**TITLE:** Conflicts of Interest in Research
**SECTION:** Research (RES)

# PURPOSE

To establish guidelines for identifying and reporting Conflicts of Interest (COI) in Research and to define the process for reviewing and managing reported COI.

# POLICY

It is the policy of Saint Luke's Health System (SLHS) to promote and maintain objectivity and integrity in Research and to ensure that the design, conduct, and reporting of Research will not be biased by any COI. All Investigators, as defined in this policy, must disclose Significant Financial Interests and Significant Conflicts of Commitment in a timely manner so that actual, potential, and apparent COIs can be identified and responsibly managed.

# APPLICABILITY

This policy applies to all Investigators responsible for Sponsored Research activities at SLHS. All Investigators engaged in PHS-funded research or research funded by agencies that have adopted the PHS regulations are also subject to the additional requirements set out in Appendix A. *Note: research staff not meeting the definition of Investigator are subject to Conflict of Interest disclosure reporting requirements, GA-028.*

# DEFINITION(S)

**Conflict of Commitment** – A Conflict of Commitment exists when an outside activity or personal consideration that reasonably appears to be related to the Investigator's Institutional Responsibilities could compromise, or have the appearance of compromising, an Investigator's judgment in conducting or reporting research.

**Conflict of Interest (COI)** – a Significant Financial Interest or Significant Conflict of Commitment that SLHS reasonably determines could directly and significantly affect the design, conduct, or reporting of Research.

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

**Family** – Any member of the Investigator's immediate family, limited to any dependent children, spouse or domestic partner.

**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 Interests** – anything of monetary value, whether or not the value is readily ascertainable. For purposes of this definition, financial interests include salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship, teaching engagements); 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.

**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.

**Institutional Official (IO)** – the individual designated in the Saint Luke's Hospital Federalwide Assurance Agreement with the Office of Human Research Protections and to whom the Research Conflict of Interest Committee reports.

**Institutional Responsibilities** – The Investigator's professional responsibilities on behalf of the Institution, which may include for example: activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards (IRBs) or Data and Safety Monitoring Boards (DSMBs).

**Investigator** – Any researcher, regardless of title or position, who is responsible for the design, conduct, or reporting of Research or proposals for funding of Research. This may include, for example, collaborators or consultants.

**IRB –** SLHS Institutional Review Board

**Manage –** Taking action to address a Conflict of Interest, which can include reducing or eliminating the Conflict of Interest to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

**Public Health Service** — Public Health Service (PHS) of the United States Department of Health and Human Services. *For a list of agencies, see https://www.federalregister.gov/agencies/public-health-service*

**Research** – A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. The term encompasses basic and applied research, product development, and clinical trials, regardless of the source of funding or support.

**Research Conflict of Interest Discipline Appeal Board (RCOI Discipline Appeal Board) –** the members appointed to review IO determination of research-related disciplinary action; members of Board must include: an HR representative, General Counsel, and one principal investigator (who does not currently serve on the SLHS IRB or Research Conflict of Interest Committee).

**Research Conflict of Interest Committee (RCOI Committee)** – the Committee appointed under Policy #RES-016 to review Conflicts of Interests in Research.

**Sponsored Research** – Research involving funds, materials or other support from sources external to SLHS.

**Significant Conflict of Commitment (SCOC)** – A Conflict of Commitment that is any of the following:

a. An executive position in a for-profit business that engages in commercial or research activities of a

biomedical nature.

b. Serving in a fiduciary role for a for-profit business that engages in commercial or research activities of a biomedical nature.

**Significant Financial Interests (SFI) —** A Financial Interest that reasonably appears to be related to the Investigator's Institutional Responsibilities, and that is any of the following:

a. With regard to any publicly traded entity, an SFI exists if the aggregate value of any remuneration received in the twelve months preceding the disclosure, and the value of any equity interest during the 12-month period preceding or as of the date of disclosure, exceeds $5,000.

b. With regard to any non-publicly traded entity, an SFI exists if the aggregate value of any remuneration received during the twelve months preceding the disclosure exceeds $5,000, or when the Investigator or his/her Family holds any equity interest (e.g., stock, stock option, or other ownership interest) of any value during the 12-month period preceding or as of the date of disclosure.

c. Any income related to intellectual property rights and interests.

d. SFI 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, 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, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

# PROCEDURE

A. Identification and Disclosure

1. Information to be Disclosed
   All Investigators are required to disclose their SFI and their SCOC as described herein, and disclosures must include the following information:
   - The person(s) having the interest;
   - The Investigator's relationship to such person(s);
   - The name of the Entity with which the Investigator has the SFI or SCOC; and
   - The nature of the SFI or SCOC and its approximate monetary value.

