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Sutter Health System

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Applicability	Sutter Health System

Research Financial Conflict of Interest Policy

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PURPOSE

The purpose of this policy is to establish procedures that provide a reasonable expectation that Financial Conflicts of Interest (FCOI) will not bias the design, conduct, and reporting of Research.

POLICY

It is policy to review Significant Financial Interests (SFI) held by Investigators, and to identify and Manage FCOIs related to Research.

SCOPE

This policy applies to Sutter Health and any legal entity for which Sutter Health or its affiliate is the sole member or directly or indirectly controls greater than 50% of the voting power or equity interest (herein referred to as Sutter).

DEFINITIONS

Designated Institutional Official (DIO) means the Sutter individual or their designee(s) identified as having responsibilities and authority under this policy. For the purposes of this policy, this is the research compliance officer (RCO), within Sutter Health Ethics and Compliance Services (ECS).

Disclosure means an Investigator's provision of information about their Financial Interests to Sutter.

Equity Interest means any interest in the profits of or stock of a commercial or non-profit enterprise, a stock option or any other ownership interest in a commercial or non-profit enterprise, the value of which

is determined through reference to public prices or other reasonable measures of fair market value.

Financial Conflict of Interest (FCOI) means a SFI that could directly and significantly affect the design, conduct or reporting of Research.

Financial Interest means anything of monetary value, whether or not the value is readily ascertainable, possessed by an Investigator and their spouse, domestic partner, or dependent child.

Institution of Higher Education means an educational institution in any state in the United States (U.S.) that meets all of the following requirements:

A. Admits as regular students only persons having a certificate of graduation from a school providing secondary education, or the recognized equivalent of such a certificate, or persons who meet the related requirements of federal law;

B. Is legally authorized within such state to provide a program of education beyond secondary education;

C. Provides an educational program for which the institution awards a bachelor's degree or provides not less than a two (2) year program that is acceptable for full credit toward such a degree, or awards a degree that is acceptable for admission to a graduate or professional degree program, subject to review and approval by the U.S. Secretary of Education;

D. Is a public or other nonprofit institution; and

E. Is accredited by a nationally recognized accrediting agency or association, or if not so accredited, is an institution that has been granted pre-accreditation status by such an agency or association that has been recognized by the U.S. Secretary of Education for the granting of pre-accreditation status, and the U.S. Secretary of Education has determined that there is satisfactory assurance that the institution will meet the accreditation standards of such an agency or association within a reasonable time.

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Investigator means any person, regardless of title or position, who is responsible for the design, conduct or reporting of the results of a Research project and the Investigator's spouse, domestic partner, and dependent children.

Institutional Responsibilities means an Investigator's professional responsibilities at the request of Sutter. 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.

Intellectual Property Rights and Interests means any direct or indirect rights or interest in intellectual property, including, but not limited to, inventorship, ownership, royalties and license fees, regardless of whether such Intellectual Property Right and Interest is owned by Sutter or an outside commercial or non-profit entity and shall be deemed to exist upon the earlier of (i) execution of an agreement securing such rights or interests; or (ii) receipt of related income.

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

Management Plan means a written plan to address a FCOI to confirm, to the extent possible, that the

design, conduct and reporting of Research 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 without limitation the National Institutes of Health (NIH).

PHS-Funded Research means any Research or sponsored activity for which funding is sought from a PHS Awarding Component through a grant or cooperative agreement, however authorized, such as a Research contract, Research grant, career development award, center grant, cooperative agreement, individual fellowship award, infrastructure award, institutional training grant, program project or Research resources award and conference grant. PHS-Funded Research does not include any Phase I Small Business Innovative Research (SBIR) Program or Phase I Small Business Technology Transfer Research (STTR) Program application or award.

PHS Awarding Component means the organizational unit of the PHS that funds the Research that is subject to 42 CFR 50 subpart F.

