

The Christ Hospital IRB

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(II.5.B)

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STANDARD OPERATING PROCEDURE

Complying with IRB Decisions

PURPOSE:

Some research projects involving human subjects require the submission of an Assurance of Compliance with HHS Regulations for the Protection of Human Research Subjects. Generally, these projects are those sponsored by the various federal agencies, i.e., NCI, NIH and DHHS/FDA. The Christ Hospital has a Federal Wide Assurance (FWA) on file with the Office of Human Research Protections (OHRP).

When implementing research activities, the investigator is responsible for complying with the IRB decisions, conditions and requirements as described below. After final IRB approval has been obtained, it is the investigator's responsibility to submit the proper certification to the sponsor/agency. The IRB Coordinator will provide necessary signatures when provided certification forms.

(Please see IRB Reference Manual Section 2.0 for more information on types of IRB review.)

REFERENCE:

45 CFR 46.102(e); 45 CFR 46.103; 21 CFR 56.109

PROCEDURE:

1. Full Board Review

Under the full review mechanism, the IRB may take one of four actions in regard to the protocol and informed consent:

- a. Approved: The investigator is sent an approval letter, noting date of required continuing review (at least annually). In some instances, approval may be given while at the same time asking for some minor modifications to an informed consent or the protocol.
- b. Approved as Amended: Revisions and/or additional information specifically designated by the IRB are sent to the investigator in an approval letter describing the revisions required. After making designated revisions to the protocol or consent, the investigator returns one copy to the IRB Chairman, with the revisions or additions underlined or highlighted, and reference made to the IRB number. If the changes are

not as requested upon review by the Chairman or designee, then the approval is withdrawn pending further information from the investigator.

- c. 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.

- d. Tabled: Significant questions are raised by the proposal requiring its reconsideration after additional information is received from the investigator and/or sponsor. Tabling cannot be given through the expedited review mechanism and may only be given by a majority vote at a convened meeting of the IRB.
- e. Disapproved: The investigator is sent a letter describing the reasons for disapproving the protocol. Disapproval of a protocol can occur when the IRB determines that the risk of the procedures outweighs any benefit to be gained, or if the study is not appropriate for The Christ Hospital.

2. Expedited Review (also see SOP 1.17 on Expedited Review)

Under certain circumstances, the expedited review mechanism of TCH IRB may be invoked. Expedited review is carried out by the Chairman (administrative review) or a subcommittee which is comprised of the chairman and/or one or two designated members of the IRB. The subcommittee may exercise all of the authorities of the IRB, except that it may not approve new protocols, or disapprove the research. All actions of expedited review are reported to the IRB at its next regularly scheduled meeting (where quorum is present). Administrative review, or revisions, usually in the form of changes in phone numbers, addresses, typographical errors, etc., are not reportable to the IRB, but filed with the protocol.

The subcommittee's recommendations usually fall into three categories. The subsequent procedures are identical to those described above.

- a. Approved: An approval letter is sent to the investigator following the expedited review.

- b. **Additional Information Requested:** A letter is sent to the investigator, explaining what additional information is requested.
 - c. **Protocol Requires Full Board Review:** The investigator is notified that a full review is necessary and the revisions or clarifications necessary are outlined for the submission of the protocol for review by the full board. The investigator submits 17 copies of the revised protocol to the IRB Chairman. The decision to require full review is made if the protocol fails to meet the expedited review categories which are specified by federal regulations, if the subcommittee is unable to satisfy its concerns regarding the rights and wellbeing of the subjects, and/or crucial aspects of the protocol or consent statement require clarification.
3. **Exempt Review (See SOP 1.16 for information on submitting “No Humans” Application for determining exempt research)**

Exemption certification review is conducted by the Chairman and/or a designated representative. The reviewer may take one of three actions:

- a. **Exemption Certification Approved:** Investigator is sent an approval letter. A report upon completion of the study may be required at the Chairman’s discretion.
- b. **Additional Information Required:** The investigator is sent a letter describing the information requested. The investigator returns two copies to the IRB Chairman for review. If the reviewer is satisfied that the protocol then meets the exemption criteria, then approval letter is sent to the investigator.
- c. **Exemption Certification Disapproved:** The investigator is sent a letter indicating that the new protocol does not fall within the exemption categories. A new application must be prepared and submitted for either expedited (if appropriate) or full review by the IRB.

Unless otherwise required by federal regulations, the following categories of research may be deemed exempt from full IRB review:

- Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as regular and special educational strategies or research on the effectiveness or on comparison among instructional techniques, curricula or classroom management methods.
- Research involving the use of educational tests (cognitive, diagnostic, achievement) if information taken from these sources is recorded in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects.

Research involving survey or interview procedures are not exempt from full board review when the following conditions exist:

- Subjects can be linked directly or through identifiers linked to the subjects.
- The subject's responses could place the subject at risk or criminal or civil liability or be damaging to the subject's financial standing or employability.
- The research deals with sensitive aspects of the subject's own behavior, such as illegal conduct, drug abuse or use of alcohol.
- Research involving the observation (including observation by participants) of public behavior, except where all the following conditions exist:
Observations are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects.

4. IRB Submissions

Hand delivery is the best method of assuring prompt submission to the IRB Office, however it is not required. The IRB address is:

The Christ Hospital IRB Office
2139 Auburn Ave., Room 3140 (3 North)
Cincinnati, OH 45219
Phone (513) 585-2298; Fax (513) 585-2107

The following information should be readily available when telephoning the IRB Office (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

5. 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.**

REVISION HISTORY:

Date Revised	Reason For Change	Revised By
4/14/2010	New method of approval	Becky

4/30/15	Changed IRB address	Becky

