



Confidential Financial Disclosure Statement

This form should be submitted in a sealed envelope with a grant application or human subject protocol. Alternatively, a signed copy can be submitted electronically as a PDF file to COI@pobox.upenn.edu. Submitted forms will be acknowledged electronically.

Name of Investigator _____ Phone _____ E-mail address _____

Department/Division _____

Mailing Address _____

Name of Department Chair & Mailing Address _____

Title of Project or Protocol _____

Funding Source _____ Is this a Clinical Trial?* _____ Y _____ N

Penn views technology commercialization and industry collaborations as natural extensions of the traditional research enterprise to facilitate the use of its research for the benefit of society. Proactive management of the real and perceived conflicts of interest and commitment resulting from collaborations with industry and the private sector will foster continued trustworthiness in our academic enterprise.

*For purposes of this disclosure a **Clinical trial** means any research involving human subjects that is designed to test the safety and/or efficacy of an intervention to diagnose, treat, or prevent disease, and that exposes research subjects to procedures or treatments which they would not have received from their own health care providers as part of their clinical care. For these purposes this usually excludes investigations involving the consented use of human tissue or participant information used for analysis of disease mechanisms or for outcome evaluations. **FOR CLINICAL TRIALS, ALL FINANCIAL INTERESTS MUST BE DISCLOSED (REGARDLESS OF THRESHOLD LEVELS LISTED BELOW). ALSO COMPLETE PART IV: CLINICAL TRIALS.**

Part I: Significant Financial Interests.** (Check all appropriate boxes). Please note that these questions apply as well to financial interests you may hold in a *competitor company**** since the results of this research may affect those interests. If any “YES”, complete: **Parts II, III, V& VI.**

For any company whose value may be affected by this research, do you, your spouse or dependent children:	YES	NO
a. Own any shares of stock, stock options, partnership interest, or other ownership interest if the company is not publicly traded?		
b. Own shares of stock, stock options, partnership interest, or other ownership interest of greater than 5% or >\$10,000 if the company is publicly traded?		
c. Receive or expect to receive >\$10,000 in compensation for consulting from the company?		
d. Receive or expect to receive >\$10,000 in compensation for any position in the company?		
e. Serve as Management or on the Board of Directors of the company?		
f. Serve on an Advisory Board of the company?		
g. Have an interest in a patent, copyright or licensing agreement whose value may be affected by this research?		
h. Have assigned your interest in any invention, patent application etc to an outside entity?		
i. Receive or expect to receive >\$10,000 in personal income directly from this company for licensing your discoveries?		
j. Receive or expect to receive >\$10,000 in honoraria or royalties for book, publications or lectures from this company?		
k. Does the sum of i. and j. exceed \$10,000?		

A financial interest is a “significant financial interest**” if income from one company is expected to exceed \$10,000 over the next 12 month period (total income to the investigator, spouse and dependent children), or if an equity interest is worth \$10,000 or more, or represents 5% or more ownership interest (total ownership interest of the investigator, spouse and dependent children.)

***AAMC Guidelines recommend that if an investigator has an interest in and has actual knowledge that a competing company's interests would reasonably appear to be affected by the research, then the investigator should disclose such interests in the

competing company. This term means companies that compete with the sponsor of the research or the manufacturer of the investigational product.

Part II: Financial Interests that May Affect or Be Affected by the Research Project or Protocol

II. A. Consulting income or other compensation for services from any entity whose interests might reasonably be expected to be affected by the outcome of the sponsored research, or human subject protocol. **According to University Policy you may be required to provide a copy of the consulting agreement.**

Company	Personal Income received or expected over the next 12 months (\$)			Consulting Agreement?
	0-10,000	>10,000 – 25,000	>25,000	Y/N, # of days

II. B. Equity positions you hold whose value might reasonably be expected to be affected by the outcome of the sponsored research or human subjects protocol.

Company	Publicly Traded? (Y/N)	Value of stock held or optioned (\$)			=>5% Ownership	Options only?
		0-10,000	>10,000 – 25,000	>25,000		

II. C. Personal income, other than II.A income, through honoraria, licensing fees, or non-University royalty payments whose value might reasonably be expected to be affected by the outcome of your sponsored research or human subjects protocol.

