



Current Status: Active

PolicyStat ID: 1488991



|                        |   |
|------------------------|---|
| <b>Effective:</b>      | 7/24/2015   |
| <b>Final Approved:</b> | 7/24/2015   |
| <b>Last Revised:</b>   | 7/24/2015   |
| <b>Next Review:</b>    | 7/23/2018   |
| <b>Owner:</b>          | <i>Karen Mottola: Research Compliance Officer</i> |
| <b>Policy Area:</b>    | <i>Research</i>                                   |
| <b>References:</b>     |   |
| <b>Applicability:</b>  | <i>Sutter Health System</i>                       |

## Research Financial Conflict of Interest Policy

### PURPOSE

The purpose of this policy is to promote objectivity in Research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of Research will be free from bias resulting from Investigator FCOI. To ensure that Research is conducted with integrity and transparency, and that the rights and interests of human subjects are protected, arrangements involving Investigators who have a financial or fiduciary interest in an outside entity, to the extent such arrangements may represent a source of conflict or an appearance of conflict, must be identified and addressed. All requirements of Sutter Health's general Conflict of Interest Policy apply.

### POLICY

It is the policy of the Research Governance Committee (RGC)<sup>1</sup> to ensure procedures are in place to identify Financial Conflicts of Interest ("FCOI") in Research activities and manage them effectively.<sup>2</sup>

<sup>1</sup>Or, should the RGC undergo a name change, the subject matter expert committee designated to govern research policy-making.

<sup>2</sup>This policy employs language taken directly from "Promoting Objectivity in Research" (42 CFR 50, Subpart F).

### SCOPE

This policy applies to Sutter Health, its Affiliated Entities and Operating Corporations (as those terms are defined in the Sutter Health Bylaws) and other entities or organizations in which Sutter Health or an Affiliated Entity or Operating Corporation has a direct or indirect equity interest of greater than 50% (hereafter referred to as "Sutter Health").

### DEFINITIONS

As used in this policy, terms are defined following the language of "Promoting Objectivity in Research" (42 CFR 50, Subpart F):

**Designated Official** is the Sutter Health individual identified to solicit and conduct review of disclosures of Significant Financial Interests from each Investigator.

**Financial Conflict of Interest ("FCOI")** means a Significant Financial Interest that could directly and significantly affect the design or conduct of Research or reporting of Research results.

**FCOI Regulation** means "Promoting Objectivity in Research" (42 CFR 50, Subpart F).

**Financial Interest** means anything of monetary value, whether or not the value is readily ascertainable.

**Investigator** means the project director or principal investigator (PD/PI) and any other Senior/Key Personnel, regardless of title or position, who is responsible for the design or conduct of Research or reporting of Research results.

**Investigator Responsibilities** means an Investigator's professional responsibilities on behalf of Sutter Health. Such professional responsibilities may include activities such as Research, Research consultation, teaching, professional practice, clinical service, outreach, public service, institutional committee memberships, and service on panels such as Institutional Review Boards or data, quality and safety monitoring boards or committees.

**Manage** means taking action to address an FCOI, which can include reducing or eliminating the FCOI, to ensure, to the extent possible, that the design or conduct of Research or and reporting of Research results will be free from bias.

**Public Health Service ("PHS")** means the PHS of the United States 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.

**PHS Research** means research funded by PHS, which could include the following: research contracts, research grants, career development awards, center grants, cooperative agreements, individual fellowship awards, infrastructure awards, institutional training grants, program projects or research resources awards and conference grants. Only Phase I Small Business Innovative Research ("SBIR") and Small Business Technology Transfer Research ("STTR") awards programs are excluded. When research sponsored by the National Cancer Institute within the National Clinical Trials Network ("NCTN") is funded by a PHS cooperative agreement with designated NCTN groups, it is not PHS Research.

**PHS Awarding Component** means the organizational unit of the PHS that funds the Research that is subject to this subpart.

**Research** means a systematic investigation, study or experiment designed to develop or contribute to general knowledge (basic research) or specific knowledge (applied research) relating broadly to public health by establishing discovering, developing, elucidating or confirming information about, or the underlying mechanism relating to, biological causes, functions or effects, diseases, treatments, or related matters to be studied.

**Senior/Key Personnel** means any person identified as Senior/Key Personnel by Sutter Health in the grant application, progress report, or any other report submitted to the PHS by Sutter Health or, in the case of non-PHS Research, as identified by those authorized by Sutter Health to determine Senior/Key Personnel. Senior/Key Personnel are understood to be personnel whose replacement would constitute a threat to the continuation of the Research. It does not include Research coordinators and administrators unless such individuals are named as sub-investigators in the Research project.

