**The Christ Hospital IRB**
**Submitted By:** Erica Jones, CIP
**Reviewed By:** Steve Roberts, MD
**Approved By:** Steve Roberts, MD

**Number:** 3.15
**Effective Date:** 03/27/09
**Revised/Reviewed Date:** 01/23

**STANDARD OPERATING PROCEDURE**

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

## 1.0 PURPOSE

In certain situations, the IRB may waive or alter the informed consent process in accordance with laws, regulations, codes, and guidance. This policy establishes the procedure by which the IRB may approve an informed consent process that waives the requirement to obtain informed consent, alters some or all of the elements of informed consent, and/or waives the requirement to document informed consent.

## 2.0 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; 21 CFR 50.27). However, federal regulations allow for a waiver under special circumstances (45 CFR 46.116(f); 21 CFR 56.109(c)). 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 (45 CFR 46.116(a),(b), and (c); 21 CFR 50.25), and waive the requirement to obtain informed consent provided that the pertinent regulations are met (45 CFR 46.116(f); 21 CFR 56.109(c)).

### 2.1 Non-FDA Regulated Research

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

#### 2.1.1 Requirements for Waiver and Alteration

In order for an IRB to waive or alter consent, the IRB must find and document that:

**2.1.1.1** The research involves no more than minimal risk to the subjects;
**2.1.1.2** The research could not practicably be carried out without the requested waiver or alteration;
**2.1.1.3** 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;
**2.1.1.4** The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
**2.1.1.5** Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

Ref. 45 CFR 46.116(f)(3)

**2.2 Research Subject to FDA Requirements**

For investigations under the jurisdiction of the FDA, the FDA has provided guidance on regulations governing informed consent for studies that involve no more than minimal risk to human subjects for which obtaining informed consent is not practicable. The IRB may therefore approve a consent procedure that does not include, or that alters, some or all of the elements of informed consent as set forth in 21 CFR 50.25, or waive the requirements to obtain informed consent when the IRB finds and documents that such approval is supported by requirements noted in 2.1.1 above. (Ref. FDA Guidance: IRB Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More than Minimal Risk to Human Subjects; III. Discussion, page 3)

The IRB shall require documentation of informed consent in accordance with 21 CFR 50.27 except as follows:

a. The IRB may, for some or all subjects, waive the requirement that the subject, or the subject's legally authorized representative, sign a written consent form if it finds that the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context;
- or -
b. The IRB may, for some or all subjects, find that the requirements in 21 CFR 50.24 for an exception from informed consent for emergency research are met. Ref. 21 CFR 56.109(c); SOP 1.10 Emergency Use Exemption

**2.2.1 Waiver of Documentation of the Consent Process – Consent Normally Not Required**

In cases where documentation is waived where consent is normally not required outside the research context, the IRB shall require that:

**2.2.1.1** The oral or written information provided to subjects includes all required and appropriate additional elements of consent disclosure.

**2.2.1.2** The IRB determines whether the investigator should provide subjects with a written statement regarding the research (21 CFR 56.109(d)).

**2.3 Waiver of Documentation of the Consent Process: Screening, Recruiting, and 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 subject or the subject's legally authorized representative, if the following conditions are met:

**2.3.1** The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, or

**2.3.2** The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens, and

Ref. 45 CFR 46.116(g)(1) and (2)

### 2.4 Public Demonstration Projects

A waiver or alteration of the consent process may be requested for a public demonstration project conducted or approved by state or local government officials. The following criteria apply:

**2.4.1** The research is conducted by or approved by state or local government officials

**2.4.2** The research or demonstration project is designed to study, evaluate, or otherwise examine:

**2.4.2.1** Public benefit or service programs

**2.4.2.2** Procedures for obtaining benefits or services under those programs

**2.4.2.3** Possible change in or alternatives to those programs or procedures

**2.4.2.4** Possible changes in methods or levels of payment for benefits or services under those programs

**2.4.3** The research cannot practicably be carried out without the waiver or alteration

**2.4.4** The research is not regulated by the FDA

## 3.0 PROCEDURE & RESONSIBILITIES

### 3.1 Investigator

The investigator must complete and submit in the study application the request that the IRB waive or alter the informed consent requirement or waive documentation of informed consent.

### 3.2 IRB Chair or Experienced Designee

The following review may be done by the expedited review process with presentation to the next full board meeting for information purposes, or the Chair/designee may determine that the full board must perform the review and make the determination.

#### 3.2.2 Waiver or Alteration of Informed Consent

The reviewer must determine and document that:

**3.2.2.1** The research involves no more than minimal risk to the subjects;

**3.2.2.2** The research could not practicably be carried out without the waiver or alteration;

**3.2.2.3** 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;

**3.2.2.4** The waiver or alteration will not adversely affect the rights and welfare of the participants; and

**3.2.2.5** Whenever appropriate, the participants will be provided with additional pertinent information after participation.

Ref. 45 CFR 46.116(f)(3)

#### 3.2.3 Waiver of Documentation of Informed Consent

##### 3.2.3.1 Non-FDA Regulated Research

If the research is non-FDA regulated, the reviewer must determine and document that all 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:

a. That the only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;
b. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; or
c. 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.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects or legally authorized representatives with a written statement regarding the research.

Ref. 45 CFR 46.117(c)

**3.2.3.2 FDA Regulated Research**

For FDA regulated research, in order to waive requirements for documentation of informed consent for some or all subjects, or the subject's legally authorized representative, the reviewer must determine and document that all of the following are true:

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

Ref. 21 CFR 56.109(c)(1)

## 3.3 IRB Office

### 3.3.1 Expedited Review

If reviewed by the expedited procedure, the IRB office shall:

**3.3.1.1** Ensure that 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

**3.3.1.2** Send approval letter to the PI confirming approval of waiver or alteration of consent as directed by the IRB Chair or designee

### 3.3.2 Full Board Review

If reviewed by the full board procedure, the IRB office shall:

**3.3.2.1** Ensure that 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

**3.3.2.2** Send correspondence to the PI confirming or denying approval of waiver or alteration of consent as directed by the IRB

## 4.0 DOCUMENTS

FDA Guidance: IRB Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More than Minimal Risk to Human Subjects

## 5.0 DEFINITIONS

Not Applicable

## 6.0 REFERENCES

**6.1** Standard Operating Procedures: SOP 1.10 Emergency Use Exemption

**6.2** Code of Federal Regulations: 45 CFR 46.116, 45 CFR 46.117(c), 21 CFR 50.24, 21 CFR 50.25, 21 CFR 50.27, 21 CFR 56.109(c)

**6.3** AAHRPP Standards: II.3.G