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**EFFECTIVE DATE:** *February 25, 2022***PROCEDURE TITLE:***Operations of the Institutional Review Board**To be reviewed every three years by:  
Institutional Review Board***REVIEW BY:** *February 24, 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 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, including promoting the conduct of ethical and compliant research.

**I. IRB Committees****a. Meetings**

The Trinity Health Mid-Atlantic (THMA) Institutional Review Board (IRB) meets monthly or as needed to review prospective research. The schedule is set annually by the IRB Administrator and published with associated submission dates.

When the Board is not physically convened in the same location, reviews and votes will be conducted via teleconference. All documents are available to all committee members the day the agenda (including review assignments) is sent via e-mail.

Each member, including those that attend via teleconference, will actively and equally participate in the discussion of the research projects. Minutes of such meetings will clearly document that these two conditions have been met.

The IRB Chair will facilitate the meeting, ensuring that all announcements are made and agenda items for business are conducted.

**b. Assignments for Full Board Meetings (Convened)**

Primary reviewers may be appointed by the IRB Administrator in advance of the full board IRB meeting and documented in the meeting agenda. In conducting reviews of proposed research and continuing research, IRBs must obtain information in sufficient detail to make

the determinations required under appropriate regulations, as well as meet the regulatory criteria necessary for approval (45 CFR 46.111 and 21 CFR 56.111).

Primary reviewers perform the in-depth review of the assignments under consideration. For initial studies, the primary reviewers will provide a brief synopsis of the study to the IRB and provide a detail review of recommendations for all of the study documents. When there are multiple primary reviewers, the subsequent reviewers and other members present any findings and recommendations that the initial presenter did not discuss. The primary reviewers are responsible for the initial determination of criteria for approval. The primary reviewers recommend a motion for the study to the convened IRB.

The entire board membership has access to all documents for new studies under consideration and all members are encouraged to review submitted documents and participate in the review discussion. Reviews for addenda revisions, continuing reviews and internal adverse events are conducted in a similar manner.

All reviewer assignments are documented in the agenda and meeting minutes. Members are expected to attend the meeting prepared with their comments and recommendations. Members who are unable to attend will notify the IRB Administrator or IRB Chair in advance.

The IRB will determine which protocols require continuing review more often than annually, as appropriate, that considers:

- to the degree of risk,
- novel route of treatment,
- experience of the investigator,
- potential risk to the participants, and
- other considerations.

The IRB will also determine which studies require verification from sources other than the investigator that no material changes have occurred since previous IRB review. Verification from other sources may include, but is not limited to, observation of the consent process, use of consultants, or review of the research by IRB members, or others.

**c. IRB's Use of a Consultant**

Prior or during review, the IRB may determine that a research project requires expertise that is not represented by the membership. The IRB may invite a consultant who is a subject matter expert to review the research and answer specific questions posed by the reviewer or membership. The use of a consultant requires that the person sign a conflict of interest

and confidentiality of intellectual property prior to being invited to provide a consultation or receive the study materials.

It is recommended that the consultant be asked to provide a written report of his/her recommendations and points or that the consultant either attend or phone-into the convened meeting. The use of a consultant will be documented in the minutes of the meeting where the consultant was used. The consultant may not be present for the discussion and voting of any research studies.

## II. Motions and Voting

### a. Motions

#### i. Research Under Review

IRB members may make a motion to take any of the following actions on the research under discussion:

- **Approve (without changes).** Approved as is or with changes that have been made for the PI by the membership.
- **Approve with changes or conditions.** All criteria for approval are met, all justifications and determinations can be made, determination of the risk/benefit ratio has been made, but verification of assumptions used to meet criteria may be needed and/or minor changes are being requested.
- **Table.** Research may be tabled at a convened meeting because the study could not be reviewed for administrative reasons, such as all materials were not given to members in advance of the meeting, or other such reasons.
- **Disapprove.** The research may have critical flaws, may be unethical, may be missing key documents or have numerous contradictions, criteria for approval not met, risk/benefit ratio may be unfavorable or unknown, or the study requires complete revision and resubmission as a new study in order to be reviewed by the IRB.
- **Defer.** The criteria for approval could *not* be met, justifications and determinations could not be made, research requires substantive revisions, research may have critical flaws, the risk/benefit ratio could not be determined, or key document(s) are missing that are required in order to judge and make regulatory determinations and justifications.
- **Acknowledge.** To confirm receipt and review of miscellaneous study documents not requiring approval (e.g., Investigator's Brochure, FDA letters, DSMB recommendations, etc.).

