The Christ Hospital IRB
Submitted By: Erica Jones, CIP
Reviewed By: Steve Roberts, MD
Approved By: Steve Roberts, MD
(II.3.F, II.4.B, III.1.F)

Number: 2.02
Effective Date: 1/09/09
Revised/Revised Date: 09/22

STANDARD OPERATING PROCEDURE

Informed Consent: Elements, Process and Documentation

POLICY:

It is The Christ Hospital's policy that research may not include human subjects without the informed consent of the subject or his/her legally authorized representative unless a recognized exception or waiver applies under federal regulations. (See TCH IRB SOP 3.15, *Waiver of Informed Consent*) An investigator will seek informed consent in accordance with federal regulations at 45 CFR 46.116 and, if applicable, 21 CFR 50.20, 50.25 and any applicable regulations of the sponsor unless the IRB grants a waiver of informed consent in accordance with 45 CFR 46.116(f)(1), 45.116(d) and, if applicable 21 CFR 50.23(d), 50.23(e), 50.24 and DHHS waiver for emergency research at 61 FR 51531, or any applicable regulations of the sponsor. Also, an investigator will document informed consent in accordance with 45 CFR 46.117 and, if applicable, 21 CFR 50.27 or other applicable regulations of the sponsor unless the IRB waives documentation of informed consent in accordance with 45 CFR 46.117(c)(1), and if applicable, 21 CFR 56.109(c), 56.109(d), or other regulations of the sponsor. The principal investigator is responsible for ensuring informed consent is obtained from each subject before the subject participates in a research study. Although the principal investigator may delegate duties for obtaining informed consent to other members of the research team, he/she remains ultimately responsible for the informed consent process.

If consent or documentation of consent has not been waived by the IRB, in order to approve research, the IRB will determine that informed consent will be sought from each prospective subject or his/her legally authorized representative and appropriately documented in accordance with and to the extent required by federal regulations at 45 CFR 46.111, 46.116 and 46.117; and 21 CFR 50.20, 50.25, 50.27 and 56.111, if applicable, and any applicable regulations of the sponsoring agency. The IRB will determine whether additional information to that required by federal regulations should be included in the informed consent process in accordance with 45 CFR 46.109(b), and whether any other disclosures should be included in the informed consent process as required by other federal, state or local laws or regulations for the informed consent process to be legally effective. All IRB determinations under this policy will be made at the time of initial review, continuing review and review of modifications to research.

Additional Safeguards for Vulnerable Groups: In addition to the other responsibilities described in this policy, the IRB and investigators will employ additional safeguards to preserve the informed consent process when some or all subjects are likely to be vulnerable to coercion or undue influence. The IRB will systematically evaluate, at the time of initial review, continuing review, and review of modifications to research, whether the research involves subjects likely to be vulnerable to coercion or undue influence and will consider appropriate

additional safeguards for the informed consent process. Research will incorporate safeguards for pregnant women, fetuses and neonates in accordance with 45 CFR Part 46, subpart B, and if applicable, any applicable regulations of sponsoring agencies. (Note: The Christ Hospital does not engage in research on prisoners.)

Where federal regulations or guidance exist to provide standards for safeguards to preserve the informed consent process for subjects vulnerable to coercion or undue influence, such safeguards will conform to specific institutional policy and procedure or, when no institutional policy and procedure exists, written procedures developed by the IRB. IRB procedures developed for the informed consent process in vulnerable groups will take into account the decision-making capacity of subjects; likely circumstances producing coercion or undue influence; the magnitude of the effect on subjects' ability to knowingly and voluntarily consent; appropriate options to neutralize coercive or undue effects; and, if subjects are unable to give legally effective consent, that adequate provisions are made for soliciting the assent of the subjects and the permission of their legally authorized representatives. (See TCH IRB SOP 3.18, *Additional Safeguards for Decisionally Impaired Adults in Research*.) The IRB or IRB Chair may authorize an IRB staff member, or a disinterested third party, to observe the informed consent process. This may typically be requested if the study is felt to have more than minimal risk involved, or if the study has the potential to enroll vulnerable populations. This observation may only be performed with the consent of the research subject. [45 CFR 46.109(e); 21 CFR 56.109(f)]

