ST. JOSEPH’S REGIONAL MEDICAL CENTER
INSTITUTIONAL REVIEW BOARD
POLICY

POLICY ON CONFLICT OF INTEREST/FINANCIAL DISCLOSURE
IN RESEARCH

EFFECTIVE DATE: 5/1/2014

GENERAL POLICY STATEMENT:

The Institutional Review Board (“IRB”) of St. Joseph’s Regional Medical Center (“SJRMC”) realizes that actual or potential conflicts of interest may occur in the normal course of clinical research. The IRB has developed this policy relating to conflicts of interest applicable to all IRB approved clinical research. The policy is to be administered in conjunction with federal and state law governing the conduct of such clinical research, including but not limited to Title 42 Code of Federal Regulations (CFR) Part 50, Subpart F and Title 45 CFR Part 94.

The U.S. Department of Health and Human Services/Public Health Service (“PHS”), which includes the National Institutes of Health (“NIH”), and the National Science Foundation (“NSF”), have regulations promoting objectivity in research by requiring that an individual or entity applying for grants or cooperative agreements for research ensure that there is no reasonable expectation that the design, conduct, and reporting of the research to be funded pursuant to the application will be biased by any significant financial interest of the investigator or other personnel with decision making capacity working on the research and that the research environment is one that promotes faithful attention to high ethical standards. In further support of this expectation the federal government has issued an agency-wide requirement (PHS) that policies and procedures regarding financial conflicts of interest be issued on research and other sponsored programs.

The IRB has adopted this Policy on Conflict of Interest/Financial Disclosure in Research (hereinafter referred to as “Policy on Conflict of Interest”) to prevent or resolve, through management and/or mitigation, real or apparent conflicts that may exist in relation to all clinical research that is subject to the review and approval of the IRB, regardless of whether the activities are sponsored by PHS.

It is the purpose of this Policy on Conflict of Interest to ensure that no proposed, awarded, or ongoing SJRMC clinical research shall be biased by a Significant Financial Interest, as defined below, of an Investigator (defined below). All Investigators seeking approval of the IRB, who have a Significant Financial Interest with an Entity (defined
below) will disclose that ownership to allow a review of a potential FCOI (defined below).

Prior to seeking IRB approval, each Investigator, must have submitted to SJRMC’s RCO (defined below), a Statement of Financial Interest form certifying he/she has no conflict of interest or, if the Investigator believes he/she has a conflict of interest, listing all Significant Financial Interests of the Investigator and the Investigator’s Immediate Family (defined below). Each such financial disclosure statement must be updated during the course of the clinical trial both as new reportable Significant Financial Interests are obtained and on an annual basis.

It is not the intent of this Policy on Conflict of Interest to eliminate or prohibit all situations involving potential conflicts of interest. Rather, the Policy on Conflict of Interest is intended to enable Investigators to recognize situations that may pose a FCOI, to provide processes for reporting these situations to SJRMC and for working with the IRB and the Research Institute to manage these situations. The IRB believes that, with clear guidelines and principles and with appropriate supervision and monitoring, it is possible for interaction between industry and SJRMC to take place in a fair and effective manner.

**DEFINITION OF TERMS:**

A. **Conflict of Interest Committee (CIC).** This committee serves as a resource with respect to matters involving Significant Financial Interests and the identification, management, mitigation or elimination of FCOIs. The CIC will also provide oversight for implementation of the Policy on Conflict of Interest and recommend to the IRB all future changes/modifications to the Policy on Conflict of Interest.

The CIC shall consist of four (4) members. Two (2) members shall be appointed by the Vice President for Academic Affairs and two (2) members shall be appointed by the RO. At least one (1) of the four (4) members must be a non-employee of SJRMC. The RCO and an attorney from the SJRMC Department of Legal Affairs will serve as liaison (non-voting) members. The chair of the CIC will be appointed by the Vice President for Academic Affairs. The appointed members of the committee shall serve three (3) year staggered terms.

B. **Entity.** Entity means any domestic or foreign, public or private, organization (excluding a federal agency) from which an Investigator (or the Investigator’s Immediate Family) receives remuneration or has an ownership or equity interest.

