

---

**EFFECTIVE DATE:** *April 28, 2023***PROCEDURE TITLE:***Informed Consent**To be reviewed every three years by:  
Institutional Review Board***REVIEW BY:** *April 27, 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, the *Ethical and Religious Directives for Catholic Health Care Services*, including promoting the conduct of ethical and compliant research.

Consent or its waiver is required for all non-exempt research. The investigator is accountable for ensuring that:

- Legally effective informed consent (which may not be altered or omitted) is obtained from each research participant (or their Legally Authorized Representative (LAR)) *or* a waiver of consent is obtained from the IRB in advance of conducting the non-exempt study.
- Certain elements are required to be included in consent, or an alteration or omission of one or more of certain consent elements is permitted when obtained from the IRB in advance of conducting the study.
- Broad consent can only be used in certain circumstances and is optional. Currently there is not an operational gateway to use this method and the IRB does not allow for broad consent at this time.
- Informed consent is an on-going process in which the researcher may need to re-consent participants.
- Each research participant is provided with information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information (the IRB may not omit or alter this requirement).

- An investigator shall seek informed consent only under circumstances that provide the prospective participant or the LAR sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence (the IRB may not omit or alter this requirement).
- The information that is given to the participant or the legally authorized representative shall be in language understandable to the participant or the LAR (the IRB may not omit or alter this requirement).
- Documentation of consent or its waiver is required for all non-exempt research.
- Assent is appropriate for children.
- Research that was approved by the IRB prior to January 21, 2019 does not need to comply with the new Common Rule regulations but would rather continue to follow the regulations in effect prior to this date.

The IRB is responsible for reviewing and ensuring that consent for all non-exempt research contain a process for obtaining legally effective informed consent that is free of coercion and undue influence and that is documented or granting appropriate requests that meet all of the federal criteria for a waiver of consent and/or waiver of documentation of consent and/or alteration of consent.

## **I. Importance of informed consent**

The informed consent process is one of the primary ethical requirements in research with participants and reflects the Belmont Report principle of respect for persons. Informed consent assures that prospective participants will be provided information to fully understand the nature of the research in language understandable to him/her, so that the decision of whether or not to participate can be made in an autonomous way.

## **II. Applicability**

Informed consent is delineated in the federal regulations regarding when it can be obtained verbally, with a signed document, and when it can be waived by an IRB. Informed consent, the elements of consent, and the documentation of consent are **optional for research that meets an exemption category**.

The informed consent requirements in this procedure are not intended to preempt any applicable federal, state, tribal law passed by the official governing body of an American Indian or Alaska Native tribe, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law.

### **III. General requirements for the informed consent process**

#### **A. Consent process**

Except as provided elsewhere in this procedure, no investigator may involve a research participant in non-exempt research unless the investigator has obtained the legally effective informed consent of the participant or the participant's LAR.

Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective participant or legally authorized representative in understanding the reasons why one might or might not want to participate in the research.

The consent process must assure that each potential participant understands what the aim of the study is, as well as the experimental vs standard of care procedures; risks; benefits; and that participation in the study is voluntary; in addition to other information. The obligation to provide complete information required for informed consent is the responsibility of the investigator. The informed consent process involves meeting with a potential participant, finding out whether he or she is capable of giving consent, and discussing the purpose, methods, interventions, risks, and benefits of participation. Consent is a continuing process and occurs throughout the conduct of the study. **The initial application and protocol must provide details concerning how the consent process will be carried out.**

#### **B. Language understandable to the participant or the Legally Authorized Representative**

The information given to the potential participant, which could include information provided orally during the consent discussion or written information in the consent form, must be in language understandable to the potential participant or LAR (21 CFR 50.20 and 45 CFR 46.116). "Understandable" means the information presented to potential participants is in a language and at a level the participants can comprehend (including an explanation of scientific and medical terms). In ensuring that information is understandable, it should be presented in a sixth-grade level.

