

Saint Luke's Health System Research Conflict of Interest Disclosure Form

INSTRUCTIONS: As required by SLHS's [Conflicts of Interest in Research Policy \(RES-052\)](#), Investigators must complete this form:

- a. **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).
- b. **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.
- c. **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.
- d. **PHS-funded Research.** Investigators must submit an RCOI Disclosure Form no later than the time of application for PHS funds.

Please direct questions regarding this form to the Ethics, Compliance & Privacy Department at Compliance@Saint-Lukes.org.

DEFINITIONS:

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.

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.

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.

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).

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:

- 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.

INVESTIGATOR INFORMATION:

Name: _____ **SLHS Entity/Department:** _____

Email: _____ **Phone:** _____

Date completed: _____

****CONTINUED ON NEXT PAGE****

DISCLOSURE OF SIGNIFICANT FINANCIAL INTERESTS AND SIGNIFICANT CONFLICTS OF COMMITMENT:

Respond to each question below and disclose any interest that reasonably appears to be related to your Institutional Responsibilities.

1. This submittal is for (check all that apply):

- Annual Disclosure
- Newly Acquired Conflict
- New IRB Application
- Updated Disclosure
- New Investigators joining the research team of an ongoing Sponsored Research project

2. If you are disclosing due to a new IRB application, or joining an ongoing Sponsored Research project, supply the protocol title. *If not applicable, enter NA.*

3. If you are disclosing due to a new IRB application, or joining an ongoing Sponsored Research project, supply the name of the study sponsor. *If not applicable, enter NA.*

4. In the 12 months preceding this disclosure, have you or your Family received any salary or other payments for services that exceeds \$5,000 in total? *Disclosures should include salary or payments for services from any publicly or non-publicly traded entity, whether foreign or domestic, and any foreign institution.*

___ Yes ___ No

If yes, please provide the following information:

Name of person who received the payments: _____

Your relationship to such person (self or family member): _____

Name of the Entity: _____

Nature and approximate monetary value of the payments: _____

5. During the 12 months preceding or as of the date of this disclosure, do you or your Family hold, in any publicly traded Entity, whether foreign or domestic, any equity interest that exceeds \$5,000?

___ Yes ___ No

If yes, please provide the following information:

Name of person who received the payments: _____

Your relationship to such person (self or family member): _____

Name of the Entity: _____

Nature and approximate monetary value of the equity interest: _____

6. During the 12 months preceding or as of the date of this disclosure, do you or your Family hold, in any non-publicly traded Entity, whether foreign or domestic, any equity interest (regardless of amount)?

If yes, please provide the following information:

Name of person who received the payments: _____

Your relationship to such person (self or family member): _____

Name of the Entity: _____

Nature and approximate monetary value of the equity interest: _____

7. During the 12 months preceding the date of this disclosure, have you or your Family received any income related to intellectual property rights and interests?

___ Yes ___ No

If yes, please provide the following information:

Name of person who received the payments: _____

Your relationship to such person (self or family member): _____

Name of the Entity: _____

Nature and approximate monetary value of the intellectual property rights and interests and related income: _____

8. During the 12 months preceding the date of this disclosure, have you or your Family (a) served in an executive position in a for-profit business that engages in commercial or research activities of a biomedical nature; or (b) served in a fiduciary role for a for-profit business that engages in commercial or research activities of a biomedical nature?

___ Yes ___ No

If yes, please provide the following information:

Name of person who served in such role: _____

Your relationship to such person (self or family member): _____

Name of the business: _____

Nature of the role: _____

9. *For PHS-funded Investigators only:* During the 12 months preceding the date of this disclosure, have you undertaken any reimbursed or sponsored travel related to your Institutional Responsibilities? (Do not include travel reimbursed or sponsored by US federal, state or local governmental agencies, US institutions of higher education or US research institutes affiliated with institutions of higher education, or academic teaching hospitals and medical centers.)

___ Yes ___ No ___ Not Applicable

If yes, please provide the following information for each trip:

Purpose of the trip: _____

Identity of the sponsor/organizer: _____

Destination: _____

Duration: _____

INVESTIGATOR CERTIFICATION:

I hereby affirm that the information I have provided on this form is complete and accurate to the best of my knowledge.

Signature: _____

Date: _____