Regardless of the disclosure requirements, Investigators are encouraged to disclose any Financial Interest or Conflict of Commitment that could reasonably be perceived to present a COI.

2. Required Disclosure Timepoints
   - **Annually**. Investigators participating in Research must submit an updated RCOI Disclosure Form at least annually, even if attesting to no actual or potential conflicts. The updated disclosure will include any new information that was not disclosed initially or in any subsequent disclosure of SFIs and SCOCs, and will include updated information regarding any previously disclosed SFI or SCOC (e.g., the updated value of a previously disclosed equity interest).
   - **Initiating Sponsored Research**. Investigators with a potential or actual SFI or SCOC, that is potentially related to their Institutional Responsibilities and the proposed Sponsored Research project, must submit an RCOI Disclosure Form prior to submitting the project for IRB consideration.
   - **Joining Sponsored Research**. Investigators with a potential or actual SFI or SCOC, that is potentially related to their Institutional Responsibilities and the ongoing Sponsored Research project, must submit an RCOI Disclosure Form prior to their involvement in the project.
   - **Ad Hoc Disclosures**. All Investigators must submit an RCOI Disclosure Form within 30 days of discovering or acquiring a potential or actual SFI or SCOC that is potentially related to their Institutional Responsibilities.
   - **PHS-funded Research**. Investigators must submit an RCOI Disclosure Form no later than the time of application for PHS funds.

B. Review of Research Conflict of Interest Disclosures

1. All disclosure forms will be reviewed by the IO or designee to determine whether the SFI or SCOC is related to the Research and if so, whether the SFI or SCOC constitutes a COI. An Investigator's SFI or SCOC is related to the Research when the IO or designee reasonably determines that the SFI or SCOC could be affected by the Research or is in an Entity whose financial interests could be affected by the Research. If it is determined that the SFI or SCOC is related to the Research and it constitutes a COI, the IO or designee will refer the matter to the RCOI Committee which will make recommendations to eliminate, reduce or Manage the conflict, as appropriate. If it is determined that there is a COI that can be Managed, the RCOI Committee will develop a conflict management plan that specifies the actions that have been, or shall be, taken to Manage the COI. The conflict management plan must be approved by the IO before any related Research goes forward.
2. Examples of conditions or restrictions that might be imposed as part of a COI management plan include, but are not limited to:
   a. Public disclosure of financial interests during presentations (whether internal or external), publications, or other disseminations, whether oral or written;
   b. Disclosure of COI to prospective subjects and to the Research sponsor (governmental or private);

c. Monitoring of the Research by independent reviewers;
d. Modification of the Research plan, Research staff roles, or changes in location of certain Research activities, to address the potential bias from interests;
e. Disqualification from participation in all or a portion of the Research;
f. Require periodic reports regarding implementation of the plan and its progress;
g. Reduction or elimination of the COI; or
h. Severance of relationships that create a COI.

C. Notification

The RCOI Committee will be responsible for communicating its resolution of the matter to the Investigator, the Director of Research, and the IRB. In the event the Investigator is dissatisfied with the decision, the Investigator may file a petition for reconsideration in writing with the IO within thirty days of receipt of notice. The written petition for reconsideration should include evidence detailing the Investigator's concerns and/or compelling circumstances which support his/her claim that the conflict management plan should be revised and/or the Research should go forward. The RCOI Committee will review the request for reconsideration and may approve, modify or reject any proposed revisions to the conflict management plan.

Any COI must be resolved prior to final IRB approval of the Research. The IRB will not approve monitoring methods or other conditions that are less restrictive than those imposed by the RCOI Committee. (The IO may review the conflict management plan approved by the IRB to ensure it has not approved less restrictive management conditions than those imposed by the RCOI Committee.) No approval of a conflict management plan granted by the RCOI Committee may supersede the authority of the IRB, and the IRB may modify the conflict management plan to impose more stringent restrictions than those imposed by the RCOI Committee.

D. Review

An internal review will be conducted annually by the RCOI Committee to determine compliance with the conflict management plan. If the Investigator is found to be non-compliant, then Section F below will apply.

E. Reporting

Should any COI or noncompliance require reporting to a funding organization or agency, the IO or designee will report in accordance with the applicable organization requirements or agency regulations.

