
EFFECTIVE DATE: *May 19, 2023***PROCEDURE TITLE:***Principal Investigator Qualification and
Responsibility in the Conduct of Research**To be reviewed every three years by:
Institutional Review Board***REVIEW BY:** *May 18, 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 THMA'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.

All research studies will have a principal investigator and that person will be held accountable for the ethical conduct of the study. All research studies conducted at THMA will have one study team member from THMA.

I. DEFINITIONS**Principal Investigator**

The principal investigator of a study is defined as an individual with experience and credentials who conducts a clinical investigation/research (i.e., directs administration of a test article, or implantation of a device to a human participant, collects data using retrospective or prospective methods, etc.) and is the responsible leader of the study team. The principal investigator has overall responsibility for the conduct of the study. The principal investigator may designate others to perform duties as per written protocol, but the delegation does not absolve the requirement of his or her ultimate responsibility and authority.

Sponsor-investigator

A sponsor-investigator of a study is defined as an individual with experience and credentials who initiates and conducts alone or with others a clinical investigation / research and is responsible for all sponsor related activities. Sponsor related responsibilities include such things as authoring the protocol, assuring sound scientific study design with appropriate statistical methods to assure

objectives are met, applicable regulatory filings to agencies, reports to funding bodies, publication of study results and other oversight activities, as well as study execution.

II. QUALIFICATIONS

A member of the THMA medical staff, an allied health professional, or a member of the employed professional staff must be either the Principal Investigator, who has primary responsibility for the overall conduct of the research project, or a sub-investigator acknowledging responsibility for local conduct of the study. External physicians or allied health professionals (i.e., physicians not on the medical staff or allied health professionals not employed by THMA) may be principal investigators for studies conducted at this location, provided that a THMA physician/professional staff associate is a sub-investigator.

Residents and students can perform the duty of Principal Investigator, but there must be a THMA Attending physician or THMA Faculty Advisor identified as a sub-investigator and sign as such within the IRB New Project Application. Delay in reviews will occur if the criteria above is not addressed.

At initial new study review, the principal investigator will provide current curricula vitae/resume that outlines the education, training, and any previous research activities that establishes he/she has the necessary experience and education to conduct the study. The investigator must have thorough knowledge of the use of the investigational agents, procedures, research intervention or technique, and/or devices as described in the protocol, Investigator Brochure, product information and other material from the sponsor, as applicable.

Principal investigators, co-investigators, and study coordinators must have evidence of human subject protection training. For THMA researchers the subscription service known as Collaborative Institute Training Initiative (CITI) is used to provide the required training.

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.

There may be additional training required outside of the CITI courses. Documentation supporting additional training or experience, related to a proposed study, particularly if the proposed research involves a novel treatment/technologies or surgical techniques, or recruitment of a vulnerable population, may also need to be submitted to the IRB.

Additional Credentialing may be required by the THMA credentialing committee for novel treatments or procedures required by the protocol. THMA physicians must be credentialed through the THMA Credentialing process. Allied health professionals must have proof of current licensure for the duties assigned for execution of the protocol and must present evidence of qualifications for conducting the study that is acceptable to the IRB.

III. RESPONSIBILITIES

The principal investigator agrees to and will attest to the following in the initial application; and a similar list for exempt research:

1. The investigator must agree to conduct the study in accordance with the terms of the IRB approval (including the current IRB approved protocol) until any proposed changes have been reviewed and approved by the IRB (and sponsor, if applicable), except when necessary to eliminate apparent immediate hazards to the research participants.
2. The investigator agrees to personally conduct and supervise the study as submitted in the initial application and as reported to the IRB.
3. The investigator agrees to inform research participants that the drugs, devices or interventions are being used for investigational purposes, and will ensure that the requirements to obtaining informed consent are conducted in accordance with applicable law and THMA IRB Policy and Procedures.
4. The investigator, during the study, will provide all documents, subject to IRB review, in accordance with applicable law and THMA IRB Policy and Procedures. The investigator is responsible for assuring that the content of the continuing review report is accurate and complete and his/her signature on the form indicates this acknowledgement. The investigator is responsible for being aware and knowledgeable of correspondence to the IRB regarding protocol revisions, protocol deviations and unexpected adverse events. The investigator is responsible for ensuring that a Close-Out form is submitted to the IRB once the study is completed.
5. If applicable, the investigator must have read and understood the information in the investigator's brochure and study protocol, including the potential risks and side effects of the drug, device, or biologic. If applicable, the investigator must have knowledge and experience for the device being tested for investigational purposes.
6. The investigator will ensure that all associates, colleagues, and employees (members of the study team) assisting in the conduct of the study are informed about their obligations in meeting the requirements of the written protocol.
7. The investigator has overall responsibility for monitoring an investigation to assure that it is being conducted according to the study protocol. Periodic review that is necessary would depend on the type of study being conducted, level of risk, type of intervention and other factors.

Designated individuals may perform monitoring but the investigator must review the work of the designated individuals, which would include monitoring, maintenance of confidentiality, and oversight of research records and proper use and disclosure of source data in accordance with applicable laws and institutional policies.

8. The investigator will assure that study records will be available for inspection by regulatory authorities and the IRB Administrator in accordance with applicable law and THMA IRB Policy and Procedures.
9. The investigator will ensure that an IRB, which complies with the requirements of applicable Federal law, will be responsible for the initial and continuing review, as applicable, of the study.
10. The investigator will assure that the facilities, personnel and equipment used for the conduct of the study are appropriate for protocol execution.
11. The investigator will notify the IRB immediately of any actual or potential financial or ethical conflict of interest that arises for him/herself or any other member of the study team during the conduct of the study.
12. There may be additional responsibilities requested by the IRB of the investigator that are dependent upon the nature of the study and other considerations. These additional responsibilities would be documented during IRB review and approval.

Failure to do any of the above may be deemed non-compliance by the IRB. Serious and Continuing Non-Compliance is reportable to the federal authorities.

RESPONSIBLE DEPARTMENT

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

RELATED PROCEDURES AND OTHER MATERIALS

APPROVALS

Initial Approval: August 28, 2020

Subsequent Review/Revision(s): May 19, 2023