The Christ Hospital IRB
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(II.3.G)

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STANDARD OPERATING PROCEDURE

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 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 and 21 CFR 50.27, as applicable).

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 at 21 CFR 56.109(c)(1) 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 and documents the criteria listed in 45 CFR 45.117(c) or in 21 CFR 56.109(c)(1) for FDA-regulated research, as well as any other applicable regulations of sponsoring federal agencies and state and local laws and regulations. When documentation requirements are waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

PROCEDURE

Investigator:
The investigator must complete and submit the appropriate request in the study application form requesting the IRB waive or alter the informed consent requirement or waive documentation of informed consent.

IRB Chair or Experienced Designee/IRB:
The following review may be done by expedited review, with presentation to the next full board meeting for their information, or the Chair/designee may determine that the full board must review and make the determination.

Waiver or Alteration of Informed Consent

The reviewer must determine and document the following (45 CFR 46.116(d)):

i. The research involves no more than minimal risk to the participants;
ii. The research could not practicably be carried out without the waiver or alteration;
iii. 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;
iv. The waiver or alteration will not adversely affect the rights and welfare of the participants; and
v. Whenever appropriate, the participants will be provided with additional pertinent information after participation.

Note: The research must not be subject to FDA regulations.

Waiver of Documentation of Informed Consent

If the research is non-FDA regulated (45 CFR 46.117(c)(1)), the reviewer must determine and document that all of the following are true when waiving the requirement for the investigator to obtain a signed informed consent document for some or all of the participants:

i. The only record linking the participant and the research would be the consent document;
ii. The principal risk would be potential harm resulting from a breach of confidentiality;
iii. Each participant will be asked whether the participant wants documentation linking the participant with the research, and the participant's wishes will govern;
iv. A written statement describing the research will be provided to participants (e.g., copy of consent document, study information sheet); and
v. If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

If the research is FDA regulated (21 CFR 56.109(c)(1), the reviewer must determine and document that all of the following are true when the requirement that the subject, or the subject's legally authorized representative:

i. The research presents no more than minimal risk of harm to participants; and
ii. The research involves no procedures for which written consent is normally required outside of the research context.

IRB Office:
After the review process, the IRB Office performs the following:

If reviewed by the expedited mechanism

- Ensures the reviewer checklist addresses the necessary federal regulation requirements as listed above and documents the approval in the study approval letter and files all documentation in the study file.
- Sends approval letter to the PI confirming approval of waiver or alteration of consent as directed by the IRB Chair or designee.

If reviewed by the full board

- Ensures the IRB discussions and findings address the necessary federal regulation requirements as listed above and 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.

REVISION HISTORY:

Date Revised	Reason For Change	Revised By
10/25/21	Reviewed and revised to include Revised Common Rule	Erica Jones