

**SUBJECT: Financial Conflict of Interest in Research – ADM – 015**

**SECTION: Central Office of Research Administration**

## **PURPOSE STATEMENT**

To set forth the process for reviewing financial interests, and for identifying and addressing financial conflicts of interest (“FCOI”) in Research (as defined later in this policy), in order to eliminate, reduce or manage such conflicts and ensure compliance with federal and state laws and regulations regarding FCOI as it relates to Research.

## **POLICY**

It is the policy of Saint Luke’s Health System (“SLHS”) and its entities to follow the applicable Code of Federal Regulations as referenced in this policy regarding the conduct of Research studies and the administrative policies and procedures which support Research endeavors. This policy applies to Principal Investigators, Sub-Investigators and other key individuals engaged in the design, conduct or reporting of Research.

SLHS promotes and maintains objectivity and integrity in Research and has established standards to ensure that the design, conduct, or reporting of Research will not be biased by any FCOI of an Investigator or other individuals. Opportunities to profit from Research may affect the judgment or decisions of an Investigator. Identification of FCOI helps to ensure Research is performed in a manner that preserves the safety and welfare of human subjects and upholds the overall integrity of the Research.

## **DEFINITIONS**

**CORA**—the Central Office of Research Administration of SLHS.

**Designated Official** – the individual designated in the Saint Luke’s Hospital Federalwide Assurance Agreement with the Office of Human Research Protections and to whom CORA and the Financial Conflict of Interest Committee reports.

**Entity**—any person, corporation, limited liability company, partnership, joint venture or government agency that pays or transfers any Financial Interest to an Investigator.

**Financial Conflict of Interest (“FCOI”)** –a Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of Research, including PHS-funded Research.

**Financial Conflict of Interest Committee (“FCOI Committee”)**—the Committee appointed under Policy #ADM 016 (Link to policy) to review Financial Conflicts of Interests.

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<b>APPROVED BY:</b>	Marilyn Rymer, MD; David Cohen, MD; Jeffery Wieman, MD
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**Financially Interested Company**--an entity with financial interests that would reasonably appear to be affected by the conduct or outcome of Research. This term includes the manufacturer (including business partners) of the drug or the device or other sponsor of the Research. This term includes any entity acting as the agent of a Financially Interested Company, e.g., a contract research organization. This term also includes companies that provide *direct* and *primary* competition for the investigational product, if the Investigator actually knows that the Financial Interests of such a company would reasonably appear to be affected by the Research.

**Financial Interests**--anything of monetary value, including, but not limited to:

- Payments or other transfers of value, made by any Entity to the Investigator to engage in Research, Research consultation, teaching, professional practice, professional practice consulting or institutional committee memberships or any other duty that is similar to a duty for which the Investigator is engaged by the Institution (“Professional Duties”). A Financial Interest also includes any compensation from or equity or proprietary interests in a Financially Interested Company. Payments must be disclosed for the time period beginning one (1) year prior to the date of disclosure through one (1) year following the study termination date. Payments include:
  - Compensation of any sort including honoraria, fees or retainers for consulting, designing or conducting Research, writing, speaking, teaching, or service on advisory boards or review panels;
  - Proprietary interest (patents, trademarks, copyrights, royalties, licensing agreements);
  - Equity interest (stock or stock options or other financial interests) but excludes 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;
  - Education or Research grants;
  - Travel reimbursement and sponsored travel;
  - Equipment donation;
  - Gifts.

Excluded from the definition of “Financial Interests” are: salary, royalties and other remuneration paid by the Institution to the Investigator including Intellectual Property rights assigned to the Institution and agreements to share in royalties related to those rights; income from investment vehicles such as mutual funds as long as the Investigator does not directly control investment decisions in these vehicles; income from seminars, lectures or teaching engagements sponsored by a Federal, state or local government agency, an institution of higher education, an academic medical center (“AMC”), a medical center that is affiliated with an institution of higher education or income from service or advisory panels for a Federal, state or local government agency, an institution of higher education, an AMC, a medical center or a Research center affiliated with an institution of higher education.