Investigators can use flow charts and decision aids to assist in explaining the information. All participant materials must be IRB approved prior to use.

#### **C. Timing**

A participant requires time to decide whether or not to participate, to ask questions and to confer with family and other personal advisors. The investigator must give the participant or the LAR adequate opportunity to read the consent before it is signed. It is not appropriate to seek consent in a rush or at the time of a procedure, diagnosis or other stressful moment. It may be appropriate, however, to obtain consent and then begin the research intervention in studies that are low risk to the participants and do not involve a

stressful moment, such as research that meets an exemption or expedited category (survey study, focus group, comparing educational interventions, etc.).

The investigator shall give either the participant or the participant's LAR adequate opportunity to read the informed consent form before it is signed; alternatively, this form may be read to the participant or the participant's LAR.

#### **D. Checking for comprehension**

The written consent form provides a baseline for discussion. The consent and discussion should describe all facets of the study and answer participant questions. The investigator is responsible for insuring that research participants understand the research procedures and risks. Failure of the participants to ask questions should not be interpreted as understanding on the part of the participant.

It is recommended that researchers check for understanding by asking open ended questions or asking prospective participants to discuss the study in their own words, especially if the study involves increased risk to participants. This will help gauge comprehension and identifying gaps in the participant's understanding.

#### **E. The person obtaining consent**

The process of discussing a research study with a potential participant as part of the informed consent process may be delegated to a member of the research study staff (**Delegation of the informed consent process is not allowed in Pennsylvania as noted below**).\* The investigator is responsible for assuring that study team members executing consent are knowledgeable and have sufficient training to perform the task.

**\*Note:** In Pennsylvania, except for emergencies, an attending physician owes a duty to a patient to obtain the informed consent of the patient or the patient's authorized representative prior to conducting the following procedures:

1. Performing surgery, including the related administration of anesthesia.
2. Administering radiation or chemotherapy.
3. Administering a blood transfusion.
4. Inserting a surgical device or appliance.
5. Administering an experimental medication, using an experimental device or using an approved medication or device in an experimental way (PA MCARE Act of 2002, Chapter 5, Section 504. Informed Consent).

#### **F. Vulnerable groups**

Vulnerable groups often need special provisions and some have specific federal research regulatory requirements for obtaining consent. Vulnerable groups are often susceptible to undue influence and coercion. You are urged to review these Institutional Review Board procedures for consent requirements:

- Vulnerable Populations: Children
- Vulnerable Populations: Who do not speak, read, or comprehend English: Illiterate; Blind
- Vulnerable Populations: Individuals with Diminished Capacity
- Vulnerable Populations: Other
- Vulnerable Populations: Research Involving Prisoners

#### Other Groups

Pregnant Women are not considered vulnerable but have special regulations regarding their participation in research. Human Fetuses and Neonates are vulnerable groups and have special regulations.

#### **G. Coercion and undue influence**

As stated in the Belmont Report, “Coercion occurs when an overt threat of harm is intentionally presented by one person to another in order to obtain compliance. Undue influence, by contrast, occurs through an offer of an excessive, unwarranted, inappropriate or improper reward or other overture in order to obtain compliance.” The conditions under which informed consent is sought and the relationship between the participant and the person obtaining consent must be carefully considered to *minimize the potential for or the possibility of coercion or undue influence* (21 CFR 50.20 and 45 CFR 46.116).

Example: If an investigator who is the director of a hospital department seeks to recruit residents and nurses that report to her, the protocol will need to contain safeguards to ensure that participation is voluntary and the decision to participate or not participate will have no impact on their relationship with their supervisor/investigator or their employment. Furthermore, there will be no undue influence by supervisor, peers, or others to participate or not participate. Moreover, a justification will be provided by the investigator to the IRB regarding why a vulnerable group, employees, have been chosen for recruitment, as a group, as well as the safeguards put in place to minimize the potential for coercion and undue influence (such as, for example, the investigator being blinded to the participant’s identifiable information).