Reimbursed Travel means travel activity for which expenses are paid directly by the Investigator, who is then reimbursed by an entity for such expenses, excluding travel activity where the source of reimbursement to the Investigator is a Sutter Research study budget.

Research means a systematic investigation, study or experiment designed to develop or contribute to general knowledge or specific knowledge 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 the project director/principal Investigator and any other person identified as Senior/Key Personnel by Sutter in the grant application, contract, progress report, or any other report pertaining to the Research project submitted to the PHS by Sutter.

Significant Financial Interest (SFI) means a Financial Interest that reasonably appears to be related to an Investigator's Institutional Responsibilities consisting of one (1) or more of the following:

A. Compensation totaling more than five-thousand dollars ($5,000) received from an entity in the twelve (12) months preceding the Disclosure (e.g., salary, consulting fees, honoraria or other payments) excluding:
    1. Compensation or other remuneration paid by Sutter to the Investigator if the Investigator is currently employed or engaged by Sutter;
    2. Income from seminars, lectures or teaching engagements sponsored by and/or service on advisory committees or review panels for:
        a. Sutter;
        b. A federal, state or local government agency;
        c. An Institution of Higher Education;
        d. An academic teaching hospital; or
        e. A medical center or a Research institute affiliated with an Institution of Higher Education.

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B. Equity in a publicly traded entity valued, as determined through reference to public prices or other reasonable measures of fair market value, in excess of five-thousand dollars ($5,000) as of the date of Disclosure excluding equity in investment vehicles where the Investigator does not directly control investment decisions (e.g., mutual funds, retirement accounts).

C. Any equity in a non-publicly traded entity as of the date of Disclosure.

D. Equity in a publicly traded entity and compensation received from the same entity in the twelve (12) months preceding the Disclosure that when aggregated equals a combined total value exceeding five-thousand dollars ($5,000) at the time of Disclosure excluding the following:

    1. Compensation or other remuneration paid by Sutter to the Investigator if the Investigator is currently employed or otherwise appointed by Sutter;
    2. Income from seminars, lectures or teaching engagements sponsored by and/or service on advisory committees or review panels for the following:
        a. Sutter;
        b. A federal, state or local government agency;
        c. An Institution of Higher Education;
        d. An academic teaching hospital; or
        e. A medical center or a Research institute affiliated with an Institution of Higher Education.
    3. Equity in investment vehicles where the Investigator does not directly control investment decisions (e.g., mutual funds, retirement accounts).

E. Intellectual Property Rights and Interests excluding the following:

    1. Intellectual property assigned to Sutter;
    2. Royalty payments paid by Sutter to the Investigator; and
    3. Agreements entered into by Sutter which, either via Sutter's policies or specific provisions of the executed agreement, provide for the Investigator to share in royalties.
    4. PLEASE NOTE: in some instances, Intellectual Property Rights and Interests that are excluded under this policy may be subject to management or restrictions under other Sutter policies (e.g., Intellectual Property Policy, etc.).

F. Reimbursed Travel or Sponsored Travel (regardless of dollar value) excluding travel for which expenses are paid by the following:

    1. Sutter;
    2. A U.S. Federal, state or local government agency;
    3. An Institution of Higher Education;
    4. An academic teaching hospital; or
    5. A medical center or a Research institute affiliated with an Institution of Higher Education.

Sponsored Travel means travel activity for which expenses are paid directly by an entity on behalf of an

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Investigator; exact monetary value may not be readily available, excluding travel activity for which expenses are paid directly by a Sutter Research study budget.

PROCEDURE

A. Investigator Responsibilities – All Investigators are required to:

1. Disclose SFI:
    a. Annually;
    b. Within thirty (30) days of discovering or acquiring a new SFI;
    c. Prior to participating in Research when new to conducting Research at Sutter; and
    d. Upon direction from the DIO or designee(s).
2. Review their SFI Disclosure to validate that it is current, and update as necessary, prior to the submission of a new proposal/application for Research funding.
3. Comply with any Management Plan established by the DIO, RFCOIC, or DIO's designee(s), and upon Sutter request, verify full conformance.
4. Complete FCOI training:
    a. As directed by Sutter, but at minimum,
    b. At least every four (4) years;
    c. Prior to participating in Research when new to conducting Research at Sutter;
    d. Or as mandated by the DIO or designee(s), upon determination of noncompliance with this policy or an existing Management Plan.

