
EFFECTIVE DATE: *May 18, 2022***PROCEDURE TITLE:***Exemption Determination**To be reviewed every three years by:
Institutional Review Board***REVIEW BY:** *May 17, 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.

Activities that meet the federal definition for research and meet specific criteria will be exempt from the regulations at 45 CFR 46 (OHRP) and 21 CFR 56.104 (FDA); however, the research will be reviewed by the IRB in order to make this exemption determination.

Effective January 21, 2019, the Office of Human Research Protections (OHRP) revised the Common Rule regulations exemption categories; thus, research that satisfied an exemption category under the prior Common Rule regulations may or may not satisfy an exemption category under the newly revised Common Rule regulations.

IRB determinations previously made stand as reviewed.

FDA exemption category regulations remain unchanged.

I. Exemption Categories and Requirements

The research project may be considered exempt if it meets the definition of research, involves minimal risk to participants and meets the criteria for one of the following categories as defined below. Note that research that incidentally involves prisoners as a broader subject population in research is an allowable exemption under the OHRP regulations effective January 21, 2019 and thereafter.

A. FDA-regulated research

1. Taste and food quality evaluation and consumer acceptance studies, if:
 - a. Wholesome foods without additives are consumed, or
 - b. All food ingredients, agricultural chemicals or environmental contaminants consumed are at or below safe levels, as determined by governmental regulating agencies.
 - c. Consent will be obtained.
2. Unplanned emergency use of a test article.

B. OHRP-regulated research

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educations who provide instruction, such as:
 - a. Research on regular and special education instructions strategies,
 - b. Research on the effectiveness of or the comparison among instructional techniques, curricula or classroom management methods.
2. Research that only includes interactions involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recordings) if at least one of the following criteria is met;
 - a. *Information obtained is recorded by the investigator in such a manner that identity of the human subjects cannot be readily ascertained, directly or through identifiers linked to the subjects; (e.g., social security numbers);
 - b. *Any disclosure of the participant responses outside the research would not reasonably place the participant at risk of criminal or civil liability or be damaging to his/her financial status, employability or reputation.
 - c. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained directly or through identifiers linked to the subjects, and an IRB conducts a **limited IRB review** that entails privacy and confidentiality measures are in place to protect participant information/data and children are not involved.

**Note:* If children are involved, the exemption may not be used for research using survey or interview procedures or observations of public

behavior, except for research involving observation of public behavior where the investigators do not participate in the activities being observed.

3.

- a. Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audio-visual recording if the subject *prospectively* agrees to the intervention and information collection and at least ONE of the following criteria are met:
 - i. information obtained is recorded by the investigator in such a manner that identity of the participants/ human subjects cannot be readily ascertained, directly or through identifiers linked to the subjects; identified, directly or through identifiers (e.g., social security numbers); and
 - ii. any disclosure of the participant responses outside the research would not could reasonably place the participant at risk of criminal or civil liability or be damaging to his/her financial status, employability or reputation.
 - iii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained directly or through identifiers linked to the subjects, and an IRB conducts a **limited IRB review** to make the determination required for approval.
- b. Benign behavioral interventions are brief in duration, harmless, painless and not physically invasive, not like to have a significant adverse lasting impact on the subjects and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing.
- c. Should the research involve deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable UNLESS the subject authorizes the deception through a prospective agreement and the subject is informed that she or he will be unaware of or misled regarding the nature or the purposes of the research.

4. Secondary research uses of identifiable private information or identifiable biospecimens if at least ONE of the following criteria is met:

- a. The identifiable private information or identifiable biospecimens are publicly available;

- b. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not reidentify subjects;
 - c. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or
 - d. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.
5. Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including, procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.
- a. Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal website or in such other manner as the department or agency head may determine, a list of the research and

demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

6. Taste and food quality evaluation and consumer acceptance studies:
 - a. If wholesome foods without additives are consumed, or
 - b. If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

The following optional exemption categories will not be used at THMA and therefore are not available for consideration as exemption determinations by the THMA IRB. (Institutional tracking mechanisms for operationalizing these methods do not exist at this time.)

