

Financial Conflicts of Interest

Policy Statement

Sutra Medical implements Financial Conflicts of Interest (FCOI) disclosure to protect the integrity and objectivity of all research activities, and to ensure that the research planning, implementation, and reporting will not be biased or biased due to conflicts of interest or personal financial conflict of interest. Sutra Medical has implemented this policy to identify, manage, reduce, or eliminate financial conflicts of interest.

The procedures described in this policy are primarily developed and designed to meet the specific regulatory requirements for U.S. Public Health Service (PHS) research but are also intended to provide a basic framework and standards for identifying, assessing, and managing potential financial conflicts of interest relating to Sutra Medical's other research activities. For other non-PHS research, Sutra Medical can customize specific steps, timetables, definitions, documentation, and notifications as needed, and continue to focus on maintaining Sutra Medical's high standards for research integrity and eliminating or effectively managing potential financial conflicts of interest.

Scope

This policy and related procedures is intended to identify, manage, mitigate, neutralize, or eliminate actual, apparent, and potential financial conflicts of interest. The policy complies with the requirements of the 42 Code of Federal Regulations (CFR) Part 50, Subpart F, Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service (PHS) Funding Is Sought[1] and 45 CFR Part 94, Responsible Prospective Contractors.

The requirements do not apply to Small Business Innovation Research (SBIR)/Small Business Technology Transfer (STTR) Program Phase 1 applications or awards but do apply to SBIR/STTR Program Phase II applicants and recipients. The SBIR program is the extramural research program for small business that was 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 the purposes of this document, the term SBIR Program includes the STTR Program, which was established by Public Law 102-564.

Definitions

The following definitions shall apply:

- **Designated Official** is the individual designated by Sutra Medical to oversee solicitation and review of completed Disclosure Forms to determine significant

financial interests in the financial conflicts of interest process. References to the Sutra Medical IO in this document include their delegate.

- **Equity interest** is any stock, stock option, or other ownership interest, and its value may be determined through reference to public prices or other reasonable measures of fair market value.
- **Financial conflict of interest** is a Significant Financial Interest (SFI) that could directly and significantly affect the design, conduct, or reporting of research as determined by Sutra Medical through the Designated Official.
- **Financial interest** means anything of monetary value, whether or not the value is readily ascertainable.
- **Immediate family** includes an Investigator's spouse and dependent children.
- **Investigator** is the project director/principal investigator and any other individual regardless of title or position, who is responsible for the design, conduct, or reporting of the research, or proposed such funding, including investigators, consultants, and subcontractors.
- **PHS** refers to the U.S. Public Health Service and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health.
- **PHS Awarding Component** means the organizational unit of the PHS which funds the research that is subject to 42 CFR Part 50, Subpart F, and 45 CFR Part 94.
- **PHS-funded Research** is the research funded under PHS grants, cooperative agreements, or contracts.
- **Public Health Service Act, or PHS Act** means the statute codified at 42 U.S.C. 201 et seq.
- **Remuneration** includes any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship).
- 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). For PHS-Funded Research, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant, cooperative agreement, or contract, 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.

Significant financial interest consists of one or more of the following financial interests of the Investigator (and those of the Investigator's immediate family) that reasonably appear to be related to the Investigator's Sutra Medical project responsibilities, including:

- With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure and any equity interest in the entity as of the date of disclosure, exceeds \$5,000 when aggregated;

- 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 12 months preceding the disclosure, in which the value exceeds \$5,000 when aggregated, or when the Investigator or his/her immediate family holds any equity interest; or
- With regard to intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- With regard to 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) with value exceeding \$5,000 and reasonably related to the Investigator's Sutra Medical project responsibilities must be disclosed. However, this 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.

Significant financial interest does not include the following:

- Salary, royalties, or other remuneration paid by Sutra Medical (or a subrecipient as applicable) to the Investigator if the Investigator is currently employed or otherwise appointed by Sutra Medical, including that paid for intellectual property rights assigned or licensed to Sutra Medical and agreements to share in royalties related to such rights;
- Any ownership interest in Sutra Medical (or a subrecipient as applicable) held by the Investigator (e.g., Employee Stock Ownership Plan);
- 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.