Another situation where there is the possibility for the perception of undue influence arises is the physician-patient relationship, when the investigator is also the prospective participant’s physician.

The physician should be careful to ensure that the prospective participant understands that enrollment in the research or clinical investigation is voluntary and that a decision to forego enrollment will not adversely affect his/her medical care.

Note that coercion and undue influence may be situational.

Example: Obtaining informed consent when the potential participant is in the preoperative area *when consent could have been obtained earlier* may fail to minimize the possibility of undue influence.

Statements that claim investigational drugs, biologics, or devices are safe or effective for the purposes for which they are being investigated are prohibited. Statements that inappropriately overstate the possibility of benefit should be avoided because they may unduly influence potential participants. Careful wording is needed in order to avoid overstating potential benefits that may contribute to a participant's therapeutic misconception.

#### **H. Exculpatory language**

The informed consent document and process may not involve the use of exculpatory language through which the participant or legally authorized representative is made to waive or appear to waive any of the participant's legal rights, or releases or appears to release the investigator, sponsor, institution, or agents from liability for negligence.

### **IV. Informed consent content**

#### **A. General requirements**

General requirements for informed consent, whether written or oral, are set forth below. Broad consent may be used in only two exemption categories and the content elements are discussed below. **Investigators are responsible for ensuring that the only the current, IRB approved version of the consent document is used.**

#### **B. Required elements of consent**

The informed consent must be organized and presented in a way that facilitates comprehension. Key information may include but not limited to:

- Consent is being sought for research and that participation is voluntary.
- Purpose of the research, expected duration of participation and procedures to be followed.
- Reasonable foreseeable risks, discomforts, side effects to the participant or others.
- Benefits to the participants or others that might reasonably be expected.
- Alternative procedures or courses of treatment that a participant would want to know.
- Any costs that will be incurred during the research.

- Who is conducting the research and who is funding the research.

The informed consent document as a whole must present information in sufficient detail relating to the research and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective participant's or legally authorized representative's understanding of the reasons why one might or might not want to participate.

The informed consent document for research will include the elements required in the federal regulations, specifically FDA: 21 CFR 50.20 and OHRP: 45 CFR 46.116(a), as detailed below.

Required elements of consent:

1. A statement that the study:
  - Involves research,
  - An explanation of the purposes of the research,
  - The expected duration of the participant's participation,
  - A description of the procedures to be followed, and
  - Identification of any procedures which are experimental.
2. A description of any reasonably foreseeable risks or discomforts to the participant,
3. A description of any benefits to the participant or to others that may be reasonably expected from the research.
4. A disclosure of appropriate alternative procedures or courses of treatment, if any that might be advantageous to the participant.
5. A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained.
6. For research involving more than minimal risk, an explanation as to whether any compensation will be provided, and/or whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained.
7. An explanation of whom to contact for answers to pertinent questions about the research and research participant's rights, and who to contact in the event of a research related injury to the participant.
8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and the

participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.

9. One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:
  - i. A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or legally authorized representative, if this might be a possibility; or
  - ii. A statement that the subjects information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

The following additional elements of consent will be provided to participants, when appropriate.

These are generally required for all clinical trials:

10. A statement that the particular treatment or procedure may involve risks to the participant (or to the embryo or fetus, if the participant is or may become pregnant) that are currently unforeseeable.

In keeping with the Catholic tradition of THMA, the statement below will allow Catholic women and men with the potential for producing children the opportunity to decide whether they would like to participate in the study, based on the religious teachings of the church.

When the use of contraception is defined in the informed consent the following statement should be included in all written consent forms:

*“You should not become pregnant or father a child while on this study. We recommend abstinence as the acceptable method of birth control to be practiced while you are on this study. Please speak with your doctor if you need more information or counseling regarding preventing pregnancy while you are on this clinical trial.*

*If you become pregnant during the course of this study, you should notify the study doctor as soon as possible.*

11. Anticipated circumstances under which the participant’s participation may be terminated by the investigator without regard to the subject's or the legally authorized representative consent.



