

**UNIVERSITY OF VIRGINIA
DISCLOSURE OF FINANCIAL INTERESTS WITH OUTSIDE ENTITIES
UNIVERSITY SUBRECIPIENTS**

You have indicated that your institution, which will have a subcontract from the University of Virginia, does not maintain its own conflict of interest policy and/or review system, as required by the United States Public Health Service (PHS). The PHS requires that any individual participating on a research project funded by that agency, who is responsible for the planning, conduct, analysis or reporting of research, disclose all external financial interests that are related to their institutional responsibilities. This process allows the University of Virginia (as the recipient of the master PHS award) to meet its legal obligation to review these relationships and, when necessary, to work with the individual to develop a plan to reduce, manage, or eliminate an associated financial conflict of interest.

Note also that if you are required to disclose your financial interests as an investigator on a PHS-funded subaward (where "investigator" is defined as "the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants"), you must complete conflict of interest training before expending any funds. See <http://www.medicine.virginia.edu/research/offices/research/home/instructions-for-CITI-COI.html> to access the on-line CITI training system. Investigators must be re-trained at least every four years.

WHAT YOU MUST DISCLOSE

Under PHS policy, you must disclose the following financial interests that are related to your institutional responsibilities, except as exempted below:

- For a single publicly traded entity, income + ownership interest totaling >\$5,000;
- For a single non-publicly traded entity, any ownership interest;
- For a single non-publicly traded entity, income >\$5,000;
- Any reimbursed or sponsored travel related to institutional responsibilities. *Disclose travel under "Income other than Consulting."*

EXEMPTIONS FROM DISCLOSURE:

INCOME FROM CONSULTING (excludes travel)

- Income that is unrelated to your institutional responsibilities;
- Short-term speaking or teaching engagements provided to US federal, state, or local government agencies, or an institution of higher education, or an academic medical center/research institute associated with an institution of higher education;
- Income from the review of grant/contract proposals or advisory boards on behalf of US federal, state, or local government agencies, or an institution of higher education, or an academic medical center/research institute associated with an institution of higher education;
- For a publicly traded entity, income (in addition to ownership interest) that does not total more than \$5,000;
- For a non-publicly traded entity, income that does not exceed \$5,000;

INCOME OTHER THAN CONSULTING (includes travel)

- Income that is not related to your institutional responsibilities;
- Salary received from institutional grants or contracts;
- For a publicly traded entity, income (in addition to ownership interest) that does not total more than \$5,000;
- For a non-publicly traded entity, income that does not exceed \$5,000;
- Income from financial instruments that you do not control (e.g., mutual funds);
- Income from your institution's licensing and royalty stream;
- Reimbursed or sponsored travel paid by US federal, state, or local government agencies, or an institution of higher education or an academic medical center/academic research institute associated with an institution of

- higher education;
- Travel paid by institutional funds, including sponsored research agreements.

OWNERSHIP INTERESTS

- Ownership interests that are unrelated to your institutional responsibilities.
- For a publicly traded entity, an ownership interest (in addition to income) that does not total more than \$5,000;

BEGIN THE PROCESS HERE:

Check yes below if you, your spouse, and your dependents combined, during the past twelve months held/received any of the following financial interests related to your institutional responsibilities, as described above: (1) total income + ownership interest in a publicly traded entity exceeding \$5,000, (2) any ownership interest in a non-publicly traded entity, (3) income from a non-publicly traded entity exceeding \$5,000, or (4) reimbursed or sponsored travel.

- Yes
 No

TO CONTINUE THE PROCESS:

IF YOU ANSWERED NO, click on Submit below and complete the Certification page at the end of this document. Follow the instructions on that page for completing the certification process (the only remaining step).

IF YOU ANSWERED YES, click on Submit below and a new page will display. Follow the instructions for disclosing financial interests due to CONSULTING, OTHER INCOME, or OWNERSHIP. Copy and complete a separate form for each outside entity and activity related to your disclosure. For example, if you receive consulting fees from two outside entities and serve in a management role for a third, you must complete three forms. Disclose travel as “Income other than Consulting.”

When you have completed disclosing your external activities, complete Certification page and submit this form to the University of Virginia as directed, in addition to a copy sent via e-mail to conflicts@virginia.edu.

RELEVANT POLICY:

US Public Health Service Policy, “Promoting Objectivity in Research” of August 25, 2011:

<http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&sid=f67ea01984581d3934103b5074c05500&rgn=div5&view=text&node=42:1.0.1.4.22&idno=42#42:1.0.1.4.22.6>

INCOME OTHER THAN CONSULTING

Provide information for each entity in which you, your spouse, or your dependents have a combined financial interest that is related to your institutional responsibilities.