Company	Honoraria, fees or non-University royalties received or expected over the next 12 months (\$)		
	0-10,000	>10,000 – 25,000	>25,000

II. D. Proprietary Interest in products or processes whose current or future value or income stream might reasonably be expected to be affected by the outcome of your sponsored research or human subject protocol.

Description of Product or Process	Nature of Interest			
	Name of Patent Inventor, Owner or Licensee	Copyright author, owner or licensee	Right to receive compensation from commercialization	Other Interest (please specify)

II. E. List all other awards, institutionally sponsored research, or human subject protocols, which **may be affected** by any of the financial interests disclosed above. Use additional pages if necessary.

Sponsor	Grant # / Protocol #	Title

Part III: Students and Post Doctoral Fellows

Are students or post-doctoral fellows supported by the company in which you have a financial interest?

Y _____ N _____

Do any students or post-doctoral fellows participate in other funded research which may affect or be affected by your financial interest? Y _____ N _____

Part IV: Clinical Trials

In order to fully evaluate whether there are circumstances to permit your participation in a clinical trial, respond to the following questions on a separate page. Provide a copy of the trial protocol.

1. Are there any other Penn Investigators involved? Do any of them have a potential financial conflict of interest?
2. Did/do you or any Co-PI receive any consulting income for the design of this or other trials from the sponsor?
3. What role will you or any Co-PIs have in the selection of subjects and their informed consent? Will subjects be recruited from your/their clinical practice?
4. What role will you have in the data evaluation? Will there be a Data Safety Monitoring Board?
5. What Phase Trial is this?
6. Describe any unique qualifications, training or other compelling circumstances that would argue for your participation in the trial.
7. Is this a multi-site clinical trial? Yes _____ No _____ (if no, skip next question).
8. If so:
 - a. Who is the overall Principal Investigator?
 - b. How many subjects will be enrolled at Penn? Overall?

Part V: Research Projects Affecting a Company in which you have a Financial Interest

In order to fully evaluate whether this financial interest constitutes a conflict of interest that would need to be managed, reduced or eliminated, describe more fully the relationship of the work being proposed to the scientific interests of the company and any role you have in the company. Please add any information which would help to clarify any of the sections above. Prepare and attach a statement to address the following:

- Does the proposed research overlap or impact any other research activity whether internally or externally funded? Describe the overlap or impact.

- Describe the impact of the proposed company relationship or your financial interests on the direction of your other research projects.
- Level of your effort on each of your research projects including proposed company sponsored research.
- Provide a copy of company's sponsored research project, budget, and ORS transmittal form, if applicable.
- If company is a start-up company, your role, if any, in the founding of the new company and your continuing involvement. Describe the specific scientific interest(s) of the company and its research capabilities.
- Please add any information which would help to clarify these issues and include possible management strategies to safeguard against conflicts of interest and commitment.

Part VI: Certification & Signature of Faculty Member

I certify that the above information is complete and true to the best of my knowledge and that I have read the University's policies related to conflict of interest as described in the Handbook for Faculty and Academic Administrators Section II.E.1., Conflict of Interest Policy for Faculty and the supplementary [Financial Disclosure Policy for Research and Sponsored Projects](#), Almanac February 6, 2001 and the [Financial Disclosure and Presumptively Prohibited Conflicts for Faculty Participating in Clinical Trials Policy](#), Almanac May 6, 2003. This information is provided with the understanding that its review shall be conducted in confidence by appropriate University Officials. The information may only be released by the University 1) in statistical or aggregate form that protects my privacy, or 2) to comply with the requirements of the sponsors of my research, or 3) as may be required to comply with University policies and procedures or any applicable legal requirements, or 4) with my written permission.

I acknowledge my obligation to submit an updated disclosure statement **at least annually** or **when there is any change** in my activities or financial interests that would affect or be affected by the outcome of this research project or protocol.

Signature of Investigator

Date