SECTION 1 – OVERVIEW, APPLICABILITY AND RESPONSIBILITIES

1.1 Statement of Background and Purposes

The United States Department of Health and Human Services (DHHS) has amended its regulations (set forth in 42 CFR chapter I, subchapter D, part 50, and 42 CFR subtitle A, subchapter A, Part 94) (the Amended Regulations) to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under Public Health Service (PHS) grants or cooperative agreements, or performed under PHS contracts will be free from bias resulting from investigator financial conflicts of interest. This policy confirms the commitment of Saint Joseph’s University (SJU) to the basic values of openness, academic and scholarly integrity and objective and ethical research and is intended to conform SJU policy to the Amended Regulations and to supplement the existing Code of Conduct and Conflict of Interest policies and procedures of SJU.

In addition to supporting the basic values of SJU, this policy is also designed to:

- Identify and eliminate or manage any possible threat to the objectivity of research performed at SJU in connection with grants and sponsored projects funded by PHS/DHHS and PHS/DHHS-funded agencies (which include but are not limited to grants or sponsored projects funded by the National Institutes of Health (NIH), or under PHS contracts.

- Satisfy the Amended Regulations requiring the SJU to establish and implement policies concerning Significant Financial Interests held by:
  1. Personnel engaged in research funded by certain federal agencies, e.g., Public Health Services (Title 42 CFR Part 50, Subpart F and 45 CFR Part 94) and the National Science Foundation (Award and Administration Guide),
  2. Institutional Review Board members (Title 45 CFR Part 46.107(e)), and
  3. Any personnel who may become involved in research involving human subjects funded by the Department of Health and Human Services.

- Protect researchers and other Employees from misplaced charges of Financial Conflicts of Interest by providing a mechanism for prior objective review and approval of Financial Interests.

1.2 Applicability

This policy applies to all research grants and sponsored projects funded or proposed to be funded by PHS/DHHS-funded agencies, including but not limited to the National institutes of Health, and to research performed in connection with PHS/DHHS contracts.
Furthermore, the policy applies to Project Directors, Principal Investigators, and any other Senior/key personnel (as defined below) on the grant or sponsored project, and all subrecipients related to NIH funded grants and sponsored projects funded or proposed to be funded by a PHS Agency.

Subrecipients on PHS/DHHS-funded projects are subject to and required to comply with and follow the regulations as set forth in Financial Conflict of Interest Regulation, Promoting Objectivity in Research (42 CFR Part 50 Subpart F and 45 CFR Part 94), even though the subrecipients are not directly awarded the funds from PHS or any PHS/DHHS agency. Subrecipients must demonstrate or provide adequate assurances that the policies and procedures of their institutions are in compliance with the regulation.

Dept. of Health and Human Services (DHHS) / Public Health Services (PHS) Agencies:

Administration for Children and Families (ACF)
Administration on Children, Youth and Families (ACYF)
Administration for Community Living (ACL)
Agency for Healthcare Research and Quality (AHRQ)
Agency for Toxic Substances and Disease Registry (ATSDR)
Centers for Disease Control and Prevention (CDC)
Centers for Medicare & Medicaid Services
Food and Drug Administration (FDA)
Health Resources and Services Administration (HRSA)
Indian Health Services (IHS)
National Institutes of Health (NIH)
National Cancer Institute (NCI)
Substance Abuse and Mental Health Services Administration (SAMHSA)

1.3 Definitions

Board of Trustees
The Board of Trustees of SJU.

COI Officer
The Financial Conflict of Interest Officer, who will be the Director of Research Services or his or her designee.

Dependent
An Employee’s spouse, Domestic Partner or unemancipated child(ren), including stepchildren and adoptees, under the age of 18, or anyone who receives more than one-half of his or her financial support during a year from an Employee.

Domestic Partner
A same sex domestic partner of an Employee.
**Employee**
Any employee of SJU, wherever located and whether full-time or part-time, including, but not limited to, all executive officers, faculty and staff.

**Equity Interest**
Any ownership interest in a company or business, including, but not limited to, stocks, stock options or warrants, membership or partnership interests or rights, and similar interests.

**Financial Conflict of Interest**
Situations where an Employee’s Financial Interest (including an Investigator’s Significant Financial Interest, where applicable) compromises, or could appear to compromise, his or her judgment or ability to carry out the Institutional Responsibilities associated with his or her appointment or employment. A Financial Conflict of Interest may take many forms, but in general arises when an Employee in a relationship with an outside person or organization is in a position to influence SJU’s business, research or decisions in ways that could lead directly or indirectly to financial gain for the Employee or the Employee’s Dependents or could give an improper advantage to others to the detriment of SJU.

