

Financial Conflict of Interest (FCOI) Disclosure

As part of its commitment to promoting objectivity in research and in compliance with federal regulations, Northwestern Health Sciences University maintains a policy on Financial Conflict of Interest in Research. This policy requires that investigators submit an annual disclosure form to ensure that the design, conduct, and reporting of PHS-funded research may not be biased by significant financial conflicts of interest. In addition, a revised disclosure form must be filed whenever an investigator's significant financial interests and obligations change materially.

Definitions:

Financial conflict of interest (FCOI) means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

Investigator means 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.

PHS means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).

Significant financial interest means:

(1) A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

(i) With regard to any publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the 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;

(ii) With regard to any non-publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or

(iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

(2) Investigators also must disclose the occurrence of any reimbursed or sponsored travel (*i.e.*, that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

The FCOI disclosure is a two-part form. All investigators must complete Part I. If an investigator's answers to Part I indicate that there may be a real or apparent conflict of interest, the investigator will also need to file Part II.

The completed form(s) should be forwarded to the Chief Financial Officer and Treasurer at NWHSU. The office will not submit an application for PHS-funded research unless FCOI disclosures have been submitted for all investigators. Compliance with this requirement is a prerequisite to the acceptance of any research grant or contract.

The submission of this disclosure satisfies the requirements of the Department of Health and Human Services (PHS) and the National Science Foundation (NSF). These agencies require that, by the time an application is submitted, each investigator planning to participate in PHS or NSF-funded research has disclosed his/her known significant financial interests (and those of his/her spouse and dependent children) (42 CFR Part 50 Subpart F and 45 CFR Part 94 and Section 510 of the NSF Grant Policy Manual).

FCOI Disclosure Part I

All NWHSU investigators seeking PHS-funding to conduct scholarly activities are required to complete and file a signed FCOI Disclosure each year. Each investigator must complete this form before a proposal can be endorsed for submission.

Specific Instructions: Place a check in the appropriate column for each question. Certify the information by signing the bottom of the form.

Investigator Name:

Department:

Questions	Yes	No
Do you, your spouse, or dependent child(ren) hold a position of management, such as board member, director, officer, partner, trustee, employee or consultant with a sponsor, a vendor, or (sub) contractor related to proposed or current PHS-funded research?	<input type="checkbox"/>	<input type="checkbox"/>
Do you, your spouse or dependent child(ren) have significant financial interest (see Definitions) in a Sponsor, a vendor, or (sub) contractor related to proposed or current PHS-funded research?	<input type="checkbox"/>	<input type="checkbox"/>
Is it reasonable to anticipate that your financial interest could be directly and significantly affected by the design, conduct, or reporting of proposed or current PHS-funded research?	<input type="checkbox"/>	<input type="checkbox"/>

If you answered “No” to ALL of the questions above, your disclosure is complete; you do not have to submit Part II. If you answered “Yes” to **ANY question above**, please complete a separate Part II for **every** outside organization with which you have the relationship(s) indicated above.

Investigator Certification:

- I have read and understood the NWHSU Policy on Financial Conflict of Interest in Research.
- I agree to file a new or updated FCOI Disclosure form if the answer to any of the above questions changes.
- I certify that the answers to the declaration are accurate and truthful to the best of my knowledge.

Signature:

Date:

FCOI Disclosure Part II

Complete Part II only if you answered, "YES" to at least one of the questions in Part I.

Attach one Part II form for each organization with which you have the relationship(s) indicated in Part I.

Investigator Name:

Number of Part II forms submitted: , of which, this is number:

1. Name of organization:
2. Financial relationship(s) with the organization (check all that apply):
 - ☐ Consultant ☐ Employee
 - ☐ Equity interest ☐ Recipient of honoraria
 - ☐ Recipient of royalties ☐ Other (describe):
3. The financial relationship is between the organization and (check all that apply):
 - ☐ Self
 - ☐ Spouse
 - ☐ Dependent child(ren)
4. If the organization is a publicly traded entity, have you, your spouse, or dependent children obtained in the last 12 months or do you anticipate obtaining in the next 12 months remuneration or equity from the entity in the previous twelve months that, 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.
Y ☐ N ☐ N/A ☐
5. If the organization is a non-publicly traded entity, have you, your spouse, or dependent children obtained in the last 12 months or do you anticipate obtaining in the next 12 months remuneration that, when aggregated, exceeds \$5,000, or do you hold any equity interest (e.g., stock, stock option, or other ownership interest)?
Y ☐ N ☐ N/A ☐
6. Do you, your spouse, or dependent children hold intellectual property rights and interests (e.g., patents, copyrights) upon receipt of income related to relationship with the organization?
7. What relationship, if any, is there between the business or activities of the organization and your current or planned areas of research?

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