F. Noncompliance

1. Retrospective Review. In the event that a COI was not identified or managed in a timely manner,

including failure by the Investigator to disclose a SFI or SCOC, failure by SLHS to review or manage a SFI or SCOC, or failure by the Investigator to comply with a conflict management plan, the RCOI Committee will complete a retrospective review within 120 days of the determination of noncompliance to establish whether the Research conducted during the period of noncompliance was biased in design, conduct or reporting. Documentation of the retrospective review shall include:

- The project number;
- The project title;
- The name of the Principal Investigator;
- The name of the Investigator with the COI;
- The name of the Entity with which the Investigator has the COI;
- The reason(s) for the retrospective review;
- The detailed methodology used for the retrospective review, and
- The findings and conclusions of the review.

If bias is found, the report will include a mitigation report in accordance with applicable regulations, including the key elements from the retrospective review, a description of the impact (if any) of the bias on the Research project and the plan of action to eliminate or mitigate the effect of the bias.

2. Disciplinary Action. In the event of an Investigator's failure to comply with this policy, the IO may suspend all relevant activities or take other disciplinary action related to the study until the matter is resolved. The IO's decision to impose sanctions on an Investigator because of failure to comply with this policy, or failure to comply with the decision of the IO, will be described in a written explanation of the decision to the Investigator along with the individual's right to appeal the decision. The Investigator may appeal the decision by sending a written appeal request accompanied by supporting information explaining the reason for appeal to the RCOI Discipline Appeal Board. The decision of the RCOI Discipline Appeal Board will be final.

G. Subrecipient/Subcontractor Requirements

Reasonable steps must be taken to confirm that all SLHS subrecipients or subcontractors participating in federally-funded Research are subject to COI rules and procedures that comply with the requirements of the applicable funder. Each subrecipient or subcontractor must provide assurances to SLHS that it has policies and procedures that comply with the requirements of the funder, or otherwise agree to comply with this policy prior to the Investigator's submission of funded research proposals or applications and execution of a written agreement between SLHS and the subrecipient or subcontractor.

H. Record Retention

The IO, or delegate, will maintain a database of all disclosures, conflict management plans, and related documents for a period of three years following the conclusion at SLHS of the Research to which such documents relate.

I. Website Posting

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.

J. Training

Investigators must complete training designated by SLHS on Conflicts of Interest in Research prior to engaging in Sponsored Research, and at least every four years thereafter while participating in Sponsored Research. In the event that this policy is substantively amended in a manner that affects the requirements of Investigators, or if it is determined that the Investigator has not complied with this policy, or with a conflict management plan related to their activities, this training must be repeated within a reasonable period of time as determined by the IO.

## IN COLLABORATION WITH

Research, Institutional Review Board, and Ethics & Compliance

## REFERENCES

21 CFR Part 54 – Financial Disclosures by Clinical Investigators
42 CFR Part 50, Subpart F – Promoting Objectivity in Research
45 CFR Part 94 – Responsible Prospective Contractors
45 CFR Part 75 – Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards
FDA Guidance for Clinical Investigators, Industry, and FDA Staff: Financial Disclosure by Clinical Investigators, February 2013

## SEE ALSO

Conflict of Interest, GA-028
Research Conflict of Interest Committee, RES-016

## THIS DOCUMENT APPLIES TO:

Anderson County Hospital (d/b/a for Saint Luke's Hospital of Garnett, Inc.)

Anderson County Hospital Long Term Care Unit (d/b/a for Saint Luke's Hospital of Garnett, Inc.)

Family Care Center (FCC) at Anderson County Hospital (d/b/a for Saint Luke's Hospital of Garnett, Inc.)

Bishop Spencer Place

Hedrick Medical Center (d/b/a for Saint Luke's Hospital of Chillicothe)

Hedrick Family Care at Hedrick Medical Center (d/b/a for Saint Luke's Hospital of Chillicothe)

Saint Luke's East Hospital

Saint Luke's Hospital of Kansas City

Saint Luke's Hospital of Kansas City Crittenton Children's Center Campus

Saint Luke's North Hospital

Saint Luke's South Hospital, Inc.

Saint Luke's South Pain Management Center

Wright Memorial Hospital (d/b/a for Saint Luke's Hospital of Trenton, Inc.)

Saint Luke's Mercer County Clinic at Wright Memorial Hospital (d/b/a for Saint Luke's Hospital of Trenton, Inc.)

Wright Memorial Physician Group at Wright Memorial Hospital (d/b/a for Saint Luke's Hospital of Trenton, Inc.)

