

Joslin Diabetes Center

This policy and the procedures discussed in the policy are guidelines only. Joslin retains the right, in its sole discretion, to modify or revoke them in whole or part at any time. Therefore the policy and procedures are not a promise or contract, express or implied, and Joslin Diabetes Center retains the right to determine whether and how they will be applied.

Policy Title: Research Financial Conflict of Interest

Policy For: Research Investigators and Staff

Policy Number: RES - 010

Effective Date: February 1996

(revised 8/24/2012, minor administrative changes 9/25/2012, updated 4/1/2013,
updated November 2015, updated June 2017)

I. Introduction/Purpose

Joslin Diabetes Center is committed to ensuring its professional staff members who conduct research ("Investigators") an open and productive environment in which to do so.

Conflicts of interest may arise when an individual's interest, or those of the individual's family, take precedence over the interests of Joslin Diabetes Center ("JDC"); or when an individual is in a position to influence a business decision of JDC in such a way that it will benefit, or appear to benefit, his or herself. Conflicts of commitment may arise when outside commitments interfere, or appear to interfere, with an individual's responsibilities to JDC (refer to Policy #LC-004 for JDC's Conflict of Interest and Commitment Policy, which applies to all members of JDC's workforce).

All United States Public Health Service ("PHS") agencies (includes National Institutes of Health (NIH)) require awardee institutions to ensure objectivity in research through compliance with its comprehensive regulations, "Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought and Responsible Prospective Contractors" issued at 42 CFR Part 50, Subpart F (the "FCOI Regulations"). See: <http://www.gpo.gov/fdsys/pkg/CFR-2011-title42-vol1/xml/CFR-2011-title42-vol1-part50-subpartF.xml>. The Joslin FCOI Policy is available for review in the Research section of Joslin's publically accessible web-site (www.joslin.org).

The PHS financial conflict of interest regulations have unique financial conflict of interest reporting and conflict management requirements. This policy is for the purpose of ensuring compliance with these important regulations (hereinafter, the FCOI Policy). This policy applies to all Investigators, as defined below, and all other persons who are responsible for the design, conduct, or reporting of research for PHS-funded research, or proposed to PHS for such funding and for sponsors who have adopted these federal regulations. This policy does not apply to applications for Phase I support under the Small Business Innovation Research Program (SBIR) and Small Business Technology Transfer (STTR) programs. *Please refer to Appendix I for information on research that is not PHS-funded or from sponsors that have not adopted these regulations.*

These FCOI Regulations provide for a more comprehensive level of disclosure, together with compulsory reporting, when applicable to the sponsoring PHS or other agencies. Disclosure to JDC is required of ALL "Significant Financial Interests" that reasonably appear related to the Investigator(s) "Institutional Responsibilities" as defined below.

II. Definitions

- a. **“Contractor”** means an entity that provides property or services under contract for the direct benefit or use of the federal government.
- b. **“Disclosure of significant financial interests”** means an Investigator’s disclosure of a significant financial interest to an Institution.
- c. **“Financial Conflict of Interest (FCOI)”** means a significant financial interest that could directly and significantly affect the design, conduct or reporting of PHS or other research.
- d. **“FCOI report”** means an Institution’s report of a financial conflict of interest to a PHS Awarding Component.
- e. **“Financial Interest”** means anything of monetary value, whether or not the value is readily ascertainable.
- f. **“HHS”** means the United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.
- g. **“HHSAR”** means the Health and Human Services Acquisition Regulation
- h. **“Human Subjects Research”** means a systemic investigation, including research development, and testing and evaluation, designed to develop or contribute to generalizable knowledge that involves an individual about whom an investigator conducting research obtains data through intervention or interaction with individual or identifiable private information (as per the Office for Human Research Protections). In addition, human subject research also means an experiment that involves a test article and one or more individuals who is or becomes a participant in research, either as a recipient of a test article or as a control, or on whose specimen a device was used (as per the US Food and Drug Administration).
- i. **“Institution”** means any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for or that receives PHS or other research funding.
- j. **“Institutional official(s)”**: means the individual(s) within the Institution that is/are responsible for the solicitation and review of disclosures of significant financial interests including those of the Investigator’s Family related to the Investigator’s institutional responsibilities. For the purposes of this policy, the Institutional Official is the Institutional FCOI Official (IFO).
- k. **“Institutional Responsibilities”** means the Investigator’s responsibilities associated with his or her Institutional appointment or position, such as research, teaching, clinical activities, administration, and institutional, internal and external professional committee service.
- l. **“Institutional Review Board (IRB)”** – A Committee of individuals affiliated and not affiliated with the Institution that reviews plans for research involving human subjects and is charged with protecting the rights and welfare of the people involved in research. At Joslin, the IRB is called the *“Committee on Human Studies (CHS)”*.
- m. **“Investigator”** means any individual who is responsible for the design, conduct, or reporting of PHS or other sponsored research, or proposals for such funding. This definition is not limited to those titled or budgeted as principal investigator or co-investigator on a particular proposal, and may include postdoctoral associates, senior scientists, or graduate students. The definition may also include collaborators or consultants as appropriate. Please refer to grid in Appendix II for guidance on making a determination who is considered to be an investigator under these regulations.
- n. **“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.
- o. **“PD/PI”** means a project director or principal investigator of a PHS or other funded research project; the PD/PI is included in the definitions of senior/key personnel and Investigator.
- p. **“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).

