Waiver, Alterations, and Exceptions to Informed Consent; Waiver of Documentation of Informed Consent

POLICY:

It is The Christ Hospital policy that no investigator may involve a human being as a subject in research before the investigator has obtained and documented the legally effective informed consent of the subject or the subject’s legally authorized representative as set forth in Federal regulations (45 CFR 46.116(a)).

Federal regulations under 45 CFR 46.116(c) allows a waiver under special circumstances. The Christ Hospital IRB (TCH IRB) may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in 45 CFR 46.116(a), or waive the requirement to obtain informed consent provided the that the regulations set forth in 45 CFR 46.116(c) are met.

However, for investigations subject to FDA jurisdiction, the FDA has made no provision for waiver of informed consent by the IRB. Therefore, research subject to FDA regulation will include an informed consent process unless the research qualified for an FDA exception. The IRB may waive documentation of informed consent in accordance with FDA regulations and this policy. (Also see SOP 1.10, Emergency Use Exemption, if applicable.)

For non-FDA-regulated research, the IRB may waive or alter informed consent requirements only if it finds and documents the criteria listed in 45 CFR 46.116(c) or (d) are satisfied as well as any other applicable regulations of sponsoring federal agencies and state and local laws and regulations.

The IRB may waive the requirement for the investigator to obtain a signed informed consent document for some or all subjects if it finds that: (45 CFR 45.117(c))

- The only records linking the subject and the research would be the consent document; the principal risk would be potential harm resulting from a breach of confidentiality; and the research is not regulated by the FDA. Each subject will be asked whether he/she wants documentation linking the subject with the research, and his/her wishes will govern; or
- The research meets the FDA requirements for emergency research under 21 CFR 50.24 (see SOP 1.10, Emergency Use); or
- The research presents no more than minimal harm to subjects and involves no procedures for which written consent is normally required outside of the research context.
When documentation requirements are waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

**PROCEDURE**

**Investigator:**
- Completes and submits the appropriate form to the IRB to request waiver of:
  - Informed Consent (Form: Waiver of Informed Consent)
  - Informed Consent Documentation (Form: Waiver of Informed Consent Documentation)
  - HIPAA Waiver Authorization: (Form: HIPAA Request for Full or Partial Waiver to Individual Authorization)

**IRB Chair or Experienced Designee/IRB:**
(This process may be done by expedited review, with presentation to the next full board meeting for their information. Or, the Chair may determine that the full board must make the determination.)

- Reviews research that proposes a waiver or alteration of the consent documentation;
- Reviews a proposed consent procedure which does not include, or which alters, some or all of the requirements of informed consent process set forth in the federal regulations (45 CFR 46.116 (a) and (b)); or
- Waives the requirement to obtain informed consent provided the IRB finds and documents that:
  - 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: (45 CFR 46.116(c));
    - Public benefit or service programs;
    - Procedures for obtaining benefits or services under those programs;
    - Possible changes in or alternatives to those programs or procedures;
    - Possible changes in methods or levels of payment for benefits or services under those programs;
  - The research could not practicably be carried out without the waiver or alteration; and
  - The research is not subject to FDA regulation.
- Reviews and approves a consent procedure which does not include, or which alters, some or all of the elements of informed consent, or waive the requirements to obtain informed consent provided the IRB finds and documents that (45 CFR 46.116(d)):
  - The research involves no more than minimal risk to the participants;
  - The waiver or alteration will not adversely affect the rights and welfare of the participants;
  - The research could not practicably be carried out without the waiver or alteration;
Whenever appropriate, the participants will be provided with additional pertinent information after participation;
The research is not subject to FDA regulation.

- When the IRB waives documentation of informed consent process:
  
  - All of the following must be true when waiving the requirement for the investigator to obtain a signed informed consent document for some or all of the participants (45 CFR 46.117(c)(1):
    - The only record linking the participant and the research would be the consent document;
    - The principal risk would be potential harm resulting from a breach of confidentiality;
    - Each participant will be asked whether the participant wants documentation linking the participant with the research, and the participant’s wishes will govern;
    - A written statement describing the research will be provided to participants (e.g., copy of consent document, study information sheet);
    - The research is not subject to FDA regulations;
  
  - Or all of the following are true (45 CFR 46.117(c)(2)) (21 CFR 56.109(c)(1)):
    - The research presents no more than minimal risk of harm to participants;
    - The research involves no procedures for which written consent is normally required outside of the research context.
  
  - The IRB Chair completes the waiver form and gives a copy to the PI stating whether or not the waiver/alteration to consent was approved, and documents the protocol-specific reasons that the waiver(s) meet or do not meet the criteria of the applicable federal regulations.

**IRB Coordinator:**
- If reviewed by full IRB, ensures the IRB discussions and findings address the necessary federal regulation requirements as listed above;
- If reviewed by full IRB, documents in the minutes that the IRB approved or denied a waiver or alteration of the consent process, or approved or denied a waiver of the requirement to document consent;
- Sends correspondence to the PI confirming or denying approval of waiver or alteration of consent as directed by the IRB Chair or designee.

**REVISION HISTORY:**

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Policies/SOP 3.15 Waiver of consent