

Title: INVESTIGATOR AND IRB MEMBERS CONFLICTS OF INTEREST IN CLINICAL RESEARCH

Scope: Network

Manual: Administrative Policies and Procedure Manual

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Revision Dates:

Review Dates:

I. Purpose:

It is the policy of St. Luke's University Health Network ("St. Luke's") to promote scientific integrity, patient safety and investigator objectivity in human subjects research. Conflicts of interest on the part of investigators, IRB members, and other individuals responsible for the design, conduct, or reporting of clinical research, if not identified, assessed and either eliminated or appropriately managed, can compromise the safety and well-being of human subjects and the integrity of study data and results.

This policy reflects the purpose of 42CFR§50, Subpart F: Promoting Objectivity in Research: "This subpart promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under Public Health Service (PHS) grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest." This policy also reflects the requirements set forth in 21 CFR part 54 related to financial disclosures by clinical investigators for new drug and medical device applications to the Food and Drug Administration (FDA).

This policy requires that individuals involved in the design, conduct or reporting of clinical research at St. Luke's disclose Significant Financial Interests that could have an effect on how an individual conducts his/her professional responsibilities on behalf of St. Luke's, including research, research consultation, professional practice, and committee or board memberships. A conflict of interest exists when St. Luke's, through its **Clinical Research Integrity Committee**, determines that a Significant Financial Interest could directly and significantly affect the design, conduct or reporting of research. St. Luke's will take action to eliminate or manage identified financial conflicts of interest in research through the mechanisms set forth in this policy.

This policy is intended to supplement and not circumvent other policies adopted by St. Luke's, including, but not limited to, Conflicts of Interest Board of Trustees Policy Manual (No. 25); however, in the event of conflict, this policy shall supersede on matters related to Investigator and IRB members conflicts of interest in clinical research.

St. Luke's shall conduct on-going monitoring of compliance with this Policy and applicable federal, state, and local laws and regulations governing clinical research. This Policy shall be publically available on the St. Luke's website.

II. **Definitions:**

1. **Alternative Policy** means any conflict of interest policy maintained by a sub-recipient that purports to comply with the applicable federal regulations.
2. **Clinical Research** means a systematic investigation involving the participation of human subjects designed to develop or contribute to generalized knowledge relating broadly to public health, including behavioral health and social-sciences research, and including investigations funded and supported by the PHS or investigations regulated by the FDA. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug).
3. **Clinical Study** means Clinical Research being conducted or intending to be conducted at a Research Site.
4. **Conflict of Interest** means any activity, commitment or interest of an Investigator, including a Financial Conflict of Interest (FCOI), that could directly and significantly affect the design, conduct or reporting of Clinical Research.
5. **FCOI Report** means St. Luke's report of FCOI that is sent to a PHS Awarding Component.
6. **FDA** means the U.S. Food and Drug Administration.
7. **Financial Interest** means anything of monetary value, whether or not the value is readily ascertainable.
8. **Financial Conflict of Interest (FCOI)** means a Significant Financial Interest that could directly and significantly affect the design, conduct or reporting of Clinical Research and/or PHS-funded research.
9. **Immediate Family:** the spouse and dependent children of an Investigator.
10. **Institution** means St. Luke's and its affiliates that is applying for or that receives, PHS research funding.
11. **Institutional Official** means the executive designated by St. Luke's as the Signatory Official on the St. Luke's Federal wide Assurance.
12. **Institutional Responsibilities** means an Investigator's professional responsibilities on behalf of the Institution, as these responsibilities may be further defined in this policy. Institutional Responsibilities may include, for example, activities such as clinical service, research, research consultation, administrative management, education, professional practice, and institutional committee and board memberships, including service on the St. Luke's Institutional Review Board and the St. Luke's Clinical Research Integrity Committee.
13. **Investigator** means the project director, Principal Investigator or sub-investigator, Senior/Key Personnel, Clinical Study coordinators, and any other

person, regardless of title or position, who is responsible for the design, conduct or reporting of Clinical Research, which may include, for example, collaborators or consultants. “Investigator” also includes Subrecipient Investigators, who are those individuals or companies that St. Luke’s may contract with to carry out a Clinical Study.

