**

***Research Integrity & Compliance***

# Disclosure of Financial Conflicts of Interest, Other Support, and Foreign Components (FCOI / OS / FC) in Research Statement

*April 2020*

**Introduction to Investigators**

Historically, 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 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.

While these regulations apply to recipients and sub-recipients of PHS funded research, Trinity Health and the RHMs apply the regulations to all research.

The regulations, effective as of August 24, 2012, with additional guidance from the National Institutes of Health (NIH) on March 30, 2018 and July 10, 2019, 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), Other Support (OS), and Foreign Components (FC) 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* *all* financial interests and if a conflict of interest is identified, to participate in the development and implementation of an appropriate mitigation plan.**

**Instructions**

1. Read Trinity Health’s two (2) Research Integrity & Compliance FCOI/OS/FC Procedures: 1) Disclosure of Financial Conflicts of Interest in Research, and 2) Mitigation of Financial Conflicts of Interest in 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.
3. Complete and return the following Disclosure 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 FCOI/OS/FCs exist, then take proper actions with you to reduce, manage or eliminate identified FCOI/OS/FCs, 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 colleagues, regardless of title or position,* who are responsible for the design, conduct, or reporting of research, or proposals for funding, including collaborators and consultants. This definition refers to the function of individuals on projects, not to their amount or source of remuneration.

|  |
| --- |
| **KEY DEFINITIONS*** Research funding mechanisms include: Contracts, Grants, Cooperative agreements, Career Development Awards, Center Grant of Individual Fellowship Awards, and any other research activities funded, including those 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.
* 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.
* External Entity means any natural person, corporation, partnership, sole proprietorship, association, organization, holding company, joint stock company, receivership, trust, foreign entity, foreign institution of higher education, foreign governmental agency or subdivision (e.g., local, provincial, or equivalent governments of the United States or another country) regardless of whether organized for profit, nonprofit or charitable purposes.
* Foreign Component (FC)means the existence of any significant scientific element or segment of a project out of the Unites States, such as performance of work by a researcher or recipient in a foreign location, or performance of work by a researcher in a foreign location employed or paid for by a foreign organization.
* Other Support (OS) means all resources made available to a research in support of and/or related to all of their research endeavors, regardless of whether or not they have monetary value and regardless of whether they are based at the institution.
* 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 (domestic) federal, state, or local government agency, a domestic 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 (domestic) federal, state, or local government agency, or a domestic 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.
 |

1. **DISCLOSURE AND CERTIFICATION**

Doyou, your spouse, or dependent children have anySignificant Financial Interests, Other Support, or Foreign Components (SFI/OS/FC) related to research or your institutional responsibilities?

\_\_\_\_ [ ]  No \_\_\_\_ [ ]  Yes

**If Yes,** please complete and attach the remained of the form including the separate addendum survey for EACH entity in which a Significant Financial Interest, Other Support, or Foreign Components exists.

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

1. **INVESTIGATOR RESEARCH INFORMATION**

*Section II Must Be Completed by Any Investigator Disclosing a SFI/OS/FC*

**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 |       |

**PHS Funded 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.*

   No PHS funding – ***skip to the next page***.

|  |  |  |  |
| --- | --- | --- | --- |
| PHS Funding Agency  |       | Application or Grant/ Contract #**\*** |       |
| Title of Research Project  |       | Describe Your Project Role |       |
| Indicate with a mark if Trinity Health is    Recipient or    Sub-recipient of the PHS funding  |
| Total Award amount for the entire award period (including facilities and administrative costs), as well as the number of person-months (or partial person months) per year to be devoted to the project by the senior / key personnel involved.       |

|  |  |  |  |
| --- | --- | --- | --- |
| PHS Funding Agency  |       | Application or Grant/ Contract #**\*** |       |
| Title of Research Project  |       | Describe Your Project Role |       |
| Indicate with a mark if Trinity Health is    Recipient or    Sub-recipient of the PHS funding |
| Total Award amount for the entire award period (including facilities and administrative costs), as well as the number of person-months (or partial person months) per year to be devoted to the project by the senior / key personnel involved.       |

|  |  |  |  |
| --- | --- | --- | --- |
| PHS Funding Agency  |       | Application or Grant/ Contract #**\*** |       |
| Title of Research Project  |       | Describe Your Project Role |       |
| Indicate with a mark if Trinity Health is    Recipient or    Sub-recipient of the PHS funding |
| Total Award amount for the entire award period (including facilities and administrative costs), as well as the number of person-months (or partial person months) per year to be devoted to the project by the senior / key personnel involved.       |

**\****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.*

**Other (non-PHS)****Funded Research Application or Research Award Information**

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

   No other funding – ***skip to the next page***.

|  |  |  |  |
| --- | --- | --- | --- |
| Funding Agency  |       | Application or Grant/ Contract #**\*** |       |
| Title of Research Project  |       | Describe Your Project Role |       |
| Indicate with a mark if Trinity Health is    Recipient or    Sub-recipient of the Other funding  |
| Total Award amount for the entire award period (including facilities and administrative costs), as well as the number of person-months (or partial person months) per year to be devoted to the project by the senior / key personnel involved.       |

|  |  |  |  |
| --- | --- | --- | --- |
| Funding Agency  |       | Application or Grant/ Contract #**\*** |       |
| Title of Research Project  |       | Describe Your Project Role |       |
| Indicate with a mark if Trinity Health is    Recipient or    Sub-recipient of the Other funding |
| Total Award amount for the entire award period (including facilities and administrative costs), as well as the number of person-months (or partial person months) per year to be devoted to the project by the senior / key personnel involved.       |

|  |  |  |  |
| --- | --- | --- | --- |
| Funding Agency  |       | Application or Grant/ Contract #**\*** |       |
| Title of Research Project  |       | Describe Your Project Role |       |
| Indicate with a mark if Trinity Health is    Recipient or    Sub-recipient of the Other funding |
| Total Award amount for the entire award period (including facilities and administrative costs), as well as the number of person-months (or partial person months) per year to be devoted to the project by the senior / key personnel involved.       |

