

MODEL FORM FOR MODEL POLICY

[INSERT NAME OF YOUR ORGANIZATION]
CONFLICT OF INTEREST DISCLOSURE FORM APPLICABLE
TO A

SUBAWARD ISSUED UNDER A PUBLIC HEALTH SERVICES PRIME AWARD

Investigator's Name: _____

This Disclosure is:

- my initial Disclosure an addendum to my most recent Disclosure
 my annual Disclosure an addendum **for travel purposes only** to my most recent Disclosure

Purpose

The form you are about to complete was designed for you to satisfy the disclosure requirements mandated by the Federal Public Health Service (PHS) regulations ([42 CFR Part 50](#) and [45 CFR Part 94](#)) on *Promoting Objectivity in Research*. This Disclosure should reflect those significant financial interests that are related to your organizational responsibilities at [Insert Name of Your Organization].

Definitions

Entity: Any non-[Insert Name of Your Organization], domestic or foreign, public or private, organization (excluding a U.S. Federal agency) from which you (and - your spouse or dependent children) receive remuneration or have - an ownership or equity interest.

Equity: Any stock, stock option, or other ownership interest, whether or not the value can be determined through reference to public prices or other reasonable measures of fair market value.

Remuneration: Any payment received from an outside entity in any form, including, but not limited to, stocks, bonds, stock options, warrants, partnership interests, rights to patent or royalty payments, consulting fees, honoraria, speaking fees, salary, loans, lectureship fees, or fees for serving on boards of directors, scientific and other advisory boards.

Significant Financial Interest: Anything of monetary value that meets any of the following criteria (when combined for you, your spouse and /or your dependent children):

- Income >\$5,000 (U.S. dollars) past 12 months
- As of the date of disclosure, any combination of income + equity in a publicly traded company >\$5,000 (U.S. dollars)
- Any equity interest in a non-publicly traded company
- Third party reimbursed or sponsored travel greater than \$5,000 (U.S. dollars) for any reportable travel related to your organizational responsibilities for [Insert Name of Your Organization]
- Income >\$5,000 (U.S. dollars) for intellectual property not owned by [Insert Name of Your Organization]

Non-Reportable Interests include:

- Financial interests or activities that do not relate to your academic or professional work at [Insert Name of Your Organization];
- Salary support received through [Insert Name of Your Organization] or salary support through [Insert Name of Your Organization] administered sponsored awards;
- Income from investment vehicles, such as mutual funds and retirement accounts, as long as you do not directly control the investment decisions made in these vehicles;
- Travel expenses paid by [Insert Name of Your Organization] or by a sponsored research award to [Insert Name of Your Organization];
- Income from seminars, lectures and teaching engagements sponsored by U.S. Federal, state or local government agencies; U.S. Institutions of higher education or U.S. research institutes; U.S. academic teaching hospitals or U.S. medical centers that are affiliated with U.S. Institutions of higher education;
- Income from service on advisory committees or review panels for U.S. Federal, state or local government agencies; U.S. Institutions of higher education or U.S. research institutes; U.S. academic teaching hospitals or U.S. medical centers that are affiliated with U.S. Institutions of higher education;
- Compensated activities and income derived from U.S. Government or non-profit research entities such as Howard Hughes Medical Institute {Insert other examples as appropriate}.

Publicly Traded Entities: In accordance with PHS regulations, a *significant financial interest* exists if the value of any remuneration received from any publicly traded entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000.

For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship).

- *Equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.*

- 1. (a) During the past 12 months, did you, your spouse or your dependent children receive remuneration such as consulting fees, honoraria, speaker fees, advisory board fees from ANY publicly traded entity that when combined amounted to greater than \$5,000 (U.S. dollars)?**

*Because PHS regulations do not exclude income from authorship activities, you must include them in your response to this question. Please do **not** include equity, royalties or other payments on intellectual property rights in your response to this question.*

NO ____ **YES** ____ If yes, complete table below

Name of Entity	Type of Business	Amount in U.S. Dollars	Activity	Individual Receiving Remuneration: You/Spouse/Dependent Children

1. (b) As of the date of this disclosure, do you, your spouse or your dependent children hold any *equity* interests in a publicly-traded *entity*? If so, does the value of this *equity* exceed \$5,000 (U.S. dollars) either on its own OR when combined with any other remuneration from the same *entity*?

NO ____ YES ____ If yes, complete table below

Name of Entity	Type of Business	Type of Equity	Value in U.S. Dollars	Individual Holding the Equity: You/Spouse/Dependent Children

Non-Publicly Traded Entities According to PHS regulations, a *significant financial interest* exists if the value of any remuneration received from any non-publicly traded entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000 (in U.S. dollars), or when you (or your spouse or dependent children) holds any equity interest in the same entity.
For purposes of the PHS regulations and this question, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship). Equity interests include stock, stock options, or other ownership interests.

2. (a) During the past 12 months, did you, your spouse or your dependent children receive any remuneration from ANY non-publicly traded *entity* that when combined amounted to greater than \$5,000 U.S. dollars?

Because PHS regulations do not exclude income from authorship activities, you must include them in your response to this question. Please do not include royalties or other payments on intellectual property rights in your response to this question.

NO ____ YES ____ If yes, complete table below

Name of Entity	Type of Business	Amount in U.S. Dollars	Activity	Individual Receiving Remuneration: You/Spouse/Dependent Children

3. (b) During the past 12 months, did you, your spouse or your dependent children hold ANY equity interests in any non-publicly traded *entity*?

