Institutional Review Board Procedure No. 19

EFFECTIVE DATE: ***December 19, 2025***

PROCEDURE TITLE:

Participant Recruitment: Screening, Advertisements, and Compensation

To be reviewed every three years by:
Institutional Review Board

REVIEW BY: ***December 18, 2028***

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.

The IRB is required to ensure that appropriate safeguards exist to protect the rights and welfare of research subjects (21 CFR 56.107 (a) and 56.111). In fulfilling these responsibilities, an IRB is expected to review all research documents and activities that bear directly on the rights and welfare of the participants of proposed research. As such, the IRB must review the methods or materials used to recruit participants. The IRB will determine that the procedures for recruiting participants is not coercive and does not state or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the protocol. Additionally, the IRB will determine that the methods, materials of recruitment, and advertising ensure equitable selection of participants.

Compensation to research participants is considered a recruitment incentive that will also be reviewed and approved by the IRB, for which both the amount of payment and the proposed method and timing of disbursement will be considered to assure that neither present undue influence [21 CFR 50.20].

I. Screening, Advertising and Recruitment Requirements

When submitting a research project or an amendment to the IRB for review that includes or impacts participant recruitment, the following information is required:

1. Explain in detail the methods and process that will be used for recruitment.
2. Indicate the timing of the recruiting methods, and time between this and consenting.
3. State who will be recruiting participants.
4. State where recruitment will take place.

5. State the methods for screening participants
6. State who will be responsible for screening participants
7. Indicate the proposed media to be used and whether any subsequent advertisements in different media are planned.
8. If posters, flyers etc. are being used, assure that permission has been given for placement of these materials in the desired areas (i.e. hospital waiting rooms, emergency room or office clinic).
9. Submit all advertisements, in any media, to the IRB for review prior to use. The following are examples of typical recruitment materials that must be approved by the IRB, but is not necessarily limited to:

    - bulletin boards, posters, flyers, letters and handouts
    - magazine or journal articles (print and online)
    - newspaper or classified ads (print and online)
    - radio, television, online videos
    - social media posts
    - websites and website postings

The final advertisement printed copy will be evaluated for relative size, type used and other visual effects. A final copy of any taped media used in broadcasts must be reviewed by the IRB. To avoid re-taping of audio/video recordings a text version of your message should be submitted to the IRB for review and approval of appropriate wording.

The following materials given prior to consenting that may influence participant participation, may also be considered study recruitment materials and must be approved by the IRB.

- e-mails
- Information sheets or informational videos
- telephone calls
- verbal consent scripts

Online Recruitment and Social Media

For online recruitment material, it is recommended that the same standards be followed that are used for traditional formats. Social media platforms used for participant recruitment/advertisement should consider how participants will be interacting in respect to their privacy being protected (what information is being shared e.g., Protected Health Information) and who the information is being shared with (other participants, study staff, sponsor, etc.).

Recruiting Material Key Items

The following is a list of items that may be contained in the advertisement and applies to all recruitment items regardless of communication mode, as to encourage equitable selection of participants and minimize coercive language:

1. The name and address of the principal investigator and institution
2. The purpose of the research and the condition being studied;

3. A summary of the eligibility criteria (a complete list of eligibility criteria is not required);
4. A straightforward and truthful description of the potential benefits;
5. The amount of time or other commitment required;
6. The location of where the research will take place and the person or office to contact for further information.
7. Documents should be clear that voluntary research participation is what is being solicited.

Unacceptable Recruiting Material Content

The IRB will review advertising materials for coercive language or any promises of a cure beyond what is outlined in the consent and the protocol. DO NOT include the following in recruitment materials:

1. Do not use the phrase "Free medical treatment".
2. Do not call the intervention a "new" treatment, medication, drug, device, etc.
3. Do not make references to physical examinations or other study procedures unless stating they are “study-related”
4. Do not emphasize monetary compensation (no bolding, larger print, underlining, colored text, etc., unless all of the other text is formatted this way).
5. No claims should be made, either explicitly or implicitly, that the drug or device is safe or effective for the purpose under investigation, or that the drug, device, or intervention is in any way equivalent or superior to any other drug, device, or intervention. Such representation would also be a violation of FDA's regulations concerning the promotion of investigational drugs [21 CFR 312.7 (a)] and of investigational devices [21 812.7 (d)]. Recruitment materials should not use terms such as "new treatment", "new medication" or "new drug" without explaining the test article is investigational. Also, the materials should not include a coupon good for a discount on the purchase price of the product once it is approved for marketing.

II. Compensation to research participants

Compensation to research participants is permissible and is a common practice; however, it is not considered a benefit and should not alter the benefit-risk ratio. The method and amount of compensation a research participant is to receive, along with a schedule of all payments, should be submitted to the IRB at initial review. The IRB will consider the method of payment, amount, participant's time spent, inconvenience, discomfort, and any other considerations to determine if the participant's compensation is just and fair. Reimbursement for travel expenses to and from the study site and associated costs (including airfare, parking, and lodging) does not present undue influence. Investigators should be prepared to address these concerns, especially for research that poses little or no direct benefit for the participants.

Special precautions should be taken when payment is offered to a third party for the participation of someone else in the research. The IRB is concerned that such payments may constitute undue influence or coercion from the third party to the actual research participant. For example, a parent may be offered remuneration for volunteering their child to participate in a research project. In these cases, precautions should be taken to clearly separate the payment to the third party from the

consent/assent process with the actual research participant. Final approval for participation rests solely with the research participant and their consent/assent takes precedence over that of the person to whom payment is offered.

Since participants reserve the right to withdraw their participation from the research without prejudice, payment to participants should be pro-rated (divided proportionally throughout the individual's participation in the study). The IRB will review both the amount of the payment, to whom it is offered, and the proposed method of disbursement to ensure that payment for participation does not constitute coercion or undue influence.

Information regarding all aspects of compensation should be included in the informed consent document including payment processing for participants who withdraw before completion of the study. Compensation should not be based on whether the participant completes the study; however, a small incentive for completion is acceptable. These incentive payments must be reviewed by the IRB to determine that the amount offered will not persuade participants to stay in the study who would otherwise have withdrawn.

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 27, 2021

Subsequent Review/Revision(s): December 19, 2025