

**SAINT AGNES MEDICAL CENTER**  
**CLINICAL RESEARCH CENTER**  
Fresno, California

**STANDARD OPERATING PROCEDURES**  
**Institutional Review Board**

Date Effective: July 25, 2003  
Date Last Revised: 07/03  
Date Last Reviewed: 04/10

Index No. R – 1229

**SUBJECT: CONFLICT OF INTEREST / FINANCIAL DISCLOSURE**

1. PURPOSE

- To protect the rights of human subjects participating in research and to avoid conflicts of interest between the research participant's interest and that of the Investigators, the Institution, the research staff and the IRB.
- To protect participants from potential risks, either implied or actual, that might present themselves while members of the medical staff (researchers), IRB members and medical center employees (research staff) conduct their personal affairs simultaneously with their professional activities.
- To avoid unacceptable ethical, legal, financial or other conflicts of interest and to ensure that research activities and researchers interests do not conflict with the conduct of ethical unbiased research principles.
- To establish a process of disclosure and independent review when an Investigator, research staff, or IRB member has significant personal financial interest(s) related to a sponsored project that might reasonably appear to be directly and significantly affected by the sponsored project.
- To identify and manage such potential conflicts to assure the objectivity with which projects are designed, conducted or reported.

2. SCOPE

- 2.1. This policy is intended to define what constitutes a significant conflict of interest and the process for disclosing and addressing any conflict in the conduct of clinical research activities conducted at SAMC or approved by SAMC IRB.

- 2.2. Conflict of interest is not restricted to financial interests but includes the potential for professional or personal gain or influence that may be impacted by participation in a research project or affiliation with a sponsor.
- 2.3. This Policy is directed toward disclosure of any significant personal interests which exceed the threshold for disclosure and that would reasonably appear to be directly and significantly affected by the work performed under a sponsored project.
- 2.4. This Policy shall apply to all research projects, independent of funding status or source.
  - 2.4.1. Federal Disclosure Requirements. This Policy implements federal requirements pertaining to "Objectivity in Research" promulgated by the U.S. Public Health Service (PHS), National Science Foundation (NSF) which includes the National Institutes of Health (NIH), and which are published in 42 CFR Part 50 and 45 CFR Part 94. These federal requirements, as implemented in this Policy, are applicable to all proposals for extramural awards. Application of this Policy will be expanded if necessary to comply with official requirements imposed by other federal agencies or other extramural sponsors.
  - 2.4.2. State Disclosure Requirements. This policy will be expanded to respond to financial disclosure requirements of the California Administrative Code to include research proposed for funding to PHS, NIH, NSF will also be sponsored in part by a non-governmental entity.
  - 2.4.3. Investigator Initiated Projects. Projects for which the Investigator does or does not seek support from an entity in the form of materials, resources or monetary compensation are applicable to the Policy and completion of Financial Disclosure Forms are required.

### 3. POLICY

- 3.1. 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 common in modern research universities and do not necessarily impugn the character or actions of any individual.
- 3.2. Any Investigator, research staff member or employee responsible for the design, conduct, or reporting of a sponsored project at the SAMC will be required to disclose personal interests related to that project, pursuant to circumstances specified by this Policy.
  - 3.2.1. Consistent with current federal regulations (42 CFR Part 50.603 and 45 CFR Part 94.3), reporting requirements pertaining to financial interests as defined below require the Investigator to aggregate his or her financial interests with those of his or her spouse and dependent children.

- 3.3. Consistent with current federal regulations this Policy defines significant financial interests as anything of monetary value, including, but not limited to:
  - 3.3.1. Income from a single business entity, including salary, consulting payments, honoraria, royalty payments, dividends, loans from the entity, or any other payments or consideration with value exceeding \$10,000 during the prior twelve months when aggregated for an Investigator and the Investigator's spouse and dependent children;
  - 3.3.2. Income from a single public or nonprofit entity, including salary, consulting payments, honoraria, royalty payments, dividends, loans from the entity, or any other payments or consideration with value, exceeding \$10,000 during the prior twelve months when aggregated for an Investigator and the Investigator's spouse and dependent children, excluding income from seminars, lectures, teaching engagements, or service on advisory committees or review panels for public or nonprofit entities;
  - 3.3.3. An equity interest, in the form of stock, stock options, real estate, or any other investment or ownership interest, a 5% ownership interest, or a loan to the entity, exceeding \$10,000 in value (current market value if publicly traded; internal estimate of value if not publicly traded; otherwise, amount of investment), for any one enterprise when aggregated for an Investigator and the Investigator's spouse and dependent children;
  - 3.3.4. A management position such as board member, director, officer, partner, or trustee, held by the Investigator; or
  - 3.3.5. Intellectual property interest held by the Investigator, or Investigator's spouse or dependent children on a patent, patent application, or a copyright of software assigned or to be assigned to the sponsoring / supporting entity.
- 3.4. When investigator's involvement on the sponsored project reasonably appear to affect the Investigator's significant financial interest, the interest is regarded as related to the sponsored project and must be disclosed.
- 3.5. The designation of an Investigator's financial interest as being related to the sponsored project, under the terms of this Policy, does not in and of itself imply the existence of an actual or potential conflict of interest. The existence of a conflict of interest is determined by review of the designated SAMC Official or the OIP Officer.
- 3.6. Consistent with current federal regulations, the following are significant financial interests which are considered "related" to a sponsored project:
  - 3.6.1. The Investigator is carrying out a project and the results of that project would be relevant to the development, manufacturing, or improvement of the products or services of the entity in which there is a financial interest;