NO ____ YES ____ If yes, complete table below

Name of Entity	Type of Business	Type of Equity	Value in U.S. Dollars	Individual Holding the Equity: You/Spouse/Dependent Children

4. During the past 12 months, did you, your spouse or your dependent children receive any remuneration from a non-profit entity that when combined amounted to greater than \$5,000 U.S. dollars?

Because PHS regulations do not exclude income for authorship activities or income from external professional organizations, you must include them in your response to this question. Also in accordance with PHS regulations, you must include income from a foreign institution of higher education or the government of another country in your response to this question.

Do not include the following:

- Income from seminars, lectures and teaching engagements sponsored by U.S. Federal, state or local government agencies; U.S. Institutions of higher education or U.S. research institutes; U.S. academic teaching hospitals or U.S. medical centers that are affiliated with U.S. Institutions of higher education;
- Income from service on advisory committees or review panels for U.S. Federal, state or local government agencies; U.S. Institutions of higher education or U.S. research institutes; U.S. academic teaching hospitals and U.S. medical centers that are affiliated with U.S. Institutions of higher education; and
- Royalties or other payments on intellectual property rights in your response to this question.

NO ____ **YES** ____ If yes, complete table below

Name of Entity	Amount in U.S. Dollars	Activity	Individual Receiving Remuneration: You/Spouse/Dependent Children

5. During the past 12 months, did a third party pay for greater than \$5,000 (U.S. dollars) of travel for you, your spouse or your dependent children related to your responsibilities at [Insert Name of Your Organization]? *For the purposes of this disclosure, travel costs are those that exceed \$5,000 U.S. dollars (either for one trip or a combination of trips from a single entity). Travel costs include meals, transportation, lodging, and registration fees.*

Third party paid travel means:

- Third party directly pays in whole or in part for travel on your behalf
- You pay for travel and third party reimburses you in whole or in part

- [Insert Name of Your Organization] pays in whole or in part for travel and the third party reimburses [Insert Name of Your Organization]

PHS regulations **include** travel paid by:

- For profit entities
- Non profit entities including external professional organizations and societies
- Academic journals and publishing companies; and
- a foreign institution of higher education or the government of another country.

PHS regulations **exclude** travel paid by:

- Subrecipient Organization;
- U.S. Federal, state or local government agencies;
- U.S. Institutions of higher education or U.S. research institutes; and
- U.S. academic teaching hospitals or U.S. medical centers that are affiliated with U.S. Institutions of higher education.

NO ____ **YES** ____ If yes, complete table below

Destination	Duration of Trip	Estimated Value in U.S. Dollars	Purpose	Sponsor/Organizer Who Paid for the Travel

6. During the past 12 months did you, your spouse, or your dependent children have any income greater than \$5,000 for intellectual property rights (e.g., patents, patent applications, license agreements, or copyrights) resulting from or related to your work at [Insert Name of Your Organization]?

Do not include payments from or intellectual property owned by [Insert Name of Your Organization]

NO ____ **YES** ____ If yes, complete table below

Short Description of Invention/IP	Is it Licensed/Patented/Patent Pending?	If receiving royalties/other payments greater than \$5,000, indicate the name of the entity providing the royalty/payment.

Certification:

I certify that I have read and understand [Insert Name of Your Organization]’s Financial Interest Disclosure Policy and have completed this Disclosure to the best of my knowledge and belief. Further, as someone who is identified as an investigator on a PHS proposal/award, subaward, or non-federal sponsor adopting the Public Health Services (PHS) regulations, I agree to comply with PHS regulatory requirements adopted as [Insert Name of Your Organization]’s policy as well as acknowledge the following:

- No later than at the time of proposal/application I will ensure that a current financial interest disclosure is on file;
- I will fulfill my disclose responsibilities at least annually or within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI during the period of the award whichever comes first, including the occurrence of any reimbursed or sponsored travel which is paid on my behalf, related to my responsibilities at [Insert Name of Your Organization];
- If I fail to report a new SFI within 30 days, I will willingly participate in the required retrospective review of my research in order to determine bias;
- With the decisions of COIC Committee/designated official reflected in a management plan, if one is issued;
- If I am a PI, I will appropriately identify individuals (i.e.,” investigators”) if any, in my proposal who are responsible for the conduct, design, or reporting of the research. I will take into consideration the role of the investigator, rather than their title and the degree of independence with which the investigator will work;
- If I am a PI, I will complete my progress report in a timely fashion to assist the PHS Grantee in its reporting requirements related to any identified and previously reported FCOIs;
- That [Insert Name of Your Organization] must comply with written requests for information regarding my reported FCOIs. [Insert name of organization]’s response must be within 5 business days and will include:
 - My name;
 - My title and role with respect to the research project;
 - The name of the entity in which the significant financial interest is held;
 - The nature of the significant financial interest; and
 - The approximate dollar value of the significant financial interest will be provided in the following dollar ranges: \$0–\$4,999; \$5,000–\$9,999; \$10,000–\$19,999; amounts between \$20,000–\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value; and
- That [Insert Name of Your Organization] may impose sanctions on me if I fail to comply with the PHS regulations and [Insert Name of Your Organization] policy.

Investigator’s Signature

Date

Disclaimer: Each subrecipient is legally required to independently assess the adequacy of its COI form for purposes of compliance with legal requirements, including compliance with the PHS financial conflict of interest regulations, and with other federal, state, local and organizational requirements. This model form is provided as a tool to assist in drafting the subrecipient's own form. No representation is made that this model form complies with any organization's particular legal requirements. Prior to finalizing or implementing this Form, consult with appropriate legal counsel to determine its legal sufficiency.