

Financial Conflict of Interest (FCOI) Policy

1. Background

- 1.1. External sponsorship of research can result in the development of complex relationships between researchers and the external sponsors who support specific programs. Accordingly, the U.S. Department of Health and Human Services (HHS) has issued a final rule in 2011 that amends the Public Health Service (PHS) regulations on 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), that requires all individuals who participate in the design, conduct, or reporting of research funded by the Public Health Service complete training on financial conflicts and disclose personal financial interests that could give rise to an actual conflict of interest or the appearance of a conflict.

2. Who Is Covered by This Policy?

- 2.1. All Sonavex, Inc. ("Sonavex") employees who are research professionals that expect to work on a PHS-funded project in the upcoming year, or at any time they are named in a proposal for a PHS-funded project, they will be required to complete training and submit a financial conflict of interest screening form and disclose relevant financial interests. Key members of management and certain administrative and support department staff also will be required to complete the training and the screening form and provide relevant disclosures. This comprises any subcontracts awarded by a PHS component, and applicable to all federal awards including the Department of Defense (DoD).

3. Purpose

- 3.1. The policy promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under Public Health Service (PHS) grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest.

4. Definitions

- 4.1. *Disclosure of Significant Financial Interests* means an Investigator disclosing information about a Significant Financial Interest to Sonavex.
- 4.2. *Financial Conflict of Interest (FCOI)* means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.
- 4.3. *FCOI Report* means an Institution's report of a financial conflict of interest to a PHS Awarding Component.
- 4.4. *Financial Interest* means anything of monetary value, whether or not the value is readily ascertainable.
- 4.5. *HHS* means the United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.

- 4.6. *Institution* means any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for, or that receives, PHS research funding.
- 4.7. *Institutional Responsibilities* means an Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution in its policy on financial conflicts of interest, which may include for example: activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.
- 4.8. *Investigator* means 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 funded by the PHS (e.g., NIH), or proposed for such funding, which may include, for example, collaborators or consultants.
- 4.9. *Manage* means taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.
- 4.10. *PD/PI* means a project director or principal investigator of a PHS-funded research project; the PD/PI is included in the definitions of senior/key personnel and Investigator under this subpart.
- 4.11. *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 involved may be delegated, including the National Institutes of Health (NIH).
- 4.12. *PHS Awarding Component* means the organizational unit of the PHS that funds the research that is subject to 42 C.F.R. Part 50, Subpart F.
- 4.13. *Public Health Service Act (PHS Act)* means the statute codified at 42 U.S.C. 201 et seq.
- 4.14. *Research* means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug). The term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.
- 4.15. *Senior/key personnel* means the PD/PI and any other person identified as senior/key personnel by Sonavex in the grant application, progress report, or any other report submitted to the PHS by Sonavex.
- 4.16. *Significant Financial Interest*
- 4.16.1. 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:

- 4.16.1.1. With regard to any publicly traded entity, 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;
- 4.16.1.2. With regard to any non-publicly traded entity, 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 or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
- 4.16.1.3. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- 4.16.1.4. Investigators also must disclose the occurrence of any reimbursed or sponsored travel (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. The details of this disclosure will include, at a minimum the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. The Research Principal Investigator will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.
- 4.16.1.5. The term significant financial interest does *not* include the following types of financial interests:
 - 4.16.1.5.1. salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights;
 - 4.16.1.5.2. any ownership interest in the Institution held by the Investigator, including stock or stock options, if the Institution is a commercial or for-profit organization;
 - 4.16.1.5.3. 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;

- 4.16.1.5.4. 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
 - 4.16.1.5.5. 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.
- 4.17. Small Business Innovation Research (SBIR) Program means the extramural research program for small businesses that is established by the Awarding Components of the Public Health Service and certain other Federal agencies under Public Law 97-219, the Small Business Innovation Development Act, as amended. For purposes of 42 C.F.R. Part 50, Subpart F, the term SBIR Program also includes the Small Business Technology Transfer (STTR) Program, which was established by Public Law 102-564.

