

**UNIVERSITY OF VIRGINIA
DISCLOSURE OF FINANCIAL INTERESTS
RELATED TO RESEARCH**

WHO MUST COMPLETE THIS FORM

Any person responsible for the design, conduct, or reporting of the research including all principal investigators and co-investigators must submit this form to the Conflict of Interest Committee annually. Note: All individuals required to complete this form have an ongoing obligation to update this form immediately if answers to any of the questions below change before the research and reporting of results are completed.

DISCLOSURE INFORMATION

Do you or any member of your immediate dependents¹ have a significant financial interest exceeding \$10,000 or 3% ownership interest that could reasonably **appear** to be affected by your research project(s) and/or is in an entity that could reasonably **appear** to be affected by the research? Yes No

If you answered **Yes** to this question, please name the entity with whom the relationship exists and check below the type(s) of interest received from the entity and amount(s) for each:

NAME OF ENTITY(S): _____

(NOTE: INFORMATION MUST BE PROVIDED FOR EACH ENTITY WITH WHOM YOU HAVE A FINANCIAL INTEREST)

PROJECT TITLE: _____

SPONSOR(S): _____

(Add additional lines as needed if more than one sponsor.)

Estimated aggregate annual income from entity, including fair value of any non-monetary activities: _____.

BASIS OF INCOME:

- Participation as an employee outside your UVA appointment including any salary support derived
- Consulting Agreements including² and honoraria, including but not limited to, fees received for speaking engagements and/or service on a board of directors or other advisory committee
- Royalties, licensing fees, trademarks, copyright fees or other property (through the UVA Patent Foundation)
- Royalties, licensing fees, trademarks, copyright fees or other intellectual property (**not** through the Patent Foundation)
- Gift (including funds deposited to UVA. gift accounts)³
- Institutional Endowment from which funds were donated by entity

¹ See the University of Virginia Conflict of Interest Policy for Research Investigators for definitions of Dependents.

² Faculty members in the School of Medicine need to have prior approval for these activities.

³ If a gift is involved, you must e-mail, as an attachment, a letter from the donor explaining the purpose of the gift and any accompanying documentation to that gift.

- Dividends/capital gains
- Loan
- Travel funds
- Other: Describe the financial interest: _____

NATURE OF OWNERSHIP INTEREST:

- Equity interest including, but not limited to: stocks/stock options, real estate
- Partnership
- Other ownership interest that the investigator believe may interfere with his/her ability to protect participants (describe)

ESTIMATED VALUE OF OWNERSHIP

Estimated value of ownership stake in the entity including fair value of any non-monetary activities: _____.

PERCENTAGE OF OWNERSHIP INTEREST

- 3% or less
- More than 3%

FOR CONSULTING ENGAGEMENTS THE FOLLOWING QUESTIONS MUST BE ANSWERED:

1. Please list the entities with which you plan to consult, your position title, and the number of days of your commitment. (If additional space is needed, attach a sheet with your name, title, department, and the following headings.)

<u>Entity</u>	<u>Title</u>	<u>Days Committed</u>
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

2. Will you have a managerial or Principal Investigator role in an activity outside the University? Yes No. If yes, please attach a statement with a list of these activities and an explanation of each item.
3. Do you or members of your immediate family have an employment, consulting, or other significant financial relationship, including ownership, in any organization with one of the following relationships to the University's Academic or Medical Center divisions (questions a-c)? For each item to which you respond yes, attach an explanation. Yes No
 - a. A sponsor of your University's Academic or Medical Center divisions teaching or research activities. Yes No

- b. A company that does business with the University's Academic or Medical Center divisions that involves you as an employee of the University (including pharma and medical device manufacturers).
Yes No
- c. An outside organization contributing funds to the University that are under your control or of direct benefit to your teaching or research activities.
Yes No
- 4. Will you involve any of your students or staff in your outside consulting or *pro bono* activities? If yes, please attach a written explanation. Yes No
- 5 For SoM faculty: has your participation as a consultant been reviewed and approved by your Department Chair and the Dean's Office?

If you checked "yes" to any of the above, please answer the following questions. (Attach additional pages if necessary). If you did not check any of the above, please sign and return this disclosure form.

- 1. Where and by whom will the data be analyzed?
- 2. Identify both federal and non-federal support to be used for the research.
- 3. If human subjects are involved in the project?
 - a. Identify who will be responsible for obtaining informed consent from study participants, and
 - b. Will an independent data and safety monitoring committee be established?
 - c. Will UVA investigators and staff be blinded as to allotment in study arms?

CERTIFICATION:

Signature

Date

My signature certifies that this is a complete, accurate and truthful disclosure concerning the above financial interests which would reasonably appear to be related to this sponsored project. I further certify that I have complied with all federal regulations and Virginia state law concerning financial interests and required disclosures and if any sub-grantees, contractors or collaborators of other institutions are involved in this research that I have assured that these entities comply with PHS conflict of interest regulations.

DEFINITIONS

Immediate Family includes : (i) a spouse (ii) children and (iii) any other person residing in the same household as the investigator who is a dependent of the investigator or of whom the investigator is a dependent.

Principal Investigator: PI/Principal Investigator/Project Director the individual officially responsible for the conduct of a sponsored project. On research projects, the PI is usually a faculty member; on other types of awards, such as financial aid, the PI may have an administrative appointment.

Research: is defined as a systematic investigation designed to develop or contribute to generalizable knowledge. The term encompasses basic and applied research and product development. As used in this subpart, the term includes, but is not limited to, any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority.

Significant financial interest: is defined as anything of monetary value of more than \$10,000⁴ or more than 3% ownership interest, in value as determined through references to public prices or other reasonable measures of fair market value. This includes, but is not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); intellectual property rights (e.g., patents, copyrights and royalties) from such rights. Equity that is not under the faculty member's direct control and is managed by a third party, such as a mutual fund, is not considered a significant financial interest.

Conflict of Commitment arises when a Faculty Member undertakes Outside Activities that interfere with their primary obligations and commitments to the University.

Conflict of Interest may arise when a Faculty member, his or her Family Member, or an entity with which the Faculty Member is Associated:

has an existing or potential financial or other external interest that impairs or might reasonably appear to impair the Faculty Members independence of judgment in the discharge of his or her responsibilities to the University; or

may receive personally a material financial or other benefit from the use or disclosure of information confidential to the University.

A “**Gift**” is any transfer of an item of value (including a trip, personal belongings, or special concessions in connection with personal business) for less than fair market value, including a personal discount. Business dinners or other business outings are not considered “gifts,” unless the business component is not significant or the social component does not comport with the overall professional standard of avoiding actual and apparent conflicts of interest.⁵

⁴ Note a \$10,000 interest is defined as that amount derived from one arrangement or the total of smaller amounts resulting from arrangements with the entity.

⁵ <http://www.virginia.edu/finance/polproc/pol/ixa4.html>

Outside Activities include leadership participation in professional, community, or charitable activities, any self-employment, any participation in business partnerships, or any employment or consulting arrangements with entities other than UVA. Outside Activities may be either compensated or uncompensated. In general, any service on any board – for-profit, non-profit, advisory, honorary, or otherwise – will constitute an Outside Activity.