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B. Review of Disclosures

1. The DIO or designee(s) will review all SFI Disclosures and determine whether SFI is related to a specific Research project. SFI is related to the Research when the DIO or designee(s) reasonably determines the SFI could be affected by the Research; or is in an entity whose Financial Interest could be affected by the Research.
    a. The Research Financial Conflict of Interest Committee (RFCOIC) has responsibility and authority for the review of certain SFI that the DIO or DIO's designee has determined constitute a conflict of interest.
2. In reviewing the SFI, the DIO or designee(s) may conduct factual inquiries and consult with and receive recommendations from such person or committees as the DIO deems necessary and appropriate.
3. Depending on the nature of the disclosed SFI, the DIO or designee(s) may implement additional interim measures regarding the Investigator's participation in the Research project between the date of Disclosure and the completion of the SFI review.
4. In the case of PHS-Funded Research, reviews generally will not be conducted until after a Research proposal has been funded.

C. Management of FCOI

1. If the RFCIOC, DIO or DIO's designee(s) determines that an SFI constitutes a FCOI, the DIO or designee(s) shall develop a Management Plan specifying required actions that, in the reasonable judgement of the DIO/designee(s), will Manage the FCOI. Such actions may include, but are not limited to, the following:
    a. Public Disclosure of FCOI (e.g., when presenting or publishing the Research);
    b. For Research projects involving human subjects Research, Disclosure of FCOI 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 (e.g., sale of an Equity Interest); or
    g. Severance of relationships that create the FCOI.
2. No Investigator with a FCOI may participate in the related Research project until a Management Plan is established.
3. In developing the Management Plan, the DIO or designee(s) may conduct factual inquiries and consult with and receive recommendations from such person or committees as the DIO deems necessary and appropriate.
4. For PHS-Funded Research, Disclosure review and FCOI management will be completed prior to the expenditure of any Research project funds or within sixty (60) days of SFI Disclosure: (i) by an existing Investigator; or (ii) by an Investigator new to the project during the course of the Research.
5. After a Management Plan is implemented, the DIO or designee may, at the DIO's reasonable discretion, audit and/or monitor compliance with the Management Plan until the completion of the Research project or until the Management Plan is no longer required. Such monitoring is mandatory for Management Plans that apply to PHS-Funded Research.
6. Amendments or updates to Management Plans may be made at any time, at the DIO's (or designee's) discretion.

D. Management of Other Interests

1. When a disclosed SFI is determined not to constitute a FCOI, Sutter may nonetheless determine that some type of management or oversight of the interest is appropriate before certain Research activities may proceed. Sutter may develop additional procedures or guidance regarding these types of interests and any associated limitations or requirements.

E. FCOI Reporting to PHS for PHS-Funded Research

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1. Sutter will submit FCOI reports to a PHS Awarding Component:
    a. Prior to expenditure of any funds under a PHS-Funded Research project, if a FCOI has not been Managed, reduced or eliminated; and
    b. Within sixty (60) days of identifying an FCOI during an ongoing Research project or annually for any FCOI previously reported in regard to an ongoing PHS-Funded Research project. The report shall specify the status of the FCOI, and, if appropriate, any changes to the Management Plan. The report shall be submitted annually for the duration of the Research project.
2. Any FCOI report submitted to a PHS Awarding Component shall include the minimum elements as required by 42 CFR Part 50 Subpart F and shall contain sufficient information for the PHS Awarding Component to understand the nature and extent of the FCOI and assess the appropriateness of the Management Plan.

