
EFFECTIVE DATE: *March 24, 2023***PROCEDURE TITLE:***Institutional Official**To be reviewed every three years by:
Institutional Review Board***REVIEW BY:** *March 23, 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 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.

The Institutional Official (IO) is responsible for the Human Research Participant Program (HRPP) and the protection of human research participants as indicated in the Federal Wide Assurance (FWA) filed with the US Department of Health and Human Services, Office for Human Research Protections (OHRP). The Institutional Official is a senior official who is legally authorized to act for the institution and is responsible for ensuring that the institution provides the resources and support necessary to comply with all requirements applicable to research involving human subjects, including the HRPP. The IO has the authority to require compliance of the institution and all of its components to the terms of the FWA.

I. Appointment of the Institutional Official

Trinity Health Mid-Atlantic (THMA) will appoint an Institutional Official who is responsible for ensuring that the THMA Human Research Protection Program (HRPP) functions effectively and as stipulated by the Federal-wide Assurance.

The IO is an individual of sufficient rank and authority to ensure that all obligations of the HRPP are carried out effectively and efficiently. This individual is typically the Chief Medical Officer, but could be the President, Chancellor, Director General, Chief Executive Officer, or Chief Operating Officer for the Regional Health Ministry (RHM). The IO has authorization necessary to carry out administrative or legal action that may be required.

To prepare for the appointment of an Institutional Official, the IO must complete the Institutional Official training course at www.citiprogram.org and any other training requirements as noted in the IRB policies and procedures.

II. Authority and Duties of the Institutional Official

The Trinity Health IO is the individual authorized to act for the institution and, on behalf of the institution, shall obligate the institution to the terms of the Federal-wide Assurance. The Trinity Health Mid-Atlantic Institutional Review Board (IRB) represents Trinity Health Mid-Atlantic in the Federal-wide Assurance (FWA).

The responsibilities and duties of the Trinity Health Mid-Atlantic IO include, but are not limited to:

- Ensuring that the Human Research Protection Program functions effectively and that the RHM provides the resources and support necessary to comply with all research requirements.
- Legally authorized to act for the institution and, on behalf of the institution, obligates the institution to the terms of the Federal-wide Assurance.
- Designating the IRB that will review human subjects research covered by the institution's FWA.
- Providing sufficient resources, space, and staff to support the:
 - IRB's review and record keeping duties.
 - Training opportunities for the RHM, including the IRB Administrator, IRB committee members, investigators, and research team members.
 - Functioning of the Human Research Protection Program.
- Ensuring effective institution-wide communication and guidance about conducting ethical human subjects research and the protection of human subjects.
- Ensuring that investigators fulfill their responsibilities as outlined in the Human Research Protection Program.
- Ensure that all staff engaged in the conduct or oversight of human subject research participate in education activities.
- Serve as a knowledgeable point of contact for OHRP, FDA, HIPAA or other Federal or external body.

The IO may *not* approve research that has been disapproved (or not yet approved) by the IRB

The IO may further review and approve human subjects research that has been approved by the IRB, as appropriate.

Delegation of Duties

The IO may delegate the performance of certain oversight and operational duties to one or more appropriate and qualified individuals. Upon designation of a new IO, all delegation letters must be reviewed and renewed by the new IO if the new IO chooses to maintain delegation. The following duties, below, may be delegated if the delegation is made in writing through policy and/or job description:

- Appointing IRB members;
- Suspending or terminating the IRB membership of any individual for whom it has been determined that he/she is not fulfilling membership responsibilities and or obligations;
- Appointing the IRB chair or co-chairs;
- Suspending or terminating the appointment of any Chair who is not fulfilling his/her responsibilities and or obligations;
- Performing periodic evaluation of the performance of the IRB Chair and members, and the IRB Administrator;
- Reviewing and signing memoranda of understanding and cooperative agreements between the institution and other organizations, including those that establish reliance on IRBs of record for collaborative research (e.g., IRB Authorization Agreements, Individual Investigator Agreements);
- Being the point of contact for correspondence addressing human subjects research with the OHRP, FDA and other agencies as applicable, including reports to federal agencies;
- Ensuring that IRB members and investigators are knowledgeable to conduct research in accordance with ethical standards and all applicable regulations;
- Developing and implementing an educational plan for IRB members, IRB Administrator, investigators, and research team members;
- Ensuring that IRB members and investigators are knowledgeable to conduct research in accordance with ethical standards and all applicable regulations;
- Reviewing and approving IRB policies and procedure policies; and
- Overseeing daily operations of the HRPP in accordance with the policies.

The following responsibilities *cannot* be delegated by the IO to a designee:

- Signatory authority for the FWA;
- Completing training for the IO;
- Ensuring that the IRB functions independently and that its Chair and members have direct access to the IO for appeal if they experience undue influence or if they have concerns about the function of the IRB; and
- Ensuring that adequate resources, including funds, space, and personnel are provided to support the operation of the HRPP.

III. Term of Service of the Institutional Official

The IO may serve indefinitely.

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>
- Office for Human Research Protections (OHRP), Secretary's Advisory Committee on Human Research Protections (SACHRP), Institutional Official Responsibilities, Draft Example of Guidance to be Developed Drawing on Current OHRP Materials, Draft VA Guidance, and Subpart A Subcommittee Suggestions
<http://www.hhs.gov/ohrp/sachrp-committee/recommendations/2008-september-18-letter-attachment/>
- Form - Trinity Health Mid-Atlantic Institutional Official Delegation of Certain Duties

APPROVALS

Initial Approval: August 28, 2020

Subsequent Review/Revision(s): March 24, 2023