

SJBSM Financial Conflict of Interest Policy for PHS Investigators

Policy/Procedure

I. PURPOSE

This policy safeguards the integrity, objectivity, and transparency of research conducted at San Juan Bautista School of Medicine (SJBSM). The policy and guidelines are designed to meet the requirements of Federal regulations covering Investigator financial conflicts of interest (42 CFR Part 50 Subpart F for grants and cooperative agreements). The policy provides a framework for identifying, disclosing, managing, and resolving financial conflicts that may arise among investigators conducting research.

II. DEFINITIONS

- A. **PHS:** means the Public Health Service of the U.S. 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 (NIH).
- B. **PHS - Investigator:** a project director or principal investigator or any other person, regardless of title or position, who plans to participate in or participate in PHS federally-funded research and is responsible for the design, conduct, or reporting of the research funded by Federal sources or proposed for such funding, which may include, for example, collaborators and consultants, taking into account the degree of independence with which the person works, which may include, but is not limited to, graduate students, post-doctoral fellows, technicians, collaborators or consultants interested or recipient of PHS – funded grant. **Note:** SJBSM will consider the role, rather than title, of those involved in the research and the degree of independence in which those individuals work when determining who meets the definition of “PHS-Investigator.”
- C. **PHS-Funded Research:** Research funded or proposed to be funded by the Public Health Service of the U.S. Department of Health and Human Services and any components of the PHS to which the authority involved may be delegated, including the NIH and any entity or organization that has incorporated the PHS rules about FCOIs. The term includes but is not limited to research grants, career development awards, center grants, individual fellowship awards, infrastructure awards, institutional training grants, program projects, and research resources awards. Although the PHS regulations exclude Phase I Small Business Innovative Research (“SBIR”) or Small Business Technology Transfer (“STTR”) research from COI requirements, under this policy, Phase I and II SBIR and STTR applications or awards are subject to the exact COI disclosure requirements and review as all other PHS-Funded Research, including PHS-required COI training.’
- D. **Entity** means any domestic or foreign, public or private, organization (excluding a Federal agency) from which an Investigator (and spouse and dependent children) receives remuneration or any person has an ownership or equity interest.
- E. **Disclosure of significant financial interests:** An investigator discloses significant financial interests to an institution.
- F. **Financial conflict of interest (FCOI)** exists when the SJBSM, through its Institutional Official or official designee, reasonably determines that an Investigator’s

Significant Financial Interest is related to a Federally-funded research project (i.e., the Significant Financial Interest could be affected by the research or the Significant Financial Interest is in an entity whose financial interest could be affected by the research) and could directly and significantly affect the design, conduct, or reporting of the Federally-funded research.

- G. **FCOI report:** means a SJBSM's report of a financial conflict of interest to a PHS Awarding Component.
- H. **SJBSM Conflict of Interest Compliance Officer:** An institutional official designated to solicit and review disclosures of Significant Financial Interests from Investigators under the Human Resources Office and President of SJBSM.
- I. **Ad Hoc FCOI Committee:** The committee appointed by the SJBSM President is authorized to review, determine, and create a management plan when FCOI is found.
- J. **Sponsored Program Officer (SPO) :** The institutional official responsible for ensuring that FCOI disclosures and related documents are properly uploaded and submitted to EraCommons, such as the NIH, in compliance with applicable laws, regulations, and institutional policies.
- K. **Institutional Responsibilities** mean teaching, research, research consultation, and institutional committee membership, for example, activities such as research, research consultation, teaching, professional practice, Institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.
- L. **Manage** means taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.
- M. **Research** means a systematic investigation designed to develop or contribute to generalizable knowledge.
- N. **Senior/key personnel** means the principal investigator and any other person identified as senior/key personnel by the SJBSM in the sponsored research application, progress report, or any other report submitted to the funding agency.
- O. **Financial Interest** means all financial interests that have monetary value, whether or not the value is readily ascertainable.
- P. **Significant Financial Interest (SFI)** means:
 - 1. 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 (e.g., research, research consultation, teaching, etc.):
 - a. Regarding any publicly traded entity, if the value of any remuneration received during the 12-month period preceding the disclosure, and the value of any equity interest during the 12-month period preceding or as of the date of disclosure, when aggregated, exceeds \$5,000.
 - b. Regarding any non-publicly traded entity, if the value of any remuneration received during the 12-month period preceding the disclosure, when aggregated, exceeds \$5,000 or when the Investigator holds any equity interest in the entity.
 - c. Intellectual property rights and interests (e.g., patents, copyrights), upon the receipt of income exceeding \$5,000 related to such rights and interests (not reimbursed through SJBSM).