- q. **“PHS Awarding Component”** means the organizational unit of the PHS that funds the research that is subject to this part.
- r. **“Reimbursed or Sponsored Travel”** means any travel related to Investigator’s institutional responsibilities paid on Investigator’s behalf by an Outside Entity, regardless of dollar amount. Excluded from this definition is any travel reimbursed or sponsored by JDC or 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, or a research institute that is affiliated with an institution of higher education..
- s. **“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 or drug). Research includes any such activity for which research funding is available from a PHS Awarding Component or other sponsor through a grant, contractor cooperative agreement, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.
- t. **“Senior/Key Personnel”** means the Project Director/Principal Investigator (PD/PI) and any other person *identified* as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to funding sponsors by the Institution under the regulation. For all contracts, **“Key Personnel”** includes the PD/PI and any other personnel considered to be essential to work performance. Contracts from PHS are subject to the regulations found at HHSAR subpart 352.242-70 which defines key personnel for PHS contracts.
- u. **“Significant Financial Interest”** 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:
 - a. With regard to any publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve 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;
 - b. 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 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
 - c. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
 - (2) Investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is 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, or a research institute that is affiliated with an Institution of higher education.

(3) The term *significant financial interest* does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution 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 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, or a research institute that is affiliated with an Institution of higher education; or income from service on advisory committees or review panels for 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, or a research institute that is affiliated with an Institution of higher education.”

- v. **“Small Business Innovation Research (SBIR) Program”** means the extramural research program for small business that is established by the Awarding Components of the Public Health Service and certain other Federal agencies under Pub. L. 97-219, the Small Business Innovation Development Act, as amended. For purposes of this policy, the term SBIR Program includes the Small Business Technology Transfer (STTR) Program, which was established by Pub. L. 102-564.
- w. **“Transactional”** means driven by events; ad hoc. Examples include a change in SFI, a proposal submission, the arrival of a Notice of Award, an annual report, submission of protocol to the Institutional Review Board/Committee on Human Studies (IRB/CHS).

III. Training Requirements (42 CFR 50.604 (b))

Each Investigator must complete training on this Policy as mandated by 42 CFR 50.604(b) prior to engaging in research funded by PHS and at least every four years thereafter and within a reasonable period of time as determined by the Institutional Official when any of the following applies:

- (1) this FCOI Policy, the PHS Disclosure Form or the JDC procedures are revised in any manner that affects the requirements of the Investigators;
- (2) an Investigator is newly appointed at the Center; or
- (3) the Center finds that an Investigator is not in compliance with this FCOI Policy or management plan.

IV. Disclosure, Review and Management/Monitoring

A. Disclosure

All Joslin research personnel who meet the definition of Investigator (as defined above) are required to report their external commitments and financial interests prior to the submission of applications for funded research and at least annually during the period of the funded research for themselves and their family (spouse and dependent children). In addition, Investigators are also required to submit transactional reports as outlined below.