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**Investigator** – The Principal Investigator, Project Director and any other person who is responsible for the design, conduct, or reporting of a Research project. For purposes of this policy, “Investigator” includes the Investigator’s family members, spouse, dependent children, and any other person living in the Investigator’s household with whom the Investigator shares financial support (may be referred to separately as “Family Members”).

**Institution** –Saint Luke’s Hospital of Kansas City (“SLH”) or its affiliates (collectively “SLHS”) when SLH or the affiliate is either a PHS grantee or employs an Investigator.

**IRB** – SLH Institutional Review Board

**PHS**—Public Health Service of the United States Department of Health and Human Services.

**Research** – A systematic investigation 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 and product development and clinical trials regardless of the source of funding or support.

**Senior/key personnel**—Any person, including Investigators, identified as senior/key personnel on a grant application, protocol, progress report or other report submitted to the grantor or other sponsor by the Institution.

**Significant Equity Interests**—for companies traded on public stock exchanges, an equity interest that when aggregated for the Investigator and Family Members exceeds \$5000 (or such other amount as may be determined by law from time to time) at the date of disclosure. For privately held companies or a Financially Interested Company, any equity interest is a Significant Equity Interest.

**Significant Financial Income**—Payments or transfers of anything of monetary value (including the value of an equity interest) from a single Entity or Financially Interested Company that when aggregated for the Investigator and Family Members for the 12 months preceding the date of disclosure exceeds \$5000 (or such other amount as may be determined by law from time to time). Significant Financial Income includes the right to receive royalties or similar payments from Financially Interested Company even if the value is not readily ascertainable at the time of the disclosure.

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**Significant Financial Interests (“SFI”)**—means either a Significant Equity Interests or Significant Financial Income. SFI also includes (i) appointment to a fiduciary role (e.g., as a director, trustee or officer) in a Financially Interested Company; or (ii) remuneration from and equity or proprietary interests in a publicly-traded Entity in connection with Professional Duties that when aggregated for the Investigator and Family Members for the 12 months preceding the date of disclosure exceeds \$5000. For PHS-funded Research only, an SFI includes reimbursed or sponsored travel in connection with the Investigator’s Professional Duties.

## **PROCEDURE**

### **In accordance with:**

Title 21 CFR 54 – Financial Disclosure

Title 45 CFR Part 94 – Objectivity in PHS Funded Research

Title 42 CFR Part 50, Subpart F – Objectivity in PHS Funded Research

Title 42 CFR Part 50 – Conflicts of Interest of Investigators

Title 45 CFR Part 74 – Uniform Administrative Requirements for Awards and Subawards to Institutions of Higher Education, Hospitals, Other Non- Profit Organizations, and Commercial Organizations.

### **Identification and Disclosure**

1. Each Investigator will be informed of this policy through a training program that will be approved by the Designated Official and will include the Investigator’s reporting responsibilities under this Policy and the law. Each Investigator will complete the Conflict of Interest training program at least every 4 years or more frequently if warranted by changes to FCOI policy or the Investigator’s failure to adhere to the policy or a Plan.
2. The SLHS FD Form (link to form) will be completed by all Investigators involved in the conduct of Research at SLHS. The SLHS FD Form will be submitted the earlier of thirty days prior to IRB consideration of the project for approval or 30 days prior to the commencement of Research that does not involve human subjects. For PHS-funded research the SLHS FD Form will be submitted at the time of the application for PHS funds. In addition, each Investigator must complete updated SLHS FD Forms annually and disclose any newly-acquired SFI on the SLHS FD Forms within 30 days of acquiring the new SFI.

