

**Trinity Health-Michigan
Promoting Objectivity in Research
2024 Significant Financial Interest Disclosure Form**

Purpose

Trinity Health-Michigan and its medical staff and colleagues 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 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 a Trinity Health-Michigan ministries and locations.

Who Must Complete This Disclosure Statement?

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

Instructions:

1. Read Trinity Health-Michigan's policy on *Promoting Objectivity in Research*, available online at: <https://www.trinityhealthmichigan.org/research-compliance/ann-arbor/policies>. This policy defines key terms used throughout this form.
2. Complete the required Financial Conflict of Interest (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 of Financial Conflicts of Interest Form as directed at the end of this form. **Please TYPE the information into this form; do not hand-write.** This form will ask details about publicly traded entities, non-publicly traded entities, non-profit entities, travel, Intellectual Property Rights, foreign components, and other support,
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.

5. If you have any questions while completing this form, please contact Research Compliance Department via email at aasjrbsubmissions@trinity-health.org or by phone at (734) 712-5470.

I. INVESTIGATOR AND PHS RESEARCH INFORMATION

A. Investigator Information

Full Name:	Title:
Hospital:	Department:
Phone:	Email:

B. Type of Disclosure

- Initial Disclosure
- Annual Disclosure
- New / Updated Disclosure

C. What is your role in Clinical Research?

- Principal Investigator (PI)
- Co-PI / Sub-Investigator
- Research Nurse Coordinator
- Clinical Research Assistant / Coordinator
- Biostatistician / Data Manager
- Manager / Administrator
- Other: _____

D. Are you receiving funding to conduct research from any PHS agency?

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

- a. Grants and Contracts
- b. Cooperative agreements
- c. Career Development Awards
- d. Center Grant of Individual Fellowship Awards
- e. Any activity where funding is provided by PHS

- NO** **YES**

If YES, please complete the table below. If you have more than one PHS-funded research application or award please complete a separate table for each:

If NO, continue to the next question.

PHS Funding Agency		Application or Grant/Contract #**	
Title of Research Project		Describe Your Project Role	

Trinity Health-Michigan is the Recipient or Sub-recipient of the PHS Funding

PHS Funding Agency		Application or Grant/Contract #**	
Title of Research Project		Describe Your Project Role	
Trinity Health-Michigan is the <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	
Trinity Health-Michigan is the <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 this number, please leave this box blank.*

II. PUBLICLY-TRADED ENTITIES

In accordance with federal 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 Section II, the following definitions apply:

- **Remuneration** means salary and any payment for services not otherwise identified as salary (e.g. consulting fees, honoraria, paid authorship, etc.)
- **Publicly traded entities** are corporations that have sold their shares on a public stock exchange through an initial public offering to the general public, allowing anyone to purchase or sell ownership shares of the company.
- **Equity interest** in the case of a publicly traded entity includes the value of any stock, stock option, bonds, shares, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.



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

Please do **not** include equity, royalties or other payments on intellectual property rights in your response to this question.

NO YES

If YES, please complete table below:

Name of Entity	Type of Business	Amount in US Dollars	Activity	Individual Receiving Remuneration*

*For each entry above, please specify whether you, your spouse, and/or your children are the recipient of the stated remuneration. If you have additional remuneration to report, please submit this information on a separate page.

B. During the past 12 months, did you, your spouse and/or your dependent children hold any **equity interests** in a **publicly traded entity**? If "yes", 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?

Please do **not** include equity interests in investment vehicles, such as mutual funds and retirement accounts, as long as none of you directly controls the investment decisions in those vehicles.

NO YES

If YES, please complete table below:

Name of Entity	Type of Business	Type of Equity	Value in US\$	Individual Holding the Equity

III. NON-PUBLICLY TRADED ENTITIES



In accordance with federal 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, or when you, your spouse or dependent children hold any equity interest in the same entity (regardless of the value of such equity interest).

For purposes of this Section II, the following definitions apply:

- **Remuneration** means salary and any payment for services nor otherwise identified as salary (e.g. consulting fees, honoraria, paid authorship, etc.)
- **Non-publicly traded entities** are owned either by non-governmental organizations or by a relatively small number of shareholders or company members and do not offer or trade their company stock (shares) to the general public on the stock market exchanges, but rather the company's stock is offered, owned and traded or exchanged privately. A privately held company or closed corporation are examples of a non-publicly traded entity.
- **Equity interest** in the case of a non-publicly traded entity includes any stock, stock option, bonds, shares, or other ownership interest (e.g. "Founder's Interest") even where the value of such interest is not readily ascertainable through reference to public prices.

A. During the past 12 months, did you, your spouse and/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)?

Please do **not** include equity, royalties or other payments on intellectual property rights in your response to this question.

NO **YES**

If YES, please complete table below:

Name of Entity	Type of Business	Amount in US Dollars	Activity	Individual Receiving Remuneration*

**For each entry above, please specify whether you, your spouse, or your children are the recipient of the stated remuneration. If you have additional remuneration to report, please submit this information on a separate page.*

B. During the past 12 months, did you, your spouse or your dependent children hold any **equity interests in a **non-publicly traded entity**?**

If you do not know the exact value of the equity interest, please provide an estimate of value based on the entity's internal estimations or other reasonable measure of fair market value.

