

POLICY TITLE:	Research Conflicts of Interest – Reporting and Management
POLICY:	It is the policy of St. Luke’s Health System (SLHS) to identify, evaluate, manage, reduce and/or eliminate potential Conflicts of Interest in order to protect the safety and well-being of subjects, as well as the integrity and objectivity of SLHS Research Studies.
SCOPE:	This policy applies to St. Luke’s workforce and all locations where St. Luke’s Health System or its subsidiaries conduct business and/or care for patients. These locations include inpatient and outpatient locations that are part of St. Luke’s Boise, St. Luke’s Meridian, St. Luke’s Magic Valley, St. Luke’s Wood River, St. Luke’s McCall, St. Luke’s Jerome and St. Luke’s Elmore. ¹ A facility, business or contractor that is affiliated with St. Luke’s Health System or one of its subsidiaries may also use this policy if its processes are consistent with this policy and a different policy has not been implemented.
DEFINITIONS:	<p>Applicable Law: Federal, state and local laws and regulations as may be enacted from time to time, applicable to Conflicts of Interest.</p> <p>Compensation: Anything of monetary value, including, but not limited to gifts, consulting fees, honoraria, stipends, paid authorship, speaker’s bureau or other payments for services. It does not include salaries or other forms of compensation paid for by St. Luke’s.</p> <p>Conflict of Interest (COI): A Significant Financial Interest or Significant Non-Financial Interest that could directly and significantly affect the design, conduct, reporting or oversight of the Research as determined by the Research Conflict of Interest Committee.</p> <p>Conflict Management Plan (CMP): A plan developed by the Research Conflict of Interest Committee to manage a Conflict of Interest that is deemed manageable by the Research Conflict of Interest Committee.</p> <p>Covered Persons: Key Research Personnel, Institutional Review Board Members, Research Conflicts of Interest Committee Members, and Administration Officials with research oversight responsibilities.</p> <p>Designee: An individual or entity to whom the Research Conflicts of Interest Committee delegates the authority to perform certain of its responsibilities and exercise certain of its authorities according to guidelines promulgated by the Research Conflict of Interest Committee.</p> <p>Equity Interest: Any interest in the profits of or stock of a commercial or non-profit enterprise, a stock option or any other ownership interest in a commercial or non-profit enterprise.</p>

¹ The facilities listed are wholly owned by one of the following legal entities, the parent corporation of all of which is St. Luke’s Health System, Ltd.: St. Luke’s Regional Medical Center, Ltd. (St. Luke’s Boise, St. Luke’s Meridian and St. Luke’s Elmore); St. Luke’s Magic Valley Regional Medical Center, Ltd. (St. Luke’s Magic Valley and St. Luke’s Jerome); St. Luke’s McCall, Ltd. (St. Luke’s McCall); and St. Luke’s Wood River Medical Center, Ltd. (St. Luke’s Wood River).

St. Luke’s process for developing policies and the **content of policies is proprietary** business information and **may only be shared** outside of St. Luke’s **with permission** from a Sr. Director, Administrator, Vice President, or CEO, or as required by law. If this is a patient care policy, the information contained herein is used to provide guidance in the care of patients, but should not, and does not replace or preclude the use of clinical judgment.