C. **Financial Conflict of Interest (FCOI).** Financial Conflict of Interest means a Significant Financial Interest that could directly and significantly affect the design, conduct or reporting of clinical research.
D. **Immediate Family.** Immediate Family refers to the Investigator’s parents, spouse/civil union partner and dependent children.

E. **Investigator.** Investigator means the principal investigator, sub-investigator or project director, or any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of a clinical research trial that is subject to the review and approval of the IRB.

F. **Institution of Higher Education.** Institution of Higher Education means an educational institution in any state that:

1. admits as regular students only persons having a certificate of graduation from a school providing secondary education, or the recognized equivalent of such a certificate, or persons who meet the requirements of 20 USC 1091(d);

2. is legally authorized within such State to provide a program of education beyond secondary education;

3. provides an educational program for which the institution awards a bachelor’s degree or provides not less than a 2-year program that is acceptable for full credit toward such a degree, or awards a degree that is acceptable for admission to a graduate or professional degree program;

4. is a public or other nonprofit institution;

5. is accredited by a nationally recognized accrediting agency or association, or if not so accredited, is an institution that has been granted preaccreditation status by such an agency or association that has been recognized by the federal government for the granting of preaccreditation status, and the federal government has determined that there is satisfactory assurance that the institution will meet the accreditation standards of such an agency or association within a reasonable time;

6. any school that provides not less than a 1-year program of training to prepare students for gainful employment in a recognized occupation and that meets the provision of paragraphs (1), (2), (4), and (5) above; and

7. a public or nonprofit private educational institution in any State that, in lieu of the requirement in subsection (1), admits as regular students individuals:
   a. who are beyond the age of compulsory school attendance in the State in which the institution is located; or
   b. who will be dually or concurrently enrolled in the institution and a secondary school.
G. **Research Compliance Officer (RCO).** The RCO is appointed by the Vice-President of Academic Affairs. The RCO directs the SJRMC Office for Research Compliance and will report to the Chairman of the IRB on all matters concerning this Policy on Conflict of Interest. The RCO will be the first point of contact for Investigators on issues relating to conflict of interest and will perform the initial review of the Statement of Financial Interest. The Statement of Financial Interest is attached hereto as Exhibit A. The RCO will process all paperwork related to conflict of interest disclosures and, if appropriate, conflict of interest management plans. The RCO is responsible for keeping the appropriate external funding agency informed as required by law.

H. **Research Institute.** The Research Institute means the Division of Research at SJRMC.

I. **Responsible Official (RO).** The Responsible Official will be the Chairman of the IRB.

J. **Significant Financial Interest.** 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 Immediate Family) that reasonably appears to be related to the Investigator’s professional responsibilities on behalf of SJRMC:\(^1\):
   a. With regard to any publicly traded entity, a Significant Financial Interest exists if the value of any remuneration received from the publicly traded 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;
   b. With regard to any non-publicly traded Entity, a Significant Financial Interest exists if:
      i. the value of any remuneration received from the entity in the twelve (12) months preceding the disclosure, when aggregated, exceeds $5,000, or
      ii. when the Investigator (or the Investigator's Immediate Family) holds any equity interest (e.g., stock, stock option, or other ownership interest);
   c. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests; or

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\(^1\) Professional responsibilities on behalf of SJRMC are performed in the course of and within the scope of your appointment or employment by SJRMC, which may include activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards.
d. Travel that is reimbursed or sponsored by an Entity where the combined monetary value is more than $5000. The RCO will determine if any travel requires further investigation, including determination or disclosure of the monetary value.

The term Significant Financial Interest does not include the following types of financial interests:

1. salary, royalties, or other remuneration paid by SJRMC to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to SJRMC and agreements to share in royalties related to such rights;
2. any ownership interest in SJRMC held by the Investigator, if SJRMC is a commercial or for-profit organization;
3. 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;
4. income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an Institution of Higher Education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of Higher Education;
5. travel that is reimbursed or sponsored by a federal, state, or local government agency, an Institution of Higher Education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of Higher Education or reimbursed or sponsored by an Entity where the combined monetary value is less than $5000 for all categories. The RCO will determine if any travel requires further investigation, including determination or disclosure of the monetary value; or
6. income from service on advisory committees or review panels for a Federal, state, or local government agency, an Institution of Higher Education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of Higher Education.