Procedures

Responsibilities of Sutra Medical's Designated Official

The Designated Official or his/her designee shall be responsible for the following:

- Ensuring Sutra Medical Investigators are informed of their obligations under this policy and any related regulations;
- Ensuring inclusion of any required certifications in applications for funding or contract proposals;
- Screening and managing potential financial conflicts of interest;

- Maintaining all records relating to disclosures of financial interests, Sutra Medical's review of and response to such disclosures, and any related actions under this policy;
- Reviewing disclosures of significant financial interest with Sutra Medical's Administrator to determine whether they are related to the subject research and, if so, whether they constitute financial conflicts of interest; and
- Reporting and disclosure as required under this policy and applicable regulations.

For PHS-funded research, the Designated Official shall take reasonable steps to ensure that Investigators for subrecipients (e.g., subgrantees, subcontractors, or collaborators) fully comply with this policy or provide Sutra Medical with sufficient assurances to enable Sutra Medical's compliance with all applicable laws or regulations. The written agreement between Sutra Medical and the subrecipient will specify whether Sutra Medical's or the subrecipient's financial conflicts of interest policy will apply to the subrecipient's Investigators and, if the subrecipient's policy will apply, the Designated Official will:

- Obtain certification from the subrecipient confirming that its policy complies with Sutra Medical's policy and the applicable regulations (absent such certification, Sutra Medical's policy will apply) to the subrecipient's Investigators, and
- Establish time periods for the subrecipient to report financial conflicts of interest to Sutra Medical which enable Sutra Medical to report such conflicts in a timely manner, as required under its policy and the applicable regulations.

If Sutra Medical's policy will apply to the subrecipient Investigators, Sutra Medical will be responsible for the reporting obligations and meeting the requirements of this policy, as reflected in the applicable regulations.

Internal Reporting Requirements

As part of the PSH funding application or proposal and prior to performing any work on the research, each Investigator who is planning to participate in the PHS funded Research is required by regulation to complete a Significant Financial Interest Disclosure (SFID) Form and submit the SFID Form to Sutra Medical's Administrator, who will review SFID submissions with the Designated Official. Investigators who are or who work for subgrantees, subcontractors, or collaborators on PHS-funded research must also complete a SFID Form. Forms will be provided to Investigators in conjunction with the annual training and will be otherwise made available. The information reported on the SFID Form includes a listing of the Investigator's known significant financial interests and those of his/her immediate family that reasonably appear to be related to the research or that are in entities whose financial interests could be affected by the research.

Sutra Medical Investigators in non-PHS-funded research who have any significant financial interest that may reasonably appear to be affected by the research are also expected to complete the SFID Form and submit it to Sutra Medical's Administrator.

Investigators are expected to submit an updated SFID Form (including any SFI of their spouse or dependent children) during the period of the award as necessary 1) at least annually for PHS-funded research; and, 2) within thirty days of discovering or acquiring a new SFI (e.g., an interest acquired through purchase, marriage, or inheritance). The annual update will typically be done in conjunction with completion of the annual training and shall include any information that was not previously disclosed.

Determination and Management of Financial Conflicts of Interest

Upon receipt of a completed SFID Form, the Designated Official shall determine whether an Investigator's significant financial interest is related to the subject research, whether the interest constitutes a financial conflict of interest under this policy, and any applicable regulations. Financial interest and subject research relatability is determined either if the interest could be affected by the research or if it is in an entity whose financial interest could be affected by the research. A financial conflict of interest exists if the significant financial interest could directly and significantly affect the design, conduct, or reporting of the research. The Investigator may be required to submit additional information as part of the process.

If Sutra Medical determines that a financial conflict of interest exists, the Designated Official will implement and monitor a financial conflicts of interest management plan on an ongoing basis. If necessary, the Designated Official will also implement a retrospective review and mitigation report pursuant to this Policy. The management plan will include appropriate steps to manage, reduce, or eliminate the conflict. The following are examples of conditions or restrictions that might be imposed:

- Disclosure of significant financial interests to the public (e.g., when presenting or publishing the research) or to research participants (for Research project involving human subjects)
- Monitoring of research by independent reviewers capable of taking measures to protect the design, conduct and reporting of the Research against bias resulting from the FCOI;
- Modification of the research plan;
- Change of personnel or personnel responsibilities, or disqualification of staff from participation in all or a portion of the research;
- Reduction or divestiture of a financial interest (e.g., sale of an equity interest); or
- Severance of relationships that create actual or potential conflicts.