5. Responsibilities of Institution Regarding Investigator Financial Conflicts of Interest

- 5.1. Sonavex shall maintain an up-to-date, written, enforced policy on financial conflicts of interest that complies with 42 C.F.R. Part 50, Subpart F, and make such policy available to any requestor within five business days of a request.
- 5.2. Sonavex shall inform each Investigator of its policy on financial conflicts of interest, the Investigator's responsibilities regarding disclosure of significant financial interests, and of these regulations, and require each Investigator to complete training regarding the same prior to engaging in research related to any PHS-funded grant and at least every four years, and immediately when any of the following circumstances apply:
 - 5.2.1. Revision of financial conflict of interest policies or procedures in any manner that affects the requirements of Investigators;
 - 5.2.2. An Investigator is new to Sonavex; or
 - 5.2.3. An Investigator is not in compliance with Sonavex's financial conflict of interest policy or management plan.
- 5.3. Sonavex will take reasonable steps to ensure that any subrecipients (i.e., subcontractors or consortium members) performing work under a PHS-funded research project comply with the PHS Financial Conflict of Interest regulations by:
 - 5.3.1. Incorporating as part of a written agreement with the subrecipient terms that establish whether the financial conflicts of interest policy of the awardee Institution or that of the subrecipient will apply to the subrecipient's Investigators.

- 5.3.1.1. If the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the subrecipient shall certify as part of the agreement referenced above that its policy complies with this subpart. If the subrecipient cannot provide such certification, the agreement shall state that subrecipient Investigators are subject to the financial conflicts of interest policy of Sonavex for disclosing significant financial interests that are directly related to the subrecipient's work for Sonavex;
- 5.3.1.2. Additionally, if the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the agreement referenced above shall specify time period(s) for the subrecipient to report all identified financial conflicts of interest Sonavex. Such time period(s) shall be sufficient to enable Sonavex to provide timely FCOI reports, as necessary, to the PHS as required by this subpart;
- 5.3.1.3. Alternatively, if the subrecipient's Investigators must comply with Sonavex's financial conflicts of interest policy, the agreement referenced above shall specify time period(s) for the subrecipient to submit all Investigator disclosures of significant financial interests to Sonavex. Such time period(s) shall be sufficient to enable Sonavex to comply timely with its review, management, and reporting obligations under this subpart.

5.3.2. Providing FCOI reports to the PHS Awarding Component regarding all financial conflicts of interest of all subrecipient Investigators consistent with this subpart, i.e., prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.

6. Disclosure, Review, and Monitoring of Financial Interests Disclosed by Investigators

- 6.1. Sonavex designates the Research Principal Investigator as the institutional official to solicit and review disclosures of significant financial interest from each investigator who is planning to participate in, or is participating in, sponsored research. In the event the Research Principal Investigator has a conflict of interest or cannot participate, the CEO of Sonavex shall fulfill the duties typically performed by the Research Principal Investigator.
- 6.2. Each Investigator who is planning to participate in the PHS-funded research is required to:
 - 6.2.1. Disclose to the Research Principal Investigator the Investigator's significant financial interests (and those of the Investigator's spouse and dependent children) no later than the time of application for PHS-funded research.
 - 6.2.2. Submit an updated disclosure of significant financial interests at least annually, in accordance with the specific time period prescribed by Sonavex, during the period of the award. Such disclosure shall include any information that was not disclosed initially to Sonavex, or in a subsequent disclosure of significant financial interests (e.g., 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).
 - 6.2.3. Submit an updated disclosure of significant financial interests within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest.

- 6.3. Each FCOI disclosure will be reviewed by the Research Principal Investigator or the CEO. The Research Principal Investigator is responsible for determining when an actual or potential conflict of interest exists in a given situation — that is, when a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of PHS-funded research — and for taking action as necessary to manage such conflicts of interest, including development and implementation of a management plan.
- 6.4. If it is found that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the federally-funded research, the Director of Research will take actions as necessary to manage financial conflicts of interest, including any financial conflicts of a subrecipient Investigator. Management of an identified financial conflict of interest requires development and implementation of a management plan and, if necessary, a retrospective review and a mitigation report pursuant to §50.605(a).