14. **IRB** means the St. Luke’s University Health Network Institutional Review Board.
15. **St. Luke’s IRB Committee** means the St. Luke’s University Health Network Institutional Research Oversight Committee.
16. **Manage** means taking action to address a Financial Conflict of Interest, which can include reducing or eliminating the Financial Conflict of Interest to ensure, to the extent possible, that the design, conduct and reporting of Clinical Research will be free from bias.
17. **PHS** means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which authority involved may be delegated, including the National Institutes of Health (NIH).
18. **PHS Awarding Component** means the organizational unit of the Public Health Service that funds the Clinical Research that is subject to the requirements of this policy.
19. **PHS Funded Research** means research that is funded by PHS and any components of the PHS to which the authority involved may be delegated, including the NIH.
20. **Clinical Research Integrity Committee:** means the committee designated by St. Luke’s to determine if a Significant Financial Interest that is related to a proposed or ongoing Clinical Study constitutes a Conflict of Interest, and to approve any plans to Manage a Conflict of Interest.
21. **Research Integrity Officer (“RIO”)** means the person designated by St. Luke’s to be responsible for implementing this Policy.
22. **Research Site** means the facility or site engaged in Clinical Research that is (i) under the jurisdiction of the St. Luke’s IRB; or (ii) contractually or otherwise affiliated with St. Luke’s for the purpose of engaging in Clinical Research, including subcontractors or Subrecipients.
23. **Senior/Key personnel** means Investigators and any other person(s) identified by the Institution as Senior/Key personnel who are essential to the performance of the research project in the grant application, progress report or any other report submitted to the PHS or FDA.
24. **Significant Financial Interest** that is required to be disclosed means:
 - A. A financial interest of one or more of the following interests of an Investigator (**and those of the Investigator’s Immediate Family**) that is with an individual or entity sponsoring, conducting or seeking to engage in a Clinical Study at an St. Luke’s Research Site; reasonably appears to be related to the Investigator’s Institutional Responsibilities; and (i) for PHS funded research is conveyed in the one year prior to the disclosure required under this policy, or (ii) for FDA regulated research is conveyed during the course of the Clinical Study and for one year after completion of the Clinical Study:
 1. Publicly traded entity:
 - a) For PHS funded research, a disclosure of Significant Financial Interest exists if the value of any remuneration received from the entity in the

- twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of the disclosure, when aggregated, exceeds \$5,000 in value. 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) For FDA regulated research, a disclosure of Significant Financial Interest exists if the value of any equity interest in the entity during the time of carrying out the Clinical Study and for one year following completion of the Clinical Study exceeds \$50,000 in value. 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.
2. Non-publicly traded entity:
 - a) For PHS funded research, a disclosure of Significant Financial Interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator or Investigator's immediate family holds any equity interest in the entity (e.g., stock, stock option, or other ownership interest) or intellectual property rights and interests (e.g., patents, copy rights) upon receipt of income related to such rights and interests; and
 - b) For FDA regulated research, a disclosure of Significant Financial Interest exists if the Investigator holds any equity interest in the sponsor of a Clinical Study (i.e., any ownership interest, stock options, or other financial interest whose value cannot be readily determined through reference to public prices) during the time of carrying out the Clinical Study and for one (1) year following completion of the Clinical Study.
 3. For PHS funded and FDA regulated research, Investigators must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available); provided, however, this disclosure requirement does not apply to travel that is reimbursed or sponsored by a government agency, institution of higher education, academic teaching hospital, medical center or research institute affiliated with an institution of higher education. The disclosure must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. The Institution's RIO or Clinical Research Integrity Committee will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes a FCOI.
 4. For PHS funded and FDA regulated research, a disclosure of Significant Financial Interest consists of intellectual property or other proprietary

rights and interests (e.g. patents, copyrights, royalties, or licensing agreement) in the item being studied or tested, and any receipt of income related to such rights or interest.

5. For PHS funded and FDA regulated research, a disclosure of Significant Financial Interest consists of any compensation or remuneration made to the Investigator in which the value of the compensation or remuneration could be affected by the Clinical Study outcome.
- B. A Significant Financial Interest does not include the following interests, which are not required to be disclosed:
1. 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;
 2. Any ownership interest in the Institution held by the Investigator, if the Institution 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 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
 5. Income from service on advisory committees or review panels for a 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.
25. **Sponsor** means any person or entity that initiates, funds, or otherwise supports the Clinical Research, including the PHS, or an owner, patent-holder, license holder or other controller of the drug, device, biologic or treatment that is the subject of the Clinical Study.
26. **Subrecipient or Subrecipient Investigators** means entities or individuals that St. Luke's contracts with to carry out Clinical Study activities.

