



Disclosure of Financial Conflicts of Interest in Public Health Services Funded Research Statement

Introduction to Investigators

To enhance public trust in the objectivity of Public Health Service (PHS) funded biomedical and behavioral research, the U.S. Department of Health & Human Services adopted new regulations to strengthen and expand the following:

- Investigator disclosure of financial interests;
- Institutional transparency, management, and reporting of financial conflicts; and
- Federal oversight of financial conflicts of interest.

The regulations apply to recipients and sub-recipients of PHS funded research.

The regulations, effective as of August 24, 2012, require investigators who are planning to participate in PHS funded research to:

- Complete financial conflict of interest (FCOI) training; and
- Disclose all significant financial interests (SFIs) during the past 12 months to their institutions. Investigators must disclose all SFIs prior to submission of a PHS grant application, on an annual basis, or within thirty days of discovering or acquiring a new Significant Financial Interest.

Trinity Health and its medical staff and colleagues (employees) are committed to conducting their research activities in accordance with the highest standards of integrity and ethics and in compliance with all applicable laws and regulations related to conflicts of interest and objectivity in research.

The key to successfully handling potential conflicts is for investigators to fully disclose financial interests and if a conflict of interest is identified, to participate in the development and implementation of an appropriate mitigation plan.



Disclosure of Financial Conflicts of Interest in Public Health Services Funded Research Statement

Instructions

1. Read Trinity Health's two (2) Research Integrity & Compliance FCOI Procedures: 1) Disclosure of Financial Conflicts of Interest in Public Health Service Funded Research, and 2) Mitigation of Financial Conflicts of Interest in Public Health Service Funded Research.
2. Complete the required FCOI training module(s) via the designated learning management system. Per federal regulations, this training *must* be completed every four (4) years. Ministries may elect to have more stringent training completion deadlines (e.g., every 2 years); however, Ministries cannot have less stringent training completion deadlines (e.g., every 5 years).
3. Complete and return the following Disclosure of Financial Conflicts of Interest statement as directed. TYPE the information into this form; do not hand-write.
4. The Research Conflict of Interest Committee will evaluate your disclosure statement to determine whether any FCOIs exist, then take proper actions with you to reduce, manage or eliminate identified FCOIs, and to report them in compliance with federal law and regulations.

Who Must Complete The Disclosure Statement?

Principal Investigators, Program Directors, *and any other Trinity Health personnel, regardless of title or position*, who are responsible for the design, conduct, or reporting of PHS funded research, or proposed for such funding, including collaborators and consultants. This definition refers to the function of individuals on PHS funded projects not to their amount or source of remuneration.

KEY DEFINITIONS

- PHS research funding mechanisms include: Contracts, Grants, Cooperative agreements, Career Development Awards, Center Grant of Individual Fellowship Awards, and any other research activities funded by PHS agencies.
- Conflict of interest means a situation in which when financial interests may compromise, or have the appearance of compromising, independence and/or objectivity of an Investigator in connection with his/her research activities.
- Institutional Responsibilities means an Investigator's professional responsibilities on behalf of the institution including research, research consultation, teaching, clinical practice, institutional committee memberships, and services on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.



Disclosure of Financial Conflicts of Interest in Public Health Services Funded Research Statement

- Significant Financial Interest (SFI) includes *any of the following* for an Investigator, as defined above, and/or his/her spouse or any dependent children (Family Members):
 - Remuneration (any monetary or other financial benefit such as salary, consulting fees, honoraria or paid authorship) from any External Entity (not their Institution) that is related to the Investigator's research activities and exceeds \$5,000 during the 12-months prior to the disclosure when aggregated for the Investigator and Family Members.
 - Equity Interest in any External Entity that is related to the Investigator's research activities (for publicly-traded External Entities an SFI exists only if the Equity Interest exceeds \$5,000 in value when aggregated for the Investigator and their Family Members).
 - Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of any income related to such rights and interests that are related to the Investigator's research activities.
 - Travel reimbursed or sponsored by other than Trinity Health or travel that is not related to the Investigator's Institutional Responsibilities, such as travel required for award grant activity. *Note:* Travel may be paid on behalf of the Investigator and not directly reimbursed to the Investigator so that the exact monetary value may not be readily available but still must be estimated. *Note:* Institutional Responsibilities is defined above.
- A Significant Financial Interest (SFI) DOES NOT include the following:
 - Salary, royalties, or other remuneration paid by Trinity Health to Trinity Health Investigators.
 - Intellectual property rights assigned to Trinity Health and agreements to share in royalties related to such rights.
 - Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles.
 - Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an Institution of higher education as defined in 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.
 - Income from service on advisory committees or review panels for a federal, state, or local government agency, or 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.



Disclosure of Financial Conflicts of Interest in Public Health Services Funded Research Statement

I. DISCLOSURE AND CERTIFICATION

Do you, your spouse, or dependent children have any significant financial interests (SFI) related to PHS funded research or your institutional responsibilities? ☐ No ☐ Yes

If Yes, please complete and attach the following demographic & PHS research page and a separate addendum survey for each entity in which a significant financial interest exists.

