

PROTEOGENOMICS RESEARCH INSTITUTE FOR SYSTEMS MEDICINE CONFLICT OF INTEREST POLICY

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 42CFR Part 50, Subpart F and 45 CFR Part 94. The Financial Conflict of Interest (FCOI) regulations establish the standards that must be followed by institutions that apply for or receive research funding from PHS awarding components, including the National Institutes of Health, for all grants, cooperative agreements, and research contracts.

Proteogenomics Research Institute for Systems Medicine (PRISM) has the responsibility under these regulations to manage financial conflicts of interest between an Investigator's (and his/her spouse and dependent children) personal financial interests and his/her Institutional Responsibilities. The Institute and its Investigators must identify, and then manage or eliminate financial conflicts of interest 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 PRISM certifies that each application for which PHS funding is sought that the Institute:

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

SECTION 2. PERSONS CONCERNED:

The Financial Conflict of Interest Policy (FCOI Policy) applies to all individuals who fit the definition of Investigator: any person identified as senior/key personnel in a grant application, progress report, or any other report submitted to the NIH by the Institute under the regulation; and/or the Principal Investigator or Project Director or any other person regardless of title or position, who is eligible to submit grant application on behalf of the Institute or who will be responsible for the design, conduct, or reporting of research activities funded or proposed for funding by the PHS.

This statement is directed also to directors and officers, and to all employees who can influence the actions of PRISM. For example, this would include all who make purchasing decisions, all persons who might be described as "management personnel," and anyone who has proprietary information concerning PRISM.

SECTION 3: SIGNIFICANT FINANCIAL INTEREST DEFINED

The regulations define a SFI as 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.

- **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 any equity interest (e.g., stock, stock option, or other ownership interest). The Investigator must fully describe the nature of the equity interests (including the number of shares owned, voting rights, etc.) if at the time of disclosure there is no reasonable basis for assessing the fair market value or percentage interest in the non-publicly traded entity.
- **Intellectual Property Rights:** Upon receipt of income related to such rights and interests (e.g., patents, copyrights, etc.).

Travel Disclosures

Investigators must disclose the occurrence of any reimbursed or sponsored travel (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. The disclosure must include the following details:

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

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

Significant Financial Interests do not include the following:

1. Salary, royalties, or other remuneration received from the Institute if the Investigator is currently employed or appointed by the Institute.
Income from the authorship of academic or scholarly works;
2. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles.
3. Income from seminars, lectures, or teaching engagements sponsored by a United States (a) federal, state, or local government agency; (b) institution of higher education (as defined by 20 USC 1001(a)); (c) academic teaching hospital; (d) medical center; or (e) research institute that is affiliated with an institution of higher education.

4. Income from service on advisory committees or review panels for the Institute or a United States (a) federal, state, or local government agency; (b) institution of higher education (as defined by 20 USC 1001(a)); (c) academic teaching hospital; (d) medical center; or (e) research institute that is affiliated with an institution of higher education.
5. 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 (as defined by 20 USC 1001(a)); (c) academic teaching hospital; (d) medical center; or (e) research institute that is affiliated with an institution of higher education.
6. Intellectual property rights assigned to the Institute and unlicensed intellectual property that does not generate income.
7. Agreements with the Institute to share in royalties related to such rights.

SECTION 4: DISCLOSURE, INITIAL, ANNUAL AND UPDATES

All Investigators, Directors, and Employees to whom the policy applies will receive the Institute's FCOI policy that describes the responsibilities regarding disclosure of significant financial interests and the Federal regulations. Each Investigator, Director, Employee (and spouse and dependent children) must submit a SFI disclosure form at time of hire and annually thereafter [42 CFR 50.603 and 42 CFR 604(b)].

The Vice President, Research Administration (Institutional Official) will solicit and review SFI disclosure forms submitted by Investigators, Directors, Employees (and spouse and dependent children) who are planning to participate in, or participate in, the PHS-funded research [42 CFR 50.604(d)]

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

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

All personnel are required to disclose both existing and new SFIs (e.g., information not initially disclosed, including but not limited to any financial conflict of interest identified on a PHS-funded project that was transferred from another Institution), and shall include updated information regarding any previously disclosed significant financial interest (e.g., the updated value of a previously disclosed equity interest). SFI disclosure forms collected annually must be submitted by the deadline.

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.

