The Christ Hospital IRB
Section: 04
Effective Date: 01/07
Revised/Reviewed Date: 01/23
AAHRPP Element: II.2.E, II.5.B

IRB REFERENCE MANUAL
SECTION 04
INVESTIGATOR COMMUNCATIONS

4.0 INVESTIGATOR COMMUNICATIONS

4.1 IRB Submissions

The IRB utilizes a web-based IRB management system, Mentor IRB, for all submissions. Mentor IRB can be accessed through the following links:

4.2 IRB Office Communications

Investigators and research staff with active TCHHN credentials may log in using their single sign-on (SSO) credentials. The IRB Office can be reached for questions or consult by any of the following:

Email:	IRB_Office@thechristhospital.com
Telephone:	(513) 585-2298
Fax:	(513) 585-2107
In Writing:	The Christ Hospital IRB Office 2139 Auburn Ave., Room 3140 (3 North) Cincinnati, OH 45219

4.3 Written Communications of IRB Decisions

Decisions of the IRB will be communicated to the Principal Investigator (PI) and research coordinator through Mentor IRB in a notification letter outlining the approval status and/or the concerns, questions and/or comments of the IRB. Decisions from a full board meeting will be available the day following the meeting via verbal communication; however, written communications are not released until meeting minutes are reviewed and approved by the IRB chair. Written communication typically necessitates a period of three (3) working days from the IRB meeting date. **Initiation of the research study may not proceed until a written notification of final IRB approval has been received from the IRB office.**

Decisions of the IRB fall into one of the following categories:

4.3.1 Full Approval

The Principal Investigator may initiate the study upon written notification of full approval of the research protocol and (if applicable) the informed consent document by the IRB chair.

4.3.2 Approval with Minor Modifications

An Approval with Minor Modifications decision is conveyed when the protocol is recommended for approval by the IRB pending the investigator's response to IRB-directed changes. The PI must provide a response to the IRB's recommendations in Mentor IRB including any modified protocol and/or consent forms with the respective changes tracked. The response will be reviewed by the IRB chair or his/her designee. If the response is acceptable, the PI will receive written notification of IRB approval and may then initiate the study. Such notification is typically received by within 5-7 working days following receipt of the PI's response to the IRB's recommendations by the IRB Office. The date of approval is the date the modifications are determined to be met. If the research expires before the modifications are reviewed and approved, all research activities must stop until approval is obtained.

4.3.3 Approval Withheld Pending Major Clarifications and/or Modifications

When the IRB requests any additional information, clarifications or modifications which cannot be described as specific revisions requiring simple concurrence by the investigator, the investigator is sent a letter which includes a description of such revisions or clarifications requested by the IRB. For some studies, one or more members of the IRB may be designated to discuss reasons for the requests with the investigator. The convened IRB must then review the responsive materials subsequently submitted in Mentor IRB by the PI, or by the research coordinator on the PI's behalf. If the convened IRB approves the research based on the responsive materials, the approval date is issued as of the date of the IRB meeting in which the study was approved.

4.3.4 Tabled

This decision is conveyed when the IRB has a number of significant questions and concerns regarding the research protocol which could not be resolved at the IRB meeting. The Principal Investigator may not initiate the study until a response is received and the protocol reviewed at a subsequent full board meeting. The Principal Investigator must respond to the IRB's

concerns/comments, recommendations and/or questions in Mentor IRB. If the protocol and/or consent form is modified, the changes must be tracked. Unless otherwise requested by the Principal Investigator (e.g., timeframe necessitates review prior to next scheduled meeting), the reconsideration response will be scheduled for review by the full board committee that originally reviewed the research protocol. The Principal Investigator or designee may request to be present at the IRB convened meeting wherein his/her research protocol is being reconsidered for approval. If approval is granted after the reconsideration, the approval date will be the date of the IRB meeting during which the study was reconsidered (not the date of the meeting where the study was originally reviewed).

4.3.5 Disapproval

The IRB may disapprove a research protocol based on its identification of major scientific or ethical problems which, in the committee's opinion, cannot be readily resolved by the Principal Investigator. When a research protocol is disapproved by the IRB, the Principal Investigator is not authorized to initiate the study. In the case of IRB disapproval, a statement detailing reasons for the decision, as well as an opportunity for the investigator to respond in title of person or in writing, is provided through Mentor IRB. The Principal Investigator can respond to the IRB's concerns/comments, recommendations and/or questions in Mentor IRB. If the protocol and/or consent form is modified, the changes must be tracked. Unless otherwise requested by the Principal Investigator (e.g., timeframe necessitates review prior to next scheduled meeting), the reconsideration response will be scheduled for review by the full board committee that originally reviewed the research protocol. The Principal Investigator or designee may request to be present at the IRB convened meeting wherein his/her research protocol is being reconsidered for approval. If approval is granted after the reconsideration, the approval date will be the date of the IRB meeting during which the study was reconsidered (not the date of the meeting where the study was originally reviewed).