F. PHS-Funded Research through Subrecipients
1. If the PHS-Funded Research or portions of it will be carried out through a subrecipient or subcontractor, Sutter will take reasonable steps to confirm that any subrecipient Investigator complies with 42 CFR Part 50 by incorporating the following as part of the written agreement with the subrecipient:
    a. Language that establishes whether this policy or the subrecipient's FCOI policy will apply to the subrecipient Investigators; and
    b. Required time period(s) for the subrecipient to report all identified FCOI or for submission of all subrecipient Investigator SFI Disclosures to Sutter.

G. Retrospective Review of PHS-Funded Research
1. Whenever Sutter identifies a SFI that was not disclosed in a timely manner or was not previously reviewed by Sutter during an ongoing PHS-Funded Research project, the DIO or designee(s) shall within sixty (60) days:
    a. Review the SFI;
    b. Determine whether it is related to a PHS-Funded Research project;
    c. Determine whether a FCOI exists; and
    d. If the DIO determines a FCOI exists, they implement, at least on an interim basis, a Management Plan that specifies the actions that have been taken and will be taken to Manage, reduce or eliminate such FCOI.
2. Whenever a FCOI related to a PHS-Funded Research project is not identified or Managed in a timely manner due to noncompliance by Sutter or an Investigator, including if an Investigator fails to comply with a Management Plan, the DIO or designee(s) shall:
    a. Notify the chief research officer;
    b. Within one hundred twenty (120) days of the DIO or designee's identification of such non-compliance, complete and document a retrospective review of the Investigator's activities and the Research project. Documentation of the review will include all elements as specified by 42 CFR Part 50 Subpart F;

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c. Based on the results of the retrospective review, if appropriate, update the previously submitted FCOI report and specify the actions that will be taken to Manage the FCOI moving forward;

d. If bias is found, notify the PHS Awarding Component promptly and develop and submit a mitigation report. The mitigation report shall consist of the minimum elements as required by 42 CFR Part 50 Subpart F; and

e. Submit FCOI reports to the PHS Awarding Component annually thereafter for the duration of the Research project.

H. Publicly Accessible Information

1. This policy shall be available via the Sutter's publicly accessible web site.
2. For PHS-Funded Research, the DIO or designee(s) shall make information concerning SFIs that meet the criteria below available to the public, upon written request for such information:
    a. SFI was disclosed and is still held by Senior/Key Personnel;
    b. The DIO or designee(s) determined the SFI is related to a PHS-Funded Research project; and
    c. The DIO or designee(s) determined the SFI constitutes an FCOI.
3. The above information made available shall consist of the minimum elements as required by 42 CFR Part 50 Subpart F, and shall be provided by written response to the requestor.
4. The publicly accessible information shall remain available for public request for at least three (3) years from the date that the information was most recently updated.

I. Sanctions and Remedies for Violation of Policy

1. If the DIO or designee(s) determines an Investigator has violated this policy, including failure to submit required Disclosures or failure to comply with the requirements of a Management Plan, the DIO or designee(s) will report the violation to the chief research officer; sanctions for such policy violations may include, but not be limited to:
    a. Suspending Research activity expenditures;
    b. Administratively suspending any Research study related to the FCOI; and/or
    c. Instituting or initiating other disciplinary measures or actions as deemed appropriate.
2. If required to do so, Sutter will submit to Health and Human Services, or permit on site review of, all records pertinent to compliance with this policy and federal regulations.
3. In the case in which it is determined that a PHS-Funded Research project 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 FCOI that was not Managed or reported, Sutter shall require the Investigator involved to

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disclose the FCOI in each public presentation of the results of the Research and shall request an addendum to previously published presentations.

J. Record Keeping

1. Sutter shall maintain records relating to:
    a. All Investigator Disclosures of Financial Interests;
    b. The DIO's or designee(s) review and response to such Disclosures; and
    c. Actions taken under this policy or retrospective reviews.
2. For PHS-Funded Research, these records shall be maintained for at least three (3) years from the date the final expenditures report is submitted to the PHS Awarding Component or as required by 45 CFR 74.53(b). For all other Research, these records shall be maintained for at least three (3) years from the date of the final expenditures report.