In addition, IRB members may recommend that:

- Education be provided to or completed by an investigator and his or her research team;
- The research study be audited (for-cause); and
- The informed consent process be observed by an IRB member or designee.

**Key concepts on voting and meeting proceedings:**

IRB members who participate in a convened meeting via telephone or video conferencing will vote and be counted towards the quorum as they are part of the discussion that takes place. The minutes will document which members, if any, participated in the convened meeting via an alternative mechanism, such as telephone or video conferencing. The use of e-mail as a type of convened meeting is prohibited.

IRB members may not vote outside of the convened meeting (e.g., via email prior to the convened meeting). IRB members who cannot attend a convened meeting may not send someone (e.g., from their department or office) to vote in their place. Only IRB members that are on the roster filed with regulatory authorities have voting privileges and count towards quorum. Proxy voting is a form of voting whereby some members of a decision-making body may delegate their voting power to other members of the same body to vote in their absence, and/or to select additional representatives and this type of voting is prohibited.

Opinions of absent members that are transmitted prior to the convened meeting by mail, telephone, telefax or email may be considered by the attending IRB members but will not be counted as votes or towards the quorum for convened meetings.

The block voting method is used for continuing reviews, addenda revisions and unexpected problems and serious adverse events at convened meetings. Each primary reviewer is responsible for the reviews and presents each study at the convened meeting where there is ample opportunity to carefully consider and discuss each study. The members can individually express concerns before the voting occurs.

Therefore, IRB members can vote “approved” on some studies, “disapprove” on others, and abstain on others. Recusals will be also be recorded for individual studies when block voting is used.

- ii. Unexpected Problems and Serious Adverse Events:** IRB members will acknowledge receipt and review of unexpected problem/serious adverse event reports, and may request further information or corrective action plans (if applicable).

- iii. **Program Reviews:** IRB members will make a motion to take any of the actions listed above, for research under review.
- iv. **Non-Compliance:** IRB members will make a motion to take any of the following actions when allegations of non-compliance are brought to the IRB:

**Does not meet the definition of non-compliance.** A determination by the IRB that the event or action, or lack thereof, does not meet one of the definitions below.

- **Noncompliance.** A failure on the part of the PI or any member of the research team to abide by applicable laws, federal regulations, or THMA policies and practices or failure to comply with specific directives, timeframes for reporting to, or determinations of the IRB.
- **Continuing Non-Compliance.** A pattern of repeated non-compliance may reflect a lack of knowledge on the part of the investigator or a lack of commitment by the investigator and/or research team to protect participants. Continuing non-compliance is a finding that is determined by the convened IRB.
- **Serious Non-Compliance.** Failure to abide by applicable laws, regulations or THMA policies and practices or failure to comply with specific directives or determinations of the IRB when that failure *increases risk to participants or adversely affects the rights and welfare of the participants.*
  - Serious non-compliance is a finding that is determined by the convened IRB. The IRB will deliberate on whether approval of research will be suspended or terminated or continue. The finding of serious non-compliance must be reported to regulatory authorities and the sponsor. A single instance of noncompliance may be serious.
  - Examples of serious non-compliance may include but are not limited to the following:
    - Human subjects research conducted without IRB approval
    - Deviation from the IRB approved protocol or consent process
    - Modification of the protocol without prior IRB approval
    - Failure to maintain regulatory documents
    - Inadequate oversight of the research

- Conducting research without oversight of a functional investigator

- v. **Suspension or Termination of IRB Approval:** The IRB has the authority to suspend or terminate approval of research, as well as the authority to suspend enrollment of participants, change the continuing review date, require an audit of the study, require an inquiry into the use of a particular device, drug or biologic across all studies and other similar steps to ensure the safety and wellbeing of research participants. The IRB makes decisions on a study-by-study basis.