III. PROCEDURES (when St. Luke's is the prime recipient)

- A. When applicable to the researchers of the subrecipient, St. Luke's will enter into a written agreement with the subrecipient that provides legally enforceable terms requiring that a financial conflicts of interest policy be acceptable to St. Luke's as long as the research is carried out in cooperation with or through a subrecipient (subrecipients or consortium members) as well as applies to the researchers of the subrecipient.
- B. The subrecipient must certify its policy is consistent with the requirements of any applicable federal regulations when the policy of the subrecipient applies to its researchers.

- C. The agreement must specify the time periods for the subrecipient to report identified financial conflicts of interest to St. Luke's. The time periods must be sufficient for St. Luke's to make any reports required by federal regulation.

IV. EDUCATION

- A. Each Investigator must acknowledge annually that he or she has read this policy and is aware of his/her responsibilities regarding disclosure of financial interests and of applicable federal regulations.
- B. The individual designated as the Human Protections Administrator in the Institution's Federal wide Assurance shall serve as the Institution's Research Integrity Officer ("RIO"). The RIO or the RIO's designee is responsible for ensuring that each Investigator is informed of this policy and its requirements upon its initiation and at least annually thereafter, and within sixty (60) days of any revisions to this policy.
- C. The RIO or designee shall require that each Investigator complete the FCOI Training presented by the NIH Office of Extramural Research at [HTTP://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm](http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm) as follows:
 - 1. Prior to engaging in any Clinical Research related to any PHS-funded
 - 2. Immediately when
 - a) this policy is revised;
 - b) An Investigator is new to the Institution; or
 - c) The RIO or Clinical Research Integrity Committee determines that an Investigator is not in compliance with this policy or any management plan approved by the Clinical Research Integrity Committee to Manage an identified Conflict of Interest.
 - 3. If neither (a) nor (b) above are applicable, then no less frequently than every 4 years.
 - 4. The RIO or designee shall maintain a record of certifications of all Investigators attending each training session.

V. CONFLICT OF INTEREST

- A. **Disclosure Requirements** - An Investigator must complete or update a financial interest disclosure statement.
 - 1. Each Investigator is required to disclose Significant Financial Interests involving themselves and their Immediate Family that are related to his or her Institutional Responsibilities by submitting to the RIO a complete Conflict of Interest Statement in the form attached hereto as Attachment A, and any associated documents, in accordance with the following schedule:
 - a) Prior to the submission of an application for PHS sponsored Clinical Research;
 - b) Prior to the commencement of a Clinical Study at a Research Site for all non-PHS Sponsored Clinical Research;
 - c) At least annually, while a Clinical Study is being conducted at a Research Site;

- d) During the conduct of the Clinical Study, within thirty (30) days of discovering or acquiring a new Significant Financial Interest or any change in any prior reported information; and/or
 - e) At the request of the RIO or Clinical Research Integrity Committee.
2. At the request of the RIO or Clinical Research Integrity Committee, each Investigator is required to submit for each Significant Financial Interest or other Significant Financial Interest copies of any contracts, sponsor agreements, grants, leases, licensing agreements, corporate organization documents, equity subscriptions agreements, equity option agreements, stockholder agreements, and/or documents setting forth the current or potential terms of any Significant Financial Interest or other Significant Financial Interest.

B. Conflict of Interest Review:

1. The RIO or designee shall collect a Conflict of Interest Statement and any associated or additional documents, from each Investigator in accordance with the above schedule.
2. The RIO or designee shall review each Conflict of Interest Statement for completeness, and may request that the Investigator submit additional documents or statements in order to accurately describe any Significant Financial Interests or other Significant Financial Interests.
3. The RIO or designee will conduct a preliminary review to determine whether a disclosed Significant Financial Interest or other Significant Financial Interest could reasonably be related to Clinical Research and, if so related, could be considered a potential or actual Conflict of Interest. Significant Financial Interests are related to Clinical Research when the RIO or designee reasonably determines that the Significant Financial Interest could be affected by the Clinical Research, or is in an entity whose financial interest could be affected by the Clinical Research. The RIO or designee may involve the Investigator in this determination. A Significant Financial Interest that is related to Clinical Research can be considered a Conflict of Interest if the RIO determines that it could directly and significantly affect the design, conduct or reporting of the Clinical Research.
4. If the RIO or designee determines that the disclosed Significant Financial Interest may constitute a Conflict of Interest, he or she shall submit such completed Conflict of Interest Statement and all associated documentation to the Clinical Research Integrity Committee for review.
5. Clinical Research Integrity Committee Review. The Clinical Research Integrity Committee shall be comprised of five (5) members: the RIO, the Chair of the St. Luke's Institutional Review Board ("IRB"), Sr. VP Medical & Academic Affairs or designee; the attorney representative of the St. Luke's Legal Services Department serving as staff to the St. Luke's IRB, and the Chief Compliance and Privacy Officer or designee.
 - a) Within thirty (30) days of receipt of a completed Conflict of Interest Statement and associated documentation from the RIO, the Clinical Research Integrity Committee shall convene a meeting.

