



SILENT SPRING INSTITUTE

POLICY AND PROCEDURES ON FINANCIAL CONFLICTS OF INTEREST IN PUBLIC HEALTH SERVICE FUNDED RESEARCH

This policy implements the requirements of certain federal regulations, specifically “Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought” (42 C.F.R. Part 50, Subpart F) and “Responsible Prospective Contractors” (45 C.F.R. Part 94), and applies to all projects funded, directly or indirectly through a subaward from another organization, by the Public Health Service of the U.S. Department of Health and Human Services (PHS) other than Phase One SBIR or STTR awards. These PHS specific regulations supplement Silent Spring Institute’s Policy on Conflict on Commitment and Interest as stated in the Employee Handbook.

PHS regulations differ, in some respects, from Silent Spring Institute’s Policy. It is imperative, therefore, that every Silent Spring Institute Investigator that accepts PHS funding, whether directly or indirectly, becomes familiar with, and abides by, the provisions of these PHS regulations.

PHS includes the National Institutes of Health (NIH) and many other components, including but not limited to, the Administration for Children and Families (ACF), Administration on Aging (AoA), Agency for Healthcare Research and Quality (AHRQ), Agency for Toxic Substances and Disease Registry (ATSDR), Centers for Disease Control and Prevention (CDC), Centers for Medicare and Medicaid Services (CMS), Federal Occupational Health (FOH), Food and Drug Administration (FDA), Health Resources and Services Administration (HRSA), Indian Health Service (IHS), and Substance Abuse and Mental Health Services Administration (SAMHSA).

DEFINITIONS

Definitions

Family means any member of the Investigator’s immediate family, specifically, any dependent children and spouse or partner.

Financial Interest means anything of monetary value received or held by an Investigator or an Investigator’s Family, whether or not the value is readily ascertainable, including, but not limited to: salary or other payments for services (e.g., consulting fees, honoraria, or paid authorships for other than scholarly works); any equity interests (e.g., stocks, stock options, or other ownership interests); and intellectual property rights and interests (e.g., patents, trademarks, service marks, and copyrights), upon receipt of royalties or other income related to such intellectual property rights and interests.

Financial Interest does NOT include:

- a) salary, royalties, or other remuneration from the Institute;

b) income from the authorship of academic or scholarly works;

c) income from seminars, lectures, or teaching engagements sponsored by or from advisory committees or review panels for U.S. Federal, state or local governmental agencies; U.S. institutions of higher education; U.S. research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers; or

d) equity interests or income from investment vehicles, such as mutual funds and retirement accounts, so long as the Investigator does not directly control the investment decisions made in these vehicles.

For Investigators, **Financial Interest** also includes any reimbursed or sponsored travel undertaken by the Investigator and related to his/her institutional responsibilities. This includes travel that is paid on behalf of the Investigator rather than reimbursed, even if the exact monetary value is not readily available. It excludes travel reimbursed or sponsored by U.S. Federal, state or local governmental agencies, U.S. institutions of higher education, research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers, or Silent Spring Institute.

Significant Financial Interest means a Financial Interest that reasonably appears to be related to the Investigator's Institutional Responsibilities, and:

a) if with a publicly traded entity, the aggregate value of any salary or other payments for services received during the 12 month period preceding the disclosure, and the value of any equity interest during the 12 month period preceding or as of the date of disclosure, exceeds \$5,000; or

b) if with a non-publicly traded entity, the aggregate value of any salary or other payments for services received during the 12 month period preceding the disclosure exceeds \$5,000; or

c) if with a non-publicly-traded company, is an equity interest of any value during the 12 month period preceding or as of the date of disclosure; or

d) is income related to intellectual property rights and interests not reimbursed through the Institution.

Financial Conflict of Interest (FCOI) means a Significant Financial Interest that the Institution reasonably determines could directly and significantly affect the design, conduct or reporting of PHS-funded research.

Institutional responsibilities means the Investigator's responsibilities on behalf of Silent Spring Institute, which are defined by Silent Spring Institute as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as institutional review boards (e.g., IACUC, IBC, and IRB).

Investigator means any individual who is responsible for the design, conduct, or reporting of PHS-sponsored research, or proposals for such funding. This definition is not limited to those titled or budgeted as principal investigator or co-investigator on a particular proposal, and may include postdoctoral associates, senior scientists, or graduate students. The definition may also include collaborators or consultants as appropriate.