Illiterate English-Speaking Subjects: A person who speaks and understands English, but does not read and write, can be enrolled in a study by "making their mark" on the consent document, when consistent with applicable state law. A person who can understand and comprehend spoken English, but is physically unable to talk or write, can be entered into a study if they are competent and able to indicate approval or disapproval by other means. If 1) the person retains the ability to understand the concepts and risk and benefit of being in the study when it is explained verbally (still competent) and, 2) can indicate approval or disapproval to study entry, they may be entered into the study. The consent form should document the method used for communication with the prospective subject and the specific means by which the prospective subject communicated agreement to participate in the study. An impartial third party should witness the entire consent process and sign the consent document. A video tape recording of the consent interview is recommended.

PROCEDURE:

Investigator:

1. At the time of initial IRB submission, submits the e-application having completed the appropriate sections describing the consent process including:

    - which individuals are authorized to conduct informed consent discussions with subjects
    - when and where may informed consent be obtained

- how much time will be given to subjects to consider participation in the research (Note: Adequate time should be provided for the potential participant to read the informed consent document and consider the risks and benefits prior to signing. If consent is obtained the same day that the subject's involvement in the study begins, the subject's medical record/case report form should document that consent was obtained prior to participation in the research.)
- how it will be determined if the subject understands the information provided
- how consent will be handled when a human subject's decision-making capacity is in question
- any information to be disclosed to participants to meet the requirements for informed consent process that is NOT exhibited in the proposed informed consent documents
- any additional safeguards added to the informed consent process to protect vulnerable populations from undue influence and coercion, if applicable
- requesting a waiver or alteration of informed consent requirements, including documentation, when appropriate (see TCH IRB SOP 3.15, *Waiver of Informed Consent*)
- identifying and requesting exceptions to informed consent process, as appropriate, for clinical investigation subject to FDA regulation (see TCH IRB SOP 1.10, *Emergency Use*)
- requesting approval for the use of a Legally Authorized Representative (LAR) to consent on a subject's behalf, if appropriate for the subject population. Note: IRB-approval is required for the use of Legally Authorized Representatives (LAR's).

2. Also at the time of initial IRB submission, submits the proposed informed consent document(s) including, but not limited to, the following requirements for informed consent process unless a waiver or exception of informed consent process requested (See *TCH IRB Informed Consent Template*):

    - Basic elements of consent in accordance with federal regulations at 45 CFR 46.116(a) and, if applicable, 21 CFR 50.20.
    - Additional elements of consent, when appropriate, in accordance with federal regulations at 45 CFR 116(c).
    - Use simple language at the appropriate reading and comprehension level, or that is appropriate to the specific subject population. (approximately 6th grade reading level for adult consent documents). Avoid the use of replace complicated or medical/technical language with lay language to ease subject comprehension.

3. At the time of consent, performs the following:

    - Verifies, when applicable, that an LAR meets the order of priority for granting permission for participation of the proposed research participant.

    - Obtains signatures and dates of signature on informed consent document for the following individuals unless the IRB has waived documentation of informed consent process:
        - Participant or LAR, if applicable.

        - Witness/Person obtaining informed consent. (Note: In the case of illiterate subjects, an impartial third party should witness the entire consent process and also sign the consent document.)

- Gives a copy of the signed IRB-approved informed consent document to the individual who signed the form (participant or LAR, as applicable, unless waived by the IRB).

- Supplies copy of signed informed consent document to performance sites in accordance with the performance site's policy.

- Keeps original signed consent form in the subject's research file.

- Unless the research falls within the purview of the Food and Drug Administration, the investigator is responsible for retaining the signed consent and documents for at least three years after termination of IRB approval and closure of the protocol.

- For research that falls under FDA authority, the investigator is responsible for retaining the signed documents for the period specified in the applicable FDA regulations.

- Submits any revisions to the informed consent process or documents to the IRB for review and approval using the amendment/modification procedure (SOP 2.03 Proposed Modifications/Amendments in Previously Approved Research Studies).

IRB Chair:

Initial Review of Consent Processes

- Reviews submissions to assess if sufficient information on the proposed informed consent process and documentation for informed consent has been provided for convened IRB review and requests additional information if necessary.