NO **YES**

If YES, please complete table below:

Name of Entity	Type of Business	Type of Equity	Value in US\$	Individual Holding the Equity

IV. NON-PROFIT ENTITIES

For this Section, please note that the term **remuneration** does **not** include the following:

- Salary, royalties or other remuneration paid by a Trinity Health-Michigan ministry to the Investigator;
- Income from seminars, lectures or teaching engagements sponsored by (i) a U.S. federal, state or local government agency; (ii) U.S. institutions of higher education; or (iii) an academic teaching hospital, a medical center, or research institute that is affiliated with a U.S. institution of higher education;
- Income from service on advisory committees or review panels for a (i) federal, state, or local government agency; (ii) U.S. institution of higher education; or (iii) an academic teaching hospital, a medical center, or research institute that is affiliated with a U.S. Institution of higher education;

Please note that you must include any remuneration received from foreign institutions of higher education or the government of another country in your response to the question below.

A. 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)?**

NO YES

If YES, please complete table below:

Name of Entity	Location of Entity	Amount in US Dollars	Activity	Individual Receiving Remuneration*

V. TRAVEL

In accordance with federal regulations, investigators must disclose the occurrence of any reimbursed or sponsored travel. For purposes of this Section V, the following definitions apply:

- **Reimbursed travel** means you pay for the travel and the third-party entity reimburses you in whole or in part OR the Trinity Health-Michigan ministry that employs you pays in whole or in part for the travel and the third-party entity reimburses the Trinity Health-Michigan ministry.
- **Sponsored travel** means the third party directly pays in whole or in part for travel on your behalf.
- **Travel costs** include meals, transportation, lodging, and any registration fees.

Travel costs to be reported **include** travel paid by:

- For-profit entities;
- Non-profit entities;
- Academic journals and publishing companies;
- A foreign institution or higher education or the government of another country.

Federal regulations **exclude** travel paid by:

- U.S. federal, state or local government agencies;
- U.S. institutions of higher education; or
- an academic teaching hospital, a medical center, or research institute that is affiliated with a U.S. institution of higher education;

A. During the past 12 months, did a third party reimburse or sponsor travel for you, your spouse, and/or your dependent children in amounts greater than \$5,000 (US Dollars)?

NO YES

If **YES**, please complete table below:

Third Party Paying for Travel	Destination	Duration of Trip	Estimated Value in U.S. Dollars	Purpose

VI. INTELLECTUAL PROPERTY RIGHTS

A. During the past 12 months, did you, your spouse, and/or your dependent children receive income or royalty payments greater than \$5,000 (US Dollars) for Intellectual Property Rights resulting from or related to your work at a Trinity Health-Michigan Ministry?

Intellectual Property Rights means any patents, patent applications, license agreements, or copyrights. Please do not include any payments or royalties you receive from a Trinity Health-Michigan Ministry for intellectual property owned by Trinity Health-Michigan in your response to this question.

NO YES

If **YES**, please complete table below:

Short Description of Intellectual Property	Is it licensed / copyrighted / patented / patent pending?	If receiving royalties or other payments > \$5,000, provide the name of the entity providing the royalty / payment.

VII. Foreign Component

The questions under this Section VII **must** be completed if your research is funded, in whole or in part, by an NIH grant or award (including any grants or awards for which you

are a subrecipient). If this is not applicable to your research, you may skip these questions and move to the next section of this form.

A. Will any portion of your research be performed by a researcher or collaborator in a foreign location? (Please answer this question even if no research funds are being expended).

NO YES

If YES, please complete table below:

Name of individual performing research	Foreign location	Description of work to be performed	Amount of funds expended (if any)

B. Are any foreign entities employing or paying for any portion of the research conducted by a researcher in a foreign location? While this question is similar to the one above, the purpose is to determine whether there is any financial support for the research being provided by a foreign entity.

NO YES

If YES, please complete table below:

Name of foreign entity providing payment	Foreign location	Amount to be paid by the foreign entity	Individual receiving remuneration

VIII. OTHER SUPPORT

The questions under this Section VIII **must** be completed if your research is funded, in whole or in part, by an NIH grant or award (including any grants or awards for which you

are a subrecipient). If this is not applicable to your research, you may skip these questions and move to the next section of this form.

A. Do you hold any other positions and/or scientific appointments (both domestic and foreign) that are relevant to your research conducted at Trinity Health-Michigan and its Regional Health Ministries (RHMs) that have not otherwise been reported in this application?

Please note that this includes any titled academic, professional, or institutional appointments, whether or not remuneration is received, and whether the position is full-time, part-time, or voluntary (including adjunct, visiting, or honorary).

NO **YES**

If YES, please use the space below to provide additional information:

B. Do you or will you receive any in-kind support from any other domestic or foreign entities that will benefit research being conducted at Trinity Health-Michigan and its RHMs?

“In-kind support” includes research or laboratory personnel, laboratory space, scientific materials, selection to a foreign “talents” or similar-type program, or other domestic or foreign research collaborations that benefit the researcher’s research endeavors.

NO **YES**

If YES, please use the space below to provide additional information:



IX. CERTIFICATION

In accordance with U.S. 42 CFR 50 and 42 CFR 94, **I certify that the information in this form, 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 as required by law, or by the Trinity Health-Michigan Research Financial Conflict of Interest Committee.

I acknowledge and certify that:

- **I have read Trinity Health-Michigan's policy entitled: *Promoting Objectivity in Research-Financial Interest Disclosure***
- **I have taken the required FCOI training as set by Trinity Health-Michigan.**
- **I understand the FCOI training must be undertaken by me every four years.**
- **This is a complete disclosure of my financial interests related to research, including any PHS-supported research; and**
- **It is my responsibility to complete an FCOI disclosure form annually, and to report to Trinity Health-Michigan within 30 days any new or revised significant financial interests.**

Signature

Date

Print or Type Name

Scan and confidentially e-mail this completed/signed form to:

aasjrbsubmissions@trinity-health.org