2. The occurrence of any reimbursed or sponsored travel exceeding \$5,000 undertaken by the Investigator and related to the Investigator's institutional responsibilities. It includes travel that is paid on behalf of the Investigator rather than reimbursed, even if the exact monetary value is not readily available. The disclosure requirement excludes travel reimbursed or sponsored by U.S. Federal, state or local governmental agencies, U.S. institutions of higher education, academic teaching hospitals, medical centers, and research institutes that are affiliated with U.S. institutions of higher education.

The term Significant Financial Interest does not include the following types of financial interests; therefore, Investigators do not need to disclose these interests noted below:

- salary, royalties, or other remuneration paid by SJBSM to the Investigator if the Investigator is currently employed or otherwise appointed by SJBSM, including intellectual property rights assigned to SJBSM and agreements to share in royalties related to such rights;
- any ownership interest in the Institution held by the Investigator if the Institution is a commercial or for-profit organization;
- 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 U.S. Federal, state, or local government agency, a U.S. Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a U.S. Institution of higher education; or
- income from service on advisory committees or review panels for a U.S. Federal, state, or local government agency, a U.S. Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a U.S. Institution of higher education.

Note that disclosure of foreign financial interests differs from disclosure of domestic financial interests as it relates to the exclusions described above. Investigators must disclose all foreign financial interests (which includes income from seminars, lectures, or teaching engagements, income from service on advisory committees or review panels, and reimbursed or sponsored travel) received from any foreign entity, including foreign institutions of higher education or foreign governments (which includes local, provincial, or equivalent governments of another country) when such income meets the threshold for disclosure (e.g., income in excess of \$5,000).

III. TRAINING REQUIREMENTS

A. Training Requirements

1. SJBSM PHS- Investigators must complete FCOI training **before engaging** in research related to any Federally-funded grant or contract and at least every four years and immediately under the designated circumstances:
 - a. SJBSM revises FCOI policy that affects Investigator requirements

- b. A PHS- Investigator is new to the SJBSM
- c. A PHS- Investigator is not in compliance with the FCOI policy or management plan.
- 2. To meet the PHS training requirement, Investigators must review this policy and successfully complete the **NIH FCOI Training Module** at FCOI Training | grants.nih.gov.

B. Informing each Investigator

- 1. SJBSM will notify each PHS Investigator seeking or participating in PHS funding of this policy, the Investigator's disclosure responsibilities regarding all foreign and domestic SFIs, and of the FCOI regulation at 42 CFR Part 50 Subpart F to meet the training requirements.

