

Saint Joseph's University Research Financial Conflict of Interest Policy

Introduction

As a recipient of funds from public and private sources to support research activities, Saint Joseph's University ("SJU") is required to maintain policies and processes consistent with federal and state regulations and policies of individual research sponsors concerning financial conflicts of interest in research. These requirements exist to maintain the trust of the public, our research volunteers, and the SJU community.

SJU recognizes and values the importance of researcher relationships with external entities. While such relationships provide benefit and support to our research activities, in some instances such activities give rise to potential financial conflicts of interest. Conflicts of interest have the potential to influence key elements of a research program, such as study design, data collection and analysis, as well as choice of vendors for research supplies. These conflicts are not inherently bad, nor are they always evidence of bias. However, our role as stewards of research funding requires that we identify and manage such conflicts so as not to put our research, or public confidence in our research, at risk.

SJU's policy on research financial conflict of interest (hereinafter, the "FCOI Policy") is intended to conform to the 2011 revised Department of Health and Human Services' Public Health Service FCOI regulation applicable to the National Institutes of Health (NIH), [Promoting Objectivity in Research \(42 CFR Part 50 Subpart F\)](#), as well as the National Science Foundation [Grant Policy Manual \(Chapter IX-A\)](#).

This FCOI Policy applies to each Investigator (as defined below) who is planning to participate in or is participating in research, whether or not such research is federally funded. This FCOI Policy is separate from and in addition to SJU's [Business Code of Conduct and Conflict of Interest Policy](#).

Definitions

1. **Investigator** means the project director, principal investigator, co-principal investigators and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research or educational activities, which may include, for example, collaborators or consultants.
2. **Institutional Responsibilities** means an Investigator's professional responsibilities on behalf of Saint Joseph's University, including, but not limited to, teaching, research, extension/outreach, professional practice, and institutional committee memberships.
3. **Externally Funded Research** is research funded by a public or private entity separate from the university through a gift, grant, award, contract, cooperative agreement or similar arrangement and administered through the University or the Office of Sponsored Programs.
4. **Significant Financial Interest (SFI)** means a financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse or domestic partner and dependent children) that reasonably appears to be related to the Investigator's Institutional Responsibilities:
 - With regard to any publicly traded entity, a SFI exists if the value of any remuneration received from the entity in the twelve (12) 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;

- With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve (12) months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
- Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

Investigators also must disclose any reimbursed travel or travel paid on behalf of the Investigator (i.e., not reimbursed to the Investigator), related to their Institutional Responsibilities. This disclosure requirement does not apply to travel that is reimbursed or sponsored by a federal, state, or local government agency; a U.S. Institution of higher education, a U.S. academic teaching hospital, a U.S. medical center, or a U.S.-based research institute that is affiliated with a U.S. Institution of higher education.

Investigators may be required to disclose additional information as required in the applicable grant agreement or sponsored research agreement.

The following are excluded from the definition of SFI unless otherwise stated in the applicable grant agreement or sponsored research agreement:

- Salary, royalties, or other remuneration paid by SJU to the Investigator if the Investigator is currently employed or otherwise appointed by SJU;
- Intellectual Property Rights assigned to SJU and agreements to share in royalties related to such rights;
- 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, a U.S. Institution of higher education, a U.S. academic teaching hospital, a U.S. medical center, or a U.S.-based 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 federal, state or local government agency, a U.S. Institution of higher education, a U.S. academic teaching hospital, a U.S. medical center, or a U.S.-based research institute that is affiliated with a U.S. Institution of higher education.

5. **Financial Conflict of Interest (FCOI)** means an SFI that could directly and significantly affect the design, conduct, or reporting of research.