7. Management and Reporting of Financial Conflicts of Interest

- 7.1. Prior to the expenditure of any funds under a PHS-funded research project, the Research Principal Investigator shall:
 - 7.1.1. Review all Investigator disclosures of significant financial interests;
 - 7.1.2. Determine whether any significant financial interests relate to PHS-funded research;
 - 7.1.3. Determine whether a financial conflict of interest exists; and, if so, develop and implement a management plan that shall specify the actions that have been, and shall be, taken to manage such financial conflict of interest.
- 7.2. Examples of conditions or restrictions that might be imposed to manage a financial conflict of interest include, but are not limited to:
 - 7.2.1. Public disclosure of financial conflicts of interests (e.g., when presenting or publishing the research);
 - 7.2.2. For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
 - 7.2.3. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the Financial Conflict of Interest;
 - 7.2.4. Modification of the research plan;
 - 7.2.5. Change of personnel or personnel responsibilities, or disqualifications of personnel from participation in all or a portion of the research;
 - 7.2.6. Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
 - 7.2.7. Severance of relationships that create financial conflicts.

- 7.3. For any significant financial interest that Sonavex identifies as conflicting subsequent to Sonavex's initial FCOI report during an ongoing PHS-funded research project (e.g., upon the participation of an Investigator who is new to the research project), Sonavex shall provide to the PHS Awarding Component, within sixty (60) days, an FCOI report regarding the financial conflict of interest and ensure that Sonavex has implemented a management plan in accordance with 42 C.F.R. Part 50, Subpart F. Pursuant to §50.605(a)(3)(ii), where such FCOI report involves a significant financial interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed or managed by Sonavex (e.g., was not timely reviewed or reported by a subrecipient), Sonavex also is required to complete a retrospective review to determine whether any PHS-funded research, or portion thereof, conducted prior to the identification and management of the financial conflict of interest was biased in the design, conduct, or reporting of such research. If bias is found, Sonavex is required to notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component.
- 7.4. FCOI report shall include sufficient information to enable the PHS Awarding Component to understand the nature and extent of the financial conflict, and to assess the appropriateness of Sonavex's management plan. Elements of the FCOI report shall include, but are not necessarily limited to the following:
- 7.4.1. Project number;
 - 7.4.2. PD/PI or Contact PD/PI if a multiple PD/PI model is used;
 - 7.4.3. Name of the Investigator with the financial conflict of interest;
 - 7.4.4. Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
 - 7.4.5. Value of the financial interest (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;
 - 7.4.6. A description of how the financial interest relates to the PHS-funded research and the basis for Sonavex's determination that the financial interest conflicts with such research; and
 - 7.4.6.1. A description of the key elements of Sonavex's management plan, including;
 - 7.4.6.2. Role and principal duties of the conflicted Investigator in the research project;
 - 7.4.6.3. Conditions of the management plan;
 - 7.4.6.4. How the management plan is designed to safeguard objectivity in the research project;
 - 7.4.6.5. Confirmation of the Investigator's agreement to the management plan;
 - 7.4.6.6. How the management plan will be monitored to ensure Investigator compliance; and

7.4.6.7. Other information as needed.

- 7.5. For any financial conflict of interest previously reported by Sonavex with regard to an ongoing PHS-funded research project, Sonavex shall provide to the PHS Awarding Component an annual FCOI report that addresses the status of the financial conflict of interest and any changes to the management plan for the duration of the PHS-funded research project. The annual FCOI report shall specify whether the financial conflict is still being managed or explain why the financial conflict of interest no longer exists. Sonavex shall provide annual FCOI reports to the PHS Awarding Component for the duration of the project period (including extensions with or without funds) in the time and manner specified by the PHS Awarding Component.

8. Management and Reporting of Financial Conflicts of Interest

- 8.1. Sonavex shall maintain records relating to all Investigator disclosures of financial interests and Sonavex's review of, and response to, such disclosures (whether or not a disclosure resulted in Sonavex's determination of a financial conflict of interest) and all actions under Sonavex's policy or retrospective review, if applicable, for at least three (3) years from the date the final expenditures report is submitted to the PHS or, where applicable, from other dates specified in 4S C.F.R 7S.361 for different situations.