7. Storage or maintenance for secondary research for which **broad consent is required**: Storage or maintenance of identifiable private information or identifiable bio specimens for potential secondary research use. The IRB will need to conduct a limited IRB review and make the determinations as required by §46.111(a)(8).
8. Secondary research for which **broad consent is required**: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:
 - a. Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §46.116(a)(1) through (4), (a)(6), and (d);
 - b. Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §46.117;
 - c. An IRB conducts a limited IRB review and makes the determination required by §46.111(a)(7) and that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and iv. The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

II. Submission and Review Process

To have research evaluated for exemption status, the investigator must submit a THMA IRB Application for Initial Review in IRBManager with a protocol, any questionnaires/surveys, data collection tool, and any other relevant study information. CITI training completion records are also required for research that meets exemption categories, as well as the CV of the Investigator.

A. Limited IRB review

Limited IRB review is a condition for research that meets certain exemption categories under the revised OHRP regulations, while normal IRB review is required for research that meets other exemption categories. These reviews are conducted via the expedited method (one designated IRB member on behalf of the full board). This review is a onetime only review and no continuing review of the research is required.

Exemptions 2(iii) and 3(i)(c) require privacy and confidentiality protection review. In order to approve research that falls in these categories the IRB needs to determine that all of the following requirement is satisfied:

There are adequate provisions are in place to protect the privacy of subjects and to maintain the confidentiality of data, as appropriate.

In order to make this determination, the IRB should consider the following as appropriate:

1. Adequate provisions to protect the privacy of participants and to guard against group harm whereby people who did not participate in the research are inadvertently associated with the findings for one group in the research. Ensuring that when demographic information is collected and the population is small, that the researchers will not share research findings in a manner that would inadvertently allow one to ascertain the identity of the participants (i.e., study collecting location of medical school, year of residency, field of residency at a small academic Hospital).
2. Ensuring that provisions are in place to minimize impact of the research team knowing who the participants are and their responses in the case where the participants are colleagues (e.g., residents are sub-investigators on a study recruiting residents as participants).
3. Adequate provisions to maintain the confidentiality of data such as storing data on the hospital server, using links rather than storing data with identifiable information, using encryption and following the Leadership policies on sharing data.
4. The extent to which the information will be shared or transferred to a third party or otherwise disclosed or released;

5. The retention period of the information and proper means of disposal of information;

B. Consent Common Rule/OHRP Regulated Research

Consent, or its waiver, is not a requirement for OHRP-regulated research that is determined to meet the criteria for exemption; EXCEPT for optional exemption categories 7 and 8. These require the use of broad consent and consent cannot be waived. **However, the THMA IRB may still request that consent be obtained from participants in certain situations.**

C. HIPAA

HIPAA regulations may apply to research that meets an exemption category.

D. Exemption determination

The IRB Chairperson or a designated IRB member will make the final determination of the exemption status by reviewing the submitted application and supporting documents. The IRB has the authority to approve and ask for clarifications to render a determination. If the study is determined not to meet an exemption criteria, then the project will be evaluated to see if it meets the expedited or the full board review criteria.

E. Notification and Documentation

The IRB correspondence to the submitter(s) will document the exemption category as well as any applicable HIPAA authorization, waiver or other HIPAA option. For categories that required Limited IRB Review, the criteria for approval [45 CFR 46.111(a)(7)] will be documented in the IRB meeting minutes. IRB members and the Institutional Official will be apprised of exempt research determinations as they are documented in IRB agendas and subsequent IRB meeting minutes.

F. Further IRB Oversight

Once an exempt status is determined, the research is not subject to further IRB oversight and review, unless changes are made to the research which would alter the criteria for meeting an exemption category or if further review by the Privacy Board is needed (the IRB also serves as the Privacy Board for research). It is the Principal Investigator's responsibility to contact the IRB if the above occurs.

RESPONSIBLE DEPARTMENT

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

APPROVALS

Initial Approval: August 28, 2020

Subsequent Review/Revision(s): May 18, 2022