The Christ Hospital IRB
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Number: 3.15
Effective Date: 03/27/09
Revised/Reviewed Date: 11/24

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. However, federal regulations allow for 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, waive the requirement to obtain informed consent, and/or waive the requirement to document informed consent provided that the pertinent regulations are met.

2.1 Waiver or Alteration of Informed Consent

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) and 21 CFR 50.22 are satisfied as well as any other applicable regulations of sponsoring federal agencies and state and local laws and regulations. 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.

2.2 Waiver for Screening, Recruiting, and Determining Eligibility

The 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 in accordance with 45 CFR 46.116(g), if either of the following conditions are met:

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

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

2.3 Waiver of Documentation of Consent under HHS regulations

The IRB may waive the requirement for the investigator to obtain a signed informed consent form for some or all subjects in accordance with federal regulations at 45 CFR 46.117(c)(1) if it finds any of the following:

2.3.1 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;

2.3.2 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 –

2.3.3 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.

2.3.4 Waiver of Documentation of Consent under FDA Regulations

The IRB may waive the requirement for the investigator to obtain a signed informed consent form for some or all subjects in accordance with FDA regulations at 21 CFR 56.109(c) if it finds any of the following:

2.3.4.1 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 –

2.3.4.2 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. Refer to TCH IRB SOP 1.10 Emergency Use Exemption.

In cases where documentation is waived under 21 CFR 56.109(c)(1), as outlined in 2.3.4.1 above, the IRB may require under 21 CFR 56.109(d) that:

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

2.3.4.4 The IRB determines whether the investigator should provide subjects with a written statement regarding the research.

2.3.5 Waiver Alteration of Consent for Public Demonstration Projects

The IRB may waive or alter the requirement to obtain informed consent for research involving public benefit and service programs conducted by or subject to the approval of state or local officials of the consent process may be requested for a public demonstration project conducted or approved by state or local government officials in accordance with federal regulations at 45 CFR 46.116(e) if it find and documents the following criteria:

2.3.5.1 The research or demonstration project is (1) conducted by or subject to approval by state or local government officials, (2) not regulated by the FDA, and (3) is designed to study, evaluate, or otherwise examine the following:

2.3.5.1.1 Public benefit or service programs;

2.3.5.1.2 Procedures for obtaining benefits or services under those programs;

2.3.5.1.3 Possible change in or alternatives to those programs or procedures;

2.3.5.1.4 Possible changes in methods or levels of payment for benefits or services under those programs.

2.3.5.2 The research cannot practicably be carried out without the waiver or alteration.

2.0 PROCEDURE & RESONSIBILITIES

3.1 Investigator

The investigator must request that the IRB waive or alter the informed consent requirement or waive documentation of informed consent in the e-application.

3.2 IRB Chair or Experienced Designee

The following review may be performed through an expedited review process and provided for convened IRB's awareness in the next Exempt/Expedited Report (Chairman's Report), or the Chair/designee may determine that the convened board must perform the review and make the determination. (Ref. 45 CFR 46.116(f)(3); 21 CFR 50.22).

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.

3.2.3 Waiver of Documentation of Informed Consent

3.2.3.1 Non-FDA Regulated Research

If the research is not subject to FDA regulation, the reviewer must determine and document that all the following are true in accordance with federal regulation at 45 CFR 46.117(c) when waiving the requirement for the investigator to obtain a signed informed consent document for some or all of the participants:

3.2.3.1.1 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;

3.2.3.1.2 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

3.2.3.1.3 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.

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 in accordance with FDA regulation at 21 CFR 56.109(c)(1), the reviewer must determine and document that all of the following are true:

3.2.3.2.1 The research presents no more than minimal risk of harm to participants; and

3.2.3.2.2 The research involves no procedures for which written consent is normally required outside of the research context.

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.

3.3.1.2 Generate an approval letter and send to the PI confirming approval as directed by the IRB Chair or designee.

3.3.1.3 Ensure the approval is documented accordingly when generating the approval letter.

3.3.1.4 Ensure all documentation is contained within the study record.

3.3.1.5 Include the approval on the next Exempt/Expedited Report (Chairman's Report) for IRB awareness at the next convened meeting.

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 Generate correspondence and send to the PI confirming approval or disapproval as directed by the convened IRB.

3.3.2.3 Ensure the approval/disapproval is documented accordingly when generating the approval letter.

3.3.2.4 Ensure all documentation is contained within the study record.

3.0 REFERENCES

4.1 Standard Operating Procedures: SOP 1.10 Emergency Use Exemption

4.2 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); 21 CFR 50.22

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

4.4 AAHRPP Standards: II.3.G