

Sciencenter Policy and Procedures on Financial Conflict of Interest Related to PHS-Sponsored Projects

I. POLICY SUMMARY

Whenever an investigator has a significant financial interest in an enterprise which might reasonably appear to be affected by discoveries in the investigator's sponsored project, there is the potential for a real or perceived conflict of interest. Although the Sciencenter does not require investigators to disclose their personal financial interests as a matter of routine, Sciencenter is sometimes obligated to require disclosure under federal regulations. Such disclosures are the most widely accepted method for identifying and managing actual or potential financial conflicts of interest related to federally sponsored projects.

It is the policy of Sciencenter that all investigators (including sub-recipients, collaborators, and consultants) on PHS-funded are required to disclose all significant financial interests (and those of the investigator's spouse and dependent children) that are related to their institutional responsibilities. When Sciencenter determines that such an interest might reasonably appear to be directly and significantly affected by the sponsored project, Sciencenter will take steps to manage the conflict.

This policy implements federal requirements pertaining to U.S. Public Health Service (PHS), which includes National Institutes of Health (NIH), and which are published in 42 CFR Part 50. NIH requires that the Sciencenter maintains an appropriate written policy on conflict of interest disclosure as a condition for receiving their grants. These requirements, as implemented in this policy, are applicable to all proposals and awards for PHS-sponsored projects at Sciencenter.

II. DEFINITIONS

Institutional Responsibilities

Institutional responsibilities are defined as an Investigator's professional responsibilities on behalf of Sciencenter, and may include activities such as research, research consultation, teaching, professional practice and Sciencenter committee memberships.

Investigator

Investigator is defined as the project director or principal investigator, and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research and projects funded by federal awards or proposed for such funding, which may include, for example, subrecipients, collaborators or consultants.

Sciencenter Reviewing Official

An official designated by Sciencenter to collect and review completed Financial Interest Disclosure Forms and to make the initial determination whether any reported financial interest would reasonably appear to directly and significantly affect the design, conduct or reporting of the sponsored project. The Sciencenter Reviewing Official is currently the Grants Manager.

Significant Financial Interest

A financial interest must be reported when required by the above-referenced federal regulations. The requirement that an Investigator must report a Significant Financial Interest under the terms of this policy does not in and of itself imply the existence of an actual or potential conflict of interest. The existence of a conflict of interest is determined subsequently by the designated Sciencenter Reviewing Official, the Vice President of Administration, and, when necessary, review committee. If a conflict is identified, additional steps to manage the conflict may be required.

Consistent with current federal regulations, Sciencenter identifies a set of definitions of Significant Financial Interest, applicable to PHS-funded project proposals and awards. This policy defines Significant Financial Interest as anything of monetary value, including, but not limited to:

- a. A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse/domestic partner and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:
 - i. With regard to any publicly traded entity (domestic or foreign), a *Significant Financial Interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. 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 other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
 - ii. With regard to any non-publicly traded entity (domestic or foreign), a *Significant Financial Interest* 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 spouse/domestic partner or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or

- iii. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests. A \$5,000 threshold applies to income received related to intellectual property rights and interests, royalties from such rights, and agreements to share in royalties related to licensed intellectual property rights.
- b. Investigators also must disclose the occurrence of any reimbursed or sponsored travel above the \$5,000 annual threshold (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their Institutional Responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

In all cases, the term *Significant Financial Interest* does not include the following types of financial interests: salary, royalties, or other remuneration paid by Sciencenter to the Investigator if the Investigator is currently employed or otherwise appointed by Sciencenter, including intellectual property rights assigned to Sciencenter and agreements to share in royalties related to such rights; 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; income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education; or income from service on advisory committees or review panels for a federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

Investigators must disclose all foreign financial interests (which includes income from seminars, lectures, or teaching engagements, income from service on advisory committees or review panels, and reimbursed or sponsored travel) received from any foreign entity, including foreign Institutions of higher education or a foreign government (which includes local, provincial, or equivalent governments of another country) when such income meets the threshold for disclosure (e.g., income in excess of \$5,000).

III. POLICY TEXT

Investigator Responsibilities

All Investigators on proposed or funded PHS-supported projects are required to become familiar with the current Sciencenter policy and procedures for managing conflicts of

interest (this document), and to distribute copies of the policy and procedures to all individuals who will participate as Investigators on the PHS-supported project.

The federal regulations require that Investigators submit to the Sciencenter Reviewing Official all Significant Financial Interests in advance of submission of the application to the agency. Specifically, an Investigator must disclose all Significant Financial Interests (and those of their spouse and dependent children) that are related to their institutional responsibilities. .