When applied to an Investigator, Financial Conflicts of Interest occur in situations in which such Investigator’s Financial Interest (including Significant Financial Interest) compromises, or could appear to compromise, his or her professional judgment regarding the design, conduct or reporting of research or if such Financial Interest could directly and significantly affect the design, conduct or reporting of research. The bias such conflicts may conceivably impart not only affects collection, analysis and interpretation of data, but also the hiring of staff, procurement of materials, sharing of results, choice of protocol, involvement of human participants and the use of statistical methods.

Financial Conflicts of Interest also include the use of SJU facilities, personnel, equipment, Information Technology Resources, confidential information or other resources for purposes that could lead directly or indirectly to financial gain for the Employee and/or his or her Dependents.

**Financial Interest**
Any interest that will, could, or is intended to lead to a profit or an ascertainable increase in the income or net worth of an Employee and/or a Dependent. Such a profit or increase in income or net worth could be realized through the receipt of anything of monetary or potential monetary value, including, but not limited to, payments of any kind (e.g., salary, consulting fees, honoraria, gifts, dividends, distributions, rent, paid authorship, etc.), Equity Interests, an increase in the value of real estate or Equity Interests, or Intellectual Property Rights.

**Institutional Responsibilities**
An Employee or Investigator’s professional responsibilities on behalf of SJU, including, but not limited to, 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.
Intellectual Property Rights
Any interest in intellectual property, including, but not limited to, patents, copyrights, licenses, royalties from such rights, agreements to share royalties and similar interests.

Investigator
A project director, a principal investigator of a research project and any other person, regardless of title or position, who has responsibility for the design, conduct or reporting of research or project results at or involving SJU, including Employees, subgrantees, contractors, subcontractors, collaborators and consultants. In general, any individual specifically named in a proposal and any individual whose resume or curriculum vitae is appended to a proposal is an Investigator for the purposes of this policy.

Management Plan
A plan specifying the actions to be taken to manage an identified Financial Conflict of Interest.

PD
A Project Director.

PI
A Principal Investigator.

President
SJU’s President.

Provost
SJU’s Senior Vice President for Academic Affairs and Provost.

SJU
Any campus, unit, program, or entity of Saint Joseph’s University.

Regulatory Committee
Any SJU committee or board with regulatory oversight responsibilities, including any Institutional Review Boards or similar board or committee.

Research
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 or drug). This includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.
**Senior/key personnel**
The Program Director, Principal Investigator and any other person identified by SJU in a grant application, progress report and any other report submitted to the PHS (or other grant provider) by SJU.

**Significant Financial Interest**
A Financial Interest held by an Investigator and/or an Investigator’s Dependent that reasonably appears to be related to the Investigator’s Institutional Responsibilities and that consists of one or more of the following:

- Remuneration (including salary, consulting fees, honoraria, and paid authorship) received from a publicly traded company during the twelve-month period preceding the date on which an Investigator is making a disclosure, and/or an Equity Interest held in such publicly traded company, if the aggregate value of such remuneration, plus the value of the Equity Interest as of the date of disclosure, exceeds $5,000;
- Remuneration (including, but not limited to, salary, consulting fees, honoraria and paid authorship) received from a non-publicly traded company during the twelve-month period preceding the date on which an Investigator is making a disclosure, if the remuneration exceeds $5,000;
- Any Equity Interest in a non-publicly traded company or business, regardless of value; and
- Any Intellectual Property Rights, regardless of value.

Significant Financial Interest does not include:

- An Employee’s salary or royalties received from the SJU,
- Income from seminars, lectures or teaching engagements sponsored by a federal, state or local government agency or an institution of higher education, or
- Income from service on panels for a federal, state or local government agency or institution of higher education.

**1.4 Exceptions**

Exceptions to this policy are applications for Phase I support under the Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) programs.

**1.5 Project Directors, Principal Investigators, Senior/Key Personnel Responsibilities**

Project Directors, Principal Investigators and other Senior/key personnel are expected to adhere and conform to the requirements as set forth in the policy. Project Directors, Principal Investigators and other Senior/key personnel will be referred to as investigators in the body of this policy.
1.6 Responsibilities

SJU
SJU and its assigned designees are responsible for the overall management and administration of the Financial Conflict of Interest Policy. SJU will maintain and post on its internet Web site a written and enforced policy related to the amended federal Financial Conflict of Interest regulations (FCOI Regulations) and will be responsible for informing Investigators of the FCOI Regulations, SJU’s Financial Conflict of Interest policy, and Investigators’ disclosure responsibilities under the FCOI regulations and SJU’s Financial Conflict of Interest policy.

Office of Research Services
The Office of Research Services (ORS) shall review and make determinations about Financial Conflicts of Interest. In the course of reviewing a Significant Financial Interest, the ORS will determine how the significant financial interest is tied to activities within an Investigator’s field of scientific expertise or medicine as well as teaching, clinical, administrative and purchasing responsibilities. The ORS shall be under the supervision of and report to the Provost Office. ORS, in its responsibilities, may employ and seek review and approval of an Investigator’s significant financial interests from the dean of his or her school and/or chair of his or her department or Institute/Center, as well as the Office of General Counsel.