**Significant Financial Interest ("SFI")** means:

- A. A Financial Interest consisting of one or more of the following interests of the Investigator (and those of his or her immediate family, including dependent children or spouse, or those with whom the Investigator maintains living arrangements approximating a family relationship) that reasonably appears to be related

to the Investigator's institutional responsibilities, unless the project is sponsored by an NCTN group, in which case SFI means an SFI as determined by the National Cancer Institute and NCTN group:

1. With regard to any publicly traded entity, an SFI 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;
  2. With regard to any non-publicly traded entity, an SFI 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 Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
  3. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- B. 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. This includes: the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with this policy, the Designated Official shall determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI.
- C. The term Significant Financial Interest does not include the following types of Financial Interests: salary, royalties, or other remuneration paid by Sutter Health to the Investigator if the Investigator is currently employed or otherwise appointed by Sutter Health; 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.

## PROCEDURE

- A. Each Investigator shall:
1. read, understand and abide by this policy;
  2. disclose SFI; and
  3. complete training regarding FCOI prior to engaging in Research related to any PHS-funded grant and before commencing non-PHS Research activities and, thereafter, at least every four years, and immediately any of the following circumstances apply:

- a. Sutter Health revises its FCOI policies or procedures in any manner that affects the requirements of Investigators;
  - b. An Investigator is new to Sutter Health;
  - c. Sutter Health finds that an Investigator is not in compliance with this policy or the Research FCOI processes.
- B. Sutter Health shall comply with the requirements set forth in the FCOI Regulations, including but not limited to:
1. maintaining an up-to-date, written, enforced policy on FCOI that complies with the FCOI Regulations and make such policy available via a publicly accessible Web site;
  2. informing each Investigator of this policy, the Investigator's Responsibilities regarding disclosure of Significant Financial Interests, and of the FCOI Regulations;
  3. requiring each Investigator to complete FCOI training;
  4. taking reasonable steps to ensure that any subrecipient Investigator complies with the FCOI Regulations;
  5. providing guidelines consistent with the FCOI Regulations for the Designated Official to determine whether an Investigator's SFI is related to Research and, if so related, whether the SFI is an FCOI;
  6. taking such actions as necessary to Manage FCOI, pursuant to the FCOI Regulations;
  7. providing FCOI reports to the PHS Awarding Component, as required under the FCOI Regulations, regarding any Investigator's SFI found by Sutter Health to be a conflict, and ensuring that a management plan has been implemented;
  8. maintaining records relating to all Investigator disclosures of FI;
  9. establishing adequate enforcement mechanisms and providing for employee sanctions or other administrative actions to ensure Investigator compliance as appropriate.
- C. Investigator disclosure of SFI shall proceed as follows:
1. Each Investigator who is planning to participate in Research must disclose to the Designated Official his or her SFI (and those of his or her immediate family, including dependent children or spouse, or those with whom the Investigator maintains living arrangements approximating a family relationship and those of his or her spouse and dependent children) no later than the time of application for Research funding. The disclosure shall be made using the disclosure form and process authorized by Sutter Health.
  2. Each Investigator who is participating in Research must submit an updated disclosure of SFI before commencement of new Research and at least annually during the period of the award. This will be accomplished by completing the annual FCOI form that will be distributed by the Designated Official. Such disclosure shall include any information that was not disclosed initially to Sutter Health or in a subsequent disclosure of SFI and any updated information regarding any previously disclosed SFI. If the time between initial disclosure and Research commencement is less than one year and SFI has not changed, the Investigator need not update the disclosure until the annual disclosure deadline.
  3. Each Investigator who is participating in Research must submit an updated disclosure of SFI within 30 days of discovering or acquiring a new SFI.
  4. Each Investigator who is new to participating in an ongoing Research project must submit a disclosure of SFI within 30 days of joining the Research project.