Circumstances that may result in suspension or termination of previously approved research or other actions listed above include:

- When research is not conducted in compliance with the IRB's requirement, federal research regulations or state law. If such non-compliance is determined to be serious or continuing, the IRB will take action to protect participants, such as suspension or termination.
- When research is associated with serious unanticipated risk or harm to participants or others. If the IRB determines that the risk or harm of the unanticipated problem seriously threatens the health status or well-being of participants or others, the study may be suspended or terminated.

#### **b. Voting**

IRB members who do not have COIs may vote on the proposed action as indicated:

- **For**
- **Against** (opposed to the action) or
- **Abstain** (due to arriving late to the meeting and missing the discussion or not reviewing the study in preparation of the meeting, or similar)

Members who recuse from voting on a specific study because of conflicting interests may not be counted toward the quorum. That is, their recusal may not be recorded as an abstention.

#### **c. Quorum**

Quorum is a properly constituted membership required to transact business at a convened meeting as indicated below:

- i. Quorum of the IRB shall be 50% of the total voting membership as listed on the official roster as filed with OHRP and the FDA, plus one (1), provided that such quorum includes at least one non-scientific member and one scientific member.
- ii. Those IRB members in attendance who vote to abstain are considered a part of quorum.
- iii. Per federal regulations, those members in attendance who declare a conflict of interest must recuse themselves, do not count towards quorum, and may not be part of the discussion or vote, except to provide information requested by the IRB.
- iv. In order for research or other business to be approved, it must receive the approval of a majority of those members present at the meeting, provided that the above conditions are met.

### **III. IRB Administrator**

The IRB is assigned an IRB Administrator who is responsible for supporting the administrative work of the committee in a manner that is compliant with all Federal, State, and local laws and research regulations. The IRB Administrator is the liaisons between the IRB committees and the investigators, communicating the IRB decisions and actions to the investigators. They provide assistance in the submission process, as well as other duties that ensure that participants are protected. The IRB Administrator is the designated signatory on correspondence from the IRB, as appropriate.

Additional IRB Administrator support may include:

- Maintaining the official IRB membership rosters and promptly reporting changes in IRB membership to the Federal Registry and the IRB.
- Drafting and issuing reports and correspondence directed to research officials, federal officials, and others on behalf of the IRB.
- Maintaining and updating the IRB Policies and Procedures and IRB forms.
- Providing research regulatory information and guidance about submission procedures and completion of forms.
- Receiving new study applications and other submissions to the IRB.
- Assigning primary reviewers for all proposed research according to the membership's expertise and experience.
- Scheduling IRB meetings and distributing pre-meeting materials to IRB members.

- Compiling meeting minutes in compliance with governmental regulatory requirements and Trinity Health Ethical and Religious Directives (ERDs).
- Maintaining all IRB documentation and records in accordance with regulatory requirements.

### **III. Correspondence regarding IRB deliberations**

#### **a. To the investigator for additional information**

The Principal Investigator will be notified in writing of the results of its deliberation and actions, including requests for additional information. If the IRB determines that the investigator has not provided the required information, it will be the responsibility of the investigator to provide the necessary information before further consideration by the IRB can occur.

#### **b. Investigator notification of IRB decisions**

The IRB shall notify the Principal Investigator in writing of its decision of the proposed research. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in writing or in person at the next regularly scheduled IRB meeting.

#### **c. For non-compliance, suspensions and terminations of IRB approval**

The investigator will promptly be notified in writing of the IRB's deliberation and actions. Researchers also may voluntarily suspend or terminate their research projects to protect the rights, welfare and safety of participants. Voluntary suspension by the researcher may or may not also require suspension by the IRB to ensure sustainability of the suspension. Suspension by another entity (such as a sponsor) or voluntary suspension by the researcher does not necessarily require suspension by the IRB. Only suspensions and terminations of IRB approval by the IRB are reported to federal authorities.