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3. SLHS Investigators conducting Research through sub-recipients, sub-grantees, contractors, or collaborators must obtain completed SLHS FD Forms from the sub-recipients, sub-grantees, contractors, or collaborators and submit the forms to CORA. Forms must be updated annually by August 1 and/or as new reportable financial interests are identified. All such completed SLHS FD Forms will be processed in accordance with this policy. In the alternative, if any PHS-funded research is carried out by a sub-recipient, the Institution may permit the sub-recipient to follow its own FCOI policies as long as the Institution ensures that the requirements of 42 CFR section 50.604 (as may be amended) are fulfilled.
4. The completed SLHS FD Form will be submitted to CORA. All disclosed SFIs will be recorded in a database maintained by CORA.
5. If an SFI is identified by CORA, CORA will inform the Chairperson of the FCOI Committee who will convene a meeting of the FCOI Committee.
6. If any individual is aware of an SFI that has not been reported, as required by this policy, the individual must report this SFI through established System compliance reporting guidelines.

#### Resolution and Management of Conflicts of Interest

1. The FCOI Committee (See separate policy ADM – 016), will review each SLHS FD Form referred by CORA to determine whether an FCOI exists. The FCOI Committee will request and the Investigator will provide detail as to amounts reported on the SLHS FD Form and the FCOI Committee will consider whether the SFI is related to the Research. If the FCOI Committee's review concludes that a FCOI exists, it will determine required methods to manage, reduce or eliminate such FCOI.
  - A. For proposed and/or ongoing projects, the FCOI Committee will determine the degree to which the FCOI impacts the Research, if compelling circumstances exist to begin or continue the Research, and whether a plan to mitigate any effects of a SFI can be sufficient and will be implemented to allow the Research to proceed in the face of the conflict.
  - B. The FCOI Committee will consider the following factors to determine the impact of the FCOI:
    - o Nature and amount of the disclosed SFI,
    - o How closely the SFI is related to the Research,
    - o and the extent to which the Research results could be influenced by the SFI. For PHS funded research, the FCOI Committee will also require that the Investigator submit

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details of any travel (including its purpose, duration and destination) reimbursed by any Entity in connection with the Investigator's performance of Professional Duties for the Entity. The travel expenses will be considered by the FCOI Committee in its determination of whether a FCOI exists.

C. The following list of factors to consider may be used by the FCOI Committee, at its discretion, in evaluating whether compelling circumstances are present to permit commencement or continuation of Research:

- Research is appropriate to the mission of SLHS;
- Potential gains to patients and the community in the immediate and long-term future in the event the Research is successful;
- Any unique expertise of the Investigator (e.g. inventorship, experience, special insights, knowledge, perseverance, laboratory resources or a need for a special patient population) that may make his or her involvement essential, including the degree to which the safety or effectiveness of the Research might be compromised without that individual;
- The risks to human subjects Research are sufficiently low;
- Steps proposed by the Investigator for effective oversight and management of the SFI;
- What role others involved in the Research will play and whether such role is appropriate and free from bias.

2. The FCOI Committee will determine the Management Plan ("Plan") to properly oversee and manage the FCOI.

A. The following requirements may be imposed within the Plan to manage conflicts of interest including, but not limited to:

- Public disclosure of financial interests during presentations, publications, or other disseminations, whether oral or written ;
- Disclosure of Financial Interests to prospective subjects and to the Research sponsor (governmental or private);
- Monitoring of the Research by independent reviewers;
- Modification of the Research plan, Research staff roles or changes in location of certain Research activities to address the potential bias from interests;
- Disqualification from participation in all or a portion of the Research;
- Required periodic reports regarding implementation of the Plan and its progress to oversee and monitor the entire project;
- Divestiture of SFI, or;

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- Severance of relationships that create actual conflicts.

B. In addition to the requirements, the Plan shall describe:

- Nature and magnitude of the SFI;
- Conditions under which the activity may proceed and the individuals, including the Principal Investigator, subject to the Plan (the “Interested Parties”);
- The depth and frequency of any reports due from the Investigator during the study, and a statement regarding any compliance audits that are required by the Plan;
- The method of amending the Plan which requires the approval of the FCOI Committee

C. The Plan for any FCOI will be approved by the FCOI Committee prior to study commencement (including any enrollment of Research subjects).