Public Health Service or PHS means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority of the PHS may be delegated. The components of the PHS include, but are not limited to, the National Institutes of Health and the Centers for Disease Control.

Research means a systematic investigation, study, or experiment designed to contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research.

DISCLOSURE REQUIREMENTS

Full and prompt disclosure is critical to Silent Spring Institute's ability to identify, manage, and eliminate Financial Conflicts of Interest. There are three types of disclosures:

1. Annual Disclosures. Investigators must disclose their Significant Financial Interests to Silent Spring Institute on an annual basis, and must also disclose certain information with respect to conflicts of commitment and interest as prescribed in the Employee Handbook.
2. Proposal-related Disclosures. Prior to submitting a proposal for funding, the Principal Investigators identified in the proposal and other Investigators associated with the proposal must disclose whether the Investigator's Significant Financial Interests may be related by the proposal. If there is a potential relationship, the Investigator must file a full disclosure with additional information regarding the relationship of the project to the Related Company prior to submission of the proposal to the sponsor.
3. Ad hoc Disclosures.
 - A) An Investigator must disclose on an ad hoc basis any new Significant Financial Interest within 30 days following the date on which the Significant Financial Interest is acquired or arises. This 30 day requirement is specific to the PHS regulations.
 - B) An Investigator must disclose on an ad hoc basis his or her Significant Financial Interests prior to the Investigator commencing participation in an existing research project.

Silent Spring Institute's Deputy Director acts as the Institute's Designated Official with respect to implementation of this FCOI policy. The Designated Official will:

1. Solicit disclosures of SFIs from Silent Spring Institute Investigators.
2. Review disclosures provided by new Investigators or new disclosures provided by existing Investigators within sixty (60) days of submission.
3. Review disclosures to determine if:
 - a. Any SFIs relate to PHS/NIH-funded research
 - b. An FCOI exists
4. Submit FCOI reports to NIH as required within 60 (sixty) days of identification of a new investigator participating in a project.
5. Notify NIH promptly if bias is found with the design, conduct or reporting of PHS/NIH-funded research, and submit mitigation report to delineate actions that have been or will be taken to mitigate the effects of the bias.
6. Develop and implement a management plan to manage any FCOI(s) identified through the normal disclosure process or for disclosures not made in a timely way or not disclosed for whatever reason.
7. Monitor Investigator compliance with management plans until completion of relevant projects

The Institute will employ appropriate administrative actions to ensure Investigator compliance with the FCOI disclosure process and any management plans developed for an identified FCOI. Any failure to comply with the disclosure process or an enacted management plan will result in the immediate cessation of that Investigator's activity on the project. The Investigator will not commence activity on the project until evidence of compliance is sufficiently documented.

TRAVEL DISCLOSURES

Public Health Service (PHS) regulations require disclosure of third-party reimbursed or sponsored travel.

You are NOT required to disclose travel expenses if you are NOT responsible for the design, conduct or reporting of research funded by the PHS or PHS is not the sponsor.

You MUST disclose third party paid travel related to your institutional responsibilities if you ARE responsible for the design, conduct or reporting of research funded by the PHS (or other agencies/sponsors that have adopted the PHS regulations). The regulation requires disclosure of reimbursed or sponsored travel related to institutional responsibilities over the previous twelve-month period no later than at the time of application for PHS-funded research, within 30 days of each occurrence throughout the term of the sponsored award.

Third party paid travel means:

- A third party directly pays in whole or in part for travel on your behalf;
- You pay for travel and the third party reimburses you in whole or in part; or
- Silent Spring Institute pays in whole or in part for travel and the third party reimburses Silent Spring Institute.

PHS regulations require you to disclose travel paid by:

- External professional organizations and societies, academic journals and publishing companies; and
- ANY travel reimbursed or sponsored by a foreign institution of higher education or the government of another country.

PHS regulations exclude travel paid by:

- Silent Spring Institute or funded by a sponsored award to Silent Spring Institute;
- U.S. Federal, state or local government agencies;
- U.S. Institutions of higher education or U.S. research institutes; and
- U.S. academic teaching hospitals or U.S. medical centers that are affiliated with U.S. Institutions of higher education.