POLICY:

Procedure

A. All Investigators must complete the Statement of Financial Interest form and certify to the RCO knowledge of and compliance with the Policy on Conflict of Interest by identifying, managing, and reducing or eliminating conflicts of interest as outlined herein and completing the Statement of Financial Interest. This Statement of Financial Interest form also requires similar information about members of the Investigator’s Immediate Family. Statements must include detailed supplemental information as required by the form.

B. Investigators must disclose to the RCO on an annual and ad hoc basis all Significant Financial Interests that are obtained within 30 days of obtaining such financial interest.
C. The RCO will review the Statement of Financial Interest and any newly disclosed Significant Financial Interest. If the Investigator discloses a Significant Financial Interest or the RCO determines that a Significant Financial Interest exists based on information provided by the Investigator, the RCO will review the Statement of Financial Interest to determine whether there is a reasonable possibility that an FCOI exists. The RCO may seek additional information from the Investigator if the RCO decides that additional information is needed to make the determination. If it is determined that it is not reasonably possible that an FCOI exists, the RCO will sign the Statement of Financial Interest and seek and obtain the signature of the RO.

D. If the RCO determines that it is reasonably possible an FCOI exists, the RCO will forward this determination along with the submitted materials to the RO.

E. Should the RO agree that there is a reasonable possibility that an FCOI exists, the RCO shall work with the Investigator to develop the plan to manage, reduce, or eliminate the actual or potential FCOI.

F. The plan will then be submitted to the CIC for review. The CIC may recommend approval of the plan to the IRB as developed or may recommend modification of the plan.

G. The following are examples of conditions or restrictions that might be part of the plan to manage, reduce, or eliminate actual or potential conflicts of interest:
   1. Public disclosure of Significant Financial Interests;
   2. Monitoring of the clinical research by independent reviewers;
   3. Modification of the clinical research plan and/or procedures;
   4. Disqualification from participation in all or a portion of the clinical research in question;
   5. Divestiture of Significant Financial Interests; and
   6. Severance of relationships that create actual or potential FCOI.

H. The clinical research will then be forward to the IRB for approval, along with the recommendations of the CIC. The IRB may approve the proposed plan or may modify the plan proposed by the CIC. The final authority to decide whether and FCOI exists, how the FCOI may be managed appropriately and ultimate approval of the research will lie with the IRB.

I. Any plan approved by the IRB will be forwarded to the RCO. Once a plan approved by the IRB is developed, the RCO will work with the Investigator on the implementation and management of the plan.

Investigator Responsibilities

A. All Investigators submitting a clinical research to the IRB for review and approval shall be responsible for:
   1. Reading, understanding, and following this Policy on Conflict of Interest;
   2. Completion of the required FCOI training at least every four (4) years or when the Policy on Conflict of Interest is revised and affects the Investigators’ reporting requirements. The required FCOI training can be obtained by completing the NIH Financial Conflict of Interest Tutorial and

3. Disclosing financial interests to the RCO by completing, signing, and submitting the Statement of Financial Interest as follows:
   a. **PHS funded research.** The disclosure should be filed prior the submission of the grant or contract/application.
   b. **All other clinical research.** The disclosure should be filed prior to or concurrent with the application to the IRB.

B. Updating the statement with the RCO annually so that the statement on file is current and accurate at all times when an award is pending or in force;

C. Updating the statement with the RCO as changes occur (within 30 days of discovering or acquiring a new or increased financial interest) so that the statement on file is current and accurate at all times when an award is pending or in force;

D. To the extent possible, ensuring that funded clinical research carried out through subgrantees, contractors, or collaborators complies with the Policy on Conflict of Interest or that these entities provide assurance of compliance with all federal regulations and state law.

**Reporting**

A. In cases where the IRB identifies a FCOI and eliminates it prior to the expenditure of PHS awarded funds, no report is required to be made to PHS or a PHS related agency.

B. In cases where the FCOI has not been eliminated prior to the expenditure of PHS funds, for clinical trials funded by the PHS or a related agency, SJRMC must report any FCOI to the funding agency within sixty (60) days of the identification. Any FCOI identified subsequent to the initial report must be reported within sixty (60) days of that identification.