In addition to the conditions or restrictions described above, Sutra Medical may require the management of conflicting financial interests in other ways as it deems appropriate.

External Reporting Requirements

All disclosures regarding financial conflicts of interest from Sutra Medical shall be as required by applicable laws or regulations. Before expending any funds under a PHS award, Sutra Medical will ensure public accessibility by posting financial conflicts of

interest information on a publicly available web site or by responding in a timely manner to written requests concerning any SFI disclosed to Sutra Medical as required under the regulations. The Designated Official will also report to the PHS Awarding Component, as detailed in the regulations, the existence of any financial conflict of interest that has not been eliminated and will ensure that Sutra Medical has implemented a plan to manage the conflict.

If a financial conflict of interest is identified after its initial reporting and during ongoing research (e.g., through participation of a new Investigator) and has not been eliminated, Sutra Medical will provide the PHS Awarding Component with an update within 60 days and ensure that it has implemented a plan to manage the conflict. If the financial conflicts of interest report involves a significant financial interest that was not disclosed by an Investigator or not previously reviewed or managed by Sutra Medical (e.g., not reviewed or reported by a subrecipient in a timely manner), Sutra Medical will undertake a retrospective review. Such retrospective review will determine whether there was bias in the design, conduct, or reporting of the PHS-funded research, or portion thereof, conducted prior to the identification and management of the conflict. If bias is found, Sutra Medical will promptly notify the PHS Awarding Component and submit a mitigation report. Upon request, Sutra Medical will provide HHS with information relating to any Investigator disclosure of significant financial interests; Sutra Medical's review of, and response to, such disclosure; and whether the disclosure resulted in Sutra Medical's determination of a financial conflict of interest.

Confidentiality

Sutra Medical will, to the extent possible, protect the confidentiality of disclosures. In every instance, Sutra Medical will endeavor to balance the privacy interests of individuals with its responsibility and obligation to identify and manage conflicts of interest. Disclosures will be available to Sutra Medical staff only on a need-to-know basis and will not be disclosed outside of Sutra Medical unless necessary to comply with contractual, legal, or regulatory requirements.

Investigator Noncompliance

If an Investigator knowingly fails to comply with this policy (e.g., fails to identify an actual or potential financial conflict of interest, Sutra Medical may take appropriate disciplinary action, which may include, without limitation, termination of the Investigator's participation in the research. In addition, if the Investigator's failure to comply with the policy or a FCOI management plan for PHS-funded research has biased the design, conduct, or reporting of the PHS-funded research, Sutra Medical shall promptly notify the PHS Awarding Component of the corrective action taken or to be taken. Failure to comply with this policy or the applicable regulations shall result in the following:

- Sutra Medical will make available to HHS all records pertinent to financial conflicts of interest and the management of those conflicts; and
- If HHS determines that PHS funded project of clinical research whose purpose is 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 neither reported nor managed, Sutra Medical shall require the Investigator involved to disclose the conflicting interest in each public presentation of the results of the research and shall request an addendum to previously published presentations, if necessary.

Training and Education

Investigators receive training and must complete it prior to engaging in PHS funded research to promote objectivity in research and to ensure Investigator compliance regarding the applicable regulations and significant financial interest disclosure obligations. The training module and other resources developed by NIH will be updated as appropriate and can be accessed through the [NIH Web site](#).

Sutra Medical requires Investigators to complete such training annually, and when any of the following occurs:

- Sutra Medical revises its financial conflicts of interest policy or procedures in any manner that affects the Investigator's obligations;
- An Investigator is new to Sutra Medical; or
- Sutra Medical finds that an Investigator is not in compliance with this policy or a financial conflicts of interest management plan.

Retention of Records

Records of all financial disclosures, whether or not they result in a reporting obligation, and all actions taken by Sutra Medical with respect to each financial conflict of interest will be retained by the Designated Official for at least 3 years beyond the date of submission of the final expenditures report or final payment on the contract or, where applicable, from other dates specified in 45 CFR 74.53(b) or 48 CFR Part 4, Subpart 4.7.

Point of Contact

If you have a conflict of interest or if you have a question to discuss, contact the Sutra Medical Administrator at FCOI at [Sutra Medical.com](http://SutraMedical.com).

Download Sutra Medical SIF Disclosure Form from our website.