What must be reported:

- Irrespective of dollar amount, the individual’s external commitments or financial interests with an external entity that could constitute a conflict of commitment, such as employment, service or consulting; or intellectual property or licensing;
- Irrespective of dollar amount, the individual’s family’s financial interest or commitments with an external entity, whose activities could be related to the individual’s Joslin duties;

- Significant financial interest, as defined in this policy, for the individual or family with any external entity whose activities could be related to the individual's Joslin duties'.
- Any financial interests or external commitments not explicitly stated in the reporting form.

For each such external relationship or financial interest, the individual must provide all of the information required via the Joslin Electronic Conflict of Interest (e-COI) Reporting System.

Prior to the Submission of Applications for Funded Research

All research personnel, who are identified as Investigators as defined above, by the Principal Investigator, for a new or competing continuation/renewal proposal are required to report proposal-specific external commitments and financial interests, including any sponsor-required information, prior to the submission of the proposal. Principal Investigators are responsible for ensuring that Investigators submit reports prior to proposal submission. OSR may not submit any grant proposal for which the proposal-specific reports for all Investigators have not been submitted.

Annually during the Period of the Funded Research

All research personnel, who are identified as Investigators as defined above, by the Principal Investigator on the research are required to report proposal-specific external commitments and financial interests, including any sponsor-required information. Principal Investigators are responsible for ensuring that Investigators submit their annual reports.

Transactional Reports

- New Appointments:* Upon the appointment of a new faculty member, academic staff member, or other research employee, each Principal Investigator determines whether he or she is responsible for the design, conduct or reporting of research and is subject to this policy. The new appointee must complete the annual report within 30 days of his or her Joslin start date.
- Newly Assigned Responsibilities:* Individuals, who become newly responsible for the design, conduct, or reporting of research are required to complete annual reports within 30 days of their assumption of such responsibilities.
- Material Change in Circumstances:* All research personnel must amend their annual reports within 30 days of any material changes to their responses. Material changes include but are not limited to the initiation or elimination of a reportable external commitment or financial interest for the individual and family, a change in, or the initiation of, a sponsor, or any change that might affect a current management plan.

Travel

Investigators must also disclose reimbursed or sponsored travel related to their institutional responsibilities as defined above. Disclosure of such travel must include, at a minimum the following:

- Purpose of the trip;
- Identity of the sponsor/organizer;
- Destination and duration, and;
- If known, monetary value.

Additional information may be requested if needed to determine whether the travel constitutes a Financial Conflict of Interest with the Investigator's research.

Excluded from disclosure is any travel reimbursed or sponsored by Joslin or 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, or a research institute that is affiliated with an institution of higher education.

B. Review

As required by the regulations, the Joslin has a process in place to review all Investigators' disclosures of financial interests prior to the expenditure of funds to determine if any interest is related to the funded research, if the interest constitutes a financial conflict of interest (FCOI) and to develop and implement a management plan as needed to manage any FCOI that is not eliminated.

Relatedness Standard:

An Investigator's significant financial interest is related to the funded research when Joslin, through its review process reasonably determines that the significant financial interest:

- Could be affected by the funded research; or
- Is in an entity whose financial interest could be affected by the research.

FCOI Standard:

A financial conflict of interest exists when Joslin, through its review process, reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

This process is managed through the Office of Sponsored Research as outlined in Appendix III.

C. Management/Monitoring

As required by the regulations, the Joslin has a process in place to manage any financial conflict of interest including any financial conflict of a sub-recipient, and monitor Investigator compliance with management plans until the completion of the project.

Management Techniques:

For any identified FCOI, Joslin will take appropriate action to manage the conflict in order to reduce the potential for it to compromise the safety or validity of the research. Research in which an Investigator is found to have an FCOI will not be permitted to proceed until the Investigator has agreed to implement an acceptable management plan.

The following are potential elements of a management plan for the management, reduction or elimination of an FCOI:

- Public disclosure of FCOIs (i.e. when presenting or publishing)
- Reduction or elimination of the financial interest (i.e. sale of an equity interest)
- Change of personnel or personnel responsibilities, or disqualification of personnel from participating in all or a portion of the research
- Severance of relationships that create financial conflicts
- Modification of the research plan
- Appointment of an independent monitor who is capable of taking measures to protect the design, conduct and reporting of the research against bias resulting from the SFI/FCOI
- For Human Subject Research, disclosure of FCOI directly to subjects (i.e. statement in consent documents)

Monitoring/Compliance with Management Plans:

Investigators have an on-going obligation to adhere to an imposed management plan and failure to do so may be grounds for sanctions under this policy. Joslin will monitor Investigator compliance with an imposed management plan on an ongoing basis until the completion of the sponsored research project.