C. Any FCOI report shall include sufficient information to enable PHS (or a related agency) to understand the nature and extent of the financial conflict, and to assess the appropriateness of the management plan. Elements of the report should include:
   1. Project number;
   2. PD/PI or Contact PD/PI if a multiple PD/PI model is used;
   3. Name of the Investigator with the FCOI;
   4. Name of the Entity with which the Investigator has a FCOI;
   5. Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
   6. 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;

7. A description of how the financial interest relates to the PHS-funded research and the basis for the IRB’s determination that the FCOI conflicts with such research; and

8. A description of the key elements of the management plan, including:
   a. Role and principal duties of the conflicted Investigator in the research project;
   b. Conditions of the management plan;
   c. How the management plan is designed to safeguard objectivity in the research project;
   d. Confirmation of the Investigator's agreement to the management plan;
   e. How the management plan will be monitored to ensure Investigator compliance; and
   f. Other information as needed.

D. Further, SJRMC agrees to make conflict of interest information available, upon request, to any external funding agency potentially or actually affected by this information.

E. Prior to the Investigator’s expenditure of any funds under a PHS-funded research project, SJRMC shall ensure public accessibility, via a publicly accessible Web site or written response to any requestor within five (5) business days of a request, of information concerning any Significant Financial Interest disclosed to SJRMC that meets the following three (3) criteria:
   1. The Significant Financial Interest was disclosed and is still held by the Investigator;
   2. The IRB has determined that the Significant Financial Interest is related to the PHS-funded research; and
   3. The IRB determines that the Significant Financial Interest is a FCOI.

The information that SJRMC makes available via a publicly accessible Web site or written response to any requestor within five (5) business days of a request, shall include, at a minimum, the following:

1. the Investigator's name;
2. the Investigator's title and role with respect to the research project;
3. the name of the Entity in which the significant financial interest is held;
4. the nature of the significant financial interest; and
5. the approximate dollar value of the significant 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.
If SJRMC uses a publicly accessible Web site for the purposes of this subsection, the information that SJRMC posts shall be updated at least annually. In addition, SJRMC shall update the Web site within sixty (60) days of SJRMC’s receipt or identification of information concerning any additional Significant Financial Interest of the Investigator for the PHS-funded research project that was not previously disclosed, or upon the disclosure of a Significant Financial Interest of an Investigator new to the PHS-funded research project, if the IRB determines that the Significant Financial Interest is related to the PHS-funded research and is a FCOI. The Web site shall note that the information provided is current as of the date listed and is subject to updates, on at least an annual basis and within sixty (60) days of the IRB’s identification of a new FCOI. If SJRMC responds to written requests for the purposes of this subsection, SJRMC will note in its written response that the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within sixty (60) days of SJRMC's identification of a new FCOI, which should be requested subsequently by the requestor.

Information concerning the FCOIs of an individual subject this section shall remain available, for responses to written requests or for posting via SJRMC’s publicly accessible Web site for at least three (3) years from the date that the information was most recently updated.

**Enforcement**

SJRMC anticipates that its Investigators will comply fully and in a timely manner with this policy. Instances of deliberate breach include: (i) failure to submit the required Statement of Financial Interest or updates thereof; (ii) failure to provide additional information requested by the RCO, CIC, or the Research Institute; (iii) knowingly filing an incomplete, erroneous, or misleading statement; (iv) knowingly violating applicable laws or SJRMC policies or procedures; or (v) failure to comply with prescribed conditions or restrictions that have been imposed pursuant to this policy, may subject the Investigator to disciplinary action under SJRMC policies or procedures. Such action could result in a formal reprimand, non-renewal of appointment, termination of appointment for good cause, or any other enforcement action mandated by a funding agency.

The IRB shall, within 120 days of the IRB’s determination of non-compliance, conduct a retrospective review in those cases of non-compliance with the regulations. The IRB will document the retrospective review. Such review shall include:

1. Project number;
2. Project title;
3. PD/PI or contact PD/PI if a multiple PD/PI model is used;
4. Name of the Investigator with the FCOI;
5. Name of the Entity with which the Investigator has a financial conflict of interest;
6. Reason(s) for the retrospective review;
7. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
8. Findings of the review; and
9. Conclusions of the review.