6. **Sponsor or Financially Interested Entity** with respect to any research conducted by an Investigator is an entity which:

- Funds such research in whole or in part, whether through a gift, contract, or other arrangement;
- Supplies devices or other goods that are the subject of such research, or services or other deliverables in connection with the research by a research agreement or otherwise;
- Owns, licenses, or has other contractual interest in a technology or intellectual

- property investigated in the research; or
 - Acts for or on behalf of another entity, directly or indirectly that meets one or more of the preceding criteria.
7. **Public Health Service (PHS) Agencies** are the United States Department of Health and Human Services public health agencies, including the National Institutes of Health (NIH), Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC), Indian Health Service (IHS), Health Resources and Services Administration (HRSA), Substance Abuse and Mental Health Services Administration (SAMHSA), Agency for Healthcare Research and Quality (AHRQ), Centers for Medicare & Medicaid Services (CMS), Administration for Children and Families (ACF), Agency for Toxic Substances & Disease Registry (ATSDR), Office of Global Affairs (OG), Office of the Assistant Secretary for Health (OASH), Office of the Assistant Secretary for Planning & Evaluation (ASPE), Office of the Assistant Secretary for Preparedness & Response (ASPR), Office of Public Health and Science (OPHS), Administration on Aging (AoA), Federal Occupational Health (FOH).
- Other sponsors also follow the same policies as PHS agencies. At the time of this policy these include (but may not be limited to) the Alliance for Lupus Research (ALR), the Alpha-1 Foundation, the American Cancer Society (ACS), the American Heart Association (AHA), the American Lung Association (ALA), the Arthritis Foundation (AF), CurePSP, the Juvenile Diabetes Research Foundation (JDRF), the Lupus Foundation of America (LFA), the Patient-Centered Outcome Research Institute (PCORI), Susan G. Komen for the Cure, the Alzheimer's Drug Discovery Foundation (ADDF), the Crohn's and Colitis Foundation (CCF), Johnson & Johnson.

Mandatory Training

Each investigator must complete FCOI training prior to engaging in research related to any Externally Funded Research and at least every four years, and immediately under the following circumstances:

- this FCOI Policy changes in a manner that affects Investigator requirements;
- An Investigator is new to SJU; or
- SJU finds an Investigator noncompliant with this FCOI Policy or management plan.

SJU's current FCOI training is offered through the Collaborative Institutional Training Institute (CITI). To meet the mandatory training requirement in this section of this FCOI Policy, Investigators must complete the CITI Conflict of Interest mandatory modules. Instructions for registering, adding an affiliation with SJU, and adding the COI modules are available via the Office of Research Services website.

SFI Disclosure Procedure & Timing

For submission of SFI disclosures, see the information provided on the following page of the Office of Research Services website.

At Time of External Funding Application

- Each Investigator, including subrecipient Investigators, if applicable, must submit an

updated Research-Based Disclosure to the Office of Research Services at time of application.

Annually

- Each Investigator must submit an updated disclosure of SFI at least annually.

At Time of Acquisition or Discovery

- Within 30 days: Each Investigator must submit an updated disclosure of SFI within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI.

Review of Disclosed SFIs

The Director of Research Services will review all disclosure forms within 10 working days of receipt. If the Director, Research Services concludes that an SFI could directly and significantly affect the design, conduct, or reporting of sponsored projects or research, the Director, Research Services will consult with the Associate Provost for Faculty and Academic Support to determine if the SJU FCOI Committee should be convened to decide if an FCOI exists.

A FCOI exists when the Research FCOI Committee reasonably determines that any SFI could directly and significantly affect the design, conduct, or reporting of the research.

Management of FCOIs

Where a FCOI has been identified, the Office of Research Services and the Research FCOI Committee will work with the Investigator(s) to develop a management plan to manage, reduce, or eliminate any actual or potential financial conflict of interest presented by a significant financial interest. Possible approaches include, but are not limited to the following:

- Public disclosure of FCOIs, or in the case of human subjects research, disclosure of FCOIs to research participants;
- Appointment of independent monitor(s) capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the FCOI;
- Modification of the research plan;
- Change of personnel or personnel responsibilities or disqualification of personnel from participation in all or a portion of the related project or research;
- Reduction or elimination of the significant financial interest (e.g., sale of an equity interest); and/or
- Severance of relationships that create actual or potential FCOIs.

