

**EFFECTIVE DATE:** *November 17, 2023*

**PROCEDURE TITLE:**

*Authority of the IRB*

*To be reviewed every three years by:  
Institutional Review Board*

**REVIEW BY:** *November 16, 2026*

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**POLICY**

It is the policy of Trinity Health Mid-Atlantic to have an Institutional Review Board (IRB), and its primary responsibility is to protect the rights and welfare of human participants in research.

Trinity Health Mid-Atlantic (THMA) is cognizant of its responsibility for insuring that the privacy, safety, health and welfare of research participants are adequately protected; therefore, the IRB has been established to provide independent review and continuing compliance with human subject protection regulations. The IRB is designated as the THMA Institutional Review Board.

Through and under the authority of THMA's Federal-wide Assurance (FWA) and THMA policies and procedures, the IRB reviews and monitors human subject research to determine that it is conducted ethically and in compliance.

As noted in the terms of the FWA, this institution assures that whenever it engages in human subjects research conducted, supported or otherwise subject to regulation by any federal department or agency, including those which have adopted the Federal Policy for the Protection of Human Subjects and its revision, also known as the Revised Common Rule, the institution will comply with the terms of the FWA for institutions within the United States (contained in a separate document on the OHRP website), unless the research is otherwise exempt from the requirements of the Revised Common Rule or a department or agency conducting or supporting the research has determined that the research shall be covered by a separate assurance.

Additionally, the THMA IRB is registered at a site maintained by the Department of Health and Human Services (DHHS) as the THMA IRB reviews clinical investigations regulated by the Food and Drug Administration (FDA) and research regulated by OHRP.

## **The IRB's Authority**

Any research or clinical investigation which meets a federal definition of research (e.g., research sponsored by the Food and Drug Administration, Office of Human Research Protections, HIPAA, Department of Health and Human Services, and others) and which engages THMA shall not be initiated unless that research has been reviewed and approved by, and remains subject to continuing review by, the THMA IRB.

The THMA IRB shall review and have the authority to approve, require modifications in (to secure approval) or disapprove all research activities covered by this policy.

Under 45 CFR 46.113 and 21 CFR 56.113, the THMA IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the board's determinations or has been associated with unexpected serious harm to participants. Any such action will be reported promptly to the investigator, institutional officials, OHRP or FDA, as appropriate, citing the reasons for the Board's actions.

45 CFR 46.103(b)(5)(i) and 21 CFR 56.108(b)(5) require that any instances of serious or continuing non-compliance with DHHS human subjects regulations or the determinations of the IRB must be promptly reported to the appropriate institutional officials, OHRP, the FDA, and the study sponsor.

Research that has been approved by the THMA IRB may be subject to further review and approval by the Institutional Official. The Institutional Official may not approve research that was disapproved by the IRB.

The THMA IRB has the authority to observe the consent process and review or audit any study which it approved or determined to be exempt.

The THMA IRB has been authorized as the Privacy Board for the use and disclose of protected health information (PHI) for research purposes, under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). All requests to use and disclose PHI for research purposes must be submitted to the IRB for review and approval *prior* to the use and disclosure of the PHI, including preparatory to research activities.

## **Scope of the IRB's Authority**

### **A. Definitions**

Research conducted within THMA means:

1. Research taking place in any facility owned or operated by Trinity Health including wholly-owned subsidiaries and such other entities controlled by Trinity Health Mid-Atlantic, doing business as THMA, or utilizing equipment, materials, or other resources owned by THMA.

2. Research involving medical records or other information from patients registered in THMA.

Research may be requested, conducted or led by THMA colleagues, affiliated physicians, including residents, consultants or contractors or external researchers (including students).

THMA is considered *engaged* in a particular human subjects research project when **its employees or agents** for the purposes of the research project obtain:

1. Data about the participants of the research through intervention or interaction with them;
2. Identifiable private information about the participants of the research; or
3. The informed consent of participants for the research.

THMA's *employees or agents* refers to individuals who:

1. Act on behalf of the THMA;
2. Exercise institutional authority or responsibility; or
3. Perform institutionally designated activities.

“Employees and agents” can include staff, students, residents, fellows, contractors, and volunteers, among others, regardless of whether the individual is receiving compensation.

## **B. Single IRB Approval**

The National Institute of Health (NIH) Policy on the Use of a Single Institutional Review Board for Multi-Site Research (NOT-OD-16-094) will be upheld. This policy applies to research supported through grants, cooperative agreements, or the NIH Intramural Research Program. This means research funded by the NIH that are carried out at more than one site in the United States will have a single IRB review and an IRB of Record will be determined prospectively. This policy applies to domestic awardees and participating domestic sites.

The THMA IRB may, at its sole discretion, rely upon approval by another IRB.

## **C. IRB Authorization Agreements**

A formal, signed agreement between THMA and one or more other institutions may be established to provide for cooperative review by a single IRB for research conducted at multiple study sites. When such an agreement is in place, alternate review methods by the THMA IRB may take place. Alternate review procedures will be documented in the IRB Authorization/Reliance Agreement.

## DEFINITIONS

**IRB** means the Institutional Review Board designated by Trinity Health Mid-Atlantic to represent Trinity Health Mid-Atlantic in the Federal-wide Assurance.

**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.

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

## RESPONSIBLE DEPARTMENT

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

## RELATED PROCEDURES AND OTHER MATERIALS

- DHHS 45 CFR 46  
<https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#sp45.1.46.a>
- FDA 21 CFR 50  
<https://www.ecfr.gov/cgi-bin/text-idx?SID=179a53e663a8d7ffa008276846e4a84a&mc=true&node=pt21.1.50&rgn=div5#sp21.1.50.a>
- FDA 21 CFR 56  
<https://www.ecfr.gov/cgi-bin/text-idx?SID=8244acf890023a89ccd4af32ae9f2130&mc=true&node=pt21.1.56&rgn=div5#sp21.1.56.a>

## APPROVALS

**Initial Approval:** August 28, 2020

**Subsequent Review/Revision(s):**