- Examines submissions for requests for waiver of informed consent, waiver of consent documentation, or HIPAA partial waiver request (see TCH IRB SOP 3.15 *Waiver of Informed Consent*)

- Reviews all informed consent documents submitted for IRB review for required and additional elements, as appropriate.

- Requests additional information, as needed, to the protocol or informed consent documents, and drafts correspondence to the investigator requesting this information.

Initial Expedited Review of Consent Processes

- Reviews submissions to assess if sufficient information on the proposed informed consent process and documentation for informed consent has been provided for convened IRB review and requests additional information if necessary.

- Examines submissions for requests for waiver of informed consent, waiver of consent documentation, or HIPAA partial waiver request (see TCH IRB SOP 3.15 *Waiver of Informed Consent*)

- Reviews all informed consent documents submitted for IRB review for required and additional elements, as appropriate.

- Requests additional information, as needed, to the protocol or informed consent documents, and drafts correspondence to the investigator requesting this information.

Expedited Review of Minor Modifications to Consent Documents of Previously Approved Research

- Reviews minor modifications to the informed consent documents by the expedited procedure or refers for review by the convened IRB (see TCH IRB SOP 2.03 *Proposed Proposed Modifications/Amendments in Previously Approved Research Studies*)

Consent Observations

- May request that an observation of obtaining informed consent be performed by a member of the IRB staff or by a third party.

Convened IRB Responsibilities:

Initial Review of Consent Processes

- Reviews all informed consent documents for required and additional elements, as appropriate.

- Reviews the nature of the proposed participant population including vulnerable targeted populations.

- Assesses whether the purpose, risks and benefits in the informed consent accord with the research protocol.

- Reviews the circumstances under which the consent process will occur:
  - Personnel involved.
  - Manner and setting, and any waiting period involved.
  - Opportunities for exchange of information.

- Use of additional protections for informed consent for vulnerable populations:
  - For non-English speaking participants, a plan for involvement of a translator fluent in both English and participant's language.
  - Determines the request for the use of an LAR is justifiable for the subject population, if applicable.
  - Incorporation of consent procedures in accordance with policies and procedures for pregnant women and fetuses, and decisionally impaired adults as applicable.

- Any other procedures proposed to minimize coercion and undue influence.

- Approves the research only if the IRB determines and documents that the requirements for informed consent are satisfied by making the following findings unless the IRB waives or alters informed consent:
  - The informed consent process appears legally effective.
  - The informed consent process provides the participants ample opportunity to consider whether or not to participate.
  - The information given to the participant will be in language understandable to participants.
  - For non-English-speaking participants, this requires confirmation that translations of informed consent documents are certified by qualified personnel.
  - No exculpatory language is present in which the participant waives or appears to waive legal rights.
  - The informed consent process minimizes risk to coercion and undue influence including use of additional protections for vulnerable targeted populations.
  - The informed consent disclosures accurately portray the purpose, risks and benefits of the study.

- Approves the research only after determining that the requirements for documentation of informed consent are satisfied (unless the IRB waives documentation of informed consent) by assuring that:
  - The written informed consent document embodies the elements and disclosures of informed consent.
  - The informed consent provides for the document to be signed and dated by the participant, witness, and if applicable the investigator.
  - The study gives the participant adequate time to read the consent.
  - The consent states that a signed copy will be given to the person signing the form.

- Reviews all amendments to the informed consent process or documentation of informed consent process that potentially changes the risk-benefit ratio to participants and determines whether information affects participants' willingness to participate and, if so, the appropriate manner to inform participants.

IRB Office:

- Prepares and sends correspondence as directed by the IRB Chair requesting more information, or granting approval, of informed consent documents reviewed by expedited review.

- Prepares and sends correspondence, as outlined in the IRB meeting minutes, granting approval, or requesting modifications, to the informed consent document reviewed by the IRB.

- Issues the informed consent documents with the current IRB approval stamp and date of expiration. The informed consent bearing the approval stamp must be used when consenting participants.

- Provides the stamped approved informed consent documents and appropriate correspondence.

- If directed to perform an observation of obtaining informed consent, schedules this with the Investigator and reports back to the IRB of findings, assuring that there is no identification of the patient.