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<p>DEFINITIONS continued...</p>	<p>FCOI Report: St. Luke’s report of a Financial Conflict of Interest to a PHS Awarding Component.</p> <p>Financial Conflict of Interest (FCOI): A Significant Financial Interest of a Covered Person or a Covered Person’s spouse and dependent children that could directly and significantly affect the design, conduct, reporting or oversight of the Research.</p> <p>Institutional Responsibilities: A Covered Person’s professional responsibilities on behalf of St. Luke’s, which may include research, research consultation, teaching, and institutional committee membership and service on panels such as IRBs.</p> <p>Institutional Review Board (IRB): An entity established under federal regulation to protect the rights, safety, and welfare of research participants and to uphold the ethical principles for human subject’s research regardless of the funding source.</p> <p>Intellectual Property: Any direct or indirect rights or interests in a patent, trademark, copyright, trade secret, know-how or other Intellectual Property right, including but not limited to ownership, royalties and license fees.</p> <p>Key Research Personnel: Any individual, regardless of title or position, who is responsible for the conduct, design, or reporting of research.</p> <p>New Significant Financial Interest: A different type or nature of Significant Financial Interest (e.g., speaker’s bureau versus equity) than what had previously been disclosed from the same source that meets or exceeds the threshold. In addition, a New Significant Financial Interest is also considered to be the same type or nature of Interest (e.g., equity) from a different source (e.g., company A versus company B).</p> <p>Non-Financial Conflict of Interest: A Significant Non-Financial Interest of a Covered Person or a Covered Person’s spouse and dependent children that could directly and significantly affect the design, conduct, reporting or oversight of the Research.</p> <p>PHS: The Public Health Service of the U.S. Department of Health and Human Services and any PHS Awarding Components to which authority may be delegated, including without limitation the National Institute of Health.</p> <p>PHS Awarding Component: The organizational unit of the Public Health Service that is subject to 42 CFR 50 Part F.</p> <p>PHS Funded Research: Research for which funding is available from a PHS Awarding Component through a grant or cooperative agreement.</p> <p>Principal Investigator (PI): The SLHS individual who has the authority and responsibility to direct the management, monitoring and integrity of the design, conduct, and reporting of the SLHS Research Study.</p> <p>Reimbursed Travel: Travel activity for which the travel expenses are paid directly by the Key Research Personnel, who is then reimbursed by an entity for such travel expenses.</p> <p>Research: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. 45 CFR 46.102(d).</p> <p>Research Conflicts of Interest Committee (RCOIC): The St. Luke’s committee organized to identify, review and manage Conflicts of Interest of Covered Persons, including any Designees.</p> <p>Senior Key Personnel: The project director and/or principal investigator and any other person identified as senior/key personnel by St. Luke’s in the grant application, progress report or any report submitted to the PHS by St. Luke’s under this policy.</p>
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<p>DEFINITIONS continued...</p>	<p>Significant Financial Interest (SFI): A financial interest consisting of one or more of the following interests of a Covered Person or a Covered Person’s spouse and dependent children that reasonably appears to be related to the Covered Person’s Institutional Responsibilities. A SFI includes one or more of the following:</p> <ol style="list-style-type: none"> 1. With respect to a publicly traded entity, the value of Compensation (anything of monetary value, including, but not limited to gifts, consulting fees, honoraria, stipends, paid authorship, speaker’s bureau, or other payments for services) received from the entity in the 12 months preceding the date of disclosure that is more than \$5,000 in aggregate; 2. With respect to a publicly traded entity, Equity Interest (stocks, stock options, warrants, contractual rights to acquire or receive ownership interests or other ownership interests in a publicly-traded company) as determined on the date of disclosure that is more than \$5,000; 3. With respect to with a publicly traded entity, the aggregated value of #1 and #2 above (Compensation + Equity interest) that is more than \$5,000; 4. With respect to any non-publicly traded entity, the value of Compensation (anything of monetary value, including, but not limited to gifts, consulting fees, honoraria, stipends, paid authorship, speaker’s bureau, or other payments for services) received from the entity in the 12 months preceding the date of disclosure that is more than \$5,000 in aggregate; 5. With respect to any non-publicly traded entity, any Equity Interest on the date of disclosure of any amount; 6. Intellectual Property: Patents, copyrights, and royalty income or the right to receive future royalties under a patent or license or copyright; and, 7. Reimbursed or Sponsored Travel (only applicable to Key Research Personnel) that exceeds \$5,000 when aggregated per entity in the 12 months preceding the date of disclosure. Disclosures shall include the purpose of the travel, the identity of the sponsor/organizer, the destination and the duration of the travel. <p>But, excluding the following:</p> <ol style="list-style-type: none"> 1. Salary or other compensation paid by St. Luke’s; 2. Income from investments in mutual funds or retirement accounts, as long as the investigator does not make the investment decisions; 3. Income for services (honoraria, advisory committees, review panels, etc.) and travel expenses paid by a federal, state, or local government agency, a U.S. institution of higher education or a research institute affiliated with a U.S. institution of higher education, a medical center, or an academic teaching hospital; 4. Travel that is sponsored or reimbursed by a federal, state, or local government agency, SLHS or an institution of higher education an academic teaching hospital, a medical center, or research institute that is affiliated with an institution of higher learning; 5. Travel that is reimbursed or paid directly by a St. Luke’s study budget; 6. Travel that is reimbursed to you by St. Luke’s or paid by St. Luke’s; and, 7. Self-funded travel
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DEFINITIONS continued...	<p>Significant Non-Financial Interests (SNFI): A non-financial interest that includes one or more of the following:</p> <ol style="list-style-type: none"> 1. Serving as an officer, director, consultant, or fiduciary for a study sponsor or its affiliates; and, 2. Having a non-financial interest that may compromise, or have the appearance of compromising, professional judgment in the design, conduct, reporting or oversight of the Research. <p>SLHS Research Study: A research study that falls within the scope of the SLHS Research Program.</p> <p>Sponsored Travel: Travel expenses paid directly by an entity on behalf of the Key Research Personnel and not reimbursed directly to the Key Research Personnel so that the exact monetary value may not be readily available.</p>
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GENERAL INFORMATION