3. The FCOI Committee will be responsible for communicating its resolution of the matter to the Investigator, Designated Official, CORA, and the IRB. Any FCOI must be resolved prior to final IRB approval. The IRB will not approve monitoring methods or other conditions that are less restrictive than those imposed by the FCOI Committee. No approval of a Plan granted by the FCOI Committee may supersede the authority of the IRB and the IRB may modify the Plan to impose more stringent restrictions than those imposed by the FCOI Committee.
4. The FCOI Committee will inform the Director of Research of the Central Office of Research Administration, the IRB and the applicable Service Line Director of Research of the actions and decisions of the FCOI Committee, including any applicable Plan.
5. An internal review will be conducted by a Compliance Department designee to determine compliance with the Plan. If the investigator is found to be non-compliant, then the internal review results will be referred to the FCOI Committee for determination of sanctions.
6. Prior to expenditure of any Public Health Service (“PHS”) funds under the award, the Institution will report to the PHS Awarding Component the existence of FCOI in accordance with PHS FCOI reporting instructions [link to PHS report form] and assure that the FCOI has been managed, reduced or eliminated all in accordance with Title 42 CFR Part 50.605 as may be amended from time to time. Whenever the FCOI Committee becomes aware of a FCOI that was not timely disclosed or was not timely identified while research is ongoing, the Investigator would be allowed to participate in the research only pursuant to a Plan. In the cases of such noncompliance involving PHS-funded research, the FCOI Committee will have an interim Plan in place within 60 days of the disclosure or review of the SFI.

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- A. Within 120 days of the finding of such noncompliance, or a finding of noncompliance with a Plan, the FCOI Committee will complete and document a retrospective review of the Investigator's activities and the PHS-funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct or reporting of such research. If bias is found, the FCOI Committee will provide the required notification and in cases of such noncompliance involving PHS-funded research, the FCOI Committee will forward a mitigation report to the PHS Awarding Component. In the cases of such noncompliance involving non-PHS-funded research, retrospective reviews may be conducted at the discretion of the FCOI Committee.

If the Department of Health and Human Services determines that a PHS-funded project of clinical research to test the efficacy of a drug, medical device or treatment has been designed, conducted or reported by an Investigator with a financial conflict of interest that was not reported or managed, the Institution will require that the Investigator involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

#### Reconsideration and Appeals

1. Determinations of the FCOI Committee may be reconsidered by submitting a written request for reconsideration to CORA who will collaborate with the FCOI Committee.
2. The written request for reconsideration should be submitted within 30 days of notice of the proposed Plan or denial and should include evidence detailing the investigator's concerns and/or compelling circumstances which support his/her claim that the Plan should be revised and/or the Research should go forward.
3. The FCOI Committee will review the request for reconsideration and may approve, modify or reject any proposed revisions to the Plan. The FCOI Committee may also appoint an external ad hoc group to provide an additional level of review in the reconsideration process and report its findings to the FCOI Committee.
4. Any requests for reconsideration that have been denied may be appealed in writing within 30 days of notice of the denial to the Designated Official for review. The decision of the Designated Official is final.

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Sanctions

1. The failure of an Investigator to comply with the approved Management Plan for the FCOI may result in any or all of the following sanctions:
  - A. Suspension from any or all Research activity
  - B. Termination of any or all Research activity

Public Accessibility

1. This policy upon adoption will be posted on the web site of SLHS. If the policy is modified, such modification shall be posted within 30 days.
2. For PHS-funded research, the FCOI Committee will make available through a written response within five business days of request, information concerning any FCOI with respect to Senior/key personnel identified by the Institution. The response will include the Investigator's name, title and role in the Research and the nature of the SFI and the approximate dollar value reported in a range. The response will note that this information is current as of that date will be updated at least annually, and each time Senior/key personnel disclose a relevant change and the requestor will be encouraged to request such updates. The information concerning the FCOIs in response to written requests will remain available for at least three years from the date that the information was most recently updated.

**IN COLLABORATION WITH:**

Mid America Heart Institute  
Saint Luke's Cancer Institute  
Saint Luke's Hospital Institutional Review Board  
SLHS Ethics and Compliance Program

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