Based on the results of the retrospective review, if appropriate, the RCO shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward. If bias is found, SJRMC is required to notify the PHS awarding component promptly and submit a mitigation report to the PHS awarding component. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and SJRMC 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). Thereafter, SJRMC will submit FCOI reports annually or as otherwise required by law.

Depending on the nature of the FCOI, the RO may determine that additional interim measures are necessary with regard to the Investigator’s participation in the PHS-funded research project between the date that the FCOI or the Investigator’s noncompliance is determined and the completion of the IRB’s retrospective review. The RO may implement such measures immediately pending the IRB’s review.

In any case in which PHS 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 has been designed, conducted, or reported by an Investigator with a FCOI that was not managed or reported by SJRMC as required by law, SJRMC shall require the Investigator involved to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

**Subrecipient Institution**

SJRMC will incorporate as part of a written agreement terms that establish whether the SJRMC Policy on Conflict of Interest or that of the subrecipient will apply to subrecipient investigators and include time periods to meet disclosure and/or financial conflict of interest reporting requirements. Subrecipient institutions which rely on their financial conflict of interest policies must report identified financial conflict of interests to SJRMC within 30 days of identification of the conflict of interest to provide sufficient time for SJRMC to report the financial conflict of interest to the funding agency to meet reporting obligations.
EXHIBIT A
STATEMENT OF FINANCIAL INTEREST

Name of Investigator:

Address:

Title of Research Project:

Funding Entity/Agency:

Email:

Phone Number:

Please indicate whether you, your spouse or your dependent children have any of the following Significant Financial Interests that may reasonably be related to your professional responsibilities at SJRMC

If you answer yes to any of the following questions, please provide a detailed and thorough written description and explanation in an attachment.

[See Exhibit 1 hereto for Exclusions]

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<td>1. Have you read the Policy on Conflict of Interest/Financial Disclosure in Research?</td>
<td>Yes</td>
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<td>2. With regard to any publicly traded entity, received any remuneration from the publicly traded entity in the last twelve (12) months preceding the disclosure and the value of any equity interest 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</td>
<td>Yes</td>
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<tr>
<td>3. With respect to any non-publicly traded entity, a total of any remuneration (salary and any payment for services not otherwise identified as a salary, e.g. consulting fees, honoraria, paid authorship) received from the entity in the past twelve (12) months in excess of $5,000.</td>
<td>Yes</td>
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1 Professional responsibilities on behalf of SJRMC are performed in the course of and within the scope of your appointment or employment by SJRMC, which may include activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards.
4. With respect to any **non-publicly traded entity**, any equity interest in the entity (including any stock, stock option, or other ownership interest), regardless of value.  
   | Yes | No |

5. Intellectual property rights and interests (for example, patents and copyrights).  
   | Yes | No |

6. Travel that is reimbursed or sponsored by an Entity\(^2\) where the combined monetary value is more than **$5000**.  
   | Yes | No |

**Agreement & Signature:**

By signing this form, I certify the following:

- The above statements are complete, true and accurate.
- I have read and understand the Policy on Conflict of Interest.
- I will submit an updated Form annually, prior to submission of annual progress reports; and also within 30 days of any material change to the above-disclosed Significant Financial Interest(s) or discovering or acquiring a new Significant Financial Interest.
- I will comply with all applicable regulations, SJRMC policies, sponsor requirements and any conflict of interest management and oversight plans issued by SJRMC.

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Signature:  
Date
Name:__________________________

\(^2\) As defined by the Policy on Conflict of Interest.
Exhibit 1

The term Significant Financial Interest does not include the following types of financial interests:

1. salary, royalties, or other remuneration paid by SJRMC to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to SJRMC and agreements to share in royalties related to such rights;

2. any ownership interest in SJRMC held by the Investigator, if SJRMC is a commercial or for-profit organization;

3. 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;

4. income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an Institution of Higher Education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of Higher Education;

5. travel that is reimbursed or sponsored by a federal, state, or local government agency, an Institution of Higher Education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of Higher Education or reimbursed or sponsored by an entity where the combined monetary value is less than $5000 for all categories. The RCO will determine if any travel requires further investigation, including determination or disclosure of the monetary value; or

6. income from service on advisory committees or review panels for a Federal, state, or local government agency, an Institution of Higher Education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of Higher Education.