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**EFFECTIVE DATE:** *June 10, 2022***PROCEDURE TITLE:***External/Central IRB Reliance Process**To be reviewed every three years by:  
Institutional Review Board***REVIEW BY:** *June 09, 2025*

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**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 THMA's IRB operations fully comply with applicable laws, regulations, professional standards, and the *Ethical and Religious Directives for Catholic Health Care Services*, including promoting the conduct of ethical and compliant research.

**I. PURPOSE**

The purpose of this Standard Operating Procedure (SOP) is to define a process for all THMA researchers engaging in an External or Central IRB collaborative relationship. This SOP provides our current thinking of the external IRB reliance review process which includes descriptions of the information flow between the IRB of Record and Relying IRB throughout the lifecycle of the initial protocol review, amendments, reporting, continuing review and study closure. This guidance includes responsibilities for the IRB of Record, Relying IRB(s), lead study team, and the relying study team(s).

**DEFINITIONS**

*Central IRB (CIRB)* is a single board that reviews research studies for multiple sites. A Central IRB can be any registered IRB that functions to review multiple sites but most commonly the term Central IRB references an independent IRB. Regardless of the group providing it, centralized IRB review is one review for a number of sites. Commonly, the sponsor determines which sites are to participate and suggests or requires those sites to use the Central IRB selected to perform the centralized review.

*External IRB* is outside the institutional framework. It could refer to being external to the immediate institution or to a larger system or framework of coordinating agreements. External IRBs are also called remote IRBs as they are generally geographically removed from the performance site.

*Internal IRB* exists within the institution engaged in the study.

*IRB of Record* is the lead IRB who will oversee the conduct of research related activities at all research.

## II. SCOPE

The policies and procedures described in this SOP apply to all parties involved in research with THMA. Any institutions or organizations engaged in research with THMA researchers must have an IRB Reliance Agreement and standard operating procedures for multisite research in place. The delegation of duties between lead and relying institution and the responsibilities of each party conducting research are outlined in the Reliance Agreement and the research application submitted to the IRB of Record.

## III. APPLICABLE REGULATIONS AND GUIDELINES

The same regulatory framework applied to research reviewed by THMA IRB applies for all external IRB reliance review requests. All research involving human subjects must follow one or more of the below regulations, policies, and/or procedures.

- **Federal Regulations (45 CFR 46, 160, 164 & 21 CFR 50, 56 at minimum. Additional FDA regulations may apply based on the study design)**
- **State and local regulations**
- **Institutional Policies**
- **ICH-GCP (E6) (as applicable)**
- **IRB of Record Policies**
- **Whenever possible, the IRB of Record procedures should also be consistent with the Association for the Accreditation of Human Research Protections Program's (AAHRPP) guidelines for "Reviewing IRBs."**

## IV. EXTERNAL IRB RELIANCE REQUEST PROCEDURES

- A. All external IRB reliance requests are considered on a case-by-case basis. This review process could involve one or more THMA IRB members/administrative staff. For studies considered greater than minimal risk, review by the IRB Chair, IRB Administrator, Institutional Official, legal counsel, &/or other institutional departments/components may be required.

Criteria reviewed by this ad hoc group include, but is not limited to, the size of the study, level of risk involved, the lead and relying study team members, institutional committees involved, contract language (when applicable), local or state regulations, accreditation status of the institution(s) and/or expertise of the IRB.

- B. All requests to rely on an external IRB for research occurring at THMA should include a copy of the protocol, consent document(s), and any other relevant study documents,

including identification of the lead principal investigator (PI) and study coordinator submitted via the IRBManager system for consideration by the THMA IRB.