In each case in which a management plan is developed, the Office of Research Services and the Research FCOI Committee will monitor the implementation of such management plan through the earlier of the elimination of any FCOI or the conclusion of the research and any related publications.

Whenever SJU receives notice or becomes aware of a SFI that was not disclosed in a timely manner by an Investigator or, for whatever reason, was not previously reviewed by the University, within 60 days the Research FCOI Committee will review the SFI; determine whether it is related to the Investigator's Institutional Responsibilities; determine whether a

FCOI exists; and, if so:

- Implement, on at least an interim basis, a management plan that specifies the actions that have been, and will be, taken to manage such FCOI going forward; and
- Within 120 days of the determination, complete a retrospective review of the Investigator's activities to determine whether any research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research; and
- If necessary, SJU will notify any Sponsor or Financially Interested Entity, including, without limitation, any federal or state agency, in accordance with the Reporting section below; and
- Implement such other additional measures as SJU or the Research FCOI Committee determine are necessary.

In the event that the Research FCOI Committee determines that there was any bias, the Research FCOI Committee, in consultation with the Institutional Official and appropriate advisors and University offices, will develop, and, as required, report, a corrective action plan.

Violations

In the event that the Research FCOI Committee determines that a SFI was not timely disclosed in compliance with this FCOI Policy and that such failure was a breach or violation of the requirements of this FCOI Policy, the Research FCOI Committee shall report such breach or violation to the Provost and the Chief Human Resources Officer, and as necessary or appropriate, develop a corrective action plan. Violators of this FCOI Policy may be subject to institutional sanctions up to and including termination of employment or appointment.

Reporting of FCOIs

Public Health Service (PHS)-funded Research

SJU is required to file certain reports to PHS funding agencies, including, without limitation in the event that an Investigator is determined to have a FCOI and/or there is a retrospective review, determination of bias or corrective action. These reports will be completed by the staff of the Office of Research Services, and do not need to be completed by the investigator.

In addition, SJU may be required to report certain information about certain FCOIs, including information about the Investigator and the SFI, either via a publicly accessible website or within five (5) days following a request for such information. The Office of Research Services will be responsible for publishing or providing such information as required.

All disclosures and other information and records, including, without limitation, regarding SFIs, FCOIs, retrospective reviews and corrective actions, are subject to review by the PHS Agencies.

National Science Foundation (NSF)-funded Research

SJU is required to notify the NSF's Office of the General Counsel if SJU finds that it is unable to satisfactorily manage a FCOI. FCOIs that cannot be managed, reduced, or eliminated must be submitted electronically via the NSF FastLane system.

Other Sponsor or Financially Interested Entity

SJU may be required to report certain information regarding Investigators, SFIs, FCOIs, retrospective reviews and corrective actions to other Sponsors or Financial Interested Entity(ies), including pursuant to applicable grant agreements or sponsored research agreements. The Office of Research Services will provide all such reports and information to the applicable Sponsor or Financially Interested Entity.

Subrecipient Monitoring

When SJU carries out any Externally Funded Research through a subrecipient, the University will take reasonable steps to ensure that any subrecipient Investigator complies with applicable regulations, this FCOI Policy and any applicable grant agreement or sponsored research agreement terms by:

1. Incorporating terms as part of a written agreement with the subrecipient that establish whether this FCOI Policy or the subrecipient's policy will apply to the subrecipient's Investigators.
2. If the subrecipient's Investigators are to comply with the subrecipient's FCOI policy, the subrecipient must certify that its policy complies with any sponsor imposed FCOI regulations and the agreement will specify the time period(s) for the subrecipient to report all identified FCOIs to SJU. If the subrecipient cannot provide such certification, its Investigators must comply with this FCOI Policy.
3. If the subrecipient's Investigators are to comply with this FCOI Policy, the agreement will specify the time period(s) for the subrecipient to submit all Investigator disclosures of SFIs to SJU.