Sciencenter Reviewing Official Responsibilities

[It is the responsibility of the Sciencenter Reviewing Official to determine if the Significant Financial Interest is related to the research or project. The Sciencenter Reviewing Official can consult with the Investigator in making this determination. If the Significant Financial Interest is related to the research or project, the Sciencenter Reviewing Official then asks the following questions: 1) Could the Significant Financial Interest be affected by the research or project? 2) Is the Significant Financial Interest in an entity whose financial interest could be affected by the research or project? If the Significant Financial Interest is related to the research or project and if the answer is yes to either of these two questions, then a financial conflict of interest exists and will be managed and reported to the NIH via the eRA Commons FCOI Module.]

To comply with federal regulations, Sciencenter will require the following actions from Investigators on PHS-funded projects:

- An Investigator with no Significant Financial Interest to disclose must so certify by signing the annual Financial Interest Disclosure Form.
- An Investigator with Significant Financial Interests must submit a Financial Interest Disclosure Form to the Sciencenter Reviewing Official prior to proposal submission.
- Within 30 days of discovering or acquiring a new reportable Significant Financial Interest, submission of a Financial Interest Disclosure Form to the Sciencenter Reviewing Official is required from all Investigators with current awards or pending applications for PHS-funded projects.
- Completion of a Financial Interest Disclosure Form will be required at the beginning of the calendar year from all Investigators with current awards.

Additional Investigator Responsibilities under PHS-funded Projects

- PHS-funded Investigators must disclose reimbursed or sponsored travel related to their Institutional Responsibilities (that is above the \$5,000 annual threshold), as defined above. The disclosure will include the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. The Sciencenter Reviewing Official will determine if further information is needed, including a

- determination or disclosure of monetary value, in order to determine whether the travel constitutes a Significant Financial Interest with the PHS-funded project.
- PHS-funded Investigators (including subrecipient Investigators) must complete training on Financial Conflicts of Interest prior to engaging in research related to a PHS-funded project and at least every four years thereafter, and immediately under any of the following circumstances:
 - Sciencenter Financial Conflict of Interest policies change in a manner that affects Investigator requirements;
 - An Investigator is new to Sciencenter; or o Sciencenter finds that an Investigator is not in compliance with Sciencenter's Financial Conflict of Interest policy or management plan.
 - Investigators may utilize resources available on NIH's Office of Extramural Research Financial Conflict of Interest Web page found at <http://grants.nih.gov/grants/policy/coi/> to satisfy some of the training. Information on the training requirement will be provided by the Sciencenter Reviewing Official.

Sciencenter Responsibilities

Sciencenter is responsible for monitoring Investigator compliance with a management plan until completion of the PHS-sponsored project or until the financial conflict of interest no longer exists.

The Investigator will forward the Financial Interest Disclosure Form to the Sciencenter Reviewing Official, who will review it and confer with the VP of Administration as appropriate. Disclosures that in the opinion of the VP of Administration need the review of an ad hoc committee will be referred to a committee appointed by the VP of Administration; composition of the committee will be determined by the VP of Administration, and will typically include both scientists or educators and administrators. An Investigator who desires to have his/her own disclosure reviewed by the committee may so inform the Sciencenter Reviewing Official, for referral to the VP of Administration. Investigators may also elect to have the committee review other financial interests not related to PHS-sponsored projects covered by this policy (in which case the portion of the policy regarding Sciencenter's responsibility to report certain circumstances to the funding agency is not applicable). The committee will review disclosures referred to it and initiate steps to manage potential conflicts in consultation with the VP of Administration. The information disclosed will be kept confidential to the extent permitted by law.

When an Investigator who is new to participating in the research or project or when an existing Investigator discloses a new Significant Financial Interest, the Sciencenter Reviewing Official shall within 60 days review disclosures, determine whether the Significant Financial Interest is related to PHS/NIH-funded research or project; determine whether a financial conflict of interest exists; and if so, implement, on at least

an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest.

Additional Sciencenter Responsibility for Retrospective Review of PHS-funded Projects

If Sciencenter determines that a financial conflict of interest was not reviewed or managed in a timely manner, including but not limited to an Investigator's failure to disclose a Significant Financial Interest that is determined by Sciencenter to constitute a financial conflict of interest, or failure by the Investigator to comply with a management plan for a financial conflict of interest, the VP of Administration and/or their review committee will, within 120 days of a determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS-funded project to determine whether the project (or any portion thereof) conducted during the period of non-compliance was biased in the design, conduct or reporting. Sciencenter will document the review, develop a plan to manage any identified financial conflict of interest, and notify PHS and submit a mitigation report, as required.

