Institutional Review Board Procedure No. 12

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

PROCEDURE TITLE:

Permanent Study Closure

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 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. Study Closure

A. The IRB considers a study to be active until a *Study Close-Out Report* is submitted through IRBManager and receives expedited review. A study can be considered for closure when **all** the participants have fulfilled protocol requirements including follow-up visits **and** the data analyses are complete; **or** if requested by sponsor. It is the continued responsibility of the PI and study team to maintain confidentiality of the collected and stored data after closure. The IRB office must be contacted if stored data is accessed for research purposes other than the original intent.

B. The Study Close-Out Form must contain the following information:

1. Reason for study closure.
2. Indication of whether the study was audited within the past year (either by regulatory authority, sponsor or other internal audit) and, if applicable, a summary of any findings that were noted.
3. Indication that informed consent was performed for each participant and documentation to that effect, if applicable.
4. Number of participants enrolled, withdrawn and reason for withdrawal (or number of records collected/used).
5. Indication that confidentially was maintained. If not, explain.
6. Brief summary of any preliminary results, findings, or abstract of the study results. Indicate if information will be published and expected timeframes.

II. IRB Administrative Closure

The IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with IRB Policy and Procedures, such as but not limited to:

- Late continuing review report submission,
- Failure to complete the study close out form when study complete,
- Investigator has left the institution and did not notify the IRB,
- Confirmed documented scientific misconduct, and
- Unexpected serious harm to participants.

Any suspension or termination of approval shall be documented and include a statement of the reason for IRB action. Correspondence from the IRB regarding administrative closure is sent to the principal investigator. The institutional official is notified. Appropriate regulatory authorities such as the Food and Drug Administration (FDA) or Department of Health and Human Services (DHHS), are notified of administrative closures as determined by IRB review. Correspondence to regulatory authorities will be recorded and maintained.

III. Reactivation after Permanent Closure

Once a study is permanently closed it may not be reactivated or "opened" unless a THMA Application for Initial Review with the reason for re-opening is submitted and reviewed by the IRB. The investigator will be notified in writing of the determination by the IRB.

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): April 28, 2023