V. Reporting Requirements to NIH

The Joslin Diabetes Center is required to report to the applicable PHS funding agency the existence of any FCOI (as defined above) and assure that the institution has implemented a management plan in accordance with the FCOI Regulations at the following:

- Prior to the expenditure of funds
- Within 60 days of identification for an Investigator who is newly participating in the project
- Within 60 days for new, or newly identified, FCOIs for existing Investigators

If the Joslin identifies a FCOI and eliminates it prior to the expenditure of any PHS-awarded funds, then the institutions is not required to submit a FCOI report to the respective agency.

For any FCOI reported to the respective agency relating to an on-going PHS-funded research project, an annual report that conforms to the requirements of the regulations shall be made to the applicable funding agency by the institution for the duration of the research project in the time and manner specified by the applicable funding agency.

For any FCOI that was not timely reported or reviewed for whatever reason, the Joslin is required to conduct a retrospective review of the Investigator's activities and the research project. If bias is found during the course of this review, documentation of this review along with a mitigation report will also be required to be submitted to the applicable agency in accordance with the requirements of the regulations.

If an Investigator fails to comply with this FCOI Policy or a management plan and the non-compliance appears to have biased the design, conduct or reporting of the funded research, the Joslin as required under the regulations must promptly notify the agency of the corrective action taken or to be taken. The agency may take its own action as it deems appropriate, which may include suspension of funding, or require the institution to take further action to maintain the objectivity of the research.

The information that must be reported to NIH is:

- Project number
- Project title
- Name of Investigator with FCOI
- Name of entity with which the Investigator has the FCOI
- If applicable, reason for retrospective review, detailed methodology used for the review, and findings and conclusions of the review

VI. Maintenance of Records

The Joslin Diabetes Center is required under 42 CFR 50.604(i) to maintain all PHS Disclosure Forms and all related records of actions taken by the Center with respect to disclosures of financial interests for a period of three years from the date of submission of the final expenditures report to the PHS or, where applicable, from other dates specified in 45 CFR 74.53(b) and 92.42(b) for different situations.

VII. Enforcement Mechanisms and Remedies and Non-Compliance

In the event of an Investigator's failure to comply with this policy, the Institutional Official may suspend all relevant activities or take other disciplinary action until the matter is resolved or other action deemed appropriate by the Institutional Official is implemented.

If a determination of non-compliance has been made for a significant financial interest not disclosed timely or previously reviewed or whenever an FCOI is not identified or managed in a timely manner has been made, the Institution is required to complete and document a retrospective review within 120 days of the determination in accordance with the regulations.

For clinical research projects supported by the PHS, if the Department of Health and Human Services determines that a PHS-funded project of clinical research, whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, was designed, conducted, or reported by an Investigator with a FCOI that was not properly disclosed or managed as required under the FCOI Regulations, the Institution must require the Investigator(s) to disclose the FCOI in each public presentation (such as articles, manuscripts and oral presentations) of the results of the research and to request an addendum to previously published presentations.

VIII. Sub-Recipient Requirements

The sub-recipient of an award where Joslin is the prime recipient will certify that it has in effect an up-to-date, written, and enforced conflicts of interest policy and administrative process (COI Policy) to identify and manage financial conflicts of interest (FCOIs), which complies with the provisions of 42 CFR Part 50, Subpart F and 45 CFR Subtitle A, Part 94 (COI Regulations). The sub-recipient will certify that its COI Policy applies to sub-recipient's Investigators performing work under in a written agreement and that such individuals have completed training as required by the COI Regulations.

The sub-recipient will certify that at the time of execution of the written agreement, there is no FCOI related to the work contemplated by the agreement, or if the sub-recipient has identified an FCOI related to the work contemplated by the agreement it has implemented an appropriate management plan and notified Joslin of the existence of the FCOI and all information required to be included in an FCOI report under 42 CFR 50.605(b)(3) (FCOI Report). If an FCOI is identified by the sub-recipient during the term of the written agreement, the sub-recipient will also report to the Joslin the existence of the FCOI and all information required to be included in an FCOI Report. Such information regarding the newly identified FCOI shall be provided to the Joslin within thirty (30) days of sub-recipient's Investigator disclosing the significant financial interest that forms the basis of the FCOI to sub-recipient. Annual updates will be provided to the Joslin, as required by Section 50.605(b)(4). Reports of FCOIs should be provided to Joslin's Administrative Contact listed on the agreement. Upon request, the sub-recipient shall make available to the Joslin, to the extent applicable to the work conducted under the written agreement: (i) a copy of any proposed or implemented management plan; (ii) documentation of review of significant financial interests; and (iii) evidence of monitoring compliance with any existing management plan.

