Institutional Review Board Procedure No. 9

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

PROCEDURE TITLE:

Human Subjects Research Determinations and Quality and Other Projects

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.

This procedure outlines the decision-making process for determining if a project is research, quality, or another type of project.

- All projects that meet a federal definition of human subjects research or clinical investigation must prospectively be reviewed by the THMA IRB.

- Projects that are believed to meet the definition of quality may:

    - Be self-declared by the project leader by using the Research vs Quality Determination Checklist, or

    - Be submitted to the IRB for a formal determination reflected in a document (email).

- Projects that are believed be research, but do not meet the *definition* of human subjects research must be prospectively reviewed by the IRB (e.g., research on a data set that was stripped of identifiers before being provided to the researcher).

- FDA regulated investigations are considered to be research involving human subjects and must be submitted to the IRB for prospective review.

- This policy only defines human subjects research under the Office of Human Research Protections.

I. Definition of human subjects research

Research involving humans as participants is defined differently by different federal research regulatory authorities. This policy outlines Office of Human Research Protection's (OHRP) definitions.

A. **OHRP:** Under OHRP regulations (45 CFR 46), projects that **meet both the definition of "human subjects" and "research" are under the purview of the IRB**.

Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. ***Systematic*** refers to a prescribed way of performing an activity, such that (1) the investigation is testing a hypothesis; (2) the intention is to contribute to and build upon existing science; and (3) the results or answer to the hypothesis will make a contribution to the scientific community generalizable beyond the local context.

Human subject means a living individual about whom an investigator (whether professional or student) conducting research:

a. Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens;

or

b. Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Intervention includes both physical procedures by which information or biospecimens are gathered (*e.g.,* venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

Interaction includes communication or interpersonal contact between investigator and subject.

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (*e.g.,* a medical record).

Identifiable private information is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

An identifiable biospecimen is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

Clinical trial means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

B. Anything that does not meet the definition of research and human subjects is not considered to be **human subjects research**. The following activities are not human subjects research:

- Scholarly and journalistic activities such as oral history, journalism, biography, literary criticism, legal research, and historical scholarship;
- Public health surveillance activities, including the collection and testing of information or biospecimens conducted, supported, requested, ordered, required or authorized by a public health authority to identify, monitor, assess, or investigate potential public health disease outbreaks. Such activities include those associated with an event or crisis that threatens public health.
- Collection and analyses of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order for criminal investigative purposes;
- Authorized operational activities in support of intelligence, homeland security, defense or other national security missions.
- Blood spot collection is not considered research with human subjects.

II. Definition of quality

Quality improvement is a formal approach to the analysis of performance and systematic efforts to improve performance. It can be both prospective and retrospective. It is a measurement of a particular and numerous models are used. Some commonly used examples are:

- Six Sigma (DMAIC - define, measure, analyze, improve, control)
- CQI: Continuous Quality Improvement

- TQM: Total Quality Management

These models are all means to get at the same thing: improvement. They are forms of ongoing efforts/iterative methods to make performance better by reducing re-work, increasing efficiency, and/or increasing safety within a process or care continuum. Typically Six Sigma (DMAIC) projects do not require IRB review.

However, determination of whether a project is quality improvement or human subjects research can be a difficult task. Researchers/project leaders should utilize the **Quality vs. Research Determination Checklist** to assist them in this decision-making task.

III. Submissions and Determinations

A. **Not human subjects research**:

Complete the **Quality vs. Research Determination Checklist** to assist in decision-making. If it is determined to fall under the definition of quality improvement, then he/she retains the completed checklist and work can begin. Prospective IRB review is not required. The IRB cannot review a project retrospectively to make a determination.

B. **Determination**

1. The process for a determination regarding a project is as follows:

    - Does the proposal meet the definition of human subjects research, or is it FDA regulated or does it meet HIPAA's definition of research?

    - If yes, does the proposal qualify for exemption?

    - If no, does the proposal qualify for expedited review?

    - If no, the proposal will be reviewed by the full-board IRB.

    Ultimately it is the responsibility of the IRB during full board or expedited review to render decisions.

IV. Special types of projects

A. Single Case Report

A single case study is a review of an unusual disease or condition ***in a single patient*** that is prepared for educational purposes, typically for presentation at a professional meeting by a staff physician or resident. Prospective IRB review of a single case study is not required because it does not meet the definition of research and it is not considered a systematic investigation undertaken to produce general knowledge. Case report preparation is an educational activity, and thus is permissible under the Privacy Rule (HIPAA) as a part of health care operations (45 CFR 164.501).

Reports of this nature should use the terms "Single Case Report", Single Case Study", "Single Case Review" or something similar in the title.

In the event that the public presentation and/or publication of a case report may compromise the hospital's defense of an actual or potential lawsuit, an abstract will need to be forwarded to the THMA Risk Management Department for review prior to presenting at a meeting or submission for publication. The Legal Department may be consulted as necessary.

Any time a presentation includes personally identifiable patient features, e.g. where a picture of a patient's face is used, a signed release from the patient or his/her legal representative is required. In this case the form "Patient consent for use of medical record information to be used in a publication" will be required.

B. Case Series

A case review of three (3) or more patients with an unusual disease or condition is referred to as a "case series". A prospective submission to the IRB of an initial submission, as appropriate, with an associated protocol is required. When a larger series of patients is being prepared for presentation or publication, ordinarily a specific research question is defined, and then a systematic collection of data occurs. Such a systematic investigation more closely resembles a prospectively designed research project and will need to be prospectively reviewed by the IRB.

C. Medical Education

Medical education or medical consultation, such as when a colleague presents a difficult case at a teaching conference, does not require IRB review.

Generalizing comments presented in an accepted educational setting by a caregiver who describes their perspective or opinion of an outcome of his/her clinical care of a group/type or in general of treating patients, such as commonly occurs at THMA during clinical management, is not research.

V. Failure to obtain prospective IRB approval before conducting research

The implications of engaging in human subjects research activities that are subject to IRB review, without submitting such activities for prospective IRB review, are serious and significant.

Failure to submit research protocols for prospective IRB review, or failure to obtain IRB approval before initiating such research proposals, may result in one or more of the following:

1. Suspension/termination of the ability to conduct future research.

2. Suspension/termination of physician privileges.

3. Suspension/termination of employment.

4. Notification of federal government agencies having jurisdiction over human subjects research, e.g., the Office of Human Research Protection, the Food and Drug Administration, or the National Institutes of Health.

5. Referral to legal authorities for civil or criminal prosecution.

Clinical data obtained in the conduct of a research study prior to approval of such research by the IRB may not be used. To do so is in violation of this procedure.

The IRB does not allow for retrospective approvals, i.e., after research has commenced. Research investigators should be aware that any human subjects research conducted without IRB approval is not only likely to be rejected for publication in a peer-reviewed medical journal but also may affect future new study considerations by the IRB.

The IRB Administrator and IRB Chair are available for consultation to help in making a determination of research vs. quality improvement activity.

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