SECTION 5: REVIEW OF SFI DISCLOSURES

The Institutional Official (IO) initially review the SFI disclosure forms and may request further information or clarification about a SFI. The IO will make a preliminary determination whether an SFI appears to relate to funded research. If so, the matter will be referred to the COI Committee for further review. The COI Committee will be comprised of at least four members from the following:

- Director of Research Administration
- Faculty
- Finance
- Board of Directors

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

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

SECTION 6: MANAGEMENT PLAN

If an FCOI is identified by the COI Committee, the Director of Research Administration will develop a Management Plan to manage or eliminate the conflict. The COI Committee will review and approve the Management Plan. 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 or eliminate the FCOI. Examples of conditions or restrictions that might be imposed include, but are not limited to [42 CFR 50.605(a)(1)]:

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

As appropriate, the COI Committee may meet with the Investigator during the design and development of the Management Plan that will include mechanisms appropriate for the specific situation. The Institute's Management Plan will contain all elements required by the FCOI 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.

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

SECTION 7: REPORTING FINANCIAL CONFLICTS OF INTEREST TO PHS

The Institute must report to PHS any SFI that meet the following three criteria: (1) The SFI is still held by the senior/key personnel as defined by this policy. (2) The Institute determines that the SFI is related to the PH-funded research. (3) The Institute determines that the SFI is a FCOI.

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

The report will contain all elements required by the FCOI Regulations, which may include: (i) Project number; (ii) project title; (iii) PD/PI or contact PD/PI; (iv) name of the Investigator with the FCOI; (v) name of the entity with which the Investigator has an FCOI; (vi) nature of the financial interest; (vii) value of the financial interest, or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value; (viii) a description of how the financial interest relates to the PHS-funded research and the basis for the Institute's determination that the financial interest conflicts with such research; and (ix) 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; conditions of the Management Plan; how the Management Plan is designed to safeguard objectivity in the research project; confirmation of the Investigator's agreement to the Management Plan; how the Management Plan will be monitored to ensure Investigator compliance; and other information as needed.

Ongoing PHS Research Projects: Whenever a new or existing Investigator participating in the research project discloses a new SFI, 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. [42 CFR 50.605(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 eliminated, a report to the PHS is not required. [42 CFR 50.605(b)(2)]

Period of Non-Compliance during an Ongoing PHS Funded Project: 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 manage or eliminate the FCOI. The Director of Compliance will submit the FCOI report through the eRA Commons FCOI Module. In addition to the FCOI report, 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 Director of Compliance will update the previously submitted FCOI report, specifying the actions that will/have been taken to eliminate the FCOI. [42 CFR 50.605(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. [42 CFR 50.605(a)(3)]

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

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

Annual Reports: For any FCOI previously reported, 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. [42 CFR 50.605(b)(4)]

SECTION 8: PUBLIC ACCESSIBILITY

The Institute's FCOI policy will be made accessible through the Institute's public web site (www.sbpdiscovery.org). In addition, in compliance with the FCOI Regulations, the Institute will provide the following information in response to requests about identified FCOIs in writing within five (5) business days of a request: [42 CFR 50.605(a)(5)(ii)]

- 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.

SECTION 9: FINANCIAL CONFLICT OF INTEREST MONITORING

The Director of Research Administration will monitor the FCOI and 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 a Management Plan at any time. [42 CFR 50.605(a)(4)]

SECTION 10: 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 FCOI 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). [42 CFR 50.604(c)]

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

If the Subrecipient cannot provide certification of an established FCOI Policy, the written agreement issued by the Institute will state that subrecipient Investigators are subject to the FCOI policy of the Institute 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 the Institute to allow sufficient time to review the disclosures and comply timely with its review, management, and reporting obligations under this Policy. [42 CFR 50.604(c)(1)(iii)]

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

SECTION 11: ENFORCEMENT AND NON-COMPLIANCE

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

A person is non-compliant and in violation of the COI Policy if they **fail** to:

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

If an Investigator fails to comply with the Institute's FCOI 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 regarding 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.

SECTION 12: PROJECT SPECIFIC CERTIFICATION

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

SECTION 13: MANDATORY TRAINING

The Institute requires all Investigators to complete FCOI training prior to engaging in federally funded research and at least every 3 years thereafter, or as directed by the Institute. Training is required immediately when any of the following circumstances apply: [42 CFR 50.604(b)]

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

PRISM will require a current (within 3 years) Certificate of Completion of the National Institutes of Health Office of Extramural Research Financial Conflict of Interest Tutorial for all new Investigators and within 3 years of submitting an application for PHS funding. The link to the training program will be available on-line via the Institute's intranet. A copy of the completion certificate is maintained by the Institutional Official for each Investigator who has completed training.

SECTION 14: RECORD MAINTENANCE

Records relating to all Investigator SFI disclosures 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 or, where applicable, from other dates specified in 45 CFR 75.361 for different situations. [42 CFR 50.604(i)]