REPORTING TO PHS

The PHS regulations require Silent Spring Institute to provide information regarding Financial Conflicts of Interest at specified times:

1. if a Financial Conflict of Interest exists prior to award, prior to expenditure of funds;
2. if a Financial Conflict of Interest arises during the term of the award, then within 60 days following the Investigator's disclosure of the Significant Financial Interest (see Disclosure Requirements above);
3. as part of the Silent Spring Institute's annual progress report on the Research;
4. as part of any requests for an extension of the award; and
5. following a retrospective review as discussed in more detail under RETROSPECTIVE REVIEW below.

Each report Silent Spring Institute provides to PHS must include sufficient information to enable PHS to understand the nature and extent of the potential financial conflict and to assess the appropriateness of the management plan. The required information includes:

1. project number;
2. Principal Investigator;
3. name of the Investigator with the Financial Conflict of Interest;
4. name of the entity with which the Investigator has a Financial Conflict of Interest;
5. nature of the Significant Financial Interest (e.g., Equity, consulting fees, travel reimbursement, honorarium);
6. value of the Significant Financial Interest, which value may be expressed as being within a range(\$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, if the value of the interest cannot be

- readily determined through reference to public prices or other reasonable measures of fair market value, a statement confirming that fact;
7. a description of the relationship of the Significant Financial Interest to the PHS-funded research and the basis for Silent Spring Institute's determination that the Significant Financial Interest conflicts with the research; and
 8. a description of the key elements of the management plan, including:
 - a) the role and principal duties of the conflicted Investigator in the research;
 - b) the conditions of the management plan;
 - c) how the management plan is designed to safeguard the objectivity of the research;
 - d) confirmation of the Investigator's agreement to the management plan;
 - e) how the management plan will be monitored to ensure Investigator compliance; and
 - f) other relevant information.

Silent Spring Institute's Designated Official, the Deputy Director, will submit these reports on behalf of the Institute.

PUBLIC ACCESSIBILITY

This FCOI policy is available on Silent Spring Institute's publicly available web-site at:
www.silentsspring.org/about-us/employment

PHS requires Silent Spring Institute to make information regarding Financial Conflict of Interests reported to PHS, available to the public upon written request, within five (5) business days of receipt of the request. The information that must be made available includes the following, at a minimum:

1. Investigator's name;
2. Investigator's title and role with respect to the research;
3. name of the entity in which the Significant Financial Interest is held or from which it is received;
4. nature of the Significant Financial Interest; and
5. approximate value of the Significant Financial Interest, which value may be expressed as being within a range as described above or if the value of the interest cannot be readily determined through reference to public prices or other reasonable measures of fair market value, a statement confirming that fact.

Information will remain available for three (3) years from date information was last updated for a specific FCOI. Silent Spring Institute may also disclose information regarding the management of the Financial Conflict of Interest.

SUBAWARDS ISSUED BY SILENT SPRING INSTITUTE UNDER PHS FUNDED PRIME AWARDS

When Silent Spring Institute issues a subaward to another organization to carry out a portion of a PHS funded project, the sub-awardee must comply with the PHS conflict of interest regulations. Silent Spring Institute, therefore, will only grant subawards under PHS funded awards to institutions that have financial conflict of interest policies that comply with the PHS regulations. This requirement will be set forth in the Silent Spring Institute subaward and the sub-awardee will be asked if they have a PHS-compliant Conflict of Interest Policy through a standard pre-award questionnaire.

If a sub-awardee Investigator has a Financial Conflict of Interest, Silent Spring Institute is responsible for reporting the Financial Conflict of Interest to the PHS on behalf of the sub-awardee. As a result, sub-awardees must report Financial Conflicts of Interest to the Designated Official for Silent Spring Institute within 45 days of discovering the Financial Conflict of Interest so that Silent Spring Institute may report it to the PHS in a timely manner. In addition, Silent Spring Institute is required by PHS to make information regarding sub-awardee Financial Conflicts of Interest available to the public. Silent Spring Institute uses the same method it

uses to disclose Silent Spring Institute Financial Conflicts of Interest and notifies the sub-awardee of any requests for information. Questions regarding the specifics of sub-awardee Financial Conflicts of Interest are directed to the sub-awardee.

