PROCEDURE TITLE:

Disclosure of Financial Conflicts of Interest in Public Health Service Funded Research

To be reviewed every three years by:
Research Integrity & Compliance Committee

EFFECTIVE DATE: December 1, 2018

PROCEDURE

This Procedure implements the requirements of Integrity & Compliance Policy No. 1 Integrity and Compliance Program which requires Trinity Health to establish policies and procedures to ensure Trinity Health's operations fully comply with applicable laws, regulations and professional standards, including promoting the conduct of ethical and compliant research.

The objectivity of research is of paramount importance and the basis for obtaining and maintaining public trust. To address the increasing complexities of the financial interests held by biomedical and behavioral researchers and the resulting interactions among government, research institutions, and the private sector, the Public Health Service (PHS) and the Office of the Secretary of the U.S. Department of Health and Human Services (HHS) published revised regulations on the Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought and Responsible Prospective Contractors (commonly known as the Financial Conflict of Interest (FCOI) regulations). These regulations establish new standards and clarify previously established standards to be followed by institutions that apply for or receive research funding from PHS Awarding Components, including the National Institutes of Health (NIH), for grants, cooperative agreements, and research contracts. The 2011 revised regulations (implemented August 24, 2012) were written to increase accountability, add transparency, enhance regulatory compliance and effective institutional management of Investigators’ financial conflicts of interest, and strengthen NIH’s compliance oversight. The primary goal is to promote objectivity by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under PHS grants, cooperative agreements and contracts will be free from bias resulting from Investigator financial conflicts of interest.

Disclosure of Significant Financial Interests

Investigators, employees, and medical staff members of Trinity Health conducting research are required to identify, disclose and address Financial Conflicts of Interest (FCOI) in PHS funded research following a standard process in compliance with applicable regulations.
Trinity Health requires disclosure of all Significant Financial Interests (SFIs) on an ongoing basis. A Significant Financial Interest (SFI) means an Investigator’s (and/or his/her Family Members):

1. Remuneration (any monetary or other financial benefit such as salary, consulting fees, honoraria or paid authorship) from any External Entity (not Trinity Health) that is related to the Investigator’s PHS-funded research activities and exceeds $5,000 during the 12 months prior to the disclosure when aggregated for the Investigator and their Family Members; Equity Interest in any External Entity that is related to the Investigator’s PHS-funded 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);

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

3. Reimbursed or sponsored travel (sponsored travel is defined as travel paid on behalf of the investigator from an External Entity);

4. An SFI does not include the following:
   a. Salary, royalties or other remuneration paid by Trinity Health to the Investigator and intellectual property rights assigned to Trinity Health;
   b. Income from seminars, lectures or teaching engagements sponsored by a federal, state or local government agency, or an institution of higher education as defined at 20 U.S.C. 1001(a);
   c. 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);
   d. 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;
   e. Travel 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.

A Research Conflict of Interest Committee will be established by each Ministry conducting PHS-funded research and will evaluate all disclosures to determine whether a Financial Conflict of Interest exists and, as appropriate, will require proper actions be taken to address any FCOI. Proper action includes reducing or eliminating the FCOI to ensure that the design, conduct and reporting of research is free from bias, or the appearance of bias, as well as disclosing and reporting each such FCOI in compliance with federal law and regulations.
Public Accessibility

This Procedure will be made available via a publicly accessible website by each Ministry conducting PHS-funded research.

Required Investigator Training

Investigators must complete training prior to engaging in PHS-funded research and at a minimum every four (4) years to ensure awareness and understanding of this Procedure and Investigators responsibilities for disclosure of SFIs. Training must be completed immediately when any of the following circumstances apply:

1. An Investigator is new to Trinity Health;
2. Trinity Health revises its conflict of interest policies or procedures in any manner that affects the requirements of Investigators; or
3. Trinity Health finds that an Investigator is not in compliance with this procedure or FCOI management plan.

Required Investigator Disclosure

Trinity Health Investigators must disclose all SFIs:

1. Prior to submission of an application for PHS-funded research;
2. At least annually during the period of the award; and
3. Within thirty (30 days) of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI.

Implementation Responsibilities

The Research Conflict of Interest Committee will review each submitted "Disclosure of Financial Conflicts of Interest in Public Health Service Funded Research" statement to identify any potential FCOI in accordance with applicable laws and regulations, and will document mitigation actions necessary to manage any identified FCOI.