Individuals involved in the design, conduct, reporting or oversight of SLHS research activities are required to disclose SFIs and SNFIs that are related to their Institutional Responsibilities. St. Luke’s has a Research Conflict of Interest Committee (RCOIC) that is responsible for reviewing disclosures and instituting an adequate plan for the elimination, reduction or management of any Conflicts of Interests. The ultimate goal of this Policy is to protect the integrity and credibility of activities related to Research and to maintain public trust and confidence in St. Luke’s and its employees.

I. RESPONSIBILITIES OF COVERED PERSONS

- A. Key Research Personnel are required to:
 1. Disclose SFIs and SNFIs
 - a. Annually to St. Luke’s Research;
 - b. Within 30 days after a New SFI or SNFI is received or acquired and when changes occur during the disclosure year that affect the accuracy of prior responses on the questionnaire. In the case of Reimbursed or Sponsored Travel, the disclosure must be updated within 30 days of the trip end; and,
 - c. When new to research at St. Luke’s.
 2. Ensure their disclosure is current prior to the submission of a new research application to St. Luke’s Research
 3. Comply with any Conflict Management Plan (CMP) established by the RCOIC
 4. Complete the Collaborative Institutional Training Initiative (CITI) conflict of interest course:
 - a. At least every 4 years;
 - b. When new to research at St. Luke’s; and, as required by St. Luke’s Research, upon determination of non-compliance with this policy, or an existing CMP.
- B. In addition to the responsibilities outlined for Key Research Personnel, Principal Investigators are required to:
 1. Designate those Key Research Personnel participating in a Research study who must disclose SFIs and SNFIs. The PI shall consider an individual’s role and degree of independence relative to the research in determining who to designate as a Key Research Personnel. Investigators, research managers/directors, and those in data analysis or reporting roles shall always be determined to be a Key Research

- Personnel. In general, students or other personnel whose research activities are directly supervised are excluded.
2. Ensure all Key Research Personnel participating in a Research study have submitted the required disclosures, prior to their participation on a study;
 3. Ensure all Key Research Personnel participating in a Research study promptly disclose any New SFI or SNFI;
 4. Ensure all Key Research Personnel participating in a Research study have completed the CITI conflict of interest course as required under this policy; and,
 5. Indicate, upon submission of a new research application, if any Key Research Personnel has a SFI or SNFI related to the Research study.
- C. All IRB Members, RCOIC Members and Administration Officials with research oversight responsibilities are required to:
1. Disclose SFI or SNFI:
 - a. Annually to St. Luke's Research;
 - b. Within 30 days of hire or appointment by St. Luke's; and,
 - c. Within 30 days after a New SFI or SNFI is received or acquired and when changes occur during the disclosure year that affect the accuracy of prior responses on the questionnaire.
 2. Complete the CITI conflict of interest course
 - a. At least every 4 years;
 - b. As part of new employee orientation or appointment by St. Luke's; and,
 - c. When circumstances require additional or updated conflict of interest training as determined by St. Luke's Research.
 3. Any IRB member, RCOIC member, or administration official with research oversight responsibilities that has a SFI or SNFI related to ongoing or proposed Research will be deemed to hold a conflict of interest and not be allowed to participate in the review, discussion, or vote on any Research except to provide information requested by the IRB or RCOIC.