If the sub-recipient reports an FCOI to Joslin: (i) Joslin shall make the FCOI Report to the PHS awarding component; and (ii) both Joslin and the sub-recipient shall make information about the FCOI publicly available as required by Section 50.605(a)(5) and in accordance with their respective policies.

If the sub-recipient's or any sub-recipient Investigator's failure to comply with the requirements of the section of the written agreement which outlines this information in a timely manner and a retrospective

review is necessary, as required by 42 C.F.R. § 50.605(a), the sub-recipient shall reimburse the Joslin for reasonable costs and expenses associated with such review and mitigation of any bias identified.

If the sub-recipient is not able to certify that it has a financial conflicts of interest policy that complies with the PHS FCOI Regulations, then Joslin in a written agreement will require the sub-recipient to agree that sub-recipient Investigators will comply with this Joslin policy under this award. The written agreement shall require the sub-recipient Investigators to provide their disclosures to enable Joslin to identify manage and report any identified FCOIs to the PHS.

IX. Public Accessibility Requirements

As required by the regulations (42 CFR 50.604(a)), the Joslin must post this policy on a publicly-accessible website and/or respond to a request for our policy within five business days of the request.

Prior to the expenditure of funds, the Joslin is also required (under 42 CFR 50.605(a)(5)(i)-(iv)) will publish on a publicly-accessible website or respond to any requestor within five business days of the request, information concerning any Significant Financial Interest that meets the following criteria:

- a) The Significant Financial Interest was disclosed and is still held by the Investigator;
- b) A determination has been made that the Significant Financial Interest is related to the PHS-funded research; and
- c) A determination has been made that the Significant Financial Interest is a Financial Conflict of Interest.




At a minimum, the information regarding the Significant Financial Interest that will be disclosed will be:

- a) The Investigator's name
- b) The Investigator's title and role with the respect to the research project
- c) The name of the entity in which the significant financial interest is held
- d) The nature of the significant financial interest
- e) The approximate dollar value of the significant financial interest (dollar ranges are permissible, i.e. \$0-\$4,999, \$5,000-\$9,999 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).

APPENDIX I: Information for Non-PHS Funded Research

APPENDIX II: Investigator Definition Determination Guidance Chart

APPENDIX III: FCOI Disclosure, Review & Monitoring Processes SOP & Flowchart

<i>Name/Title</i>	<i>Signature</i>	<i>Date</i>
George L. King, M.D., <i>Chief Scientific Officer/Research Director</i>		6/20/17
Sharon Harpel, <i>Vice President for Research Administration</i>		6/19/17
Leigh Read, <i>CIP Director, Research Compliance/Assurance & Programs</i>		6/14/17

This policy is subject to review every two (2) years to ensure its effectiveness and appropriateness.

APPENDIX I: Information for Non-PHS Funded Research

I. Introduction/Purpose

Joslin is committed to adhering to high standards in regards to the conduct of research including monitoring conflicts of interests that may arise when an individual's interest, or those of the individual's family, take precedence over the interests of Joslin or when an individual is in a position to influence a business decision of Joslin in such a way that it will benefit, or appear to benefit, his or herself. Conflicts of commitment may arise when outside commitments interfere, or appear to interfere, with an individual's responsibilities to Joslin.

This section outlines the policy for financial conflicts of interest including reporting and conflict management for all Investigators and all other persons who are responsible for the design, conduct, or reporting of research for non-PHS funded research.