REFERENCES

42 CFR Part 50 Subpart F

45 CFR Part 75.361

National Institutes of Health Financial Conflict of interest

Physician Administrative Services Agreements Policy

Sutter Health Conflict of Interest Policy

Sutter Health Intellectual Property Policy

Physician Administrative Services Agreements Policy

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ATTACHMENT

None

All Revision Dates

6/15/2022, 12/6/2017, 7/24/2015

Approval Signatures

Step Description	Approver	Date
Policy Owner	Roy McDonald: Research Compliance Officer	6/15/2022
System Policy & Procedure	Joyce Sklark: Compliance	6/14/2022

Committee	Officer, Eastern Di	
SPPC Pre-review	Joyce Sklark: Compliance Officer, Eastern Di	5/18/2022
Chief Compliance Officer	Ginger Chappell: SH VP, Chief Ethics & Complian	5/9/2022
System Enterprise Compliance Officer	Rachel Harlan: Sr Dpty Chief Ethics&Cmpl Ofcr	4/25/2022
Policy Owner	Roy McDonald: Research Compliance Officer	4/25/2022

Applicability

Alta Bates Summit Medical Center, Apogee Surgery Center, Briggsmore Specialty Center, California Pacific Medical Center, Capitol City Surgery Center, Carlsbad Surgery Center, East Bay Endoscopy Center, Fort Sutter Surgery Center, Golden Gate Endoscopy Center, Memorial Hospital Los Banos, Memorial Medical Center Modesto, Mid-Peninsula Endoscopy Center, Mills-Peninsula Chemical Dependency Recovery Ctr, Mills-Peninsula Medical Center, North Bay Regional Surgery Center, Novato Community Hospital, PAMF Blossom Hill Surgery Center, PAMF Surgery Center Fremont, PAMF Surgery Center Los Altos, PAMF Surgery Center Mountain View, PAMF Surgery Center Palo Alto, PAMF Surgery Center Samaritan, PAMF Surgery Center San Carlos, PAMF Surgery Center San Jose, Palo Alto Medical Foundation, Peninsula Eye Surgery Center, SMF-Surgery and Endoscopy Center, San Francisco Endoscopy Center, San Leandro Surgery Center, San Luis Obispo Surgery Center, Santa Barbara Endoscopy Center, Santa Rosa Surgery and Endoscopy Center, Stockton Surgery Center, Surgery Center of Alta Bates Medical Center, Sutter Alhambra Surgery Center, Sutter Amador Hospital, Sutter Amador Surgery Center, Sutter Auburn Faith Hospital, Sutter Auburn Surgery Center, Sutter Care at Home, Sutter Center for Psychiatry, Sutter Coast Hospital, Sutter Davis Hospital, Sutter Delta Medical Center, Sutter East Bay Medical Foundation, Sutter Eden Medical Center, Sutter Elk Grove Surgery Center, Sutter Fairfield Surgery Center, Sutter Gould Medical Foundation, Sutter Health Network, Sutter Health Plan, Sutter Health System, Sutter Health System Office, Sutter Institute for Medical Research, Sutter Lakeside Hospital, Sutter Maternity & Surgery Center, Sutter Medical Center Sacramento, Sutter Medical Foundation, Sutter Pacific Medical Foundation, Sutter Roseville Endoscopy Center, Sutter Roseville Medical Center, Sutter Santa Rosa Regional Hospital, Sutter Senior Care, Sutter Shared Lab, Sutter Sierra Surgery Center, Sutter Solano Medical Center, Sutter Surgery Center Division, Sutter Surgical Hospital North Valley, Sutter Tracy Community Hospital, Valley Laboratories, Walnut Creek Endoscopy Center

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