Research Conducted With Or Through A Sub-Recipient

When research is conducted through a sub-recipient (e.g., subcontractors or consortium members), Trinity Health will take reasonable steps to ensure that sub-recipients are in full compliance with the regulation and are reporting to Trinity Health any identified FCOI for sub-recipient Investigators.

Trinity Health will incorporate as part of a written agreement with the sub-recipient the obligation of the sub-recipient and sub-recipient Investigators to comply with the this procedure, unless Trinity Health has reviewed and determined the FCOI procedure of the sub-recipient is compliant with applicable regulations. In such cases, Trinity Health will agree to require that sub-recipient
Investigators to comply with the sub-recipient’s procedure. The written agreement or sub-
recipient’s procedure must include time periods to meet disclosure and/or FCOI reporting
requirements. The written agreement will require the sub-recipient to report identified FCOIs to
Trinity Health in sufficient time to allow Trinity Health to report the FCOI to the PHS awarding
agency to meet reporting obligations.

SCOPE/APPLICABILITY

This Procedure applies to all Public Health Service (PHS) funded research conducted in Trinity
Health. Ministries may adopt substantially equivalent procedures that include all of the elements
of this Procedure. Each Ministry that conducts PHS research will comply with all elements of this
Procedure, and may add procedures that do not conflict with this Procedure.

DEFINITIONS

**Conflict of Interest** means a situation in which a Significant Financial Interest (SFI) may
compromise, or have the appearance of compromising, an Investigator’s judgment in conducting,
reviewing or reporting research.

**Equity Interest** means any stock, option or other ownership interest in an External Entity.

**External Entity** means any natural person, corporation, partnership, sole proprietorship,
association, organization, holding company, joint stock company, receivership, trust,
governmental agency or subdivision regardless of whether organized for profit, nonprofit or
charitable purposes.

**Family Member** means the Investigator’s spouse and dependent children.

**Financial Conflict of Interest (FCOI)** means a SFI that Trinity Health has determined could
directly and significantly affect the design, conduct or reporting of research.

**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.

**Investigator** means the project director (PD), principal investigator (PI) and any other personnel,
regardless of title or position who are responsible for the design, conduct, or reporting of research,
or proposed for such funding including collaborators and consultants. This definition refers to the
function of individuals on the PHS-funded or proposed project, not to their amount or source of
remuneration.

**Ministry** means a first tier (direct) subsidiary, affiliate, or operating division of Trinity Health that
maintains a governing body that has day-to-day management oversight of a designated portion of
Trinity Health System operations. A ministry may be based on a geographic market or dedication
to a service line or business. Ministries include Mission Health Ministries, National Health
Ministries, and Regional Health Ministries.
**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).

**Policy** means a statement of high-level direction on matters of strategic importance to Trinity Health or a statement that further interprets Trinity Health’s governing documents. System Policies may be either stand alone or Mirror Policies designated by the approving body.

**Procedure** means a document designed to implement a policy or a description of specific required actions or processes.

**Research Conflict of Interest Committee** means a multi-disciplinary committee designated to manage conflicts of interest in research activities in a Ministry.

**Significant Financial Interest (SFI)** means an Investigator’s (and/or his/her Family Members’) financial interest in an External Entity or research as defined by federal regulations.

**RELATED PROCEDURES AND OTHER MATERIALS**

- Trinity Health Integrity & Compliance Procedure ICR.2, *Mitigation of Financial Conflicts of Interest in PHS-Funded Research*
- 21 CFR 54
- 42 CFR Part 50 subpart F
- 45 CFR Part 94
- 45 CFR 74.14, 74.62 and 92.43
- NIH Frequently Asked Questions, Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sough (42 CFR Part 50 Subpart F) applicable to grants and cooperative agreements (2011 Revised Regulations) [https://grants.nih.gov/grants/policy/coi/coi_faqs.htm#3158](https://grants.nih.gov/grants/policy/coi/coi_faqs.htm#3158)
- Form - Significant Financial Interest Disclosure Statement
RESPONSIBLE DEPARTMENT

Further guidance concerning this Procedure may be obtained from the Integrity & Compliance Department.

APPROVALS

Initial Approval: August 24, 2012

Subsequent Review/Revision(s): August 24, 2015
February 8, 2017
December 1, 2018