



DISCLOSURE STATEMENT

Harvard Medical School

For Investigators in Government-, Foundation- and Industry-Sponsored Research

Investigator Name: Harvard ID:

Role in Study: Date:

Principal Investigator Name:

Title of Proposal:

Sponsor/Awarding Agency:

I. Confirmation of Updated HMS Outside Activities Report

By checking the box below, you confirm that your Outside Activities Report (outsideactivities.hms.harvard.edu/OAR) is updated to reflect your Significant Financial Interests for the previous twelve (12) months (including, for PHS investigators only, reporting all Sponsored/Reimbursed Travel). If you do not report your outside activities to HMS, please check the box and attach a copy of your home institution's reporting form.

☐ I confirm that my Outside Activities Report or my home institution's financial interest reporting form is updated and acknowledge that I have a responsibility to report a new Significant Financial Interest within thirty (30) days of acquiring or discovering a new Significant Financial Interest.

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?

☐ yes ☐ no If yes, entity name:

2. Is a reported entity a subaward recipient, collaborator or contractor for this study?

☐ yes ☐ no If yes, entity name:

3. Is a reported entity supplying materials, personnel, data or other support for this study?

☐ yes ☐ no 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?

☐ yes ☐ no 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?

☐ yes ☐ no If yes, entity name:

6. Will the design, results, or publication of this study affect the compensation paid to you by a reported entity?

☐ yes ☐ no 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?

☐ yes ☐ no 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?

☐ yes ☐ no 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?

☐ yes

☐ no

If yes, entity name:

10. Please provide a brief explanation of any affirmative answers provided above or any information that you feel may be relevant to a conflict of interest review for this study?

III. 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 (citiprogram.org).

☐ YES

☐ NO

☐ NOT APPLICABLE (the proposed research is not subject to the PHS regulations)

IV. Principal Investigator Only

If you are the Principal Investigator, 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 HMS Outside Activities Reporting system (including, for PHS Investigators only, the occurrence of any Sponsored Travel). 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.

CERTIFICATION

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 HMS Policy on Conflicts of Interest and Commitment (<http://hms.harvard.edu/content/interim-policy-statement-conflicts-interest-and-commitment>); and
- c. I will update this Disclosure Statement (and my Outside Activities Report) 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 HMS 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:

Name:

Date:

Position:

Affiliation:

Please contact the Office of Professional Standards and Integrity (Outside_Activities@hms.harvard.edu or 617-432-1343) with any questions about the Disclosure Statement or the review process.

* 42 CFR Part 50 requires each Investigator who is participating in NIH-funded research to submit an updated disclosure of Significant Financial Interest 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.