- b) The Clinical Research Integrity Committee, through the RIO, shall notify the Investigator of the date and time of the Clinical Research Integrity Committee meeting.
- c) The Clinical Research Integrity Committee meeting shall consist of a review of all Conflict of Interest statements and all relevant documents and listen to any statements from any Investigator concerning any disclosed Significant Financial Interest.
- d) The interested Investigator may present any information or be available to answer any questions of the Clinical Research Integrity Committee regarding the disclosed Significant Financial Interest and the documents provided. The interested Investigator shall leave the meeting following the presentation and question and answer period.

C. Determination of Conflict of Interest:

- 1. The Clinical Research Integrity Committee shall review all information regarding the disclosed Significant Financial Interests and determine the following:
 - a) Whether the disclosed Significant Financial Interest is related to Clinical Research because it could be affected by the Clinical Research, or is in an entity whose financial interest could be affected by the Clinical Research, and
 - b) Whether a Significant Financial Interest that is related to Clinical Research is considered a Conflict of Interest because it could directly and significantly affect the design, conduct or reporting of the Clinical Research.
- 2. The RIO shall be responsible for ensuring that minutes are kept of all Clinical Research Integrity Committee deliberations.

D. Actions to Manage, Reduce or Eliminate Conflict of Interest: If the Clinical Research Integrity Committee determines that an Investigator has a Conflict of Interest, a plan to Manage the Conflict of Interest will be determined by the Clinical Research Integrity Committee and implemented by the RIO within sixty days of identifying the Conflict of Interest. All violations of federal or state statutes and guidelines shall be handled consistent with the requirements of the applicable law. Examples of conditions or restrictions that might be imposed to Manage a Financial Conflict of Interest include, but are not limited to:

- 1. Requiring public disclosure of the Conflict of Interest (e.g., when presenting or publishing the research; to staff members working on the Clinical Study; and to the St. Luke's Institutional Review Board);
- 2. Disclosing the Financial Conflict of Interest to the human subjects participating in the Clinical Study;
- 3. Monitoring the Clinical Study with independent monitors, which may include transferring oversight jurisdiction of the Clinical Study to a third party Institutional Review Board;
- 4. Requiring modification of the Clinical Study plan;

5. Change of Investigator responsibilities, or requiring disqualification of the Investigator from participation in all or a portion of the Clinical Study;
6. Requiring divestiture of the Investigator's Financial Interest;
7. Requiring severance of the Arrangement between the Investigator and the party(s), including the Sponsor, that creates the actual or potential Conflict of Interest;
8. In the case of PHS funded studies, reporting the Conflict of Interest to the PHS Awarding Component; or
9. Take such other action that the Clinical Research Integrity Committee determines to be appropriate.

E. Notification:

1. Within fifteen (15) days following the Clinical Research Integrity Committee meeting, the RIO shall provide the Investigator and/or Sponsor with a written determination and the actions that must be taken by the Investigator to Manage, reduce or eliminate a Conflict of Interest.
2. For PHS sponsored research, the RIO shall notify PHS prior to the expenditure of any governmental funds and, whenever in the course of an ongoing PHS-funded research project, an Investigator who is new to participating in the Clinical Research discloses a Significant Financial Interest or an existing Investigator discloses a new Significant Financial Interest, the RIO will, within sixty (60) days, review the disclosure and determine whether a Conflict of Interest exists pursuant to the above process.