Methods to Manage Conflicts of Interest

The VP of Administration and/or the review committee is responsible for determining what mechanisms are appropriate for managing, reducing or eliminating real or potential financial conflicts of interest. Examples of conditions or restrictions that might be imposed to manage, reduce or eliminate financial conflicts of interest include:

- Public disclosure of financial conflicts of interest. Some examples of public disclosure could include (but are not limited to), when presenting or publishing the research or project; to staff members working on the project; to Sciencenter's review committee;
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research or project against bias resulting from the financial conflict of interest;
- Modification of the research or project plan;
- Change of personnel or personnel responsibilities, or disqualifications of personnel from participation in all or a portion of the research or project;
- Elimination of the financial interest; and/or
- Severance of relationships that create actual or potential financial conflicts.

Enforcement Mechanisms

Certain federal regulations require that sanctions for non-compliance be imposed where necessary. Possible sanctions might include a letter of reprimand sent to the Investigator; a requirement for special certifications or assurances of compliance; restrictions on any grant awards involving the Investigator; barring the Investigator from

submitting any new proposals through Sciencenter; suspension; dismissal, or other action as appropriate.

Agency Notifications

1. Prior to the expenditure of any funds under a PHS award, Sciencenter must provide to PHS a financial conflict of interest report regarding any Investigator Significant Financial Interest found by Sciencenter to be a financial conflict of interest in accordance with the regulation. Sciencenter must also provide a financial conflict of interest report whenever an Investigator does not timely disclose a Significant Financial Interest or whenever Sciencenter, for whatever reason, does not review a disclosed Significant Financial Interest and Sciencenter then determines that a financial conflict of interest exists;
2. Sciencenter must submit a financial conflict of interest report within sixty days after its determination that a financial conflict of interest exists for an Investigator who is newly participating in the project or for an existing Investigator who discloses a new Significant Financial Interest to Sciencenter during the period of award; and
3. For any financial conflict of interest previously reported by Sciencenter, Sciencenter must provide an annual financial conflict of interest report that addresses the status of the financial interest and any changes to the management plan. Annual financial conflict of interest reports shall specify whether the financial conflict of interest is still being managed or explain why the financial conflict of interest no longer exists. Sciencenter will submit to PHS annual financial conflict of interest reports (e.g., through the eRA Commons for grants and cooperative agreements) for the duration of the project period (including extensions with or without funds) at the same time as when Sciencenter is required to submit the annual progress report (i.e., two months prior to the start date or 45 days prior to the start date of the noncompeting continuation award), including a multi-year funded progress report, or at the time of a project extension with or without funds.

All reports submitted will contain all elements required under 42 CFR 50.605.

Records Retention

The Sciencenter Reviewing Official will maintain records of all Investigator disclosures of financial interests, and Sciencenter's review of or response to such disclosure (whether or not a disclosure resulted in Sciencenter's determination of a financial conflict of interest), and all actions under the financial conflict of interest policy or retrospective review, if applicable, for at least 3 years from the date of submission of final expenditure report or, where applicable, from other dates specified in 45 C.F.R. 75.361 (see FAQ A.11) for different situations. .

PHS Subawards, Subcontracts and Collaborators

For all PHS-funded projects carried out through subgrantees, contractors or collaborators (e.g., those persons or institutions conducting a substantive portion of the PHS-funded project, who will design, conduct or report the results of the project, and who are accountable to Sciencenter for programmatic outcomes and compliance matters), Sciencenter will ensure that Investigators working for such entities comply with the applicable PHS regulations, either by requiring those Investigators to comply with the Sciencenter policy or by requiring the entities provide assurances of compliance with applicable PHS regulations.

Public Accessibility

Sciencenter will post its Policy and Procedures on Financial Conflict of Interest Related to PHS-Sponsored Projects on its public website at <https://www.sciencenter.org/>. Requests for information on PHS-funded financial conflicts of interest must be directed to the Sciencenter Reviewing Official; responses to requests will be issued per the PHS regulations at 42 CFR Part 50 within five business days of receipt of the request, concerning any Significant Financial Interest disclosed to Sciencenter that meets the following three criteria:

1. The Significant Financial Interest was disclosed and is still held by the senior/key personnel for the PHS-funded research project identified by Sciencenter in the grant application, progress report, or any other required report submitted to the federal awarding agency;
2. Sciencenter determines that the Significant Financial Interest is related to the PHS-funded research or project; and
3. Sciencenter determines that the Significant Financial Interest is a Financial Conflict of Interest.