IV. DISCLOSURE, REVIEW, AND MONITORING REQUIREMENTS

A. Investigator Disclosures

- 1. Investigators are required to complete the SJBSM SFI Disclosure Form as follows:
 - a. **Before** submission of a proposal to a PHS funding agency.
 - b. During the PHS-funded grants, investigators will complete an updated SFI Disclosure Form **annually** in August of each year.
 - c. **Within 30 days** of discovering or acquiring a new SFI.
 - d. **New PHS Investigators** joining the SJBSM conducting research sponsored by PHS funding agencies will provide all necessary disclosures within 30 days.
- 2. Using the SJBSM SFI Disclosure Form, each Investigator will disclose their foreign and domestic SFIs (and those of the Investigator's spouse and dependent children) that reasonably appear to be related to the PHS - Investigator's institutional responsibilities (e.g., research, research consultation, teaching, professional practice, etc.).
- 3. Travel disclosures must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration, and, if known, the monetary value.
 - a. The Conflict-of-Interest Compliance Officer will review and determine if additional information is needed (e.g., the monetary value if not already disclosed) to determine whether the travel is related to the PHS-funded research and constitutes an FCOI. The initial disclosure of reimbursed or sponsored travel should include income received over the previous 12 months. PHS- Investigators must submit an updated disclosure of reimbursed or sponsored travel within 30 days of each occurrence.

B. Review of Disclosures

The Conflict-of-Interest Compliance Officer will solicit review PHS - Investigator SFI disclosures (and those of the PHS Investigator's spouse and dependent children) related to the PHS- Investigator's institutional responsibilities for a determination of FCOI before the expenditure of any funds and determine whether an FCOI exists.

An FCOI exists, through its Conflict-of-Interest Compliance Officer, reasonably determines that an Investigator's SFI is related to a PHS-funded research project based on the criteria below:

- the SFI could be affected by the research or
- the SFI in an entity whose financial interest could be affected by the research and
- the SFI could directly and significantly affect the design, conduct, or reporting of the Federally-funded research.

C. Management Plans

If the Conflict-of-Interest Compliance Officer, with the assistance, if necessary, of appropriate members from the Ad Hoc FCOI Committee, determines that there is an FCOI, the Ad Hoc FCOI Committee must approve a written management plan to manage, reduce, or eliminate the conflict before any related research commences. Such plans will be designed to meet applicable legal requirements, facilitate resolving or managing any conflict, and protect the sensitivity of disclosed information. The affected PHS-Investigator is responsible for developing and submitting a proposed management plan to, and in consultation with, the Conflict-of-Interest Compliance Officer.

Management plans may contain one or more elements, including:

1. public disclosure of FCOIs (e.g., when presenting or publishing the research, to staff members working on the project, to the SJBSM Institutional Review Board, etc.);
2. for research projects involving human subjects research, disclosure of FCOIs directly to participants;
3. monitoring of the sponsored program by independent reviewers;
4. modifications of the research plan;
5. appointment of an oversight panel or person to review research;
6. limitations on the Investigator's involvement in all or a portion of the funded research;
7. divestiture of SFIs;
8. severance of relationships that create actual or potential conflicts and/or
9. other arrangements that manage, reduce, or eliminate a potential FCOI.

The management strategies will be incorporated into a Memorandum of Understanding (MOU) between SJBSM and the PHS-Investigator, which will detail the conditions or restrictions imposed upon the PHS-Investigator in the conduct of the project or the relationship with the business entity. The Management Plan MOU will be signed by the Investigator and the SJBSM President and filed with the Office of Human Resources.

If the Ad Hoc FCOI Committee determines that imposing the conditions or restrictions would be ineffective or inequitable or that the detrimental effects that may arise from a significant financial interest are outweighed by interests of scientific progress, technology transfer, or the public health and welfare, then the Ad Hoc FCOI Committee may decide that, to the extent permitted by Federal regulations, the research go forward without imposing such conditions or restrictions. In these cases, the Ad Hoc FCOI Committee shall make the final decision regarding resolution.

V. REPORTING REQUIREMENTS

A. Reporting Requirements to a PHS agency

The review of disclosures and development of any necessary management strategies shall be conducted before the expenditure of funds under a new award and within 60 days of identifying an FCOI during the period of an award for PHS-Investigators newly assigned to an existing project or for newly identified FCOIs for existing PHS- Investigators.

If any identified conflict or noncompliance requires reporting to the sponsoring Federal agency, the SPO will provide such a report in accordance with applicable regulations.