SECTION 2 – DISCLOSURE, REVIEW AND MANAGEMENT PLANS

2.1 Disclosure Process

Investigators identified in each grant and sponsored project funded or proposed to be funded by any PHS/DHHS agency shall disclose all Significant Financial Interests that are related to their Institutional Responsibilities and expertise.

Travel
Investigators must disclose the occurrence of any reimbursed or sponsored travel related to their Institutional Responsibilities. (Sponsored travel is travel which is paid for on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value is/may not be readily available.) SJU may inquire about and request additional information related to travel disclosed by the Investigator on disclosure forms.

Travel does not include travel reimbursed or sponsored by:

• A Federal, state or local government agency
• An Institution of higher education (as defined at 20 U.S.C. 1001(a)
• An Academic teaching hospital
• A Medical center
• A Research institute that is affiliated with an institution of higher education
Consulting Agreements and Engagements
Special attention must be paid to consulting agreements and engagements. If the consultation appears to be related to the Investigator’s Institutional Responsibilities, then that consulting agreement and engagement must be disclosed on the Significant Financial Interest Disclosure Form regardless of monetary value or aggregated value of remuneration received in the preceding 12-month period or as of the date of disclosure.

A Significant Financial Interest Disclosure Form must be completed and provided to the Office of Research Services by each Investigator:

- After receiving notice of award from the PHS/DHHS agency, but prior to the use of awarded funds.
- Annually, during the period of the award. Annual progress reports require Financial Conflicts of Interest to be disclosed.
- Within 30 days of discovering or acquiring a new Significant Financial Interest as defined above; examples include, but are not limited to, purchase, marriage, inheritance, etc.

Any new Investigator assigned to or joining the research project during either the pre-award or post-award stage of a project shall also complete and provide a Significant Financial Interest Disclosure Form to the Office of Research Services.

SJU, in the course of its duties and responsibilities, may identify a Significant Financial Interest that has not been reported by the Investigator(s). If a Significant Financial Interest is identified by the Disclosure Review Committee, then the Disclosure Review Committee will conduct a review of the Significant Financial Interest and determine if a Financial Conflict of Interest exists. If the Significant Financial Interest is determined to be a Financial Conflict of Interest, then a retrospective review of the project must occur to determine if bias exists in the research.

2.2 Retrospective Review

If a Financial Conflict of Interest is not identified or managed in a timely manner, SJU will within 120 days of making a determination of noncompliance, conduct and complete a retrospective review of the Investigator’s activities and the PHS/DHHS-funded project to determine whether any PHS/DHHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research. Examples of noncompliance include, but are not limited to:

- Failure by an Investigator to disclose a Significant Financial Interest determined by SJU to constitute a Financial Conflict of Interest
- Failure by SJU to review or manage a Financial Conflict of Interest
- Failure by an Investigator to comply with a Management Plan
- Management Plan is determined to have biased the design, conduct, or reporting of the PHS/DHHS-funded research

Each Retrospective Review shall be documented in accordance with applicable DHHS
regulations, and such documentation shall include, but shall not be necessarily limited to the following key elements: (1) Project number, (2) Project Title, (3) PD/PI, (4) Name of the Investigator with the FCOI, (5) Name of the entity with which the Investigator has a FCOI, (6) Reason(s) for the retrospective review, (7) Detailed methodology used for the retrospective review, (8) Findings of the review, and (9) Conclusions of the review.

If appropriate, based upon the results of the retrospective review, SJU shall update any previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward.

If bias is found during the course of the retrospective review, then SJU will promptly notify and submit a mitigation report to the PHS Awarding Component, which mitigation report shall include at a minimum, the key elements documented in the retrospective review and a description of the impact of the bias on the research project and SJU’s action(s) taken to eliminate or mitigate the effect of the bias. Furthermore, if the Department of Health and Human Services determines that a PHS/DHHS-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 an Investigator with an FCOI that was not managed or reported by the institution as required by the regulation, the institution shall require the Investigator to do the following:

- Disclose the FCOI in each public presentation of the results of the research
- Request an addendum to previously published presentations

### 2.3 Management Plans for Conflict

If after reviewing all Investigator disclosures of Significant Financial Interests, the Disclosure Review Committee determines that a FCOI exists with respect to a PHS/DHHS-funded project, the Disclosure Review Committee will review the Management Plan proposed by the Investigator and either approve or add conditions or restrictions to ensure that any FCOI is reduced, eliminated, or managed. Such conditions or restrictions may include, but are not limited to, the following:

- Public disclosure of significant financial interests and financial conflicts of interest;
- For Research Projects involving human subjects, disclosure of FCOIs directly to participants;
- Monitoring of the research by independent reviewers;
- Modification of the planned activities (possibly subject to sponsor approval);
- Disqualification of the affected Investigator from participation in all or part of the project;
- Divestiture by the Investigator of significant financial interests;
- Severance of relationships creating the FCOI.

