Institutional Review Board Procedure No. 3

EFFECTIVE DATE: ***April 28, 2023***

PROCEDURE TITLE:

Institutional Review Board Membership

To be reviewed every three years by:
Institutional Review Board

REVIEW BY: ***April 27, 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.

Composition of Membership

The THMA IRB must be composed of at least five members with varying backgrounds and sufficiently qualified through the experience and expertise of its members to promote respect for its advice and counsel in safeguarding the rights and welfare of human participants. The diversity of the members, including consideration of race, gender, and cultural backgrounds, and knowledgeable of the community and community attitudes will be considered. The IRB will be composed of at least one member not otherwise affiliated with THMA and who is not part of the immediate family of a person who is affiliated with the institution, at least one scientific member, and at least one non-scientific member. The same member may serve dual roles, such as not being affiliated with THMA and being a non-scientist.

The IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. If the IRB regularly reviews research that involves a vulnerable category of participants, such as children, prisoners, persons with diminished capacity, and persons with mental impairments, persons of low income, persons of no education, consideration shall be given to the inclusion of one or more IRB members or consultants who are knowledgeable about and experienced in working with these participant populations. In addition:

- All candidates for IRB membership, including alternates, must provide a resume or CV prior to consideration by the IO or designee. The CV will address earned degrees, board certifications, licensure, and professional memberships, other indications of appropriate

experience and competence. If no CV or resume a written statement of life experiences will be filed.

- All IRB members will complete research ethics training as outlined in the IRB's education procedure.

- All members will be voting members. No IRB member may participate in the IRB's initial or continuing review of any study for which the member has a conflict of interest, except to provide information requested by the IRB. Once a candidate has been added to the official roster filed with OHRP and the FDA, then he/she becomes a voting member of the IRB.

IRB Chair

The IRB will have a Chair who commands the respect of the IRB, who has IRB experience, is knowledgeable in regulations governing the involvement of human participants in research, and has the ability to facilitate the meetings and conduct the business of the IRB in an efficient and effective manner.

The duties of the IRB Chair include, but are not limited to:

- Chairing the meeting.

- Be well versed in the federal regulations, state laws, and IRB policy and procedures.

- Identify and address conflicts of interest as they apply to IRB members and staff, including themselves.

- Ensuring that all IRB members have an opportunity to participate equally in convened IRB meetings.

- Review all submitted materials for each convened IRB meeting.

- Conducting business so that each proposal is fairly and completely reviewed.

- Facilitating meetings so that the IRB reaches a decision on the disposition of each proposal in a timely manner.

- Ensuring that decisions are documented accurately in the meeting minutes.

- Performing expedited reviews and exempt concurrence determinations or designating other IRB members to perform these duties.

- Reviewing and acknowledging unplanned emergency research notifications or designating other IRB members to perform these duties.

- Reviewing new and any significant changes or updates to existing IRB Policies and Procedures to ensure compliance with all Federal, State, local, and institutional requirements for the protection of human participants in research.

- The IRB chair can designate an experienced member of the IRB from the respective roster to perform his or her duties in the event that the Chair is unable to do so.

- Perform all of the responsibilities of a regular IRB member.

The Institutional Official (IO) or designee will appoint the IRB Chair for a three-year term, with the possibility for renewal. The IO or designee will notify the IRB Chair in writing of the status of the reappointment, as well as any terms and conditions of reappointment. In the event that a new IRB Chair needs to be selected, the IO or designee will evaluate nominations and select the new Chair.

The Institutional Official or his/her designee shall have the authority to remove an IRB Chair and IRB members for cause, including, but not limited to, failure to consistently meet the obligations of the position.

IRB Members

IRB members may be nominated by the IRB Chair, current IRB members, or by the Institutional Official. The Institutional Official or his/her appointed designee, will review the nominations and appoint the IRB members in consultation with IRB Chair.

IRB Members may serve indefinitely. IRB members are required to attend at least seventy-five percent (75%) of all scheduled meetings throughout the course of a calendar year. Members are expected to:

- Attend the majority of meetings

- Conduct effective review of research protocols assigned in advance of the meeting,

- Present their findings and recommendations of research reviewed,

- Actively participate in discussion,

- Possess an understanding of the federal regulations, state laws and IRB policies,

- Serve as general reviewers on all research discussed at convened meetings, and

- Experienced members may also be expected to conduct expedited reviews or temporarily cover the duties of the Chair when so designated by the IRB Chair.

Alternate IRB Members

Alternate IRB members meet the same qualifications and backgrounds as regular IRB members and are nominated and appointed by the same process as the regular IRB members. Alternates are invited to attend IRB meetings as guests to become familiar with the practices and proceedings of the IRB. Alternates may participate as voting members only when substituting for the regular member at IRB meetings. Alternates are documented on the respective roster of the IRB and when applicable are documented in the IRB meeting minutes.

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): April 28, 2023