B. Reporting Requirements Specific to NIH

1. The Conflict-of-Interest Compliance Officer shall send initial, annual, and revised FCOI reports, including all reporting elements required by the regulation, to the SPO to submit to the PHS- agency for SJBSM and its subrecipients, if applicable, as required by the regulations in 42 CFR 50.604(h) and/or 42 CFR 50.605(b). This shall be performed:
 - a. Before the expenditure of funds
 - b. Within 60 days of identification for PHS-Investigator who is newly participating in the project
 - c. Within 60 days for new or newly identified FCOIs for existing PHS-Investigators
 - d. At least annually (at the same time as when SJBSM is required to submit the annual progress report, multi-year progress report, if applicable, or at the time of extension) to provide the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project.
 - e. Following a retrospective review, update a previously submitted report if new information is discovered following completion of the review. 42 CFR 50.605(a)(3)(iii).
2. All original FCOI reports must include sufficient information to enable the PHS agency to understand the nature and extent of the FCOI and to assess the appropriateness of the SJBSM's management plan. The original FCOI report to the National Institutes of Health and any other PHS agency that utilizes the eRA Commons FCOI Module, must be submitted through the eRA Commons FCOI Module by the SJBSM's designated FCOI SO, must include the following key elements (but are not necessarily limited to the following):
 - a. Project number;
 - b. PD/PI or Contact PD/PI if a multiple PD/PI model is used;
 - c. Name of the Investigator with the FCOI;
 - d. Name of the entity with which the Investigator has an FCOI;
 - e. Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
 - f. Value of the financial interest (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);

- g. A description of how the financial interest relates to the PHS-funded research and why SJBSM determined that the financial interest conflicts with such research;
 - h. A description of the key elements of the SJBSM's management plan, including:
 - i. Role and principal duties of the conflicted Investigator in the research project;
 - ii. Conditions of the management plan;
 - iii. How the management plan is designed to safeguard objectivity in the research project;
 - iv. Confirmation of the PHS- Investigator's agreement to the management plan;
 - v. The management plan will be monitored to ensure PHS - PHS- investigator compliance and other information as needed.
3. Based on the results of a retrospective review, the SPO shall notify the PHS agency promptly if bias is found with the design, conduct, or reporting of PHS-funded research and submit the required Mitigation Report. The Mitigation Report must include, at a minimum, the key elements of the retrospective review and a description of the impact of the bias on the research project and the SJBSM's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project, extent of harm done [including any qualitative and quantitative data to support any actual or future harm], analysis of whether the research project is salvageable). 42 CFR 50.605(a)(3)(iii)
4. The SPO shall notify the PHS agency promptly if a PHS- Investigator (or subrecipient Investigator) fails to comply with this policy or if an FCOI management plan appears to have biased the design, conduct, or reporting of the PHS-funded research. 42 CFR 50.606(a).
- a. This policy confirms the SJBSM's requirement to notify the PHS agency promptly and take corrective action for noncompliance with this policy or any management plan that has been developed.

VI. VIOLATIONS OF FCOI IN RESEARCH POLICY

A. PHS- Investigator Noncompliance

Whenever a PHS- Investigator has violated this policy or the terms of any resolution plan required by the Conflict-of-Interest Compliance Officer or Ad Hoc FCOI Committee (including failure to file or knowingly filing incomplete, erroneous, or misleading disclosure forms), the Conflict-of-Interest Compliance, who, in consultation with the SJBSM Human Resource Office, will impose sanctions or institute disciplinary proceedings against the PHS-Investigator in compliance to SJBSM Conflict of Interest Policies.

In addition, SPO shall follow federal regulations regarding notifying the sponsoring agency if a PHS Investigator fails to comply with this policy. The sponsor may take its own action as it deems appropriate, including suspending funding for the PHS Investigator until the matter is resolved.