SUBAWARDS ISSUED TO SILENT SPRING INSTITUTE UNDER PHS FUNDED PRIME AWARDS

When Silent Spring Institute makes a proposal for or receives a subaward from another organization to carry out a portion of a PHS funded project, Silent Spring Institute must comply with the PHS regulations regarding conflicts of interest. Silent Spring Institute's Policy and these PHS regulations apply to these proposals and awards rather than the policies of the sub-awarding organization. Silent Spring Institute provides reports of Financial Conflicts of Interest to the sub-awarding organization for reporting to PHS as specified in the PHS regulations. Reports are provided in the same form and format as Silent Spring Institute uses in connection with its direct awards from PHS. The sub-awarding organization is also responsible for the public accessibility reporting (see above). The sub-awarding organization may choose to do so either by posting Silent Spring Institute's report to a publicly available website or responding to written requests within 5 business days.

INVESTIGATOR NON-COMPLIANCE - RETROSPECTIVE REVIEW

In cases where a Financial Conflict of Interest is not identified or managed in a timely manner, including due to 1) failure by the Investigator to disclose a Significant Financial Interest that is determined by the Institution to constitute a Financial Conflict of Interest; 2) failure by Silent Spring Institute to review or manage such a Financial Conflict of Interest; or 3) failure by the Investigator to comply with a Financial Conflict of Interest management plan, Silent Spring Institute must, within 120 days of its determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS-funded research to determine whether the design, conduct, or reporting of the PHS-funded research, or any portion thereof, conducted during the period of noncompliance, was biased.

Silent Spring Institute is required to document the retrospective review and report detailed findings to PHS, including at least the following key elements:

1. project number;
2. project title;
3. Principal Investigator or contact Principal Investigator if there are multiple Principal Investigators on the project;
4. name of the Investigator with the Financial Conflict of Interest;
5. name of the Entity with which the Investigator has a Financial Conflict of Interest;
6. reason(s) for the retrospective review;
7. detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
8. findings of the review; and
9. conclusions of the review.

Based on the results of the retrospective review, Silent Spring Institute will update the previously submitted Financial Conflict of Interest report, if appropriate, specifying the actions that will be taken to manage the Financial Conflict of Interest. If bias is found, Silent Spring Institute must notify PHS promptly and submit a mitigation report. The mitigation report must include, at a minimum:

1. the elements documented in the retrospective review above;
2. a description of the impact of the bias on the research; and
3. Silent Spring Institute's plan of action or the actions taken to eliminate or mitigate the effect of the bias (e.g., extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research is salvageable).

Thereafter, Silent Spring Institute will submit Financial Conflict of Interest reports annually, as specified under the PHS regulations. Depending on the nature of the Financial Conflict of Interest, Silent Spring Institute may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS funded research between the date that the Financial Conflict of Interest or the Investigator's noncompliance is determined and the completion of Silent Spring Institute's retrospective review.

TRAINING

For PHS funded or proposing Investigators, Silent Spring Institute requires Investigators to be familiar with this document and to receive training via an online training module available through the Collaborative Institutional Training Initiative (CITI):

- 1) prior to an Investigator's engagement in research related to any PHS funded project;
- 2) an investigator is new to Silent Spring Institute and will be engaging in research related to any PHS funded project;
- 3) Silent Spring Institute revises its FCOI policy in a way that affects Investigator requirements;
- 2) every four years; and
- 3) whenever an Investigator is found to be out of compliance with these procedures, their governing policy, or an applicable management plan.

The Principal Investigator will be responsible for identifying all investigators who should have undergone the required training prior to their engagement in the covered research.

PHS funded researchers must complete FCOI training. An online training module is available through the Collaborative Institutional Training Initiative (CITI) at <https://www.citiprogram.org/> and includes the following modules:

- **Module 1** - Financial Conflicts of Interest: Overview, Investigator Responsibilities, and COI Rules (ID:15070)
- **Module 2** - Institutional Responsibilities as They Affect Investigators (ID: 15072)

To complete this mini-course, please follow these instructions:

- Log into <https://www.citiprogram.org/>
- Select "Add a course or update your learner groups"
- Select the "Conflict of Interest mini-course"
- Complete the course as directed

RECORD RETENTION

Silent Spring Institute will retain all disclosures, conflict management plans, and related documents for a period of at least seven years following submission of the final expenditure report for the applicable project to the PHS or the prime PHS awardee, unless any litigation, claim or negotiation, audit, or other action involving the records is commenced before expiration of the seven-year period, in which case, records will be retained until completion of the action and resolution of all issues.