

HSL DISCLOSURE AND ASSURANCES STATEMENT

This form is to be completed by all “investigators” when submitting a new application for research funding to an external entity, for example grants from government awarding agencies, research foundations, and private companies or when submitting an application for human subjects research to the IRB.

Date:

Investigator Name:

Role on Study:

Principal Investigator Name:

Title of Proposal:

Sponsor/Awarding Agency:

I. Confirmation of Updated Disclosure Statement

- I confirm that my disclosure statement(s) for all entities is updated and acknowledge that I have a responsibility to update the report(s) within thirty days (30) of acquiring or discovering a new Significant Financial Interest for the previous twelve (12) months including reporting all sponsored/reimbursed travel.

II. Relationship of Reported Financial Interests to Proposed Research

1. Is an entity for which you have reported a financial interest ("reported entity") the sponsor of the proposed study?
 No **Yes** If yes, entity name:
2. Is a reported entity a sub-award recipient, collaborator or contractor for this study?
 No **Yes** If yes, entity name:
3. Is a reported entity supplying materials, personnel, data or other support for this study?
 No **Yes** If yes, entity name:
4. Does this study investigate, significantly use or otherwise directly impact a product, device, drug, compound, technique, algorithm, or system, of any reported entity?
 No **Yes** If yes, entity name:
5. Is this study designed to validate any product, device, drug, compound, technique, algorithm, or system owned, licensed or marketed of a reported entity?
 No **Yes** If yes, entity name:
6. Will the design, results, or publication of this study affect the compensation paid to you by a reported entity?
 No **Yes** If yes, entity name:

7. To the best of your knowledge, could the design, results, or publication of this study affect the value of the equity or other financial interest of the reported entity?
 No **Yes** If yes, entity name:
8. Is the scope of any work you provide to a reported entity of the same nature as or significantly overlap with the work to be performed during the study?
 No **Yes** If yes, entity name:
9. Is there any relationship between your acquisition of equity in or receipt of income from a reported entity and this study?
 No **Yes** If yes, entity name:

10. If you have answered ‘yes’ to any of the questions above, please provide a brief explanation:

III. Application for human subjects research to the IRB

Complete this section *ONLY* when submitting your protocol to the IRB.

Please identify any holdings valued at \$0-\$4,999 that have not been disclosed on the **HSL ANNUAL CONFLICT OF INTEREST DISCLOSURE FORM** because it is not considered a Significant Financial Conflict of Interest.

- Entity Name: \$
- Entity Name: \$
- Entity Name: \$
- Entity Name: \$
- Entity Name: \$
- Entity Name: \$

IV. Training

By checking the box below, you are confirming that you have completed the mandatory (for all research subject to the PHS regulations) training on conflicts of interest via [CITI](#).

- Yes** **No** **NOT APPLICABLE** (the proposed research is not subject to the PHS regulations)

V. Principal Investigator : Each PI must complete both sections below

By checking this box, you are confirming that 1) the information submitted within the application is true, complete and accurate to the best of your knowledge; 2) any false, fictitious, or fraudulent statements or claims may subject you to criminal, civil, or administrative penalties; and 3) you agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of the application.*

** If multiple PIs are proposed in an application, this assurance must be retained for all named PIs.*

Certification: You are responsible for identifying all Investigators on the proposal and for informing these Investigators of their responsibilities to report Significant Financial Interests related to one's institutional role through the HSL Annual Conflict of Interest Disclosure Form.

An Investigator includes the project director and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research. An Investigator may include, for example, significant collaborators or consultants.

Please list here any individual that meets the definition for Investigator on this proposal.

- 1.
- 2.
- 3.
- 4.
- 5.
- 6.

By executing below, I hereby certify:

- a. I have fully and to the best of my ability accurately completed this Disclosure Statement;
- b. I have reviewed and am in compliance with the HSL Conflict of Interest Policy; and
- c. I will update this Disclosure Statement (and my **HSL ANNUAL CONFLICT OF INTEREST DISCLOSURE FORM**) within thirty (30) days if, at any time, circumstances change such that the information provided in this Disclosure Statement is inaccurate or incomplete.*
- d. If I am the Principal Investigator, I have identified above all individuals that currently meet the definition of Investigator and have informed those individuals of their responsibilities to complete this Disclosure Statement and the required training (if PHS funded research). I acknowledge that it is my responsibility to notify HSL prior to allowing any new Investigator to commence research under this proposal, so that full compliance with this policy and regulation may be ensured.

Signature:

Date:

Written Name:

Position:

** 42 CFR Part 50 requires each Investigator who is participating in PHS-funded research to submit an updated disclosure to the Institution's designated official(s) within thirty (30) days of discovering or acquiring (e.g.), through purchase, marriage, or inheritance) a new Significant Financial Interest.*