



Project Specific Disclosure Statement for
Research Related Financial Conflicts of Interest

Investigator Name:	
Department:	
Research Project Title:	
Research Project Funded by:	<input type="checkbox"/> National Institutes of Health – NIH <input type="checkbox"/> National Science Foundation <input type="checkbox"/> American Cancer Society – ACS <input type="checkbox"/> American Heart Association – AHA <input type="checkbox"/> NCI – Cooperative Group <input type="checkbox"/> Subaward – List Subaward agency and Prime Funding Names Subaward Agency Name: Subaward Prime Funding Agency Name:

This statement is submitted (check either a or b):

- a. As a new disclosure statement; or
 An annual renewal disclosure statement, as to my financial interest with my proposed research project; or
- b. As a “single-transaction” disclosure statement, as to my newly acquired financial interest in my proposed research project.

The phrase “my financial interest” as used in this Disclosure Statement, includes any interest of myself, my spouse or my dependent child(ren).

Principal Investigator Disclosure and Certification

Do you, your spouse, or dependent children have any financial interests related to the work to be conducted under the proposed project?

- No
- Yes, please complete the: **Addendum Form** for each entity in which a financial interest exists.

I acknowledge and certify: 1) my responsibility to disclose any new reportable financial interests obtained during the term of the project, 2) all Co-Principal Investigators, Other Investigators, and Key Personnel, who will have the responsibility for the design, conduct, or reporting of research will submit the Project Specific Disclosure Form for Investigators' Conflicts of Interest, 3) this is a complete disclosure of my financial interests related to the proposed project, 4) I have read and understood CSM's Policy on Research Conflict of Interest and Financial Disclosure, and 5) I will cooperate fully with CSM to identify any resulting real or potential conflicts of interest and to take appropriate steps to manage, reduce, or eliminate these conflicts prior to receipt of any sponsor award resulting from this proposal.

Signature, Principal Investigator

Date

Project Specific Disclosure Statement for Research Related Financial Conflicts of Interest

Co-Principal Investigator, Other Investigators or Key Personnel Disclosure and Certification

Do you, your spouse, or dependent children have any financial interests related to the work to be conducted under the proposed project?

No

Yes, please complete the: **Addendum Form** for each entity in which a financial interest exists.

I acknowledge and certify: 1) my responsibility to disclose any new reportable financial interests obtained during the term of the project, and 2) all Co-Principal Investigators, Other Investigators, and Key Personnel, who will have the responsibility for the design, conduct, or reporting of research will submit the Project Specific Disclosure Form for Investigators' Conflicts of Interest, 3) this is a complete disclosure of my financial interests related to the proposed project, 4) I have read and understood CSM's Policy on Research Conflict of Interest and Financial Disclosure, and 5) I will cooperate fully with CSM to identify any resulting real or potential conflicts of interest and to take appropriate steps to manage, reduce, or eliminate these conflicts prior to receipt of any sponsor award resulting from this proposal.

Signature

Date

Print or Type Name

Email Address

When to submit this form:

1. For any New Research Project: A Project Specific Disclosure Statement must be submitted as part of the initial research application package for each and every CSM Investigator on the research project, as identified by the Principal Investigator.
2. For any Material Change in the Research Project: At any time during the life of the research project, the Project Specific Disclosure Statement must be submitted by the Investigator in the event of any Material Change, such as:
 - A new investigator is added to the project; or
 - There is a material change in the information previously disclosed; or
 - Within 30 days of acquiring or discovering any new Significant Financial Interest.
3. At least annually during the period of PHS funding.

For CSM use only:

Task:	Date Sent/Filed:
Date Project Disclosure Statement Received	
CSM Clinical Trials Manager sends a copy of "YES" FI Statements to NEIRB and CSM's Privacy Officer.	
CSM Clinical Trials Manager files all "NO" FI Statements.	

ADDENDUM FORM

Project Specific Disclosure Statement for Research Related Financial Conflicts of Interest

When completed and signed, this Disclosure Addendum Form should be sent to CSM's Clinical Trials Office: 2320 North Lake Drive, Room 1719, Milwaukee, WI 53211, or dlenhard@columbia-stmarys.org, or via fax to: 414-270-4869.

Please complete this Disclosure Addendum Form to describe a "Yes" answer on your Significant Financial Interest Statement related to a research proposal submitted to an external sponsor and provide information about the specific entity and your relationship to the entity. A separate Disclosure Addendum Form is required *for each entity* in/with which you have a Significant Financial Interest related to your research at Columbia St. Mary's.

Investigator Name:	
Department:	
Position within Columbia St. Mary's:	

A. Remuneration

Name of the entity from which you, your spouse, or dependent children, combined, are receiving or will receive the disclosed remuneration (> \$5,000 annually):

Type of entity (please check the appropriate boxes):

- Publicly-traded entity
- Non-publicly traded entity
- Educational Institution
- Local, State, Federal Government Agency

1. Please describe the business of this entity:

2. Please indicate the expected aggregate amount of annual remuneration you will receive in the next twelve months (remuneration includes salary and any payment for services not otherwise identified as salary, e.g., consulting fees, honoraria, paid authorship, travel reimbursement; use a best estimate approach based on your consulting/employment agreement and/or remuneration received from the above entity in the last 12 months): \$_____.

3. What is the nature of the relationship/service for which you, your spouse, or dependent children will receive compensation? Please describe your role or ownership interest in the organization, including any applicable titles (President, CEO, CFO, CSO, other - please indicate).

4. Does the disclosed remuneration include royalties and/or licensing fees? If so, please describe the intellectual property to which the payments are related and how **it is**, or **is not**, related to your CSM research and sponsored program work.

ADDENDUM FORM**Project Specific Disclosure Statement for Research Related Financial Conflicts
of Interest****B. Equity/Ownership Interest**

Name of the entity in which you, your spouse, and/or dependent children, have an equity/ownership interest: _____

Please indicate the aggregate fair market value of equity/ownership interest (equity/ownership 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) and percentage of ownership interest by checking the appropriate box/boxes:

- More than \$5,000 aggregate fair market value annually
 5% or more ownership interest/capital stock
 Any interest > 0 % if the entity is a non-publicly traded entity.

C. Please check all that apply:

- My CSM research involves human subjects.
 Products and/or services made/delivered by the above identified entity in which I have a financial interest are being used in my research work.

Please describe how your disclosed external relationship with the above identified entity does, or does not, relate to your CSM research work:

Signature: _____ **Date:** _____

Printed name: _____

When completed and signed, this Disclosure Addendum Form should be sent to CSM's Clinical Trials Office: 2320 North Lake Drive, Room 1719, Milwaukee, WI 53211, or dlenhard@columbia-stmarys.org, or via fax to: 414-270-4869.