Do not disclose:

- Income that is unrelated to your institutional responsibilities;
- Salary received from institutional grants or contracts;
- For a publicly traded entity, income (in addition to ownership interest) that does not total more than \$5,000;
- For a non-publicly traded entity, income that does not exceed \$5,000;
- Income from financial instruments that you do not control (e.g., mutual funds);
- Income from your institution's intellectual property office or clinical practice group;
- Reimbursed or sponsored travel paid by US federal, state, or local government agencies, or an institution of higher education or an academic medical center/research institute associated with an institution of higher education;
- Travel supported by your own institution's funds, including sponsored research agreements.

DISCLOSING TRAVEL

Disclose any travel that was reimbursed or sponsored by an outside entity and is related to your institutional responsibilities, except as described in the last two bullets above. Complete a copy of this form for each sponsor, as follows:

- Enter the name of the entity and total travel days ("number of days"). You can use a single form to disclose all trips that were sponsored by that entity during the past twelve months.
- Under "Basis of Income", check "Travel funds".
- Do not disclose the cost of the travel.
- Under "Explanation," state the purpose, destination, and duration of each trip paid by this sponsor (e.g., "multi-center clinical study start-up meeting, Los Angeles, 2 days; meeting with DSMB, Chicago, 1 day").

Name of Entity:

Number of days you worked for/with Entity:

Estimated aggregate family income from entity, including fair market value of any non-monetary compensation:

BASIS OF INCOME:

- Participation as an employee outside your institutional appointment (or family member's income) including any salary or remuneration support derived.
- Royalties, licensing fees, trademarks, copyright fees or other intellectual property *other than through your institution's intellectual property office*.
- Personal Gifts
- Dividends/Capital Gains
- Loan(s)
- Travel Funds (include explanation below: purpose, destination, duration of each trip)
- Other – describe the financial interest below.

EXPLANATION:

CONSULTING ENGAGEMENTS (does not include travel)

Provide information for each entity in which you, your spouse, or your dependents have a combined financial interest that is related to your institutional responsibilities. Complete a copy of this form for each sponsor.

Do not disclose:

- Income that is unrelated to your institutional responsibilities;
- Short-term speaking or teaching engagements provided to federal, state, or local government agencies, or an institution of higher education or an academic medical center/research institute associated with an institution of higher education;
- Income from the review of grant/contract proposals or advisory boards on behalf of federal, state, or local government agencies, or an institution of higher education or an academic medical center/research institute associated with an institution of higher education;
- For a publicly traded entity, income (in addition to ownership interest) that does not total more than \$5,000;
- For a non-publicly traded entity, income that does not exceed \$5,000;

Name of Entity:

Number of days you consulted for/worked with Entity:

Estimated aggregate annual income/remuneration including fair market value of any non-monetary compensation:

Your position title as a consultant:

QUESTIONS:

1. Did you have a managerial or Principal Investigator role in this activity? (If yes, please provide an explanation below.)
 Yes
 No

2. Did this consulting activity involve intellectual property that is the product of research at your institution or that you have assigned to your institution?
 Yes
 No

3. Did this activity involve research in a field in which you are presently engaged at your institution, or research otherwise related to your institutional duties and responsibilities?
 Yes
 No

4. Are any of your trainees or staff involved with these outside consulting activities? (If yes, please provide an explanation below.)
 Yes
 No

Description of Consulting Service: Please describe how your external consulting activity relates to your institutional responsibilities.

OWNERSHIP/BUSINESS RELATIONSHIP

Provide information for each entity in which you, your spouse, or your dependents have a combined financial interest that is related to your institutional responsibilities. Complete a copy of this form for each sponsor.

Do not disclose:

- Ownership interests that are unrelated to your institutional responsibilities
- For a publicly traded entity, an ownership interest (in addition to income) that does not total more than \$5,000.

Note: any ownership interest in a non-publicly traded entity that is related to your institutional responsibilities must be disclosed.

Name of Entity:

Type of organization (e.g. LLC, Corporation, Partnership):

Estimated value of ownership interest in the Entity:

Number of days you worked for/with Entity:

NATURE OF OWNERSHIP INTEREST:

- Equity interest including, but not limited to: stocks/stock options, and real estate.
- Partnership
- Other ownership interest (describe below)

QUESTIONS:

1. Do you have an employment relationship with this entity? (If yes, please provide an explanation below.)

- Yes
 No

2. Are any of your trainees or staff involved in this outside business activity? (If yes, please provide an explanation below.)

- Yes
 No

EXPLANATION:

CERTIFICATION

My submission of this document certifies:

1. I have provided a complete and accurate representation of the nature and extent of my financial interests in outside entities that are related to my institutional responsibilities.
 2. I understand that I have an ongoing responsibility to update my disclosure if my outside activities or interests change in the coming year. Updates must be entered in this system within 30 days.
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Name:

Institution:

Address:

E-mail:

Signature:

Name

Date