
INVESTIGATOR CONFLICT OF INTEREST DISCLOSURE STATEMENT FOR INVESTIGATORS NOT EMPLOYED BY THE UNIVERSITY OF PENNSYLVANIA

You are being asked to complete this disclosure because you have been identified as an *Investigator* (defined as an individual responsible for the design, conduct, or reporting of research) for the research identified below. **Please provide complete responses to the questions below.**

I. Research Identifying Information

Protocol Title:

Penn IRB Number:

Principal Investigator:

II. Investigator Identifying Information

Last Name:

First Name:

Academic Affiliation and
Title or Position (if applicable):

Email Address:

Office Phone Number:

Your role in this protocol (e.g., PI, Co-PI, Key Personnel, Other) :

III. Financial Interests Questions

Below, you will be asked several questions intended to identify *Financial Interests* and relationships that may be relevant to **THIS RESEARCH**. These may include *Intellectual Property Interests (IP Interests)*, as well as relationships with entities whose interests may affect and/or be affected by **THIS RESEARCH**. You should also consider companies that compete commercially with the research sponsor or the manufacturer of the study drug, device, or other investigational item, if you know that the competitor's *Financial Interests* would reasonably appear to be affected by **THIS RESEARCH**.

In relation to **THIS RESEARCH**, in the past 12 months, did or do you, your spouse, or your dependent children have any of the following *Financial Interests* or relationships related to your field, discipline, or professional expertise:

1) Any *Fiduciary Responsibilities* for any entity (U.S. or non-U.S.), whether paid or unpaid? Examples include service on a board of directors, (or as an officer, manager, partner, or LLC member, BUT NOT service on an advisory board in a consulting capacity)?

Do not include service in a fiduciary capacity for non-profits that have no relation to your research activities (e.g., you serve on the Board of Directors for the Boy Scouts of America).

Yes

No

If Yes, please complete the information below for each Entity.

Outside Entity Name	Payments - Actual \$ received over past 12 months	Nature of Fiduciary Role

2) Any *Equity Interest* in any publicly-traded (U.S. or non-U.S.) or privately-owned entity (U.S. or non-U.S.), including but not limited to shares of stock or stock options, that does or will do business in your field or discipline?

DO NOT include equity held in a mutual, pension, or investment fund over which you have no control with regard to investment decisions.

Yes

No

If Yes, please complete information below:

Outside Entity Name	Private or Public	If Stock: estimated value	If Stock: estimated % ownership	If Options: # held

3) Any payments received in excess of \$5,000 during the past 12 months from any U.S. or non-U.S. Outside Entity (other than your employer) (e.g., serving on a scientific advisory board, consulting, providing continuing professional education lectures or serving as an expert witness)?

Do include payments from professional societies, academic journals and publishers, CME providers, commercial entities such as pharmaceutical companies, and nonprofit companies, e.g., the American Cancer Society. Also include receipt of any royalties.

Do not include:

- Salary or other payments you receive from your employer
- Travel reimbursement
- Payments from insurance companies, managed care companies, or other payors for clinical services you performed unrelated to any research
- Research funding received from UPenn to support your research activities
- Payments from a U.S .government agency, U.S. institution of higher education or US affiliated teaching hospital, medical center or research institute

Yes

No

If Yes, please complete the information below for each Outside Entity:

Outside Entity Name	Type of Activity (e.g., consulting, lecturing)	Payments - Actual \$ Received over past 12 months	Is activity ongoing? (Yes or No)

4) An inventorship or ownership interest in any intellectual property (IP) that that is being tested, evaluated, developed in, or its commercial value will be affected by, the above research? This includes IP that is the subject of a copyright, issued patent or patent application (regardless of whether it has been licensed or optioned)

Yes

No

If Yes, please provide:

A description of your IP Interest(s) :

The identity of the assignee (entity that owns the IP) :

Whether the IP has been licensed or optioned, and if so, to what entity:

The amount of royalties or other compensation received during the past 12 months related to this IP:

5) Any reimbursed travel or travel that was paid on your behalf and not reimbursed to you for the past 12 months related to your research, teaching, or your professional practice?

Do not list travel that was paid or reimbursed by your employer, by U.S. government agencies, or U.S. institutions of higher education, or U.S. affiliated teaching hospitals, medical centers, or research institutes.

Do include travel that was paid or reimbursed by non-U.S. entities.

Yes

No

If Yes, please complete below. If you need additional space, please attach a separate sheet.

Travel sponsor	Travel purpose	Travel destination	Trips #	Total days #

6) Do any entities identified in questions 1-4 above (check if "Yes" and specify entities below):

Sponsor or provide funding for the above research?

Manufacture or distribute a drug, device or other product being studied in the above research?

Manufacture or distribute a directly competitive drug, device or other product, **if you have actual knowledge** that the competing company's interests could be affected by the above research?

Receive or provide materials or data used or generated in the above research, or have a collaborative role related to the above research?

Have a proprietary interest in a drug, product or device being studied in the above research?

Have some other relationship with the above research?

If you checked any of the above, please specify entity's name here; if more than one entity, please mention role of each entity:

No, none of the entities above are related to this research.

N/A (There are no entities mentioned in questions 1-4 above.)

IV. Additional Information

1) Do any of the responses above relate to your spouse and/or dependent children?

Yes

No

If Yes, please identify:

Family Member Name	Relationship to you

2) Are there any additional details about your or your family member's *Financial Interests* that may assist in the review of this Financial Interests Disclosure?

Yes

No

If Yes, please describe:

V. Certification

I certify that the above information is complete and true to the best of my knowledge and that I have read the *University of Pennsylvania Policy on Conflicts of Interest Related to Research*. I acknowledge my obligation to disclose updated information if I acquire a new Significant Financial Interest, within thirty (30) days of acquisition.

This disclosure is provided with the understanding that its review shall be conducted in confidence by appropriate UPenn representatives.

I also certify that I have completed the Financial Conflicts of Interest in Research – Investigator Training Course.

I am aware that failure to comply with the disclosure requirements, may subject me to sanctions. (Sanctions for failure to comply are a requirement under federal law.)

Name:

Signature:

Date:

Definitions

Equity Interest. Ownership interests or securities, including but not limited to shares of stock or securities; stock options; warrants or any other rights to purchase stock or securities; debt instruments; partnership interests in a general or limited partnership; or membership interests in a limited liability company.

Fiduciary Responsibilities. Membership on the governing board of an Outside Organization, including service on its board of directors, or having a position of authority or responsibility to act in the best interest of the Outside Organization, including being an officer, manager, partner, or limited liability company member with management responsibility.

Financial Interest. Anything of monetary value, whether or not the value is readily ascertainable, including but not limited to, any ownership, equity or investment interests, compensation arrangements, intellectual property rights and fiduciary responsibilities.

Intellectual Property Interest (IP Interest). A property or other financial interest in the product including, but not limited to, a patent or patent portfolio, trademark, copyright or licensing agreement, contract rights, or the right to receive compensation in connection with the development or sale of the product. IP Interest does not include authorship of a work or inventorship of a patent where the author or inventor has no right to receive compensation in connection with the use or exploitation of the work or patent.