F. Conflict of Interest Violations:

1. If the RIO or Clinical Research Integrity Committee has reasonable cause to believe that an Investigator has failed to disclose information on an actual or potential Conflict of Interest, the RIO shall immediately inform the Investigator of the basis for such belief and afford the Investigator an opportunity to explain the alleged failure to disclose or comply.
2. If the RIO determines that the Investigator has failed to disclose meaningful information on an actual or potential Conflict of Interest, then the RIO shall immediately notify the Institutional Official and the Clinical Research Integrity Committee, and within the next sixty (60) days, convene a meeting of the Clinical Research Integrity Committee to evaluate the presence of a Conflict of Interest.
3. If the RIO determines on evaluation that the Investigator has failed to comply with the Clinical Research Integrity Committee's instructions on Managing, reducing or eliminating the Conflict of Interest, the RIO shall:
 - a) Immediately notify the Institutional Official, who shall take such administrative, contractual or personnel actions as are necessary to address the violation of this Policy, including suspension or termination of the conduct of the Clinical Study and/or any applicable contract;
 - b) Develop and implement, on an interim basis, a management plan that shall specify the action that has been or will be taken to Manage the Conflict of Interest going forward;

- c) Take such actions necessary to protect the integrity of the data and the safety of the human subjects participating in the Clinical Study in a manner consistent with this Policy; and
 - d) Notify the PHS Awarding Component, if the Clinical Study is funded by PHS, or the Sponsor of the Clinical Study.
4. If the RIO or Clinical Research Integrity Committee has reasonable cause to believe that (i) a Conflict of Interest has not been identified or managed in a timely manner, including failure by the Investigator to disclose a Significant Financial Interest that is determined by the Clinical Research Integrity Committee to constitute a Conflict of Interest, or (ii) failure by the Investigator to comply with a Conflict of Interest management plan, St. Luke's shall:
- a) Within one hundred twenty (120) days of the St. Luke's determination of noncompliance, complete a retrospective review of the Investigator's activities and the Clinical Study to determine whether the Clinical Study, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.
 - b) Document the retrospective review, which shall include the following elements:
 - i. Project number;
 - ii. Project title;
 - iii. Name of the Principal Investigator of the Clinical Study;
 - iv. Name of the Investigator with the Conflict of Interest,
 - v. Name of the entity with which the Investigator has a Conflict of Interest;
 - vi. Reason(s) for the retrospective review;
 - vii. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed),
 - viii. Findings of the review; and
 - ix. Conclusions of the review.
 - c) Based on the findings of the retrospective review, if appropriate, St. Luke's shall update any previously submitted FCOI Report, specifying the actions that will be taken to manage the Conflict of Interest going forward.
 - i. If bias is found and the Clinical Study is sponsored by PHS, St. Luke's will notify PHS 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 Clinical Study and St. Luke's 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).

- ii. For any FCOI Report previously reported by St. Luke's with regard to an ongoing PHS funded research project, St. Luke's shall submit to the PHS Awarding Component an annual FCOI Report that addresses the status of the identified Conflict of Interest and any changes to the management plan for the duration of the PHS-funded research project (including extensions with or without funds) in the time and manner specified by the PHS Awarding Component. The annual FCOI report shall specify whether the Conflict of Interest is still being managed or explain why the Conflict of Interest no longer exists.
- iii. Depending on the nature of the financial conflict of interest, St. Luke's may determine that additional interim measures are necessary with regard to the Investigator's participation in Clinical Study sponsored by PHS between the date that the Conflict of Interest or the Investigator's noncompliance is determined and the completion of the St. Luke's retrospective review.

G. Subrecipients: St. Luke's will take reasonable steps to ensure that all Subrecipients and/or Subrecipient Investigators are held to the same requirements as Investigators. Written agreements with Subrecipients and/or Subrecipient Investigators will incorporate terms that establish their compliance with this policy and the applicable federal regulations. If the Subrecipients and/or Subrecipient Investigators cannot provide certification of this compliance, the applicable agreement will state that Subrecipients and/or Subrecipient Investigators are subject to this policy related to their work with St. Luke's.