Upon receipt of notification from the IRB, the investigator must immediately suspend all research activities and verify to the IRB:

- That the study has been suspended and all research related activity has stopped.
- Whether there are still participants enrolled in the study and if so, how the researcher will maintain or follow participants during suspension or following termination.
- That no participants will be enrolled during the suspension or following the termination.
- If investigational drugs or devices were used in this research, their disposition or status during suspension or following termination.



- If the research is funded, that no research funds for research related activities will be used except as needed to protect the safety of participants.
- That the study sponsor has been notified of the suspension.

The investigator must confirm and verify the above to the IRB in writing within ten business days of the initial suspension/termination communication.

The investigator may appeal the IRB's decision to suspend or terminate IRB approval for the investigator's study by submitting written correspondence to the IRB within 15 days of the date of the notification. If, after the IRB responds to the appeal, the investigator wishes to further appeal the IRB's decision to suspend or terminate IRB approval for the investigator's study by submitting written correspondence to the Institutional Official within 15 days of the date of the 2<sup>nd</sup> notification from the IRB. The Institutional Official's decision will be the final decision.

**d. Sponsor notification of IRB decisions**

The IRB delegates the responsibility to the Principal Investigator of informing the sponsor of all IRB related decisions with regard to the research protocol as appropriate.

**V. IRB minutes**

Meeting minutes will be submitted monthly to the IRB members for review and approval. Minutes will provide sufficient information to persons not present at the meeting (e.g., institutional officials, regulators, IRB members who could not attend) about the IRB's:

- Decisions,
- Justifications,
- Findings,
- Controverted issues, and
- Documented according to federal regulatory requirements.

The approved minutes are shared with the Institutional Official.

**VI. Reporting significant findings or actions to the IRB, Institutional Officials, Department Heads, and Regulatory Authorities**

Anyone who suspects non-compliance with a human participant research project must *promptly* report the information to the IRB via e-mail, phone, pager, or in-person communication.

Only suspensions and terminations of IRB approval by the IRB are reported to federal authorities. The IRB has the authority and obligation to then promptly notify the appropriate

institutional officials, the department head, and the appropriate federal department or agency (when applicable) of any significant or material findings or actions, including:

- Serious unanticipated injuries or death, or any other unanticipated problems involving risks to subjects or others;
- Any serious or continuing noncompliance with the federal regulations or requirements of the IRB;
- Any suspension or termination of IRB approval. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action.

## **VII. IRB Records and Retention**

Trinity Health's retention requirement for research records, including IRB meeting minutes, is six (6) years after the later of the date of their creation or last effective dates. HIPAA research record retention requirements are also six (6) years from the closure of the research for the recipient (investigator) and issuer (IRB) of a waiver of HIPAA authorization.

The following records are maintained but are not limited to the following:

- Curriculum Vitae/ resume for all IRB members, as well as the IRB roster.
- IRB policies and procedures (current and historical)
- IRB meeting Agendas and Minutes
- All documents submitted by the Principal investigator and subsequently reviewed by the IRB.
- Copies of all correspondence to and from the Principal Investigator.
- Any handwritten notes (additional to the meeting agenda) that were taken at the time of the meeting.
- The results of program reviews (internal quality assurance reports) that are routinely conducted to monitor the human subject protection program.

All records shall be accessible for inspection and copying by authorized representatives of the FDA and the DHHS at reasonable times and in a reasonable manner. The results or actual internal audit findings of routine internal inspections (referred to as program reviews or quality assurance programs) would not typically be provided to the FDA unless it is pertinent with an on-going Federal for cause inspection related to a specific trial. FDA may seek written certification that such audits and inspections have been implemented, performed, and documented and that any required corrective action has been taken.

## 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):** February 25, 2022