Institutional Review Board Procedure No. 6

EFFECTIVE DATE: ***May 19, 2023***

PROCEDURE TITLE:

Initial Review of Research – Expedited and Full Board Review

To be reviewed every three years by:
Institutional Review Board

REVIEW BY: ***May 18, 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.

Research activities cannot commence until IRB review and approval has occurred per Federal regulations. This means that data collection cannot begin, access to the medical record for purposes of research may not be performed, recruiting activities or screening (including acquiring contact information of potential participants) cannot be undertaken until review and approval by the IRB has occurred.

This procedure covers the procedures for the initial review by the IRB of research that meets and expedited category or that requires full-board IRB review. Please see the IRB procedure *Exempt Determination* for the review of initial research that meets an exemption category.

Allowable categories for expedited review of initial research are some or all of the research appearing on the HHS Secretary's list. (As of the date of issuance of this policy the categories of research eligible for expedited review are still those published in the Federal Register in 1998, although the Final Rule stipulates in 46.110(a) that the list of categories will be reviewed every eight years. At the time of the publication of this policy the list has not been revised.)

Under the Final Rule, a study is presumed to be minimal risk if it meets one of the categories of the Secretary's list. If the expedited reviewer determines that the study involves more than minimal risk, the reviewer can override that presumption, but they have to document their rationale. The documentation requirement is at 46.115(a)(8).

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

I. New study submission

Investigators are required to submit a complete research submission through IRB Manager (detailed below for full board research and research that meets an expedited category). The submission must be received by the noted deadline in order to be reviewed at the next scheduled convened IRB meeting (for full board review) or as received for expedited review. Only a complete submission will proceed for consideration.

A. Submission: In order for an initial review to be scheduled for proposed research meeting either an expedited category or receiving full board review the investigator will need to submit the following pertinent documents listed, but not limited to:

1. A completed xForm.

2. Final study protocol that details the background, methodology and instructions for the study team to consistently execute the research.

3. Informed consent document(s), including an assent document as applicable, with specific language relevant to the research endeavor and a completed HIPAA Authorization form (if applicable), **or** request for consent waiver or consent alteration form and/or waiver of HIPAA authorization as applicable.

4. Investigator's brochure (if applicable).

5. FDA approval letters for device studies including significant or non-significant risk determinations (if applicable).

6. All recruitment materials, including advertisements intended to be seen or heard by potential participants, as applicable. This can be in the form of scripts for radio, TV, website, text messages and any other type of format that will be seen or heard by the prospective participants.

7. Any questionnaires, diaries, surveys or quality of life assessments that will be used by or asked of the potential participant (if applicable).

8. Case report forms or other form to be used for data collection purposes.

9. If a Financial Conflict of Interest (FCOI) is disclosed within the new study submission, then its review by the IRB Administrator and Chair and/or FCOI committee will occur prior to the IRB review of the new study submission. If an FCOI management plan is created, this will be reviewed by the IRB at the same

time that the study is reviewed by the IRB, as the FCOI management plan and the new study submission are reviewed concurrently.

10. Curriculum Vitae for the principal investigator.

11. All research study team members must supply completed certificates of human subject protection training.

12. Any pertinent document and/or study materials as applicable.

II. Criteria Used to Approve New Studies

The principal investigator will be guided to provide information within the submission that addresses the regulatory criteria used to approve the research. In order to approve research **under an expedited category or full board IRB review**, the IRB must determine that all of the requirements listed below are satisfied in accordance with HHS regulations at 45 CFR 46.111 and 21 CFR 56.111. The IRBManager submission xForm contains the questions to be answered to assure that the information for a determination of approval is addressed. However, the Principal investigator has to assure that the answers to the questions are accurate and complete and are consistent with the protocol.

A. The IRB review of the submission for full board review research and studies meeting an expedited category shall ensure that:

1. Risks are minimized by using the safest procedures consistent with sound research design.

2. Risks to participants are reasonable in relation to anticipated benefits and the importance of the resulting knowledge. The board should consider only risks and or benefits that may result from the research that are immediate. The board should not consider possible long-range effects of applying knowledge gained in the research.

3. Selection of subjects is 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 will be sought from each prospective participant or the legally authorized representative. There are required elements that must be included in the consent document.

5. Informed consent will be appropriately documented, in accordance with, and to the extent required by 45 CFR 46.117 and 21 CFR 56.

6. The research plan makes adequate provisions for monitoring the data collected 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 have been included in the study to protect the rights and welfare of these subjects.

B. Additional Considerations

Additional regulatory determinations and protocol-specific findings justifying those determinations must also be made by an IRB in order to approve a research study using human participants:

1. Waiver or alterations of the informed consent process. OHRP and FDA regulations allow for the alteration of consent, waiver of consent, and waiver of documentation of consent under specific regulations. The regulations around these actions differ between the FDA and OHRP.
2. Research involving pregnant women, fetuses, and neonates.
3. Research involving prisoners.
4. Research involving children and gaining assent.
   The assent of children may be required when children and minors are involved in research and there are specific regulatory criteria and determinations that must be made by an IRB.
5. Significant risk/non-significant risk device determinations.
6. Other Groups that are considered vulnerable.
   Any participant or participant population that has participants that are considered vulnerable to coercion or undue influence will be examined closely by the IRB (e.g., participants who: have a decisional impairment; who do not speak, read, or comprehend English; illiterate; blind; students, employees, other groups).
7. Use and disclosure of health records and protected health information (PHI) for research purposes.

In order to use and disclose medical records and protected health information HIPAA federal regulations require that an Authorization (written signed permission) be obtained from the individual, unless a waiver or other regulatory category is satisfied.

III. Determination of the effective date of IRB approval

The effective date of IRB approval of initial studies receiving full board review is the date of the

IRB meeting that the study was reviewed and approval determined. When a study is approved with changes or conditions, an IRB member reviews and verifies that all of the requested changes or conditions of IRB approval have been addressed satisfactorily. If the nature of the requested changes are simple and do not require medical expertise, the IRB administrator or other staff person who has the appropriate expertise and qualifications to conduct such a verification may do so on a case-by-case basis.

Once all requested changes or conditions have been satisfactorily addressed, the consent(s)/assent(s) are issued and study activities can then commence.

The effective date of IRB approval of initial review for expedited review is the date that the all changes requested by the designated IRB member are satisfactorily addressed.

When a study receives approval with conditions or with changes, then the investigator may submit additional revisions or material to the IRB for review by the designated reviewer(s) (or IRB Administrator as appropriate) in an attempt to satisfy the IRB's conditions, or may choose to submit a modified research proposal to the IRB. If the investigator chooses not to submit any additional revisions or materials to the IRB for review by the designated reviewer(s) (or IRB Administrator as appropriate), then the investigator *may not* conduct the research study, including any and all research activities.

The date of IRB approval and continuing review expiry will be documented in the initial approval letter to the investigator from the IRB.

IV. Determination of the length of IRB approval

The frequency of continuing review of approved research will be determined by the IRB and will be documented in the initial approval letter for the investigator, as well as in the meeting minutes (this will be not less than once a year).

Continuing review for research initially approved using expedited review procedures no longer needs to occur. If the expedited reviewer determines that continuing review is necessary then the reviewer will document their rationale and the investigator will be informed in writing.

As stated in the THMA IRB policy- *Operations of the IRB*, "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.

V. Investigator notification of IRB decisions

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.

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.

DEFINITIONS

Investigator means the Principal Investigator (PI) and all other research staff regardless of title or position, who are engaged in or responsible for the design, conduct, or reporting of research.

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): May 19, 2023