SAINT AGNES MEDICAL CENTER

CLINICAL RESEARCH CENTER

Fresno, California

STANDARD OPERATING PROCEDURES

Institutional Review Board

Date Effective: August 24, 2012 Index No. R – 1229
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SUBJECT: **"PROMOTING OBJECTIVITY IN RESEARCH"**

FINANCIAL CONFLICT OF INTEREST (FCOI)

1. PURPOSE

Conflicts of interest or perceptions of conflicts may occur when there is a convergence of an Investigator's private interests with his or her research interests, such that an independent observer might reasonably question whether the Investigator's professional actions or decisions are improperly influenced by considerations of personal financial gain. Such conflicts are not uncommon in basic and applied research and do not necessarily impugn the character or actions of any individual. However, financial interests do have the potential to threaten scientific integrity when they foster real or perceived biases in study design, review, data collection and analysis, adverse event reporting, or the presentation and publication of research findings. Moreover, the enthusiasm for positive results and the opportunity to profit from research may affect, or *appear to affect,* a researcher's judgment about which charts to screen, which subjects to enroll, how to treat them, and the proper use of subjects' protected health information (PHI).

This policy complies with the *revised* federal regulations published as a Final Rule in the August 25, 2011 Federal Register at 42 CFR Part 50 Subpart F and 45 CFR Part 94. The revised regulation pertains to "Promoting Objectivity in Research" promulgated by the U.S. Public Health Service (PHS), which includes the National Institutes of Health (NIH). Accordingly, the purpose of this policy is two-fold:

- To establish standards and a process for providing a reasonable expectation that the design, conduct, and reporting of all research (including but not limited to human subjects research) will be free from bias resulting from Investigator financial conflicts of interests, regardless of funding source; and
- To protect the rights, safety and welfare of human subjects participating in research by establishing standards and processes that avoid, mitigate or manage conflicts of interest between research participants and those of an Investigator, the Investigator's

research staff, Saint Agnes Medical Center (SAMC) employees, and members of the SAMC Institutional Review Board (IRB).

2. SCOPE

This policy applies to: a) any SAMC employee who assumes the role of a research Investigator (see definition below); and b) any non-employee (e.g., physician and his/her research staff) that relies on the SAMC IRB for human subjects research study approval.

3. POLICY

- PHS-Funded Research: SAMC will apply the revised federal regulations pertaining to the identification, management and reporting of Investigator financial conflicts of interests (FCOI) to PHS awards with an issue date of Notice of Award **subsequent to August 24, 2012** (the "compliance date" of the Final Rule).
- Non-PHS Funded Research: SAMC will implement the identification and management of FCOI requirements with each new study with a proposed initiation date **subsequent to August 24, 2012.** Because reporting of a FCOI to an awarding federal agency is not applicable to non-PHS-funded research, SAMC will in such cases make FCOI information available within 5 business days of any public request for such information regardless of funding source.

4. DEFINITIONS

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.

Family Member – means the Investigator's spouse and dependent children.

Financial Conflict of Interest (FCOI) – means a significant financial interest that SAMC has determined could directly and significantly affect the design, conduct, or reporting of research. Significant in this context means that the financial interest would reasonably have a material effect on the research.

Institution – means any domestic or foreign, public or private, entity or organization that is applying for, or that receives, PHS research funding.

Investigator – is a broad term that means the research Project Director (PD) or Principal Investigator (PI) and any other person, regardless of title or position, who is **responsible for** the design, approval, conduct, or reporting of research funded by the PHS, or proposed for such funding. In general, this definition includes sub-investigators, research coordinators, and may include collaborators or consultants. For purposes of this definition, individuals whose only responsibility is limited to routine procedures or assessments that are consistent with their job description, even when performed on research subjects, are not considered Investigators.

Investigator's Institutional Responsibilities – means an Investigator's professional responsibilities on behalf of the Institution and as defined by the Institution in this policy. These responsibilities may include but are not limited to:

- planning, designing, conducting or approving research activities;
- professional practice;
- teaching;
- membership on an institutional committee such as the IRB, or a data/safety monitoring board;
- management or supervision of an institutional department or care unit.

Manage – means taking actions to address a FCOI, which can include reducing or eliminating the FCOI, to ensure, to the extent possible, the design, conduct and reporting of research will be free from bias.

PHS Funding – includes but is not limited to grants and cooperative agreements.

Remuneration – includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship)

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, drug or device).

Senior/Key Personnel – means the PD/PI and any other person identified by the Institution in a grant application, progress report, or any other report submitted to the PHS by the Institution under 45 CFR 50 Subpart F.

Significant Financial Interest (SFI) – is 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:

- with regards to a publically traded entity, an SFI exists when the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest at the time of disclosure, when aggregated exceeds $5,000.
- With regards any non-publically traded entity, an SFI exists when 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 spouse or dependent children) holds any amount of equity interest;
- income related to intellectual property rights paid by any source other than Saint Agnes Medical Center or the Investigator's current institution (e.g. a university);
- the occurrence of any reimbursed or sponsored travel paid by an entity, including non-profit organizations, but excluding travel sponsored by or reimbursed by a government agency, a U.S. institution of higher education or a research institute affiliated with such, a medical center, or an academic teaching hospital. The specific details that must be disclosed are the name of entity sponsoring the travel, purpose, destination, and duration of the travel;

The following are not required to be disclosed by the investigator:

- Salary, royalties, or other remuneration paid to the investigator from the Institution that currently employs the Investigator. Any ownership interest in the Institution held by the Investigator if the Institution is a commercial for-profit organization;
- Income from investments in mutual funds or retirement accounts, as long as the Investigator does not make the investment decisions;
- Income for services (honoraria, advisory committees, review panels, etc.) and travel expenses paid by a federal, state, or local government agency, a U.S. institution of higher education or a research institute affiliated with such, a medical center, or an academic teaching hospital.