If you answered "NO", go to SECTION IV VERIFICATION to date and sign the form.

II. INVESTIGATOR AND PHS RESEARCH INFORMATION

Section II Must Be Completed by Any Investigator Disclosing a Significant Financial Interest

Type of Disclosure (Check one):

- ☐ Initial Statement (covering previous 12 months)
☐ New/Updated Disclosure
☐ Annual Disclosure

Investigator Demographics

Last Name		First Name	
Title		Department	
Organization		Location (City & State)	
Phone #		Email address	



Disclosure of Financial Conflicts of Interest in Public Health Services Funded Research Statement

PHS Agency Research Application or Research Award Information

(If you are involved in more than one (1) PHS funded research application or award, please complete a separate table for each.)

PHS Funding Agency		Application or Grant/Contract #*	
Title of Research Project		Describe Your Project Role	
Indicate with a mark if Trinity Health is <input type="checkbox"/> Recipient or <input type="checkbox"/> Sub-recipient of the PHS funding			

PHS Funding Agency		Application or Grant/Contract #*	
Title of Research Project		Describe Your Project Role	
Indicate with a mark if Trinity Health is <input type="checkbox"/> Recipient or <input type="checkbox"/> Sub-recipient of the PHS funding			

PHS Funding Agency		Application or Grant/Contract #*	
Title of Research Project		Describe Your Project Role	
Indicate with a mark if Trinity Health is <input type="checkbox"/> Recipient or <input type="checkbox"/> Sub-recipient of the PHS funding			

**This is the number that eRA Commons assigns to a PHS research application during the electronic submission process. During the submission process, eRA Commons calls it the "Application #". PHS agencies use this same number to communicate with Investigators during the review and award process or grant/contract administration. At this point, the agencies call it the grant or contract or award number. The last 2 digits of the number (the suffix) refer to the calendar year and change annually. If you do not know the number, leave this box blank.*



Disclosure of Financial Conflicts of Interest in Public Health Services Funded Research Statement

SFI ADDENDUM SURVEY NO. _____

INSTRUCTIONS: Disclose all significant financial interests during the past 12 months. If you are disclosing more than on SFI, complete a separate addendum survey for each Entity.

External Entity in Which You Have a Significant Financial Interest

External Entity Name		Business Type	
Complete Address of External Entity			

Description of Financial Interest(s) with the External Entity

A. Management

1. Do you, your spouse or dependent child(ren) hold a position of management or employment with this entity? ☐ No ☐ Yes

If **Yes**, please insert a mark to indicate the position(s):

☐ Director ☐ Partner ☐ Employee ☐ Officer

☐ Member, Board of Directors/Trustees

☐ Member, Scientific Advisory Board

☐ Other (describe in detail) _____

2. Describe the responsibilities of your position(s) with the entity and how they relate to the project funded by the entity. _____

B. Income

1. *Excluding gifts, grants, contracts, or awards* administered by Trinity Health, have you, your spouse, or dependent children received income from the entity in the past 12 months? ☐ No ☐ Yes

If **Yes**, indicate the Income Range:

☐ Up to \$4,999 ☐ \$5,000-\$9,999 ☐ \$10,000-\$19,999 ☐ \$20,000-\$49,999 ☐ \$50,000 and above

Indicate the Nature of the Income:

☐ Consulting ☐ Honoraria ☐ Payment in Kind ☐ Per Diem ☐ Salary

☐ Other (Describe) _____

2. Do you have a loan arrangement with the entity? ☐ No ☐ Yes

If **Yes**, provide the loan amount: \$ _____

Describe the loan and explain the arrangements: _____

C. Equity

1. Do you, your spouse, or dependent child(ren) hold an equity interest in this entity? ☐ No ☐ Yes

If **Yes**, answer questions 2, 3 and 4.

2. Indicate the percentage of equity: _____%



Disclosure of Financial Conflicts of Interest in Public Health Services Funded Research Statement

3. What is the nature of this equity interest? ☐ Bonds ☐ Stocks/Stock Options ☐ Convertible Security ☐ Other (describe): _____

4. What is the value of this equity interest?
☐ Up to \$4,999 ☐ \$5,000-\$9,999 ☐ \$10,000-\$99,999 ☐ \$100,000-\$999,999
☐ \$1,000,000 or above

Note: If the stock is not publicly traded, provide an internal estimate of value: \$_____

D. Consulting

1. Are you or your spouse a consultant with this entity? ☐ No ☐ Yes
If Yes; Answer questions 2, 3 and 4.

2. Do either of you have a written consulting agreement? ☐ No ☐ Yes
If Yes; please submit a scanned copy with this form.

3. Describe in detail the frequency and nature of these consulting activities and how the consulting is separate from your research. _____

5. Will the terms of this consulting in any way restrict the release of information or other dissemination of research results by faculty/investigators involved in the project?
☐ No ☐ Yes
If Yes, explain: _____



Disclosure of Financial Conflicts of Interest in Public Health Services Funded Research Statement

Relationship with This External Entity:

A. Direct and Significant Impact on Financial Interests

1. Is the entity a subcontractor, consortium member, supplier of goods, lessor, or otherwise involved with the research project? ☐ No ☐ Yes
If Yes, explain: _____
2. Are you or your spouse the inventor of any device, vaccine, procedure, drug, or any other product associated with this research? ☐ No ☐ Yes
3. Does the entity manufacture or commercialize any device, vaccine, procedure, drug or any other product associated with this research? ☐ No ☐ Yes
If Yes, explain: _____
4. Will the research project purchase/lease any device/material from the entity? ☐ No ☐ Yes
If Yes, provide name and approximate cost: Name: _____ Cost: \$_____
5. Is it reasonable to anticipate that the entity will or could be directly and significantly affected by the design, conduct or reporting of the research activity? ☐ No ☐ Yes
If Yes, explain: _____
6. Is the entity a non-profit foundation? ☐ No ☐ Yes **If Yes**, answer questions a and b:
 - a. Do you or your spouse have a financial interest in the company(ies) that is (are) providing funds to this non-profit foundation? ☐ No ☐ Yes
 - b. If the sponsoring foundation is primarily a vehicle for one or two companies or a closely cooperating group or businesses, identify these firms. _____

B. Separation of Institution and External Entity Interests

1. Explain how you will keep or are keeping your interests and obligations to the entity separate from your PHS funded research and other Trinity Health institutional/professional activity. _____
2. Will you or your spouse be or have you been part of a formal committee/body that makes decisions related to funding decisions regarding this PHS research project? ☐ No ☐ Yes
If No, but you or your spouse will be present or were present when a PHS funding decision will be or was made regarding this research, please submit either a scanned written statement or a scanned copy of the meeting minutes.
If Yes, explain: _____
3. Is the entity going to provide or currently providing any proprietary data, materials or equipment for the research project? ☐ No ☐ Yes
If Yes, explain what control on access to the research will be necessary. _____
4. Will or does the entity participate in deciding the direction of this research? ☐ No ☐ Yes
If Yes, explain what role the entity will play. _____



Disclosure of Financial Conflicts of Interest in Public Health Services Funded Research Statement

C. Use of External Entity's and Trinity Health Resources and Facilities

1. Will the External Entity be or is the entity helping to fund the PHS research? ___ No ___ Yes

If Yes, what is their amount of support? _____

2. List any other entity funding this research and their amount of support. Also identify any Trinity Health funds that will supplement the project.

<u>Entity Name</u>	<u>Entity Support</u>	<u>Trinity Health Supplement</u>
_____	\$ _____	\$ _____
_____	\$ _____	\$ _____

D. PHS Research Involving Human Subjects

1. For human subjects research, describe your involvement in the proposed or actual research activities (i.e., consent patients, analyze data, etc.) _____
2. Describe how any potential conflict of interest in this research resulting from SFIs with the External Entity will be reduced, managed, or eliminated to ensure the rights and safety of human subjects.

E. Travel

1. Do you or your spouse or dependent child(ren) receive travel reimbursement or free travel from this External Entity? _____
2. Describe in detail frequency and nature of the travel: _____
3. How is it separate from your PHS research? _____
4. Indicate the value of the travel? ___ Up to \$1,000 ___ \$1,000-\$2,999 ___ \$3,000-\$4,999
___ \$5,000-\$9,999 ___ Over \$10,000



Disclosure of Financial Conflicts of Interest in Public Health Services Funded Research Statement

IV. VERIFICATION:

In accordance with U.S. 42 CFR 50 and 42 CFR 94, I certify that the information in this statement, to the best of my knowledge and belief, is true, correct and complete. I consent to the transfer of this information to any Public Health Service agency of the U.S. Department of Health and Human Services.

I acknowledge and certify that:

- I have read the Trinity Health Research Integrity & Compliance Procedures entitled, "Disclosure of Financial Conflicts of Interest in Public Health Service Funded Research" and "Mitigation of Financial Conflicts of Interest in Public Health Service Funded Research".
- I have completed the required FCOI training module(s) for Trinity Health investigators within the past 4 years, or more recently as required by Trinity Health.
- This is a complete disclosure of my significant financial interests regarding all External Entities *during the past 12 months* as well as PHS funded research, applications or awards related to these SFIs.
- I am attaching the documents that this statement requested based on my responses to specific SFI questions.
- I understand that it is my responsibility as a Trinity Health Investigator to complete an FCOI statement annually and to report to Trinity Health within 30 days any new or revised significant financial interests regarding any planned research applications to PHS agencies or funded PHS research projects.
- I agree to comply with any FCOI management plan issued by Trinity Health and to retain documentation that demonstrates compliance.

Signature

Date

Print or Type Name

Typed Email Address (required)

Please print out, sign (in black or blue ink), scan and e-mail the entire completed statement (which may contain multiple addendums) to Harriet Kinney, Director, Research Integrity and Compliance.

Email: kinneyh@trinity-health.org

Initial approval: January 07, 2015
Review/Revision(s): February 8, 2017
December 1, 2018