Plan. Violations of this policy may result in disciplinary actions as deemed appropriate by the Institute.

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

- Submit an Annual Disclosure form or provide an update to the Annual Disclosure form by the deadlines established for such submissions
- Provide the COI Committee with written acknowledgement of a Management Plan
- Provide the COI Committee with requested documentation regarding compliance with a Management Plan
- Complete required FCOI training

If an Investigator fails to comply with the Institute's COI Policy and/or Management Plan, the Institute must complete within one-hundred twenty (120) days of determining non-compliance a retrospective review of the Investigator's activities and research projects, document the Institute's determination as to whether the federal 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, the Institute must submit a mitigation report addressing the impact of the bias on the research project including the extent of harm done, and any qualitative and quantitative data to support any actual or future harm, analysis of whether the project is salvageable and the actions the Institute has taken, or will take to eliminate or mitigate the effect of the bias. 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 research project between the date of the FCOI is identified and the completion of the Institute's retrospective review. [42CFR50.604\(j\)](#)

### **Section 13: Project Specific Certification**

Investigators have an ongoing obligation to promptly update their Annual 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 Annual Financial Conflict of Interest Disclosure on file. If there are reportable changes the Sponsored Research Office will collect an updated Disclosure form for review and processing by the COI Committee.

### **Section 14: Mandatory Training**

The Institute requires all Investigators to complete COI training prior to engaging in federally funded research and at least every 4 years thereafter, or as directed by the Institute. Training is required immediately when any of the following circumstances apply:

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

The Institute's training program will be available on-line via the Sponsored Research Office web site. A confirmation email is sent to the COI Committee coordinator for each Investigator who has completed training. [42CFR50.604\(b\)](#)

### **Section 15: Record Maintenance**

Records relating to all Investigator disclosures of FCOIs and the Institute's review of, or response to, such disclosures, and all actions under the Institute's 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. [42CFR50.604\(i\)](#)