12. The compensation of the investigator, especially when there is a Conflict of Interest and / or Significant Financial Interest of the investigator (e.g., stock ownership in the sponsor, part/full owner of the sponsor).
13. Any additional costs to the participant that may result from participation in the research.
14. The consequences of a participant's decision to withdraw from the research and procedures for termination of participation by the participant.
15. A statement that if significant new findings develop during the course of the research that may be related to the participant's willingness to continue participation, the participant will be notified and given ample time to consider continued participation.
16. The approximate number of participants involved in the study.
17. A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.
18. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects and if so under what conditions; and
19. For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

In addition, the FDA requires that the following exact statement must be included in the informed consent documents of "applicable clinical trials":

"A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."

### **Use of optional broad consent**

Use of broad consent is allowable under the regulations. In order to implement broad consent, it will require institutional wide tracking systems for implementation and the functionality that does not exist at this time. This will require tracking within the electronic medical record for the life of the record.

**The IRB does NOT allow broad consent. The requirements here are presented for information only and is not being implemented.**

Broad consent is an alternative to traditional informed consent for the non-exempt storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens (collected for either research studies other than the proposed research or non-research purposes). The elements must include:

- A description of any reasonably foreseeable risks or discomforts to the subject;
- A description of any benefits to the subject or to others that may reasonably be expected from the research;
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled;
- When appropriate, a statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
- When appropriate, for research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen);
- A general description of the types of research that may be conducted with the identifiable private information or identifiable biospecimens. This description must include sufficient information such that a reasonable person would expect that the Broad Consent would permit the types of research conducted;
- A description of the identifiable private information or identifiable biospecimens that might be used in research, whether sharing of identifiable private information or identifiable biospecimens might occur, and the types of institutions or researchers that might conduct research with the identifiable private information or identifiable biospecimens;
- A description of the period of time that the identifiable private information or identifiable biospecimens may be stored and maintained (which period of time could be indefinite), and a description of the period of time that the identifiable private information or identifiable biospecimens may be used for research purposes (which period of time could be indefinite);

- Unless the subject or legally authorized representative will be provided details about specific research studies, a statement that they will not be informed of the details of any specific research studies that might be conducted using the subject's identifiable private information or identifiable biospecimens, including the purposes of the research, and that they might have chosen not to consent to some of those specific research studies;
- Unless it is known that clinically relevant research results, including individual research results, will be disclosed to the subject in all circumstances, a statement that such results may not be disclosed to the subject; and
- An explanation of whom to contact for answers to questions about the subject's rights and about storage and use of the subject's identifiable private information or identifiable biospecimens, and whom to contact in the event of a research-related harm.

Although not an element, it will be necessary for investigators to track any refusals of broad consent to assure that these records are delineated and not used in research.

### **C. Omitting or altering the required elements of consent**

Alteration of consent is only permissible under Office of Human Research Protections (OHRP)-regulated research; FDA does not allow this option. When an investigator seeks to omit or change one or more of the above 8 required elements, prospective, advanced permission will be sought from the IRB. Of note: the requirements of consent as noted above in the policy statement may not be altered or omitted when consent is obtained.

There are two regulatory options for granting an alteration of consent [under 45 CFR 46.116 (c) & (d)]. These options are identical to those allowable for waiving consent under OHRP-regulated research—see the waiving consent section of this policy for these options.

### **D. Compensation**

The consent document should include the details of the payment plan, including when the payment(s) will be received and the conditions under which a participant would receive partial payment. This should be included in the “Costs/Payments” section of the consent document and **NOT** in the “Benefits” section.