II. REVIEW OF DISCLOSURES

- A. St. Luke's Research is responsible for the initial review of annual conflict of interest questionnaires. If St. Luke's Research determines that a disclosure involves a SFI or SNFI related to a specific Research study or other Institutional Responsibilities, the disclosure shall be referred to the RCOIC for further review and determination.
- B. The RCOIC shall review all SFIs and SNFIs as they relate to SLHS Research Studies and Institutional Responsibilities to determine if they constitute Conflicts of Interest.
- C. The RCOIC shall manage, reduce or eliminate any potential or actual Conflicts of Interest to ensure SFI and SNFI will not bias the design, conduct, reporting or oversight of St. Luke's research activities.
- D. The RCOIC shall develop and implement a CMP for those Conflicts of Interest determined to be manageable. The RCOIC shall use the CMP to monitor and enforce compliance with the requirements and standards of the Policy.
- E. The RCOIC shall undertake or direct the SLHS Compliance Department or its Designee to undertake periodic audits of the SLHS COI process and functions as necessary to review compliance with this Policy.

- F. For SLHS Research Studies funded in whole or in part by the Public Health Service (PHS), sub-awardees, contractors and collaborators must either adhere to this Policy or provide written assurances to SLHS that will enable SLHS to comply with PHS Conflicts of Interest regulations.
- G. The RCOIC shall cooperate with any compliance procedures or processes set forth by SLHS System Compliance.

III. MANAGEMENT OF CONFLICT OF INTEREST

- A. If the RCOIC determines that a disclosure involving a SFI or SNFI of a Key Research Personnel constitutes a COI related to a Research study, it shall develop and implement a CMP specifying actions that will be taken that in the reasonable judgment of the RCOIC will reduce or manage the COI.
- B. No Key Research Personnel having a COI may participate in the related Research study without prior written approval from the RCOIC. A completed CMP will generally serve as written approval.
- C. In developing a CMP, the RCOIC may conduct factual inquiries and consult with and receive recommendations from such persons or committees as the RCOIC deems necessary and appropriate.
- D. Whenever a CMP is implemented, the RCOIC shall take such actions as it deems reasonable to audit and/or monitor compliance until the CMP is no longer required.

IV. ADDITIONAL REQUIREMENTS RELATED TO PHS-FUNDED RESEARCH STUDIES

- A. St. Luke's will submit all required Financial Conflicts of Interest (FCOI) reports to the PHS Awarding Component as follows:
 - 1. Prior to the expenditure of any funds under the PHS funded Research if a FCOI has not been eliminated;
 - 2. Within 60 days of identifying a FCOI during an ongoing Research study; and,
 - 3. Annually for any FCOI previously reported in regard to an ongoing PHS funded Research study. The report shall specify the status of the FCOI (if it is still being managed or explain why it is no longer exists) and, if appropriate, any changes to the CMP. The report shall be submitted annually for the duration of the Research study.
- B. Any FCOI report submitted to the PHS Awarding Component shall contain sufficient information to understand the nature and extent of the financial conflict and assess the appropriateness of the CMP. The report shall include the following elements:
 - 1. The name of the Key Research Personnel;
 - 2. The Research project number;
 - 3. Written assurance that the FCOI was managed, reduced or eliminated;
 - 4. The name of the entity with which the Key Research Personnel has the FCOI;
 - 5. The nature of the FCOI and its value in dollar increments;
 - 6. A description of how the FCOI relates to the Research;
 - 7. The basis for the decision that the reported interest is an FCOI; and;
 - 8. The key elements of the FCOI CMP.

