The Christ Hospital IRB
Section: 04
Effective Date: 01/02/07
Revised/Reviewed Date: 06/10/21
AAHRPP Element: II.5.B

IRB REFERENCE MANUAL
SECTION 04
INVESTIGATOR COMMUNICATIONS

4.0 INVESTIGATOR COMMUNICATIONS

4.1 IRB Submissions

Electronic delivery is the best method of assuring prompt submission to the IRB Office. Submissions may also be sent to the IRB Office mailing address.

The IRB Office can be reached at IRB_Office@thechristhospital.com.
The mailing address is:
The Christ Hospital IRB Office
2139 Auburn Ave., Room 3140 (3 North)
Cincinnati, OH 45219

4.2 IRB Telephone Communications

The following information should be readily available when telephoning the IRB Office at (513) 585-2298) to ascertain the status of a submitted protocol:

- The IRB number, if assigned
- The Principal Investigator's name
- Protocol title
- Date and type of submission

4.3 IRB Fax Communications

The following information should listed on the fax coversheet when faxing correspondence to the IRB office at (513) 585-2107:

- The IRB number, if assigned
- The Principal Investigator's name
- Protocol title
- Date and type of submission

4.3 Written Communications of IRB Decisions

Decisions of the IRB will be communicated to principal investigators through a letter outlining the approval status and/or the concerns, questions and/or comments of the IRB. Decisions from a full board meeting will be verbally available the next day, however written communications are not released until the minutes of the meeting are reviewed and approved by the Chair. The latter requirement 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 approval has been received from the IRB office.**

The decisions of the IRB will fall into one of the following categories:

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, from the IRB chair or co-chair.

2. **Approval with Modifications:** This decision is conveyed when the protocol is recommended for approval by the IRB pending the investigator's response to IRB-directed changes. The Principal Investigator must provide a memorandum responding to the IRB's recommendations and a modified protocol and/or consent form with the respective changes highlighted. The principal investigator's response will be reviewed by the IRB chair or his/her designee. If the response is acceptable, the principal investigator will receive (i.e., typically within 5-7 working days following receipt of the response by the IRB office) written notification of IRB approval, and may then initiate the study. The approval date will be the date of the convened meeting where the study was originally reviewed (not the date the modifications were reviewed by the chair).

3. **Approval Withheld Pending Major Clarifications and/or Modifications:** The IRB requests any additional information, any clarifications, or any modifications that cannot be described as specific revisions that require simple concurrence by the investigator. The investigator is sent a letter, which includes a description of the revisions or clarifications requested. For some studies, one or more members of the IRB may be designated to discuss the reasons with the investigator. The convened IRB must review the responsive materials. If the convened IRB approves the research based on the responsive materials, the following apply:

   Approval period: The approval date is issued as of the date of the IRB meeting in which the study was approved.

4. **Tabled:** This decision is conveyed when the IRB has a number of significant questions and concerns regarding the research protocol that 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 provide a memorandum responding to the IRB's concerns/comments, recommendations and/or questions. If the protocol and/or consent form is modified, the changes must be highlighted. 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 committee 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 where the study was reconsidered (not the date of the meeting where the study was originally reviewed).

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. When the IRB does not approve the research, a statement of the reasons for its decision and an opportunity for the investigator to respond in title of person or in writing is provided. The principal investigator can provide a memorandum responding to the IRB's concerns/comments, recommendations and/or questions. If the protocol and/or consent form is modified, the changes must be highlighted. 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 committee 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 where the study was reconsidered (not the date of the meeting where the study was originally reviewed).