The Christ Hospital IRB
Submitted By: Erica Jones, CIP
Reviewed By: S. Roberts, MD
Approved By: Steve Roberts, MD
(II.2.E.3; II.2.F.3)

Number: 2.03
Effective Date: 11/08
Reviewed/Revised Date: 09/22

STANDARD OPERATING PROCEDURE

Proposed Amendments/Modifications 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 Amendments/Modifications: The request for approval of the amendment or modification must be submitted into Mentor IRB. The request should include the following:
    - Complete description of the nature of the changes.
    - If modifications necessitate a change in the consent form, a tracked changes revised consent form must be submitted.

2. Minor Amendments/Modifications: The request for approval of the amendment or modification must be submitted into Mentor IRB. 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. In that instance, the investigator is notified that the review requires full board

review in writing and subsequently will be notified of the Board's decision in writing. Examples of minor modifications may include:

- Any changes (addition or removal) of investigators or research staff engaged in human subjects research. For key research personnel additions: The key research personnel must complete a FCOI disclosure and must remain current (taken within the last 3 years) on their required CITI course modules to be considered to be added to the study.
- The addition of research activities to exempt or minimal risk research
- An increase or decrease in proposed human research subject enrollment supported by a statistical justification.
- Narrowing the range of inclusion criteria
- Broadening the range of exclusion criteria
- Decreasing the number or volume of biological sample collections, provided that such a change does not affect the collection of information related to safety evaluations
- An increase in the length of confinement or number of study visits for the purpose of increased safety monitoring
- A decrease in the length of confinement or number of study visits, provided that such a decrease does not affect the collection of information related to safety evaluations
- Alterations in human research subject payment or liberalization of the payment schedule with proper justification
- Changes to improve the clarity of statements or to correct typographical errors, provided that such a change does not alter the content or intent of the statement
- The addition or deletion of study sites
- Minor changes specifically requested by the IRB
- Requests to extend the study beyond the period of time initially approved by the IRB

IRB CHAIR OR BOARD:

Minor Amendments/Modifications:

1. IRB Chair will review the modification utilizing the Expedited Amendment Reviewer Checklist in Mentor IRB and make one of the following determinations:
    a. Approved; forwards to IRB coordinator to draft correspondence to investigator giving notification of approval.
    b. Approved with modifications
    c. Reecommend to full board for review

Major Amendments/Modifications:

1. Full board approval is required.
2. Discussion will be documented in the minutes, and correspondence sent to the PI indicating action taken.

IRB OFFICE STAFF:

Minor Amendments/Modifications:

1. Ensures that the submission is complete and assigns to the IRB Chair for review.
2. Sends correspondence to PI as directed by IRB Chair, indicating the determination. Assigns the amendment to Exempt/Expedited Report Panel for the awareness of the convened board at the next scheduled meeting.

Major Amendments/Modifications:

1. Assigns the amendment to the Full Board Panel. This action places the protocol on the next meeting agenda for review.
2. Ensures that the submission is complete and is available in its entirety in Mentor IRB for IRB member review approximately two weeks prior to the convened meeting date
3. Records discussion and determinations on modifications in meeting minutes.
4. After the IRB Chair's initial approval of the meeting minutes, the IRB Office Staff communicates all IRB determinations through Mentor IRB in a notification letter sent to the Principal Investigator and any research coordinator(s) as outlined in SOP 1.04, IRB Meeting Minutes / Conducting IRB Meeting.