
EFFECTIVE DATE: *March 24, 2023***PROCEDURE TITLE:***Amendments to Approved Research**To be reviewed every three years by:
Institutional Review Board***REVIEW BY:** *March 23, 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 changes to approved non-exempt research must be reviewed and approved by the THMA IRB before they are implemented, unless an immediate change is necessary to eliminate an apparent hazard to the health or safety of participant(s) [21 CFR 56.108(a)(4) & 45 CFR 46.108(a)(3) (iii)].

Changes to exempt research that would make the study no longer meet the category(s) that it was determined to be exempt under AND all changes that impact privacy and confidentiality as granted under HIPAA must be reviewed by the IRB which made the original exempt determination, before the changes are made.

I. Amending approved research

Any change to an approved research study that changes the aims or design significantly will require that a new study application be submitted, rather than an amendment form.

Research participants who are presently enrolled and actively participating in research should be informed of a change if it might relate to their willingness to continue participation in the study [21 CFR 50.25(b)(5)]. The FDA regulations do not require re-consenting of participants that have completed their active participation in the study, or of participants who are still actively participating when the change will not affect their participation. For example, when the change will be implemented only for subsequently enrolled participants.

IRB review of a proposed change to a research project during the period for which approval is authorized does not constitute continuing review of the research study as a whole, and thus does not extend the date by which continuing review must occur.

II. Requesting an amendment

Each investigator is required to request approval of any proposed changes to the IRB, using the appropriate amendment form and attaching all pertinent documents. The amendment form is used, no matter if the change is reviewed by Full Board or Expedited review.

All changes to any documents should be tracked to readily ascertain the changes. For example, an amendment to a research protocol should be tracked within the document and a summary of changes of the protocol should be provided so that changes can readily be determined and reviewed. Once the changes are approved by the IRB, then changes should be incorporated into a single written protocol. This practice ensures there is only one complete protocol with the amendment dates noted. All amended documents that are submitted are maintained by the IRB Administrator.

When an immediate change is necessary to a study in order to eliminate an apparent hazard, the IRB must be notified immediately. Notification can be via phone or e-mail, fax, or memo. A follow-up written report must be submitted to the IRB shortly thereafter that addresses the nature of the changes, why it created an apparent hazard and how mitigation will occur.

III. Review method

Amendments to previously approved research are reviewed either by full board or expedited methods. The IRB Administrator, IRB Chairperson or designated expedited IRB reviewer makes the determination of whether the submission qualifies for expedited or full board IRB review based upon the criteria set forth in this policy and applicable federal regulations. The reviewer will be the IRB Chairperson or a designated IRB member when the expedited method is used.

The determination of the type of review method depends on the nature and level of the change(s). Substantive changes to research previously reviewed by the full board will most likely require full board approval and are subject to the IRB submission deadlines and meeting dates. Changes involving adding a vulnerable group of participants will likely be reviewed via the full board.

Requests that are solely for grammatical-in-nature revisions may be reviewed by the IRB Administrator. When this occurs, an administrative acknowledgement is made, rather than a review by an IRB member. For example, requests that are only for a correction of spelling, correction of punctuation, or correction to page numbering, would be examples of types of grammatical revisions that would receive review and administrative acknowledgement.

Minor and major changes - The following tables provides examples of *minor* changes (generally can be reviewed via expedited review) and *major* changes (generally reviewed by the full board depending upon the overall risk level) to previously approved protocols:

Examples of minor changes (expedited review)

- Editorial changes:
 - Changes in contact information on the consent and other documents.
 - Reduction in the number of research participants being recruited.
 - Changes that clarify but do not alter the existing meaning of a statement or document.
- Minor consent form changes.
- New risk information that is similar to other previously approved risks and not substantial; and/or when the change does *not* adversely affect the risk/benefit ratio of the study for any of the participants.
- Clarification of procedures, interventions or treatments that were previously approved by full board review.
- Decrease in the number and volume of sample collections.
- Minor changes to recruitment procedures or materials; or submission of new recruitment materials; both to be used in accordance with approved recruitment methods.
- Revising eligibility criteria (as long as vulnerable participants are not added or as long as added participants are not at a greater risk).
- Adding new or minor changes to study documents such as surveys, questionnaires or brochures.
- New study documents to be distributed to or seen by participants that are similar in substance to those previously approved.
- Changes in payment to participants, or the amount participants are paid, or compensated that are not significant enough to rise to the level of undue influence.
- Addition of or changes in study personnel, including changes to the consent to reflect this change.
- Addition of a new study site (in many, but not all cases).
- Translations of materials already reviewed and approved by an IRB.

Examples of major changes (full board review)

- New risk information when the change is substantial or when the change adversely affects the risk/benefit ratio of the study for any of the participants.
- Changes in inclusion or exclusion criteria that negatively impact the risk/benefit ratio of the study for any of any participants.
- Significant changes in study design, such as the addition of a new subject population or the elimination of a study arm.
- New or changed study documents to be distributed to or seen by participants that are substantively different from materials already approved
- New financial conflict of interest management plans or revised plans that were originally reviewed by the full board.

IV. IRB authority and documenting the IRB's decision

The IRB's authority when using the expedited review method:

The expedited reviewer may exercise all of the authorities of the full board IRB except that the expedited reviewer may not disapprove the proposed minor changes in research. The expedited reviewer can request changes to, approve, or refer the amendment to the full board IRB for review.

Communicating amendment determinations:

To the IRB:

Full board review amendments will be listed on the IRB meeting agenda and reviewed at the full board IRB meeting. Expedited reviews and approvals will be communicated to the full board as well as administrative acknowledgements. The full board IRB meeting agenda and meeting minutes will announce and document all expedited reviews that occurred. The specific details of the review are available in IRBManager, i.e., study title, nature of the change, name of reviewer, and date of approval/acknowledgement. Any IRB member may question or discuss the expedited review activities during a full-convened meeting as desired.

To the Investigator:

The IRB's decision regarding the amendment to the research will be communicated to the Investigator in writing, including the type of review and the date it occurred. Revisions that received an administrative acknowledgement will also be documented in writing to the investigator.

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): March 24, 2023