- C. St. Luke's shall specify in any written agreement with an institution that has been awarded a PHS-funded grant or contract (Grantee Institution) in which St. Luke's is acting as a sub-recipient whether the Conflict of Interest policies of St. Luke's or the Grantee Institution will apply. In the event St. Luke's acts as a sub-recipient in a PHS-funded study, St. Luke's shall promptly report any information required by this section to the Grantee Institution to enable it to meet its reporting obligations to the PHS Awarding Component.
- D. Retrospective Review of PHS Funded Research
1. In the event that St. Luke's identifies a SFI that was not disclosed in a timely manner or was not previously reviewed by St. Luke's during an ongoing Research study, St. Luke's shall within 60 days:
 - a. Review the SFI;
 - b. Determine whether it is related to a Research study;
 - c. Determine whether a FCOI exists; and,
 - d. Implement a CMP (if determined to be a FCOI) that specifies the actions that have been taken and will be taken to manage the FCOI.
 2. In the event of non-compliance with this Policy or a CMP, including untimely Key Research Personnel disclosure or St. Luke's review of a SFI that is determined to be a FCOI, St. Luke's shall within 120 days:
 - a. Conduct a retrospective review of the Key Research Personnel activities and Research;
 - b. Determine whether any portion of the Research was biased in design, conduct or reporting of the data;
 - c. If bias is identified after retrospective review, St. Luke's must promptly submit a written report to the PHS Awarding Component that includes key elements documented in the retrospective review, the impact of the bias on the research and the plan of action to eliminate or mitigate the effect of the bias; and,
 - d. St. Luke's will submit FCOI reports annually thereafter for the duration of the Research study.
- E. Ensuring Public Accessibility to Financial Conflict of Interests:
- St. Luke's will post its Research Conflicts of Interest Policy on its publically available website. St. Luke's will ensure public accessibility of information regarding SFI held by persons identified as Senior Key Personnel in the research contract proposal and contract. This information will be made available to the public, upon written request, within five (5) business days of receipt of the request. The information shall include the following:
1. The name and role of the Senior Key Personnel in the project;
 2. The nature and approximate dollar value of the SFI; and,
 3. The name of the entity in which the interest is held.

V. SANCTIONS AND REMEDIES FOR VIOLATION OF POLICY

- A. If the RCOIC determines that a Covered Person has violated this Policy, including failure to submit required disclosures or failure to comply with the requirements of a CMP, the RCOIC shall report the violation to the Medical Director for St. Luke's Research. St. Luke's shall take reasonable steps to respond appropriately to violations, including, but not limited to, suspending the research activity, administratively suspending any research study related to the SFI or SNFI, or instituting disciplinary measures up to and including suspension and termination, as appropriate.

- B. In the case of PHS Funded Research, St. Luke’s will submit to the U.S. Department of Health and Human Services, or permit on site review of, all records pertinent to compliance with this Policy and federal regulations.
- C. In the case in which it is determined that a PHS Funded Research study whose purpose is to evaluate the safety or effectiveness of a drug, medical device or treatment has been designed, conducted, or reported by a Key Research Personnel with a SFI that was not managed or reported, St. Luke’s shall require the Key Research Personnel involved to disclose the FCOI in each public presentation of the results of the Research and shall request an addendum to previously published presentations.

VI. APPEAL

If a Covered Person disagrees with the determination of the RCOIC, s/he can request that the RCOIC reconvene and review the disclosure again. If additional facts or circumstances become known to a Covered Person after an initial disclosure is made, such additional information can be given to the RCOIC for further consideration.

VII. CONFIDENTIALITY

St. Luke’s shall use reasonable efforts to protect the confidentiality of any financial information and shall disclose such information only as necessary to ensure adequate protection of subjects enrolled in St. Luke’s Research studies to maintain the integrity of the research data and to comply with this Policy and applicable law.

VIII. RECORDKEEPING

St. Luke’s shall maintain records of all disclosures and actions taken to manage any Conflicts of Interest in accordance with all applicable laws, rules, and regulations for at least three (3) years beyond the termination or completion of the Research study with the IRB of Record, whichever is greater.

RELATED DOCUMENTS:	NA
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AUTHORIZED BY: _____ Original signed by Mark Roberts, MD _____ 12/19/16
 System Medical Director of Research Date

Date	Summary of Interim Change(s) / Annual Review	Author / Title

The following list of supporting references is attached to the foregoing policy for the convenience of staff. This list is not part of the foregoing policy and may not include all resources that were used to research the subject of the policy or prepare the content of the policy.

References

KEYWORDS:	conflict, interest, coi, research conflict of interest, financial conflict, research
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