II. Definitions

Refer to "Definitions" (*pages 2-4*)

III. Training Requirements

Refer to "Training Requirements" (*page 4*)

IV. Disclosure, Review and Management/Monitoring

The prohibition of spending awarded research funds prior to the management of any potential conflict of interests will not be applied to non-PHS funded research though Investigators are still required to complete disclosures, which are subject to review and implementation of a management plan when applicable as outlined below.

a. Disclosure

All Joslin research personnel who meet the definition of Investigator (*as defined on page 2*), as identified by the Principal Investigator are required to report their external commitments and financial interests (*as outlined on page 5*) for themselves and their family (spouse and dependent children) on a prior to notification of a new award/funding and at least annually thereafter during the period of the award.

The Office of Sponsored Research will coordinate the solicitation and collection of all reports for the purpose of identifying real and apparent conflicts of interest related to the research.

Prior to New Award/Funding:

All Investigators, as identified by the Principal Investigator for a proposal are required to submit a proposal-specific report of the required external commitments and financial interests prior to notification of award/funding.

Annual Reports:

All Investigators, as identified by the Principal Investigator are required to submit an annual report disclosure of the required external commitments and financial interests in accordance with the specific time period set forth by Joslin.

Travel:

The disclosure of reimbursed or sponsored travel (*as defined on page 3*) is not required for non-PHS funded research.

b. Review

Joslin has a process in place to review all Investigators' disclosures of financial interests to determine if any interest is related to the funded research, if the interest constitutes a financial conflict of interest (FCOI), and to develop and implement a management plan as needed to manage any FCOI that is not eliminated (*the Relatedness and FCOI Standards that will be used to make these determinations are outlined on page 6*).

This process is managed through the Office of Sponsored Research as outlined in Appendix III.

c. Management/Monitoring

Joslin has a process in place to manage any financial conflict of interest and monitor Investigator compliance with management plans until the completion of the project (*refer to the Management Techniques and Monitoring/Compliance with Management Plans information on page 7*).

V. Reporting Requirements to Sponsors

Joslin is required comply with the reporting requirements of sponsors when an FCOI is identified for an Investigator.

VI. Maintenance of Records

Joslin will maintain all disclosure forms and related records of action taken by the Center as outline in "Maintenance of Record" (*on page 8*) or per sponsors' requirements.

VII. Enforcement Mechanisms and Remedies and Non-Compliance

In the event of an Investigator's failure to comply with this policy, the Institutional Official may suspend all relevant activities or take other disciplinary action until the matter is resolved or other action deemed appropriate by the Institutional Official is implemented.

VIII. Sub-Recipient Requirements

If research will be conducted at another institution under a sub-contract agreement, Joslin is required to comply with any of sponsor's sub-recipient FCOI requirements.

IX. Public Accessibility Requirements


The requirements of public accessibility/disclosure of SFIs and/or FCOIs that have been determined related to the research as outlined in "Public Accessibility Requirements" (*on pages 9-10*) will not be applied to non-PHS funded research.

APPENDIX II: Investigator Definition Determination Guidance Chart

Definitions	
Senior/Key Personnel	NIH Definition: "Senior/Key Personnel" means the PD/PI and other individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they receive salaries or compensation under the grant. Typically these individuals have doctoral or other professional degrees, although individuals at the masters or baccalaureate level may be considered senior/key personnel if their involvement meets this definition. Consultants and those with a postdoctoral role also may be considered senior/key personnel if they meet this definition. "Zero percent" effort or "as needed" is not an acceptable level of involvement for senior/key personnel.
Investigator	NIH Definition: "Investigator" means the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS (e.g., NIH), or proposed for such funding, which may include, for example, collaborators or consultants. Institutions should consider the role, rather than the title, of those involved in research and the degree of independence with which those individuals work. When the definition of Investigator is limited to titles or designations (e.g., to principal investigators, key personnel, faculty) the risk is that an unidentified FCOI may compromise the research enterprise increases.
Financial Conflict of Interest (FCOI)	NIH Definition: A Significant Financial Interest (SFI) that could directly and significantly affect the design, conduct, or reporting of NIH-funded research.

