Institutional Review Board Procedure No. 4

EFFECTIVE DATE: ***October 27, 2023***

PROCEDURE TITLE:

Education and Training on Human Subject Protections

To be reviewed every three years by:
Institutional Review Board

REVIEW BY: ***October 26, 2026***

PROCEDURE

This Procedure implements the requirements of Institutional Review Board Policy No. 1 *Authority of the Institutional Review Board*, which requires the Trinity Health Mid-Atlantic (THMA) Institutional Review Board (IRB) establish policies and procedures to ensure that the Trinity Health Mid-Atlantic's IRB operations fully comply with applicable laws, regulations and professional standards, and the Ethical and Religious Directives for Catholic Health Care Services, including promoting the conduct of ethical and compliant research.

Background

THMA is committed to maintaining the highest ethical standards in conducting research and the protection of human subjects. This commitment is fundamental to Trinity Health's mission, core values, and vision. To help achieve this, THMA provides a variety of educational and training opportunities designed to enhance the understanding of the responsible conduct of research, human subjects protection, good clinical practice, privacy and security, financial conflicts of interest, and other relevant topics to individuals in all areas of research, including leadership, IRB members and staff, investigators, research staff, and research participants and their communities.

The terms of the Federal-wide Assurance (FWA) held by THMA as submitted to the Office of Human Research Protections (OHRP) and signed by the Institutional Official (IO) state that the institution is responsible for ensuring that its investigators conducting Health and Human Services (HHS)-conducted or HHS-supported human subjects research understand and act in accordance with the regulatory requirements for the protection of human subjects. The Assurance includes that investigators maintain a continuing knowledge of, and comply with:

- Relevant ethical principles;
- Relevant federal regulations;
- Written IRB procedures;

- OHRP guidance;
- Other applicable guidance;
- State and local laws;
- And institutional policies for the protection of human subjects.

Furthermore, OHRP recommends that investigators complete appropriate institutional educational training before conducting human subject's research.

I. Collaborative Institutional Training Initiative (CITI)

The CITI Program https://www.citiprogram.org/ is an online learning management system that provides required research educational courses to all colleagues and other individuals involved in research activities in THMA.

The minimum score for passing each of the THMA required courses is 80%. At the completion of each assigned course, the individual will receive a CITI Training Completion Record that is valid for a maximum of four (4) years, except where otherwise required by applicable laws or regulations, or by this Procedure.

THMA may require additional courses to meet local needs, which are assigned by the local CITI administrator. The minimum score for passing each of THMA's assigned courses is 80%. At the completion of each assigned course, the individual will receive a CITI Training Completion Record that is valid for a maximum of four (4) years.

II. Ethical and Religious Directives Education and Training

As a Catholic health care organization, THMA is committed to performing research activities in a manner consistent with the *Ethical and Religious Directives for Catholic Health Care Services*, as defined by the United States Conference of Catholic Bishops (ERDs). The ERDs are a set of moral principles promulgated by the United States Conference of Catholic Bishops that serve to reaffirm the ethical standards of behavior in health care that flow from the Catholic teachings on the dignity of all human life and provide guidance on ethical issues and challenges facing modern health care. All individuals involved in the conduct, oversight, or management of research who are employees of Trinity Health are required to complete education and training on ERDs every four (4) years.

III. Education and Training Requirements of External Federal Funding Departments and Agencies

When conducting research that is funded and/or sponsored by a federal department or agency (e.g., National Institutes of Health, Department of Transportation), it is the responsibility of the Investigator and research staff to complete all education and training obligations prior to applying or during the term of the funding agreement as required by the funding department or agency.

IV. Research Participants and the Community – Outreach and Education

THMA is committed to promoting public awareness and trust in research through outreach efforts designed to enhance the understanding of the rights of research participants, potential participants, and their communities.

THMA's research program and IRB website, brochures, and announcements strive to present information designed to target the needs of the research community. Topics of information may include:

- What to expect as a research participant;
- Rights of a research participant;
- How to find out about local research and clinical trials;
- How to make a complaint related to participating in a research study;
- Research versus medical treatment;
- Informed consent for research;
- HIPAA and research;
- Information about what an IRB is; and
- Links to the IRB's website.

Education and Training Requirements

All individuals involved in research are required to maintain continuing knowledge of, and to ensure compliance with, the legal, regulatory and ethical obligations when conducting human subjects research. Education and training includes but is not limited to, human subject protections, good clinical practice, responsible conduct of research, privacy and security practices, and financial conflicts of interest.

V. Investigators, Study Coordinators, and Research Staff Education and Training

a. General Requirements

Education and training must be completed prior to application submission to the IRB for review. Individuals are to complete education and training from CITI or an equivalent, non-CITI resource (e.g., academic training program, certification from a recognized research professional organization, NIH). IRBs will only accept a submitted application that contains current Training Completion Records.

Renewal of education and training must be completed by the individual prior to expiration

and submitted to the IRB at the time of continuing review or through an amendment of on-going research. Timely completion of education and training for renewal is required. If this requirement is not met, an IRB may take action such as:

i) The individual may be given a brief period of time to come into compliance (e.g., no more than 10 business days);

ii) The individual may be considered for non-compliance with this procedure and may require a report to regulatory authorities;

iii) The individual may not be allowed to be involved in research activities until documented proof of the refresher education and training is provided; and

iv) Other appropriate action.

b. Human Subjects Protection Education and Training

All Investigators, study coordinators, and research staff who are involved in the conduct, oversight, or management of research are required to complete education and training in the protection of human subjects every four (4) years.

c. Good Clinical Practice (GCP) Education and Training for Investigators Conducting Clinical Trials

All Investigators, study coordinators, and research staff who are involved in the conduct, oversight, or management of clinical trials, no matter the source of the funding, are required to complete Good Clinical Practice (GCP) education and training every three (3) years.

VI. Institutional Official, IRB Members, and IRB Staff Education and Training

The Institutional Official, IRB members, and IRB staff are required to complete the CITI education and training in the protection of Human Subjects in clinical research as applicable to their roles. All IRB members and member alternates must complete CITI education and training prior to becoming a registered voting member on the IRB. The Institutional Official, IRB members, and IRB staff are required to complete education and training every four (4) years.

Individuals who have obtained Certified IRB Professional (CIP) designation by the *Council for Certification of IRB Professionals* need only produce their certificate to demonstrate adequate education and training.

Renewal of research and human subjects protection education must be completed by the individual prior to expiration. Timely completion of education and training for renewal is required. If this requirement is not met, the IRB may take action; for example:

- The individual may be given a brief period of time to come into compliance (e.g., no more than 10 business days);

- The individual may be removed from the IRB roster;
- The individual may be removed as an IRB staff member;
- Designation of a new Institutional Official; and
- Other appropriate action.

RESPONSIBLE DEPARTMENT

Further guidance concerning this Procedure may be obtained from the Trinity Health Mid-Atlantic Institutional Review Board.

RELATED PROCEDURES AND OTHER MATERIALS

Trinity Health Research Integrity & Compliance Procedure ICR.4 *Education and Training Requirements for Individuals Involved in Human Subjects Research*

APPROVALS

Initial Approval: August 28, 2020

Subsequent Review/Revision(s): October 27, 2023