In all cases, resolution of the conflict or establishment of an acceptable Management Plan must be achieved and approved by the President of SJU before expenditure of any funds under an award.
2.4 Financial Conflict of Interest (FCOI) Reporting

When a Financial of Conflict of Interest exists, then reporting of the FCOI must be performed in a timely manner and sent to the appropriate PHS/DHHS agency. Mandatory reporting of FCOIs and related documents may encompass any one of or all of the following aspects of the FCOI policy:

- Financial Conflict of Interest exists
- Management Plan
- Mitigation Report
- Noncompliance with FCOI Policy

SECTION 3 – OTHER MANAGEMENT AND ADMINISTRATION FUNCTIONS

3.1 Public Disclosure of Conflicts of Interest

Public requests to review Financial Conflicts of Interest must be made in writing and include at a minimum the following information:

- Name and address of the person requesting the information, including the address of where to send the information
- Name of Investigator(s) whose Financial Conflict of Interest information is requested

If the above information is not provided in writing, then SJU will make an attempt to obtain that information in order to process the request. Furthermore, all public requests must be directed to the following office and address location:

   Office of Research Services
   5600 City Avenue
   Philadelphia, PA 19131

The Office of Research Services must provide the requested information within 5 calendar days of receiving a public request starting on the day when all of the information from the public is received by SJU. Investigator(s) relationships that need to be made public are only Financial Conflicts of Interest that are disclosed and continue to be held. The Office of Research Services will respond to the request using the Public Request Disclosure Form.

3.2 Appeals

Appeal of the committee’s decision may be made to the Provost. After the Provost has made a final decision, the committee will inform the Investigator.
**Investigator Training**

SJU will use an online, web-based module to administer training related to the revised Financial Conflict of Interest regulation to all appropriate and applicable Investigators.

Training on Financial Conflict of Interest is mandatory for all Investigators who will propose for funding or are funded by Public Health Services (PHS) / Department of Health & Human Services (DHHS) funds or its affiliating agencies. Training is required under the following circumstances:

- Prior to engaging in covered research (PHS/DHHS Agency funded research)
- Every 4 years
- Revisions to Financial Conflict of Interest Policy and associated changes in the applicable regulations are made
- Revisions are made to procedures associated with Financial Conflict of Interest Policy, if the revised procedures affect requirements of Investigators
- The Investigator is not in compliance with SJU’s Financial Conflict of Interest Policy or with approved Management Plan(s)

**3.3 Compliance**

As part of the Disclosure Statement, each Investigator must certify that, if the Disclosure Review Committee determines a conflict exists, the Investigator will adhere to all conditions or restrictions imposed upon the project and will cooperate fully with the individual(s) assigned to monitor compliance.

**3.4 Enforcement**

Failure to properly disclose relevant financial and other interests or to adhere to conditions or restrictions imposed by the Disclosure Review Committee will be considered a deviation from accepted standards of conducting activity at SJU, which may be subject to appropriate enforcement actions as prescribed by SJU policy, faculty handbook, and employee contracts.

**3.5 Records**

Office of Research and Services and the Office of Financial Affairs will maintain records of all disclosures and associated activities securely and confidentially.

All records will be maintained for a minimum of 3 years from the later of date the final expenditures report is submitted to the PHS/DHHS agency or where applicable for the other time periods specified in Title 45 – Public Welfare Act – Subchapter A: General Administration: Subparts and Sections 74.53 (b) and 92.42 (b).

**Section 4 – Disclosures by Regulatory Committee Members**

If a member of a Regulatory Committee recognizes that he or she has a Financial Interest in a protocol to be reviewed by that Regulatory Committee, or in an entity that may be affected by
the outcome of a protocol to be reviewed by the Regulatory Committee, the committee member must:

- Inform the chairperson of the Regulatory Committee that he or she has a Financial Interest in a protocol to be reviewed.
- Recuse himself or herself from participation in the review of that protocol.
- Return to the chairperson of the Regulatory Committee all materials associated with the review of the protocol.
- Leave the committee meeting room during discussion, deliberation and voting on the protocol, both during the initial meeting and any subsequent meetings of the Regulatory Committee when the protocol is considered for purposes of initial or continuing review, for discussion of unexpected or adverse events or for non-compliance associated with the protocol.

**FEDERAL REGULATIONS REFERENCES**


45 CFR Part 46.107(e) – IRB Membership

For additional information, contact: Director, Office of Research Services at (610) 660-1206.