## **V. Documentation of informed consent**

Per the federal regulations, informed consent will be documented by the use of a written (paper or electronic) consent form (45 CFR 46.117 and 21 CFR 50.27), except as allowed elsewhere in this procedure:

- The written consent form must be signed and dated on the same day and time by the a) participant or the participant's legally authorized representative, and b) the research team member obtaining the consent.
- A copy of the signed written consent form must be given to the participant or participant's LAR, and a copy kept in the research record.
- The investigator signature is not required on consent documents, unless the investigator is obtaining the consent from the participant.
- The act of obtaining informed consent must be documented in the research record or medical record for each participant. This may be in the form of a short progress note or other method of documentation.

The printed name is required on the consent as it often is difficult to read a signature of a person. Signatures and printed names must be made with permanent ink if paper is used. The use of pencil is prohibited, unless special permission is granted in advance by the IRB for unusual circumstances. Any signature or date corrections should be made with a single line through the error and date and initials added of the person making the correction.

The informed consent document provides the participant with a record of what is explained to them by the investigator or designee. The document itself is not consent. The document is a written narrative that summarizes the information the investigator or designee discusses with the participant. It is not proof that the participant understood what will happen in the study. The informed consent document is the primary means the IRB has to determine what will be explained to the participant about the study and the language that will be used.

## **A. Electronic consent**

An electronic informed consent (eIC) document may be used if the document and process of obtaining consent complies with all parts of this policy, including giving a copy of the consent to the participant (must be a written copy if OHRP-regulated research). Whether part or all of the eIC process takes place on-site or remotely, the responsibility for obtaining informed consent remains with the investigator and the study personnel to which responsibility has been appropriately delegated. The investigator cannot delegate authority to obtain informed consent to the electronic system.

### **1. Location**

The consent process may take place at the study site when both the investigator and participant are at the same location, or it may take place remotely (e.g., at the participant's home, etc.) where the participant reviews the consent document in the absence of the investigator. The eIC materials may be provided for both on-site and remote access.

**a. On-site**

If the entire process takes place at the study site, the study personnel must personally verify the participant's identification, review the eIC content, answer questions about the material, have follow-up discussions, and witness the signing of the eIC.

**b. Remote**

If any or all of the consent process takes place remotely and is not personally witnessed by study personnel, the electronic system must include a method to ensure that the person electronically signing the informed consent is the participant who will be participating in the research study or is their LAR [see 21 CFR 11.100(b)].

Examples of various methods that could be used include: verification of a state-issued identification or other identifying documents or use of personal questions, biometric methods, or visual methods.

**2. Research under sole authority of 45 CFR Part 46 (OHRP)**

Research under OHRP allows for an alternate process as it may not be possible or necessary for all types of research to verify that the person signing the informed consent is the participant or their LAR who will be participating in the research study. Rather, a risk-based approach to the consideration of participant identity will be used. For example, social behavioral minimal risk research will not typically warrant such verification. In addition, informed consent may be waived for minimal risk research meeting the requirements at 45 CFR 46.116(d) (see waiver of consent section).

**3. Opportunity to ask questions**

Regardless of the location, the investigator will have methods in place to ensure that the eIC process allows participants the opportunity to consider whether or not to participate and to ask questions about the study before signing consent as well as at any time during the participant's involvement in the research. This may be accomplished by in-person discussions with study personnel or through a combination of electronic messaging, telephone calls, video conferencing, or a live chat with a remotely located investigator or study personnel. When live chat or video conferencing is used during the eIC process, investigators and study personnel should remind participants to conduct the eIC discussion in a private location to help ensure privacy and confidentiality. Participants should be given a description of how and when they will receive answers to their questions, and they must be provided information on how to contact an appropriate individual for pertinent questions about the research.

#### **4. Electronic signatures**

OHRP and FDA regulations permit the use of electronic signatures when written informed consent is required. OHRP permits electronic signatures if such signatures are legally valid within the jurisdiction where the research is to be conducted.

##### ***Food and Drug Administration (FDA)-Regulated Clinical Investigations***

For FDA-regulated studies, in order for an electronic signature to be considered the equivalent to a handwritten signature executed on paper, electronic signatures must comply with all applicable requirements under 21 CFR Part 11. The electronic system must also capture and record the date that the participant or their LAR provides consent.

