
EFFECTIVE DATE: *October 27, 2023***PROCEDURE TITLE:***Continuing Review**To be reviewed every three years by:
Institutional Review Board***REVIEW BY:** *October 26, 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.

Periodic review of research activities is necessary to determine whether approval should be continued. Research that is determined to meet an exempt category does not require continuing review. All other research determined to require continuing review must be reviewed no less than annually and at intervals appropriate to the degree of risk as described below.

I. Continuing Review

FDA-regulated research is required to have continuing review as well as OHRP-regulated research approved by the IRB before January 21, 2019 as detailed below:

Studies determined to meet an expedited category at initial review will typically have continuing review via the expedited method.

Studies that were reviewed by the full board at initial review will have continuing review by the convened IRB until such time that the study meets one of the following expedited categories:

- A. Where
 - a. The research is permanently closed to the enrollment of new subjects;
 - b. **All** subjects have completed all research-related interventions; *and*
 - c. The research remains active only for long-term follow-up of subjects;

or

B. Where no subjects have been enrolled *and* no additional risks have been identified;

or

C. Where the remaining research activities are limited to data analysis.

All OHRP-regulated studies that were approved by the IRB after January 21, 2019 (under the revised Common Rule):

Continuing review is not required for research that met an expedited category at initial review, *unless* an IRB reviewer justifies and documents the need for continuing review. If continuing review is required, it will be reviewed via the expedited method.

Continuing review is no longer required when the OHRP-regulated study has progressed to the point that it involves **only** one or both of the following, which were part of the IRB-approved study, and the research team notifies the IRB Administrator of this status:

A. Data analysis, including analysis of identifiable private information or identifiable biospecimens,

or

B. Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

For full board review OHRP-regulated studies (only) continuing review will be via the expedited method where no subjects have been enrolled *and* no additional risks have been identified.

Frequency of review: The IRB shall make a determination of the approval period as well as any need for additional supervision or oversight on a study-by-study basis, requiring more frequent review as appropriate.

The following criteria will be used to determine the frequency and type of periodic monitoring:

- Nature of the methods, treatments or interventions under study;
- Health and background of potential participants;
- Nature of the risks involved and potential benefits; and
- Past history of the research activities of either the Principal Investigator or research study team.

II. Continuing Review Process

It is the investigator's responsibility to submit the continuing review in a timely fashion to avoid involuntary administrative expiration of the study under authority of the IRB. The IRB is not responsible for the timely submission. **Principal investigators and study team members should be periodically monitoring their research studies and should be aware of upcoming scheduled continuing review due dates.** The IRB Administrator will run periodic continuing review reports and will be aware of the expected continuing review submissions.

A completed continuing review report form and the following attachments must be submitted:

1. Current IRB approved informed consent (if still enrolling).
2. Number of withdrawals and reason for such.
3. A summary of amendments/revisions to the protocol since the last continuing review.
4. A summary of all adverse event reports since the last continuing review.
5. Current information regarding routine monitoring to ensure the safety of research participants (attach the latest DSMB report if not already submitted, study team monitoring and/or other monitoring as required per study protocol).
6. Any abstracts or publications resulting from this research.
7. Updated conflict of interest, if applicable.
8. Updated training completion records for study team members with expired records.
9. A brief status summary of the study.
10. Documentation of whether subjects have been informed of any new important information that might affect their willingness to continue participating in the research.

The IRB will also determine whether a research study requires verification from other sources other than the investigators that no material changes have occurred since previous IRB review. The external verification process will be documented and the outcome of the external verification will be provided to the principal investigator.

Criteria for approval: In order to approve research at continuing review, the IRB must determine that all of the requirements of initial approval (criteria for approval) continue to satisfy regulations at 45 CFR 46.111 and 21 CFR 56.111. The continuing review form contains the questions to be answered to assure that the information for a determination of continuing approval is addressed. However, the Principal investigator has to assure that the answers to the questions are accurate, complete, and are consistent with the current protocol.

The IRB starts with the working presumption that the research, as previously approved, does satisfy all the criteria below. The IRB will focus on whether there is any new information provided

by the investigator, or otherwise available to the IRB, that would alter the IRB's prior determination, particularly with respect to the IRB's prior evaluation of the potential benefits or risks to the subjects and to the study's progress in terms of protection of vulnerable groups. The IRB also should assess whether there is any new information that would necessitate revision of the protocol and/or the informed consent document.

The criteria for approval are:

1. Risks continued to be monitored and minimized by using the safest procedures consistent with the protocol.
2. Risks to participants are reasonable in relation to anticipated benefits and the importance of the resulting knowledge.
3. Selection of subjects continues to be equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, people with diminished capacity, or economically or educationally disadvantaged persons.
4. Informed consent has been sought from each prospective participant or the legally authorized representative and the consent continues to contain all the required elements as published initially.
5. Informed consent has been appropriately documented, in accordance with, and to the extent required by 45 CFR 46.117 and 21 CFR 56 unless a waiver has been approved.
6. The research has been monitored to ensure the safety of research participants.
7. The investigator has provisions in place to protect the privacy of research participants and to maintain the confidentiality of data.
8. When some or all of the participants are likely to be vulnerable to coercion or undue influence, such as children, prisoners, persons with diminished capacity, or economically or educationally disadvantaged persons, additional safeguards continue to be upheld to protect the rights and welfare of research participants.

After the IRB meeting, correspondence will be issued and include the following information:

- Study title, the date of IRB approval and date of IRB approval expiry (if expiring)*;
- The frequency of continuing review;
- Notification that the Principal Investigator must report planned or unexpected changes in protocol or informed consent;

- Notification that the Principal Investigator must report adverse events which have occurred in the past year;
- A request for additional information, if applicable, or clarifications that are required to address questions that arose during the meeting;

**Note: Any revision to the protocol or consent does not alter the initial or continuing approval and expiry date.*

III. Expiration of Approval

The regulations make no provisions for any grace period or lapse in approval at continuing review. Failure to provide a timely continuing review report could lead to study suspension, a loss of funding, publication sanctions and/or reporting of noncompliance to sponsors or funding agencies.

IRB approval is considered to have expired at midnight on the expiry date of the approval. Once study approval has expired, all research activity must be stopped **unless the IRB finds that it is in the best interest of the participants to continue with the study interventions or interactions.**

The IRB will provide written notice of the expiry to the Principal Investigator indicating that the research must stop and that the study approval is expired. After receipt of the expiration notice from the IRB, the Principal Investigator may submit a written request to the IRB chair to continue the research for current research participants involved in procedures due to safety and health reasons. The IRB chair shall determine which participants, if any, may continue and what procedures may be performed. The decision made by the IRB chair will be documented and a letter sent to the Principal Investigator.

In the case of research that is stopped, the Principal Investigator must re-submit a new application to the IRB, along with all appropriate materials if he/she wishes to continue the research and participant recruitment. The submission and review process will take place as if the research protocol was a new study.

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): October 27, 2023