5. PROCEDURE

A. INVESTIGATOR RESPONSIBILITIES

1. Each Investigator (as broadly defined above) must disclose all SFIs using the 'Financial Disclosure By Research Investigator' form which can be found on the SAMC public web site by following the links under "Clinical Research" and then "Institutional Review Board Policies " (http://www.samc.com/institutional-review-board-policies). This disclosure is a requirement even if the Investigator does not directly or personally receive the financial support for his/her role in the research (e.g., SAMC employees or Medical Staff who conduct studies under cancer Group Cooperatives such as RTOG).

   This form must be submitted to the Research Center Office before any application for a PHS-funded research grant is submitted to the awarding entity, and at the time of initial protocol submission to the IRB for non-PHS-funded studies. The Financial Disclosure Form must be submitted on an annual basis or within 30 days of acquiring or discovering a new SFI.

2. Each Investigator must complete training on FCOI prior to engaging in research. Re-training must be completed every four years and immediately when any of the following circumstances apply:

   - An Investigator is new to SAMC;
   - SAMC revises its conflict of interest policies or procedures in any manner that affects the requirements of Investigators; or
   - SAMC finds that the Investigator is not in compliance with this policy or Management plan.

.B. SAMC'S OVERALL RESPONSIBILITIES

1. Maintain a written policy on FCOI that complies with applicable laws and regulations;
2. Maintain the Institution's FCOI policy on its public web site;

3. Provide and monitor FCOI training;
4. For research involving human subjects, the IRB will review each "Financial Disclosure Form" to identify any potential FCOI. For research not involving human subjects, the IRB Administrator and the Organizational Integrity Officer will review the financial disclosures to identify any potential FCOI;
5. Document mitigation actions to manage any FCOI;
6. Establish adequate enforcement mechanisms and provide for sanctions or other administrative actions to ensure researchers are in compliance with the management plan;
7. If SAMC carries out research through a sub-recipient (e.g., subcontractors or consortium members), SAMC will take reasonable steps to ensure that the sub-recipient's FCOI policy is in compliance with requirements for disclosure;
8. If the sub-recipient cannot provide such certification, a written agreement between SAMC and the sub-recipients shall state that sub-recipient investigators are subject to SAMC FCOI policy and specify time period(s) for the sub-recipient to report all identified FCOI to SAMC.

C. Management of a FCOI

1. For research involving human subjects, the SAMC will work with the researcher (and or Sponsor) to develop reasonable and possible means for the research to take place while protecting the welfare of research participants, as well as the objectivity and scientific integrity of the research. Listed below are several possible resolutions for management of the FCOI that may be recommended:

   - Modification of the research plan;
   - Change of personnel or their responsibilities, or disqualification of personnel from participation in all or a portion of the research;
   - Disclosure of an FCOI within the informed consent document (for human subjects research);
   - Public disclosure of an FCOI when presenting or publishing the research;
   - 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;
   - Reduction or elimination of the SFI (e.g., sale of an equity interest); or
   - Severance of relationships that create FCOI.

2. Notify the Investigator of the Management Plan and obtain confirmation of the Investigator's agreement with it;

3. Take steps to properly oversee compliance with the Management Plan;

4. Reporting of a FCOI

   - For PHS-funded research, SAMC will provide the federal funding agency all FCOI information prior to the expenditure of funds and within 60 days of any subsequently identified FCOI;

- For all research regardless of funding, SAMC shall provide a written response to any request (within five business days of the request) for information concerning a SFI that meets the following three criteria:

  a) The SFI was disclosed and is still held by the Investigator;
  b) SAMC officials determine that the SFI is related to the research;
  c) SAMC officials determine that an FCOI exists (SFI could directly and significantly affect the design, conduct, or reporting of the PHS-funded research).

  Such written response shall include the following information:

  a) Investigator's name;
  b) Investigator's title and role with respect to the research project;
  c) Name of the External Entity in which the SFI is held;
  d) Nature of the SFI; and
  e) Approximate dollar value of the SFI (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.

5. Sanctions

- No-Compliance

  Sanctions and penalties for non-compliance with this policy or Management Plans arising from this policy will be determined by the IRB with advice from the Organizational Integrity Officer, the Chief Medical Officer, and possibly the President of the Medical Staff (when there is non-compliance by a physician member of the Medical Staff). Sanctions may include, but are not restricted to:

  a) Removal of Investigator from participation in research;
  b) IRB suspension of study approval;
  c) Letter of reprimand;
  d) Termination of financial support from a PHS-funded SAMC award;
  e) Notification to funding agencies and/or professional journals and societies;
  f) Corrective action up to an including termination for non-compliant SAMC employees.

- Maintenance of Records

  All records related to the implementation of this policy (e.g., disclosure forms, minutes of meetings called to manage conflicts, notifications to funding agencies) shall be maintained by the Research Center. These records will be kept in a

secured fashion for a period of at least three years following the termination or completion of the research activities.

REGULATORY REFERENCES:

42 CFR 50 Subpart F	Promoting Objectivity in Research
45 CFR 94	Responsible Prospective Contractors
21 CFR 54	Financial Disclosure By Clinical Investigators