The FDA regulations permit a wide variety of methods to create electronic signatures and does not mandate any particular method. Examples of allowable methods include using:

- computer-readable ID cards,
- biometrics,
- digital signatures, and
- user name and password combinations.

##### ***HIPAA authorization and signatures***

HIPAA authorizations may be obtained electronically, provided that the signature of the participant or their personal representative is a valid electronic signature under applicable laws and regulations. The Electronic Signatures in Global and National Commerce Act (E-Sign Act; Public Law 106-229) addresses what constitutes a valid electronic signature and provides that a signature may not be denied legal effect because it is in electronic form.

For additional federal guidance, see *Use of Electronic Informed Consent* at <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/use-electronic-informed-consentquestions-and-answers/index.html>.

#### **B. Non-English-speaking participants**

A *short form* written consent document in the potential participant's language will be used and will state that the elements of informed consent have been presented orally to the participant or their LAR.

### **C. Verbal and waiving the *documentation* of consent**

Investigators wishing to undertake research that involves an Internet survey or telephone survey are encouraged to consider requesting a Waiver of Documentation of Consent. When a waiver of documentation of consent is granted by an IRB, the waiver allows the researcher to obtain consent either verbally or in writing with no signature lines. Consent will still contain the 8 required elements, as noted above. The waiver must be sought and granted in advance of use.

The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all participants if it finds either:

#### **OHRP-regulated research:**

1. That the only record linking the participant and the research would be the consent document *and* the principal risk would be potential harm resulting from a breach of confidentiality. Each participant or legally authorized representative will be asked whether the participant wants documentation linking the participant with the research (wants to sign anyways), and the participant's wishes will govern;

*or*

2. That the research presents no more than minimal risk of harm to participants *and* involves no procedures for which written consent is normally required outside of the research context.

*or*

3. If the participants are members of a distinct cultural group or community in which signing a form is not the norm. The research must present no more than minimal risk of harm to participants and provide an appropriate alternative mechanism for documenting that informed consent was obtained (for example documenting in the progress notes or study record files).

#### **FDA-regulated research:**

1. That the research presents no more than minimal risk of harm to participants *and* involves no procedures for which written consent is normally required outside of the research context.

Please note that when the documentation requirement is waived, the IRB may require the investigator to provide participants with a written statement regarding the research.

#### **D. Pre-review of the written consent document**

Researchers may request a pre-review of the consent document by contacting the IRB Administrator. Receiving feedback resolves issues such as the reading comprehension level of the form, proper structure for required items such as signature lines, and completeness of information before the consent form is sent to the IRB for approval.

#### **E. Consent revisions and addendums**

Any change or revision to the consent must be reviewed and approved by the IRB prior to use.

Changes should *not* be made by hand (handwritten correction, deletion or notation), but rather electronically. Please contact the IRB Administrator to request a word version of the currently approved consent document for your use.

In some cases, a Consent Addendum is used to summarize changes to the original IRB approved consent form. The Consent Addendum must be prospectively approved by the IRB along with the process that will be used by the research team to make the change.

#### **F. Issuing the approved consent document**

The IRB Administrator issues consent documents in Adobe Acrobat PDF format, to prohibit unapproved changes. The IRB Administrator stores and manages the consent versions using a database with restricted access.

**The IRB Administrator will not issue a consent document if the study is closed to accrual at continuing review.**

### **VI. Waiver of informed consent**

**Partial waiver of consent** - waives the federal requirement for obtaining consent from some or all of the participants for a portion of the research.

**Full waiver of consent** - waives the federal requirement for obtaining consent from all of the participants for the entire study.

**Regulations differ based upon whether the research is OHRP- or FDA-regulated.**

#### **A. FDA-regulated research:**

##### **1. Partial waiver of informed consent**

The FDA does not consider *screening in the medical chart* for eligibility criteria or contact info to constitute research, so no waiver needed, however be aware that HIPAA regulations still apply.



