

The Christ Hospital IRB

Submitted By: Erica Jones, CIP

Reviewed By: S. Roberts, MD & M. Jennings, MD

Approved By: Steve Roberts, MD

(II.2.D, II.2.E.)

Number: 2.03

Effective Date: 11/08

Reviewed/Revised Date: 03/17

STANDARD OPERATING PROCEDURE

Proposed Modifications/Amendments in Previously Approved Research Studies

POLICY:

Modification means proposed changes in the conduct of the study that may affect the protection of human subjects. Minor changes proposed for previously approved research may be reviewed in an expedited procedure by the IRB Chair in accordance with 45 CFR 46.110 and 21 CFR 56.110. Any significant modifications or amendments to IRB-approved protocols must be approved by the full Board at a convened meeting, and the modifications to the protocol or consent form may not be implemented until approval is granted. The only exception is when a change is necessary to eliminate apparent immediate hazards to the research subjects.

Unanticipated risks to subjects or new information that may affect the risk-benefit assessment must be promptly reported to, and reviewed by, the IRB to ensure adequate protection of human subjects. (See Section 3.0 of the IRB Reference Manual for detailed information on reporting modifications.)

REFERENCE:

45 CFR 46.110; 21 CFR 56.110

PROCEDURE:

INVESTIGATOR:

1. Major Modifications: Original plus 17 copies of the request for approval of the modification or amendment must be submitted to the IRB chairman. The request should include the following:
 - TCH IRB number.
 - Exact title of the protocol as originally submitted to the IRB.
 - Complete description of the nature of the changes.
 - If modifications necessitate a change in the consent form, a revised consent form with the revisions underlined or highlighted (on all copies) must be submitted.
2. Minor Modifications: Minor changes, amendments or administrative modifications may be reviewed on an expedited review basis. Approval may be granted by the Chairman and/or a designated representative, unless the reviewer(s) determine the nature of the

proposed changes warrants a review by the full Board. The investigator is notified in writing of the Board's decision.

3. A change in principal investigator or addition of co-investigators must be reported to the IRB. A new investigator must fill out a financial disclosure form and must have taken the CITI course within the last 3 years in order to be added to the study. If the Investigator plans to leave The Christ Hospital and intends to continue the research activities at another institution, the researcher must notify the IRB office so the active file can be closed.
4. If the research study is expected to extend beyond the period of time initially approved by the IRB, then the investigator should submit a request for an extension of time to the IRB Chairman.

IRB CHAIR OR BOARD:

Minor Modifications:

1. IRB Chair will stamp the modification as:
 - a. Approved; forwards to IRB coordinator to draft correspondence to investigator giving notification of approval.
 - b. Reviewed, but needs full board consideration; forwards to IRB coordinator to add to next full board meeting agenda for review and approval.

Major Modifications:

1. Full board approval is required. Copies are distributed to IRB board members with IRB packet approximately 2 weeks prior to next convened meeting.
2. Discussion will be documented in the minutes, and correspondence sent to the PI indicating action taken.

IRB COORDINATOR:

Minor Modifications:

1. Stamps cover sheet/letter with date stamp and forwards to IRB Chair for review/approval.
2. Sends correspondence to PI as directed by IRB Chair, indicating decision.
3. Copies are available, upon request, to any IRB member.

Major Modifications:

1. Adds modifications to agenda for next convened IRB meeting.
2. Distributes copies of the major modifications/amendments to the IRB board members with the IRB packet, approximately 2 weeks prior to convened meeting.
4. Records in meeting minutes discussion and decision on modifications.
5. Composes and sends correspondence to PI of the IRB's decision, with IRB Chair's approval.

REVISION HISTORY:

Date Revised	Reason For Change	Revised By
4/23/15	Added submission details when adding a new investigator to a study	Becky