Title and/or Role	Senior/Key Personnel When does the Title/Fit the Definition of Senior/Key Personnel?	Investigator When does the Title/Fit the Definition of Senior/Key Personnel?	FCOI Reporting Requirements Is FCOI reporting required?	Comments
Project Director/Principal Investigator (PD/PI)	Always	Always	Yes	
Co-Investigator	Always	Always	Yes	An individual involved with the PD/PI in the scientific development or execution of a project. The co-investigator (collaborator) may be employed by, or be affiliated with, the applicant/grantee organization or another organization participating in the project under a consortium agreement. A co-investigator typically devotes a specified percentage of time to the project and is considered senior/key personnel. The designation of a co-investigator, if applicable, does not affect the PD/PI's roles and responsibilities as specified in the NIH Grants Policy Statement (NIH GPS), nor is it a role implying multiple PD/PI.
Post-Doctoral Fellows (paid on fellowships or training grants)	Always	Always	Only if the postdoctoral fellow meets the definition of "Investigator"	
Post-Doctoral Fellows (paid on research grants)	Sometimes	Sometimes	Only if the postdoctoral fellow meets the definition of "Investigator"	

<i>Title and/or Role</i>	<i>Senior/Key Personnel</i> When does the Title/Fit the Definition of Senior/Key Personnel?	<i>Investigator</i> When does the Title/Fit the Definition of Senior/Key Personnel?	<i>FCOI Reporting Requirements</i> Is FCOI reporting required?	<i>Comments</i>
Graduate Students	Rarely	Rarely	Only if the graduate student meets the definition of "Investigator"	
Other Significant Contributors (OSC)	Sometimes	Sometimes	Only if the OSC meets the definition of "Investigator"	NIH defines OSCs as individuals who have committed to contribute to the scientific development or execution of the project, but are not committing any specified measurable effort (i.e., person months) to the project. These individuals are typically presented at "effort of zero person months" or "as needed." Individuals with measurable effort may not be listed as Other Significant Contributors (OSCs). Consultants should be included if they meet this definition.
Consultants	Rarely	Sometimes	Only if the consultant meets the definition of "Investigator"	Consultants are individuals who generally provide a "fee for service" and do not typically conduct research. They may provide insight and expertise to the PI but independently are not responsible for the design, conduct or reporting of research. In most cases, they do not fit the definition of investigator.
Collaborators (unpaid)	Sometimes	Sometimes	Only if the collaborator meets the definition of "Investigator"	
Collaborator (paid)	Sometimes	Usually	Only if the collaborator meets the definition of "Investigator"	Collaborator's institution should be included in proposal as sub-recipient.
Sub-Recipient Principal Investigator and Senior/Key Personnel	Always	Always	Sub-Recipient investigators must comply with FCOI policy of their home institution	

	SOP: Financial Conflicts of Interest (FCOI) Disclosure, Review and Management and Monitoring Processes				
	NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
	FCOI-001	6/2017	FCOI Team	Sharon Harpel	1 of 2

1. PURPOSE

To outline Joslin's financial conflicts of interest (FCOI) disclosure, review and management and monitoring processes.

2. POLICY

As required by the federal regulations (42 CFR Part 50, subpart F) and Joslin policy, the Joslin has a process in place to review all Investigators' disclosures of financial interests to determine if any interest is related to the funded research, if the interest constitutes a financial conflict of interest (FCOI) and to develop and implement a management plan as needed for any FCOI that is not eliminated.

For PHS-funded research and for sponsors who have adopted the federal regulations, the review, determination and the implementation of an appropriate management plan must be done prior to the expenditure of funds.

3. RESPONSIBILITIES

FCOI Team (OSR-FCOI Responsible Staff and Institutional FCOI Official (IFO)) and Investigators

4. PROCEDURE

Disclosure

- 4.1 Investigator completes proposal specific disclosure (via the Joslin Electronic Conflict of Interest (e-COI) Reporting System at the time of application, annually during the course of the award or on a transactional basis per Research Financial Conflict of Interest Policy (RES-010).