- C. The THMA IRB's concurrence of the external IRB reliance request means that the lifecycle of the research is under the purview of the external IRB. The external IRB's policies and procedures will prevail for the conduct of the research. This includes review of the:
  - a. New Project submission.
  - b. Modification(s). Any change in the conduct of a study. Changes must be reviewed and approved by the IRB of Record prior to implementation. The exception to this is when the change is necessary to eliminate apparent immediate hazards to subjects.
  - c. Continuing Review. The IRB of Record is required to review and approve all research projects at intervals appropriate to the degree of risk, but not less than once a year.
  - d. Reportable Event(s). A Reportable Event can be any unanticipated problem, serious adverse event, receipt of new information, or a form of noncompliance. Investigators are required to report these to his or her respective IRB, the IRB of Record, regulatory agencies and sponsors as applicable.
  - e. Project Closure. When a study ends, the PI must complete a Project Closure Form.
- D. All requests for the THMA IRB to serve as the lead IRB of record for a multi-site study is considered by selecting the requested IRB of record as designated in the IRBManager application. The THMA IRB/administrative staff will review the request for the THMA IRB to serve as the IRB of Record for all designated research study locations outside of THMA-associated campuses.
- E. *Other Committee Review*. All research, regardless of the IRB of record, will be required to complete the THMA IRB Application for Initial Review xForm in IRBManager to ensure appropriate review and other Institutional reviews occur as per THMA policies. The responses provided in the IRB Manager application process determine(s) which committee reviews will apply to the study, verification of research team member's human subjects protections training, and Institutional Conflict of Interest disclosure requirements. All department/committee approvals must be in place prior to final signoff to any External IRB reliance process.

## **F. ROLES AND RESPONSIBILITIES**

Relying on an external IRB, whether it is for a single protocol or a portion of the organization's research portfolio creates a different set of responsibilities for both the THMA IRB and the THMA research team. It is important to develop a formal written agreement which clearly delineates the roles and responsibilities of each party. In addition, there should be a working and communicative relationship between the two parties. Below are roles for the IRB of Record and relying IRB(s) that should be included in written agreements.

### *Lead Site IRB (IRB of Record) Responsibilities*

It is the responsibility of the Lead Site IRB to serve as the IRB of Record. This includes approval of new studies and consents, determining procedures for modifications and continuing reviews, instructing relying institutions how to report unanticipated problems and serious adverse events and instances of noncompliance. It is also the IRB of Record's responsibility to ensure processes for data protection, conflict of interest management, and confirmation of human subjects protection training.

THMA considers the following to always be responsibilities of the IRB of Record:

1. Conduct review of research according to all applicable regulations and laws, including initial review, continuing review, and review of modification to previously approved research.
2. Suspend or terminate IRB approval.
3. Reviews unanticipated problems involving risks to participants or others.
4. Review incidents of serious or continuing non-compliance.
5. Notify the researchers and organizations in writing of its decisions.
6. Make available relevant IRB minutes to the relying organization upon request.
7. When appropriate, conduct on-site or remote post-approval monitoring or audits, unless delegated to the relying organization.
8. Specify the contact person and provide contact information for the reviewing IRB.
9. Reportable events reviewed according to policies and procedures outlined by the IRB of Record. Additional reporting may occur by relying IRBs if federal funding or other local institutional policies apply
10. If items 2, 3, or 4 should occur, the IRB of Record is responsible for reporting these occurrences to the Relying IRB(s).

### *Relying IRB Responsibilities*

Each Relying IRB is responsible for ensuring compliance with respective local context issues and requirements. Relying IRBs are responsible for adhering to all content outlined in the IRB Reliance agreement (i.e. financial interest disclosure, record documentation, etc.).

THMA considers the following to always be Relying Site responsibilities:

1. Researchers must comply with the determinations and requirements of the IRB of Record. The lead study team is responsible for ensuring compliance with the IRB of Record requirements at the research site.