- 3.6.2. The Investigator has a financial interest in an entity which might manufacture or commercialize a drug, device, procedure, or any other product used in the project, or that will predictably result from the project;
- 3.6.3. The Investigator has consulting income from a single entity that exceeded \$10,000 during the prior twelve months, and the financial interests of that entity, or the Investigator's financial interests related to consulting for that entity would reasonably appear to be affected by the research.
- 3.6.4. In assessment of which, if any, of the Investigator's financial interests related to consulting (or which, if any, of the financial interests of the entity to which the Investigator consults) would reasonably appear to be affected by the proposed research may be made by the Investigator based on his or her expertise in his or her professional field; those interests are to be reported if they exceed the reporting threshold of \$10,000 from a single entity during the prior twelve months.
- 3.6.5. The Investigator has a financial interest in an entity and the sponsored project proposes to subcontract a portion of the work, or to make referral of participants to, or make purchases from the entity; or
- 3.6.6. The Investigator has a financial interest in an entity that is part of a consortium or that will otherwise participate in the sponsored project.
- 3.7. Financial interests not related to the sponsored project do not need to be disclosed.
- 3.8. The Organizational Integrity Program Officer will review projects that may appear to have a conflict of interest either directly and significantly affected by the sponsored project.
- 3.9. Any project that involves an investigator with an identified potential conflict of interest may not be reviewed via expedited review even if the project satisfies the expedited review criteria [R-1211]. This project will be referred to the Organizational Integrity Officer and reviewed by the full Board.

#### 4. PROCEDURE

- 4.1. Conflict of Interest and Financial Disclosure forms are required for all new submissions following initiation of this policy and will be received from all projects currently
- 4.2. The IRB administrative office will be responsible for reviewing forms and documenting completeness.
- 4.3. A designated official [i.e. IRB Chair, Research Director] will review completed Disclosure of Financial Interest forms to determine whether any reported financial interest would reasonably appear to be directly and significantly affected by the sponsored project.

- 4.4. A 'direct impact' occurs when the project results would be directly relevant to the development, manufacturing, or improvement of the products or services of the organization in which the Investigator has a financial interest, or when the organization is a proposed subcontractor or participant in the project.
- 4.5. A 'significant impact' on the financial interest is one that will materially affect the value of the organization, its earnings, or the sales of its products, or the organization is a proposed subcontractor or participant in the project.
- 4.6. Based on information provided in the Disclosure SAMC may determine that there is no reasonable basis on which to conclude that a project could directly and significantly affect the financial interest and that the financial interest is not likely to affect the design, conduct, or reporting of the project. In this case, a record should be made of the Reviewing Official's action and the project can proceed without further review.
- 4.7. In the event that either the Investigator or the Reviewing Official concludes that a project might have a direct and significant impact on the financial interest and that the financial interest could affect the design, conduct or reporting of the project, the Disclosure and appropriate documentation shall be forwarded to the OIP Officer. The same review process takes place when an Investigator files an Update form reporting a new, related financial interest.
- 4.8. When an Investigator has a significant financial interest that is related to the sponsored project, as those terms are defined below, a written disclosure form detailing that interest is required.
- 4.9. When an Investigator does not have a financial interest that is significant and related to the sponsored project, a simple negative statement, in some documented form, may be substituted for the full written disclosure.
- 4.10. The financial interest status will be included in the review process for all projects reviewed either by expedited review or full board review.
- 4.11. This reporting responsibility is separate from an Investigator's ongoing duty to update financial disclosures either annually or as new significant and related financial interests are obtained throughout the period of the project / contract.
- 4.12. If it is determined that such an interest might reasonably appear to be directly and significantly affected by the sponsored project, SAMC will refer the project to the Organizational Integrity Program Officer for review and to initiate steps either to manage or to eliminate the conflict. The OIP Officer makes a final recommendation to the IRB about whether the project should proceed and whether any conditions or restrictions should be placed on the project to manage the conflict of interest. The same review process takes place when an Investigator files an Update form reporting a new, related financial interest.
- 4.13. The OIP Officer may appoint a committee to review disclosures and relevant features of the sponsored project(s) and, on the basis of the review, to make a determination of whether the project does or does not present a potential conflict of interest. Their recommendation is reported to the IRB.