However, full prospective consent must be obtained if:

- a. The research team plans on accessing the medical record for other research reasons and/or gathering other information from the record, or
  - b. Screening *tests or procedures* are being used solely to determine eligibility.
2. Full waiver of informed consent

**FDA regulations permit a waiver of consent for some FDA-regulated studies.**

- a. **In limited circumstances** for *emergency use* of a test article (21 CFR 50.23) or for planned *emergency research* (21 CFR 50.24).
- b. The FDA allows for waiver of consent in other circumstances (Guidance document issued July 2017) The FDA does not object to an IRB approving a consent procedure that does not include, or that alters, some or all of the elements of informed consent set forth in 21 CFR 50.25, or waiving the requirements to obtain informed consent when the IRB finds and documents that:
  1. The clinical investigation involves no more than minimal risk (as defined in 21 CFR 50.3(k) or 56.102(i)) to the participants;
  2. The waiver or alteration will not adversely affect the rights and welfare of the participants;
  3. The clinical investigation could not practicably be carried out without the waiver or alteration; *and*
  4. Whenever appropriate, the participants will be provided with additional pertinent information after participation.

**B. OHRP-regulated research**

**Screening, recruiting, or determining eligibility.** An IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects **without the informed consent** of the prospective participant or the their legally authorized representative, if either of the following conditions are met:

- The investigator will obtain information through oral or written communication with the prospective participant or legally authorized representative, or

- The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

1. Partial or full waiver of informed consent

An IRB may waive the requirement to obtain informed consent, provided the IRB finds and documents that:

- a. The research involves no more than minimal risk to the participants;
- b. The research could not practicably be carried out without the waiver or alteration;
- c. If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
- d. The waiver or alteration will not adversely affect the rights and welfare of the participants; **and**
- e. Whenever appropriate, the participants or Legally Authorized Representative will be provided with additional pertinent information after participation. This is typically done in prospective studies.

***OR***

- a. The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:
  - i. public benefit or service programs;
  - ii. procedures for obtaining benefits or services under those programs;
  - iii. possible changes in or alternatives to those programs or procedures; ***or***
  - iv. possible changes in methods or levels of payment for benefits or services under those programs; ***and***
- b. The research could not practicably be carried out without the waiver or alteration.

**C. Requesting a Waiver of Consent**

Requests for a partial or full waiver of informed consent must be submitted to the IRB in the initial submission.

## **VII. IRB Review**

The IRB will review the consent process or waivers in accordance with the requirements outlined in this procedure. Informed consent will be sought from each prospective participant or their legally authorized representative, in accordance with, and to the extent required by this policy and federal regulations and this will be a criteria for approval of all new research studies and continuing studies.

The non-scientific members of the IRB have the expertise of representing the average research participant and such bring this perspective to the IRB deliberations. All members, but especially non-scientific IRB members, are asked to consider whether the consent requirements have been met and are appropriate for the community that comes to THMA.

When an electronic informed consent will be used in research, the IRB will review the usability of the eIC materials to ensure that they are easy to navigate, including any hyperlinks. The IRB will review the contents to which participants are referred in order to determine if the study-related information is accurate and appropriate. The IRB must maintain the version of the Web site information that contains the study-related information that the IRB reviewed and approved, either electronically or as a hard copy, as website information changes over time (45 CFR 46.115 and 21 CFR 56.115).

## **RESPONSIBLE DEPARTMENT**

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

## **RELATED PROCEDURES AND OTHER MATERIALS**

MEDICAL CARE AVAILABILITY AND REDUCTION OF ERROR (MCARE) ACT of 2002, Chapter 5, Section 504. Informed Consent

<https://www.health.pa.gov/topics/Documents/Laws%20and%20Regulations/Act%2013%20of%2002002.pdf>

## **APPROVALS**

**Initial Approval:** September 25, 2020

**Subsequent Review/Revision(s):** April 28, 2023