2. Prior to the IRB of Record review, provide the IRB of Record with any local context issues relevant to the research protocol.
3. Research may be disapproved by officials of the relying organization, but they may not approve the research if it has not been approved by the designated IRB of Record.
4. The Relying IRB and the researchers acknowledge and agree to cooperate in the IRB of Record's responsibility for initial and continuing review, record keeping and reporting requirements. All information requested by the Relying IRB will be provided in a timely manner.
5. Researchers and research staff agree to disclose financial conflicts of interest according to the agreed upon process and comply with any conflict management plans that may result. If their institution has a PHS-compliant conflict of interest policy, they must comply with all aspects of that policy. All managed financial conflicts of interest will be reported to the IRB of Record. If a Relying IRB does not have a PHS-compliant conflict of interest policy, it will follow the conflict of interest policy of the IRB of Record.
6. The Relying IRB or researchers will report promptly to the IRB of Record any proposed changes in the research. The investigator will not initiate changes in the research (including changes in the consent document) without prior IRB of Record review and approval, except where necessary to eliminate apparent immediate hazards to the participants.
7. Researchers will not enroll individuals in research prior to review and approval by the IRB of Record.
8. The researchers, when responsible for enrolling participants, will obtain, document, and maintain records of consent for each participant or each participant's legally authorized representative as stipulated by the IRB of Record.
9. Researchers will report to the IRB of Record any unanticipated problems involving risks to participants or others according to the IRB of Record's reporting policy.
10. Researchers will provide any data safety monitoring reports they receive, either at continuing review, upon request by the IRB of Record, or on an emergent basis if appropriate.
11. Researchers will report, to the IRB of Record, any non-compliance, research misconduct, or protocol deviations according to the IRB of Record's reporting policy. If a THMA researcher reports such an instance to the IRB of Record, the IRB of Record will report it to the THMA IRB.
12. Emergency medical care may be delivered without IRB review and approval to the extent permitted under applicable federal regulations and state law.

13. The organization and researchers acknowledge that they are primarily responsible for safeguarding the rights and welfare of each research participant, and that the participant's rights and welfare must take precedence over the goals and requirements of the research.
14. The relying IRB may conduct post-approval monitoring in addition to, or in cooperation with, the IRB of Record.
15. The written agreement does not preclude the organization or researchers from taking part in research not covered by the agreement.
16. Specify points of contact for both the research team and the relying IRB to the IRB of Record for ongoing communication.

#### *Lead Site Study Team Responsibilities*

The lead study team will typically be the study team affiliated with the institution serving as the IRB of Record. The Lead Site Study Team's responsibilities include, but are not limited to:

1. Serve as the coordinating center for the study. This includes coordinating communication across sites throughout the course of the study and ensuring that all participating sites are provided with the IRB-approved versions of all study documents (e.g. consent and authorization forms, protocol, recruitment materials).
2. Designate a single point of contact whose responsibilities will include responding to questions or requests for information from the study teams at relying sites.
3. Assist study teams from relying sites in ensuring consent documents use the IRB of Record's template form and include the applicable institutional required language (e.g. compensation for injury, who to contact with questions) from each relying site.
4. Notify other study teams' points of contact of all IRB of Record determinations and communications, including those for initial review, continuing review, amendments, and reportable events.
5. Upon request, provide access to study records for audit by the relying sites' institutions, the IRB of Record's institution, and other regulatory or monitoring entities.
6. Obtain information from relying sites regarding local variations in study conduct, such as in regard to recruitment materials and process, consent process, and subject identification process.

#### *Relying Site Study Team Responsibilities*

Study teams from sites which are approved to rely on THMA IRB as a single IRB of Record for a study have responsibilities that include, but are not limited to the following:

1. Designate a single point of contact. The primary role of the point of contact is to serve as the single point of contact for the study team throughout the review process and after the study has been approved by the THMA IRB of Record.
2. Promptly respond to questions or requests for information from the lead study team.
3. Each relying site study team will be responsible for drafting consent documents using the THMA IRB of Record template, including applicable institutionally required language (e.g. compensation for injury, who to contact with questions) from the relying site.
4. Upon request, provide access to study records for audit by the relying site's institution, the IRB of Record's institution, and other regulatory or monitoring entities.
5. Report to the lead study team any changes (including funding changes and personnel changes), reportable events, and information applicable for continuing review progress reports in accordance with the THMA IRB of Record's policies and procedures.

### **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:** June 10, 2022

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