**SFI ADDENDUM SURVEY NO.**

*INSTRUCTIONS: Disclose all Significant Financial Interests during the past 12 months. If you are disclosing more than one SFI/OS/FC, complete a separate addendum survey for each Entity.*

**External Entity in Which You Have a SFI/OS/FC**

|  |  |  |  |
| --- | --- | --- | --- |
| External Entity Name |       | Business Type  |       |
| Complete Address of External Entity |       |

**Description of Financial Interest(s) with the External Entity**

|  |
| --- |
| 1. **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)       * 1. Describe the responsibilities of your (or their) position(s) with the entity and how they relate to the project funded by the entity:

       |
| 1. **Income**
	1. 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?
	2. 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 aboveIndicate the Nature of the Income:    Consulting    Honoraria    Payment in Kind    Per Diem    Salary    Other (Describe)      * 1.
	2. 2. Do you have a loan arrangement with the entity? [ ]    No    [ ] Yes
	3. **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:      %1. What is the nature of this equity interest? [ ]    Bonds [ ]    Stocks/Stock Options [ ]    Convertible Security [ ]    [ ]  Other (describe):

[ ] 1. What is the value of this equity interest?

[ ]    Up to $4,999    $5,000-$9,999 [ ]    $10,000-$99,999 [ ]    $100,000-$999,9999[ ]  [ ]    $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. **If No,** skip to the next section. 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.      4. 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:       |
| **E. Other Support**1. Do you hold a position or appointment with this External Entity?  This includes titled academic, professional, or institutional appointments, whether or not remuneration is received, and whether full-time, part-time, or voluntary (including adjunct, visiting, or honorary)    No    Yes2. List all resources and other support that you or any individual designated in the award as senior / key personnel receive to support the award, irrespective of whether such support is through another domestic or foreign organization or is provided directly to an individual that supports the senior/key personnel's research efforts for this award.       3. List all resources of current projects and activities that involve senior / key personnel who receive Other Support, even if the support is only in-kind. This includes, but is not limited to, foreign financial support, research or laboratory personnel, laboratory space, scientific materials, selection to a foreign "talents" or similar-type program, or other foreign or domestic support.       |
| **F. Foreign Component** 1. Will there be performance of work by senior / key personnel in a foreign location, whether or not funds are expended?    No    Yes**If YES**, describe the work to be performed by each senior / key personnel, the foreign location, and the amount of funds to be expended.      2. Will there be performance of work by senior / key personnel in a foreign location employed or paid for by a foreign organization, whether or not the funds are expended?    No    Yes**If YES,** describe the work to be performed by each senior / key personnel, the foreign location, the foreign organization providing payment, and the amount to be paid by the foreign organization.       |

**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:       1. Will the research project purchase/lease any device/material from the entity?[ ]

  [ ]  No   [ ]  [ ] Yes **If Yes**, provide name and approximate cost: Name:       Cost: $     1. 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:      1. 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 research and other Trinity Health institutional/professional activity.       * + - * 1. 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 research project?

  [ ]  No   [ ]  Yes **If No,** but you or your spouse will be present or were present when a 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:      * + - * 1. 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:      1. Will or does the entity participate in deciding the direction of this research? [ ]

  [ ]  [ ] No   [ ]  [ ] Yes  **If Yes,** explain what role the entity will play.        |
| **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 research?

  [ ]  [ ] No   [ ]  [ ] Yes  **If Yes,** what is their amount of support?       1. List any other entity funding this research and their amount of support. Also identify any Trinity Health funds that will supplement the project.

. Entity Name Entity Support Trinity Health Supplement       $      $             $      $       |
| **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.):      1. 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?

  [ ]  [ ] No   [ ]  [ ] Yes 1. Describe in detail frequency and nature of the travel:
2. How is it separate from your research?
3. 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 |

**IV. Verification:**

|  |
| --- |
| In accordance with U.S. 42 CFR 50 and 42 CFR 94 and this policy, 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 I **acknowledge and certify that:** * I have read the Trinity Health Research Integrity & Compliance Procedures entitled, “Disclosure of Financial Conflicts of Interest in Research” and "Mitigation of Financial Conflicts of Interest in 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, Other Support, and Foreign Components regarding all External Entities *during the past 12 months* as well as PHS and other funded research, applications or awards related to these SFI/OS/FCs.
* I am attaching the documents that this statement requested based on my responses to specific SFI/OS/FC questions.
* I understand that it is my responsibility as a Trinity Health Investigator to complete a FCOI/OS/FC statement annually and to report to Trinity Health within 30 days any new or revised Significant Financial Interests, Other Support, or Foreign Components regarding any planned research applications, including those applications to PHS and other agencies or PHS or other funded research projects.
* I agree to comply with any FCOI/OS/FC 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

 April 15, 2020