- 4.14. When an Investigator has financial interests that would reasonably appear to be directly and significantly affected by the sponsored project, the OIP officer may recommend that the project may not proceed. Alternatively, the OIP officer may recommend that special conditions or restrictions be imposed to manage the conflict of interest to minimize the effect of the related financial interest(s) on the design, conduct, or reporting of the sponsored project(s).
- 4.15. Investigators may also be asked to make recommendations about how to manage the conflict of interest. Examples of conditions or restrictions that may be imposed to manage or eliminate conflicts of interest include:
  - 4.15.1. Public disclosure of the Related Financial Interest(s), including notice of the interest as an addendum to all publications arising from the project;
  - 4.15.2. Monitoring of the project by independent reviewers;
  - 4.15.3. Modification of the research or project plan;
  - 4.15.4. Disqualification from participation in all or a portion of the project;
  - 4.15.5. Divestiture of the Related Financial Interest(s); or
  - 4.15.6. Severance of relationships that create actual or potential conflicts.
- 4.16. The review of the Disclosure(s) and adoption of conditions or restrictions to manage or eliminate the conflict of interest must be completed within 90 days of receipt of IRB approval before initiating the project, unless the sponsor requires action by an earlier date. Some sponsors may also require a report of the existence of a conflict of interest and assurance that it has been managed, reduced, or eliminated.
- 4.17. In determining whether salary, royalties or other payments constitute significant financial interests, federal regulations require institutions to ensure that their Investigators make their best reasonable estimates of expected income, from a single entity, over the next twelve months.
- 4.18. The best reasonable estimate of expected income from an entity over the next twelve months is the amount of income the Investigator received from the entity, exceeding \$10,000, during the previous twelve months.
- 4.19. The IRB or OIP officer may request more detailed financial information at a later point in the review process if they deem such detail necessary to assess and manage a potential conflict of interest.
- 4.20. A written form or statement is to be completed by Investigators either annually or whenever they acquire new significant financial interests that are related to their projects but were not listed in the original Disclosure of Financial Interest form. The Disclosure and Update form(s) must:
  - 4.20.1. Indicate whether the Investigator has any significant financial interests related to the work to be conducted under the sponsored project(s);

- 4.20.2. Provide the name of each entity in which the Investigator has a significant and related financial interest and the type of the financial interest (income, equity, management position, or intellectual property);
  - 4.20.3. Indicate, for income interests in each entity, whether the aggregate value exceeds \$10,000;
  - 4.20.4. Indicate, for equity interests in each entity, whether the current value exceeds \$10,000;
  - 4.20.5. Indicate, for equity interests in each entity, whether the current percentage of ownership exceeds 5%;
  - 4.20.6. Indicate whether the entity in which the Investigator has a significant financial interest is a proposed subcontractor, consortium member, supplier of goods [i.e. drugs / equipment / devices] or otherwise involved with the sponsored project(s);
  - 4.20.7. Indicate whether the entity in which the Investigator has a significant financial interest might manufacture or commercialize any drug, vaccine, device, procedure or any other product involved in or that will predictably result from the sponsored project(s); and
  - 4.20.8. Provide notice to the Investigator that the disclosure may be released or transmitted to the sponsor, including federal agency representatives, and, according to state law, may also be released to the public upon request.
  - 4.20.9. Finally, the Disclosure and Update form(s) may provide the Investigator with a direct opportunity to indicate whether or not he or she believes the project(s) could directly and significantly affect the Related Financial Interest(s) he or she is reporting.
- 4.21. Failure to file a complete Disclosure of Financial Interest or Update or to comply with any conditions or restrictions imposed on the conduct of the project under this Policy will be reported to the OIP Officer, the IRB Chairperson and the Chief Medical Officer pursuant to SAMC's Policy
  - 4.22. In addition, federal regulations may require reports to the federal sponsor of any information, which may show a violation of policy. Sponsors may suspend or terminate the award and/or debar an Investigator from receiving future projects in the event of failure to comply with applicable regulations on disclosure, review, and management of significant financial interests related to federally sponsored projects.

## REGULATORY REFERENCES:

42 CFR 50.603	Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding Is Sought: Definitions
42 CFR 50.604	Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding Is Sought: Institutional responsibility regarding conflicting interests of investigators
45 CFR 94.3	Responsible Prospective Contractors: Definitions
45 CFR 94.4	Responsible Prospective Contractors: Institutional responsibility regarding conflicting interests of investigators