

St. Luke's University Health Network
INVESTIGATOR or IRB MEMBER CONFLICT OF INTERESTS DISCLOSURE
STATEMENT

*To be completed by all Investigators, Investigator's Staff and IRB Members as defined in St. Luke's Policy -
 Investigator Conflicts of Interest in Clinical Research*

Principal Investigator, Sub-Investigator or Research Team	Name:
<u>(One name per form)</u>	
IRB Committee Member	Name:

This statement is to be completed in connection with the St. Luke's University Health Network (St. Luke's) policy Investigator Conflicts of Interest in Clinical Research, which is available on the www.sluhn.org website. This statement is to be completed on your behalf as an "Investigator" under the Policy (see applicable definition of "Investigator" at the end of this form) and on behalf of your Immediate Family (spouse and dependent children). Complete your answers based on the time frames indicated below. St. Luke's and its agents intend to treat, as confidential, all information disclosed in this Statement, to use such disclosure to meet the requirements under 21 CFR Part 54 and 42 CFR Part 50, and to disclose such information to the extent required by applicable law.

Definitions of key terms are found at the end of this statement and in Policy Investigator Conflicts of Interest in Clinical Research. Your disclosure of a Significant Financial Interest does not automatically imply that the interest is improper or impermissible. However, failure to report a Significant Financial Interest or furnishing false, misleading or incomplete information may constitute professional misconduct and be cause for disciplinary action or other action as set forth in the Policy.

Return the completed form to the IRB Administrative Coordinator at St. Luke's University and Health Network 801 Ostrum Street, Bethlehem, PA 18015. You may call the IRB Administrative Coordinator with any questions at (484) 526-6742.

Reason for Disclosure:

- Annual Disclosure
- Change in Significant Financial Interest

Indicate by marking YES or NO if you, your spouse or your dependent children have any of the following Significant Financial Interests with an individual or entity sponsoring, conducting or seeking to engage in a Clinical Study at an St. Luke’s Research Site that reasonably appears to be related to the your Institutional Responsibilities and (i) for Public Health Service (“PHS”) funded research is conveyed during the one (1) year period prior to the date of this disclosure, or (ii) for Food and Drug Administration (“FDA”) regulated research is conveyed during the course of the Clinical Study and for one (1) year after completion of the Clinical Study: (Note: Income from investment vehicles, such as mutual funds and retirement accounts, does not need to be disclosed as long as the Investigator does not directly control the investment decisions made in these vehicles)

YES <input type="checkbox"/>	NO <input type="checkbox"/>	Publicly traded entity, PHS funded research: Have you or your Immediate Family received any remuneration in the one (1) year period prior to the date of this disclosure from a publicly traded entity, and do you or your Immediate Family have any equity interest in the publicly traded entity as of the date of this disclosure that, when aggregated with any remuneration, 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.
YES <input type="checkbox"/>	NO <input type="checkbox"/>	Publicly traded entity, FDA regulated research: For FDA regulated research, do you or your Immediate Family hold any equity interest in a publicly traded entity during the time of carrying out the Clinical Study that exceeds \$50,000 in value, or do you anticipate you or your Immediate Family will hold any equity interest in a publicly traded entity during the one (1) year period following completion of the Clinical Study that 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.
YES <input type="checkbox"/>	NO <input type="checkbox"/>	Non-publicly traded entity, PHS funded research: Have you or your Immediate Family received any remuneration from a non-publicly traded entity in the one (1) year period prior to the date of this disclosure that, when aggregated, exceeds \$5,000, <i>or</i> do you or your Immediate Family hold any equity interest in the non-publicly traded entity (e.g., stock, stock option, or other ownership interest)?
YES <input type="checkbox"/>	NO <input type="checkbox"/>	Non-publicly traded entity, FDA regulated research: Do you or your Immediate Family hold 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 or do you anticipate that you or your Immediate Family will hold such an interest during the one (1) year period following the completion of the Clinical Study?
YES <input type="checkbox"/>	NO <input type="checkbox"/>	For PHS funded and/or FDA regulated research: Have you been reimbursed for any travel or sponsored for any travel involving you or your Immediate Family? Sponsored travel is any travel that is paid on your behalf or on behalf of your Immediate Family and not reimbursed so that the exact monetary value may not be readily available. 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, the duration, and monetary value, if known. The Institution’s RIO or Clinical Research Integrity Committee will determine if further information is needed in order to determine whether the travel constitutes a Financial Conflict of Interest.
YES <input type="checkbox"/>	NO <input type="checkbox"/>	For PHS funded and/or FDA regulated research: Do you or your Immediate Family have any intellectual property or other proprietary rights and interests (e.g. patents, copyrights, royalties, or licensing agreement) in the item being studied or tested, and/or any receipt of income related to such rights or interest.
YES <input type="checkbox"/>	NO <input type="checkbox"/>	For PHS funded and/or FDA regulated research: Have you or your Immediate Family received any compensation or remuneration in which the value of the compensation or remuneration could be affected by the Clinical Study outcome?

For those statements checked YES, please attach details of the terms and conditions of the Significant Financial Interest, specifically describing all financial terms. In addition, please state whether you believe that the Clinical Study results may be biased as a result of the disclosed Significant Financial Interest, and if so, provide a description of steps you intend to take or have taken to minimize the potential for such bias.

CERTIFICATION

I certify that I have read St. Luke's Policy Investigator Conflicts of Interest in Clinical Research. In accordance with 21 CFR parts 54.1 to 54.6, I certify that the information provided on this form is, to the best of my knowledge and belief, true, correct and complete. Furthermore, if Significant Financial Interests or those of my spouse or dependent children change from the information provided above during the course of a Clinical Study or within one year of Clinical Study completion, I will notify the St. Luke's Research Integrity Officer. I agree to comply with any conditions or restrictions imposed by St. Luke have to manage, reduce or eliminate actual or potential Conflicts of Interest.

Signature: _____

Print Name: _____

Date: _____

Received by Research Integrity Officer or designee:

Signature: _____

Date: _____

Definitions of Key Terms:

- A. **Clinical Study** means Clinical Research being conducted or intending to be conducted at a Research Site.
- B. **Financial Interest** means anything of monetary value, whether or not the value is readily ascertainable.
- C. **Financial Conflict of Interest (FCOI)** means a Significant Financial Interest that could directly and significantly affect the design, conduct or reporting of Clinical Research.
- D. **Immediate Family:** the spouse and dependent children of an Investigator.
- E. **Institution** means St. Luke's and its affiliates that is applying for or that receives, PHS research funding.
- F. **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.
- G. **PHS Funded Research** means research that is funded by the Public Health Service ("PHS") of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health ("NIH").
- H. **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.
- I. **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.
- J. **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 and 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

<p>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.</p> <p>K. 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.</p> <p>L. Subrecipient or Subrecipient Investigators means entities or individuals that St. Luke's contracts with to carry out Clinical Study activities.</p>	