Review

- 4.2 OSR-FCOI Responsible Staff reviews completed disclosure
 - 4.2.1 If the Investigator reports no financial interests (FIs):
 - 4.2.1.1 Review process is completed and OSR-FCOI Responsible Staff sends notifications to all necessary parties (i.e. Investigator, OSR Pre-Award Administrator, OSR Post-Award Administrator)
 - 4.2.1.2 Investigator's completed Disclosure Form is entered in OSR-FCOI records
 - 4.2.2 If the Investigator reports financial interests (FIs):
 - 4.2.2.1 Proceed to 4.2.3
 - 4.2.3 If the Investigator reports any FIs:
 - 4.2.3.1 OSR-FCOI Responsible Staff determines if the FIs meet the definition of a significant financial interest (SFI)
 - 4.2.3.1.1 If no SFIs identified
 - 4.2.3.1.1.1 Review process is completed and OSR-FCOI Responsible Staff sends notifications to all necessary parties (i.e. Investigator, OSR Pre-Award Administrator, OSR Post-Award Administrator)
 - 4.2.3.1.1.2 Investigator's completed Disclosure Form is entered in OSR-FCOI records
 - 4.2.3.2.2 If SFIs are identified
 - 4.2.3.2.2.1 Proceed to 4.2.4
 - 4.2.4 If it has been determined that the Investigator has SFIs
 - 4.2.4.1 OSR-FCOI Responsible Staff gathers any additional information needed (i.e. abstract and specific aims from grant application) to determine if the SFIs identified are related to the funded research and/or constitute a financial conflict of interest (FCOI)
 - 4.2.4.2 FCOI Team (OSR-FCOI Responsible Staff and/or Institutional FCOI Official (IFO)) reviews Investigator's disclosure form and additional information

- 4.2.4.2.1 If it has been determined that the SFIs identified are not are related to the funded research and/or constitute a financial conflict of interest (FCOI)
- 4.2.4.2.1.1 Review process is completed and OSR-FCOI Responsible Staff sends notifications to all necessary parties (i.e. Investigator, OSR Pre-Award Administrator, OSR Post-Award Administrator)
- 4.2.4.2.1.2 Investigator's completed Disclosure Form and documentation of the review/determination made is entered in OSR-FCOI records
- 4.2.4.2.2 If it has been determined that the SFIs identified are related to the funded research and/or constitute a financial conflict of interest (FCOI)
- 4.2.4.2.2.1 Proceed to 4.2.5

Management/Monitoring

- 4.2.5 If it has been determined that the SFIs identified are related to the funded research and/or constitute a financial conflict of interest (FCOI)
- 4.2.5.1 The IFO will draft/prepare a management plan to either, manage, eliminate, or reduce the SFI and/or FCOI and review the plan with the Investigator.
- 4.2.5.2 When plan has been reviewed and finalized by the IFO and Investigator
 - 4.2.5.2.1 IFO and Investigator will sign/accept plan
 - 4.2.5.2.1.1 If management plan eliminates SFI and/or FCOI
 - 4.2.5.2.1.1.1 Investigator will take the required steps as outlined in management plan to eliminate the SFI and/or FCOI
 - 4.2.5.2.1.1.2 Investigator will notify FCOI Team when the SFI and/or FCOI has been eliminated and provide any required document.
 - 4.2.5.2.1.1.3 OSR-FCOI Responsible Staff will send notifications to all necessary parties (i.e. Investigator, OSR Pre-Award Administrator, OSR Post-Award Administrator) that this process has been completed.
 - 4.2.5.2.1.1.4 Investigator's completed Disclosure Form, documentation of the review/determination, accepted management plan and any additional documentation is entered in OSR-FCOI records
 - 4.2.5.2.1.2 If management plan does not eliminate SFI and/or FCOI
 - 4.2.5.2.1.2.1 Investigator will take the required steps as outlined in management plan to reduce and/or manage the SFI and/or FCOI
 - 4.2.5.2.1.2.2 Investigator will notify FCOI Team when the SFI and/or FCOI has been reduced and/or managed and provide any required document.
 - 4.2.5.2.1.2.3 OSR-FCOI Responsible Staff will send notifications to all necessary parties (i.e. Investigator, OSR Pre-Award Administrator, OSR Post-Award Administrator) that this process has been completed.
 - 4.2.5.2.1.2.4 Investigator's completed Disclosure Form, documentation of the review/determination, accepted management plan and any additional documentation is entered in OSR-FCOI records
 - 4.2.5.2.1.2.5 For PHS-funded research, the FCOI Team will submit an electronic FCOI through eRA Commons
 - 4.2.5.2.1.2.6 The FCOI Team will monitor Investigator's compliance with the management plan to reduce and/or manage the identified SFI and/or FCOI as outlined in the accepted management plan.

5. MATERIALS

Joslin Research Financial Conflict of Interest Policy (RES-010)

6. REFERENCES

42 CFR Part 50, Subpart F

FCOI Disclosure, Review and Management/Monitoring Processes Flowchart

