*Institutional Review Board Procedure No. 28*

**EFFECTIVE DATE:** ***April 20, 2022***

**PROCEDURE TITLE:**

***Deviations from Protocol and/or Standard Operating Procedures***

***To be reviewed every three years by:***
***Institutional Review Board***

**REVIEW BY:** ***April 19, 2025***

## 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.

## SCOPE

Investigators are responsible for conducting human-subjects research in accordance with all applicable federal and state regulations, THMA IRB policies and procedures, and a study protocol. During the conduct of the study, unintentional events or deviations from standard operating procedures and/or the protocol may occur or subsequently be discovered upon periodic reviews.

### I. Protocol Deviations and/or Deviations from Standard Operating Procedures

A deviation occurs when there is a discrepancy or departure between the protocol and/or standard operating procedures and the activities that were performed for a study. While a deviation may or may not increase risk to subjects, it is particularly important that the IRB be notified immediately when the deviation could potentially cause increased harm to subjects or others or alters the outcome of a study. The Investigator must report the following to the IRB: when the deviation occurred, how it was discovered, who discovered it, what affect it has (if any) on current or future research subjects, and the remedial action taken to avoid recurrence of the deviation.

### II. IRB Authority

The IRB Chairperson or designee will expeditiously review deviations to determine whether the risk/benefit ratio has increased as a result of the deviation. Potential or real

harm to any subjects will be assessed. If deemed necessary by the IRB Chairperson or designee, the report will be sent to the next convened full IRB meeting for review and assessment of further actions that may need to be taken. The range of actions may include revisions to the protocol, audit/review of the conduct of the study, and change in frequency of continuing review reports, or additional protective procedures requested by the IRB (i.e. observation of the informed consent process). If the IRB is notified of an excessive number of protocol deviations, it is within the authority of the IRB to conduct an inspection to promote integrity and compliance.

## III. Definitions

Deviations may be either minor or major in nature, and may or may not have a direct effect on individual subjects.

Major deviations: The deviation posed a significant risk of substantive harm to the individual research participant or others; the deviation has compromised the scientific integrity of the data collected for the study; or there is continuing occurrence of deviations that will lead to issues of noncompliance as stated in federal regulations. Major deviations must be reported to the IRB within 5 working days of the occurrence.

Minor deviations: The deviation has no substantive effect on the risks or benefits to the individual research participant; the deviation has no substantive effect on the data collected; or the deviation was an inadvertent error on the part of the research team or the participant. Minor deviations can be reported at continuing review or periodically as needed, at the discretion of the principal investigator or study sponsor.

## IV. Examples

Major Deviations (Please note: the list of examples is intended as a guide and is not all-inclusive)

- Failure to obtain informed consent, i.e., there is no documentation of informed consent or informed consent obtained after initiation of study procedures
- Informed consent for IND/IDE studies obtained by someone other than individuals authorized by IRB to obtain consent, e.g. someone other than a licensed physician investigator or research coordinators
- Inappropriate documentation of informed consent (such as no signatures applied)
- Enrollment of a participant who did not meet inclusion/exclusion criteria
- Failure to perform a required lab test that, in the opinion of the PI, may affect subject safety or data integrity
- Drug/study medication dispensing or dosing error
- Study visit conducted outside of required timeframe that, in the opinion of the PI, may affect participant safety
- Failure to follow approved safety monitoring plan
- Enrollment/recruitment during an expired study period (continuing review not conducted as per IRB policy)

- Use of invalid consent form, i.e. consent form not reviewed/approved by the IRB (with footer information).

Minor Deviations (Please note: the list of examples is intended as a guide and is not all-inclusive)

- Implementation of unapproved recruitment procedures except for the purpose of participant safety
- Missing original signed and dated consent form (only a photocopy available)
- Missing pages of executed consent form
- Copy not given to the person signing the form
- Failure to follow the approved study procedure that, in the opinion of the PI, does not affect participant safety or data integrity
- Failure to perform a required lab test
- Missing lab results
- Study visit conducted outside of required timeframe (unless this would potentially jeopardize patient safety or monitoring of patient safety.
- Failure of participant to return study medication
- Over-enrollment or over-accrual

**IRB review documentation:**
The review of the above scenarios will be reported in the IRB agenda and meeting minutes.

Review determinations by the IRB will be sent to the PI and the submitter.

## RESPONSIBLE DEPARTMENT

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

## APPROVALS

**Initial Approval:** April 20, 2022

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