H. Reporting, Recordkeeping and Record Retention:

1. Prior to the Research Site expenditure of any funds under a PHS sponsored Clinical Study and, during the conduct of a Clinical Study, within sixty (60) days of determining that a Conflict of Interest exists, the RIO shall provide the PHS with a Conflict of Interest report, including any management plan. If the Clinical Research Integrity Committee identifies a Conflict of Interest and eliminates it prior to the expenditure of PHS sponsored funds, St. Luke's shall NOT submit a Conflict of Interest report to the PHS.
2. Prior to the commencement of any non-PHS sponsored Clinical Study, and, during the conduct of a Clinical Study, within sixty (60) days of determining that a Conflict of Interest exists, the RIO shall provide to the Sponsor a Conflict of Interest report and any management plan.
3. For a PHS sponsored Clinical Study, the RIO shall respond within five (5) business days to any public request for information about a Significant Financial Interest disclosed to St. Luke's by an Investigator that has been determined by the Clinical Research Integrity Committee to constitute a Financial Conflict of Interest. The written response shall note 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 60 days of the Institution's identification of a new Financial Conflict of Interest. The information included in the written response shall include the following:
 - a) Investigator's name;

- b) Investigator's title and role with respect to the Clinical Study;
- c) Name of the entity in which the Significant Financial Interest is held;
- d) Nature of the Significant Financial Interest;
- e) Approximate dollar value of the Significant Financial Interest (dollar ranges are permissible)
 - i. \$0-\$4,999;
 - ii. \$5,000-\$9,999;
 - iii. \$10,000-\$19,999;
 - iv. amounts between \$20,000-\$100,000 by increments of \$20,000;
 - v. amounts above \$100,000 by increments of \$50,000); or
 - vi. 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.
- 4. The RIO shall maintain as confidential documents the originals of all Conflict of Interest Statements and any other documents submitted by the Investigator, and copies of the minutes or other documents setting forth the determination and actions taken by the Clinical Research Integrity Committee.
- 5. The RIO shall maintain these records as follows:
 - a) Three years (3) years following the submission of the final expenditure report for PHS sponsored research, or, for awards that are renewed quarterly or annually, from the date of the submission of the quarterly or annual financial report, subject to the exception in subparagraph (c), below; or
 - b) Two (2) years following the approval of the marketing application for FDA regulated Clinical Study, and all other Clinical Research, subject to the exception in subparagraph (c), below.
 - c) If any litigation, claim, financial management review, or audit is started before the expiration of the three (3) year period set forth in subparagraph (a) or the two (2) year period set forth in subparagraph (b), the records shall be retained until all litigation, claims or audit findings involving the records have been resolved and final action taken.
- 6. PHS Awarding Components and the U.S. Department of Health and Human Services ("HHS"), the HHS Inspector General, the U.S. Comptroller General, the FDA, or any of their duly authorized representatives, have the right of timely and unrestricted access to any books, documents, papers, or other records of Institution that are pertinent to governmental awards, in order to make audits, examinations, excerpts, transcripts and copies of such documents. This right also includes timely and reasonable access to the Institution's personnel for the purpose of interview and discussion related to such documents. The rights of access are not limited to the required retention period set forth in paragraph 5, above, but shall last as long as the records are retained.

VI. COMPLIANCE

- A. In the event of an Investigator’s non-compliance with this policy, St. Luke’s may implement a range of enforcement mechanisms, including but are not limited to:
1. suspension or termination of a Clinical Study;
 2. suspension or termination of research privileges;
 3. dismissal from IRB and other board or committee membership;
 4. discipline under St. Luke’s employee disciplinary policies, if applicable; and/or
 5. termination for cause of any contract, agreement or award.
- B. Violations of federal or state statutes and guidelines shall be handled consistent with federal and state laws and requirements.

IV. Attachments

Investigator Research Conflict of Interests Disclosure Statement

V. References

Conflict of Interest Board of Trustees Policy Manual (No. 25)

SLH-Allentown	AVP, Medical Affairs	Lead Preparer
SLH-Bethlehem	AVP, Medical Affairs	Lead Preparer
SLH-Miners	AVP, Medical Affairs	Lead Preparer
SLH-Quakertown	AVP, Medical Affairs	Lead Preparer
SLH-Anderson	AVP, Medical Affairs	Lead Preparer
SLH-Warren	AVP, Medical Affairs	Lead Preparer

VI. Policy Responsibility

This policy is for the entire St. Luke’s network and its affiliates.

VII. Disclaimer Statement

This policy and procedure is intended to provide a description of a course of action to comply with legal requirements and/or operational standards. There may be specific circumstances not contemplated by this policy and procedure that may make compliance either unclear or inappropriate. For advice in these circumstances, consult with your Chain of Command, Administrator on Call, Clinical Risk Management, Legal Services, Accreditation and Standards, or Network Chief Compliance & Privacy Officer, as appropriate.

VII. Approval

St. Luke's IRB Committee every two years.