5. The Investigator may be requested to provide further details regarding financial disclosure information to assist with the determination of whether SFI exists.
  6. Sutter Health shall maintain a process for review, determination and appropriate action for management of FCOI related to Research. Upon disclosure of an SFI, the Designated Official will determine whether an Investigator's SFI is an FCOI.
- D. Sutter Health shall take actions as necessary to Manage any identified FCOI. Such actions include development and implementation of a management plan and, if necessary, a retrospective review and a mitigation report. The management plan shall specify the actions that have been, and shall be, taken to Manage such FCOI.
1. All identified FCOI shall be taken to the Sutter Health Conflict of Interest Committee for Research, for development and implementation of a management plan. The Sutter Health Chief Medical Officer shall direct the committee or assign a designee to direct the committee.
  2. Sutter Health shall develop and impose conditions or restrictions to Manage an FCOI. Such actions may include, but are not limited to:
    - a. public disclosure of FCOI (e.g., when presenting or publishing the Research);
    - b. for Research projects involving human subjects Research, disclosure of FCOI directly to participants;
    - c. appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the Research against bias resulting from the FCOI;
    - d. modification of the Research plan;
    - e. change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the Research;
    - f. reduction or elimination of the Financial Interest; or
    - g. severance of relationships that create the FCOI.
  3. Whenever an SFI is identified that was not, for whatever reason, disclosed as required by an Investigator, the Designated Official shall, within 60 days upon discovering the SFI: initiate a review of the SFI; determine whether it is related to PHS-funded Research; determine whether an FCOI 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 FCOI going forward.
  4. Whenever an Investigator fails to comply with an FCOI management plan, Sutter Health shall, within 120 days of the determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS-funded Research project to determine whether any PHS-funded Research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such Research.
  5. If the failure of an Investigator to comply with this policy or an FCOI management plan appears to have biased the design, conduct, or reporting of PHS-funded Research, Sutter Health shall promptly notify the PHS Awarding Component of the corrective action taken or to be taken and shall adhere to the direction, if given, of the PHS Awarding Component.
  6. If the failure of an Investigator to comply with this policy or an FCOI management plan appears to have biased the design, conduct, or reporting of Research, Sutter Health shall take appropriate action and impose sanctions, which may include a written warning and placement of a letter in the Investigator's personnel file, termination of award, suspension of the privilege to apply for external

funding, permanent suspension of the ability to perform Research activities at Sutter Health, suspension for a specified period of time, or termination of employment/affiliation.

7. In any case in which Sutter Health determines that a 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 an FCOI that was not Managed in accordance with a prescribed management plan or reported by the Investigator as required by this policy, Sutter Health shall require the Investigator involved to disclose the FCOI in each public presentation of the Research and to request an addendum to previously published presentations. If the FCOI is related to PHS-funded Research, Sutter Health may report the non-compliance to the Office for Human Research Protections of HHS. Any FCOI may be reported to the supervising Institutional Review Board and/or any other individuals and/or agencies Sutter Health determines should be informed.

8. Appeal of the management plan may be made to the designee authorized by Sutter Health.

E. Regarding FCOI related to PHS-funded Research, Sutter Health shall maintain records relating to all Investigator disclosures of Financial Interests and the Sutter Health's review of, and response to, such disclosures (whether or not a disclosure resulted in determination of an FCOI) and all actions under this policy or retrospective review, if applicable, for at least three years from the date the final Research expenditures report is submitted to the PHS or, where applicable, from other dates specified in "Retention and access requirements for records" [45 CFR Part 74.53(b) and 45 CFR Part 92.42(b)].

1. Sutter Health shall maintain documentation on all reporting to the PHS Awarding Component including corrective action plans and documentation of completion of prescribed plans.

## REFERENCES

42 CFR Part 50 Subpart F

45 CFR Part 74

45 CFR Part 92.42(b)

[Sutter Health Conflict of Interest Policy](#)

National Institutes of Health Financial Conflict of Interest Policy: <http://grants.nih.gov/grants/policy/coi/>

## ATTACHMENTS

Exhibit A - 42 CFR Part 50 Subpart F - Promoting Objectivity in Research

Exhibit B - 45 CFR Part 74 - Uniform Administrative Requirements for Awards and Subawards to Institutions

Exhibit C - National Institutes of Health Financial Conflict of Interest Policy - Web Page

Exhibit D - 45 CFR 92.42(b) - HHS Retention and Access Requirements

All revision dates:

7/24/2015

## Attachments:

-  [Exhibit A - 45 CFR 50 Subpart F - Promoting Objectivity in Research](#)
-  [Exhibit B - 45 CFR Part 74 - Uniform Administrative Requirements for Awards and Subawards to Institutions](#)

-  [Exhibit C - National Institutes of Health Financial Conflict of Interest Policy - Web Page](#)
-  [Exhibit D - 45 CFR 92.42\(b\) - HHS Retention and Access Requirements](#)

|  | <b>Committee</b>                    | <b>Approver</b>                                 | <b>Date</b> |
|--|-------------------------------------|---|-------------|
|  | Policy Owner                        | Karen Mottola: Research Compliance Officer [EK] | 6/29/2015   |
|  | Research Governance Council         | Karen Mottola: Research Compliance Officer [EK] | 6/29/2015   |
|  | VP ECS                              | Ginger Chappell: SH VP, Chief Compliance Ofcr   | 7/10/2015   |
|  | System Policy & Procedure Committee | Joyce Sklark: Policy & Procedure Mgmt Mgr       | 7/16/2015   |
|  | Policy Owner                        | Karen Mottola: Research Compliance Officer      | 7/24/2015   |

COPY