B. Enforcement Mechanisms and Remedies and Noncompliance Specific to PHS-agency

1. The Conflict-of-Interest Compliance Officer shall complete and document a retrospective review of the PHS Investigator's activities and the PHS-funded research 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 the PHS- funded research. The retrospective review will be performed within 120 days of the SJBSM's determination of noncompliance for SFIs when they are:
 - a. not disclosed in a timely manner or
 - b. not previously reviewed or
 - c. whenever an FCOI is not identified or managed in a timely manner, including:
 - i. Failure by the Investigator to disclose an SFI that is determined by SJBSM to constitute an FCOI;
 - ii. Failure by SJBSM to review or manage such an FCOI;
 - iii. Failure by the Investigator to comply with the FCOI management plan.
2. The retrospective review shall include, at a minimum, the following key elements:
 - a. Project Number;
 - b. Project Title;
 - c. PD/PI or contact PD/PI if multiple PD/PI model is used;
 - d. Name of the Investigator with the FCOI;
 - e. Name of the entity with which the Investigator has an FCOI;
 - f. Reasons for the retrospective review;
 - g. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documentation reviewed);
 - h. Findings of the review; and
 - i. Conclusions of the review
3. The Conflict-of-Interest Compliance Officer shall ensure that in any case in which the Department of Health and Human Services determines that a PHS or NIH-funded research 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 a PHS-Investigator with an FCOI that was not managed or reported by the SJBSM as required by the regulation, the SJBSM shall require the Investigator involved to:
 - a. Disclose the FCOI in each public presentation of the results of the research and
 - b. Request an addendum to previously published presentations.

VII. MAINTENANCE OF RECORDS

The Office of Human Resources shall maintain all FCOI-related records pertaining to all PHS-Investigator disclosures of SFIs and the SJBSM's review of and response to such disclosures (whether or not a disclosure resulted in the SJBM's determination of an

FCOI) and all actions under the SJBSM's policy or retrospective review, if applicable, shall be retained for at least three years from the date the final expenditure report is submitted, or, where applicable, from other dates specified in 45 CFR 75.361.

VIII. COLLABORATIVE PROJECTS/SUBRECIPIENT REQUIREMENTS

A. Collaborative Projects/Subrecipient Requirements

The awardee institution is responsible for ensuring any subrecipient's compliance with the regulation and reporting identified FCOIs for subrecipient Investigators to the PHS. Awardee institutions must incorporate as part of a written agreement with a subrecipient terms that establish whether the FCOI policy of the awardee institution or that of the subrecipient will apply to subrecipient PHS-Investigators and include time periods to meet disclosure and/or FCOI reporting requirements.

Subrecipient institutions that rely on their FCOI policy must report identified FCOIs to the awardee institution in sufficient time for the awardee institution to report the FCOI to the PHS agency to meet its reporting obligations.

Subrecipient institutions that must comply with the SJBSM's policy must submit all Investigator disclosures of SFIs directly related to the subrecipient's work for the SJBSM. The submission of disclosures to the SJBSM must be in sufficient time to allow the SJBSM to review, manage, and report identified FCOIs to the PHS-agency.

The SJBSM is responsible for monitoring the subrecipient's compliance with the FCOI regulation and management plans and reporting all identified FCOIs to the PHS-agency.

IX. PUBLIC ACCESSIBILITY REQUIREMENTS

- A. The SJBSM will make this FCOI policy publicly accessible on the website.
- B. The SJBSM will make available information concerning identified FCOIs held by senior/key personnel (as defined above and by the regulation) publicly accessible within five business days. The information will:
 - 1. Include the minimum elements as provided in the regulation
 - 2. Be posted on a public website or made available within five business days of a written request
 - 3. Be updated at least annually (website only, but any response to a written request should include the updated information)
 - 4. Be updated within 60 days of a newly identified FCOI (website only, but any response to a written request should include the updated information)
 - 5. Remain available for three years from the date the information was most recently updated.

Endorsed by the SJBSM Institutional Research Committee: October 23, 2024

Approved by: Dr. Yocasta Brugal, SJBSM President

Effective Date: Nov-6-2024