Saint Luke's Health System

Saint Luke's Health System Home Care and Hospice

Saint Luke's Neighborhood Clinics, LLC

Advanced Urologic Associates, Inc.

Medical Plaza Imaging Associates, Inc.

Risk Retention Group

Rockhill Orthopaedic Specialists, Inc.

Saint Luke's Physician Group

Saint Luke's Care

Saint Luke's Radiation Therapy - Liberty

Allen County Regional Hospital (d/b/a for Saint Luke's Hospital of Allen County, Inc.)

Allen County Regional Clinic at Allen County Regional Hospital (d/b/a for Saint Luke's Hospital of Allen County, Inc.)

**REPLACES PREVIOUS DOCUMENTS**
Conflict of Interest in Research (RES-015)

# APPENDIX A

Additional Requirements on Financial Conflicts of Interest Related to Public Health Service Funding

***The following disclosure criteria apply to Investigators that apply for and/or receive PHS funding through grant or cooperative agreement.***

A. Annual Reporting. All Public Health Service-funded Investigators must submit to the IO a Research Conflict of Interest Disclosure Form, on an annual basis throughout the life of the sponsored project. Subsequent proposals for PHS funding will not be submitted if the Investigators are not up to date on their annual reports and disclosures.

B. Disclosure of Financial Interests: Travel. In addition to the disclosure requirements set forth in the body of this policy, Public Health Service-funded Investigators must also disclose reimbursed or sponsored travel within the past 12 months, related to their Institutional Responsibilities as outlined above in the definition of Financial Interest. Such disclosures must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration and the monetary value (or, if unknown, a reasonable approximation). The IO will determine if additional information is needed to determine whether the travel constitutes a COI with the Investigator's Research.

C. Reporting to the Agency. Should any reported conflict require reporting to the Public Health Service, the IO will report in accordance with the following:

1. Prior to the expenditure of any funds under a PHS-funded research project, SLHS shall submit to the agency a financial COI report and conflict management plan regarding any Investigator's SFI or travel disclosure that SLHS has deemed a COI.

2. Upon learning of a COI in the course of any PHS-funded research, or of a previously unreported COI related to ongoing research, SLHS shall submit to the agency a financial COI report and conflict management plan within 60 days of identification of the conflict. All financial COI reports submitted to PHS shall include the following relevant information needed for the agency to understand the nature and extent of the conflict and to assess the appropriateness of SLHS's conflict management plan:

- The project number;
- The name of Principal Investigator;
- The name of Investigator with the financial COI;
- The name of the Entity with which the Investigator has the financial COI;
- The nature of the SFI;
- The value of the SFI (as $0-4,999, $5,000-9,999, $10,000-19,999, by increments of $20K if between $20,000 and 100,000, or by increments of $50,000 if above $100,000) or a statement that a value cannot be readily determined through references to public prices or other reasonable measures of fair market value;

- A description of the relationship of the SFI to the PHS-funded Research;
- A description of the basis for SLHS's determination that the SFI conflicts with the Research; and
- A description of the key elements of the conflict management plan, including:
  i. The role and principal duties of the conflicted Investigator in the Research;
  ii. The conditions of the conflict management plan;
  iii. How the conflict management plan is designed to safeguard the objectivity of the Research;
  iv. Confirmation of the Investigator's agreement to the conflict management plan;
  v. How the conflict management plan will be monitored to ensure Investigator compliance; and
  vi. Any other relevant information, as needed.

For all COIs reported to PHS, SLHS will submit annual reports for the duration of the award. These reports will include (1) the status of the COI, (2) any changes to the conflict management plan, and (3) a statement of whether the COI is still being managed or an explanation of why the COI no longer exists.

D. Public Accessibility. In the event a written request is received from any member of the public, the following information regarding SFIs will be disclosed within five business days of the receipt of the request:
- The Investigator's name;
- The Investigator's title;
- The Investigator's role on the project;
- The name of any Entity with which the Investigator has or has had within the past three years a SFI constituting a COI;
- The nature of the SFI; and
- Approximate value of the SFI (as $0-4,999, $5,000-9,999, $10,000-19,999, by increments of $20,000 if between $20,000 and 100,000, or by increments of $50,000 if above $100,000) or a statement that a value cannot be readily determined through references to public prices or other reasonable measures of fair market value.

E. Record Retention. All records related to disclosures of financial interests by a PHS-funded Investigator and SLHS's review of, and response to, such disclosures and all actions under this policy must be retained for at least 3 years after the date the final expenditures report is submitted to PHS or longer if required by 45 CFR 75.361.