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 and/or regulated by the various federal agencies, i.e., NCI, NIH, 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 Office staff will provide necessary signatures when provided certification forms.

(Please see IRB Reference Manual Section 2.0 IRB Review of Research 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 regarding 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 with Minor Modifications: 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 submits the revisions or additions tracked into Mentor IRB. The modifications may be approved by the IRB Chairman or designee. 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changes are not as requested upon review by the Chairman or designee, then the approval is withdrawn pending further information from the investigator.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 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 any revisions or clarifications necessary are outlined for the submission of the protocol for review by the full board. 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 (also see SOP 1.16 Exempt Research)

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

a. Exemption Approved: Investigator is sent an approval letter. A study closure request must be submitted upon completion of the study.

b. Exemption Approved: Investigator is sent an approval letter. A study closure request must be submitted upon completion of the study.

c. Exemption Not Approved: The investigator is sent a letter indicating that the new protocol does not fall within the exemption categories. A new e-application must be submitted for either expedited (if appropriate) or full review by the IRB.

d. Additional Information Required: The investigator is sent a communication describing the information requested. The investigator responds to the request in Mentor IRB for review by the IRB Chair or designee. If the reviewer is satisfied that the protocol then meets the exemption criteria, then an approval letter is sent to the investigator.

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 IRB 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, educational advancement, or reputation.
- The research deals with sensitive aspects of the subject's own behavior, such as illegal conduct, drug abuse or use of alcohol.

Limited IRB Review: Research where the information obtained is recorded by the investigator in such a manner that the identity of the Human Subjects can be readily ascertained, directly or indirectly through identifiers linked to the subjects require limited IRB review. The purpose of Limited IRB Review is to ensure privacy and confidentiality protections are in place with exempt research that involves the collection of sensitive, identifiable data (45 CFR 46.104(d)(2)(iii) and 45 CFR 46.104(d)(3)(i)(C)). The "Limited IRB reviewer" must determine that, per 45 CFR 46.111(a)(7), "When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data."

4. IRB Submissions

IRB members often rely solely on the documentation submitted by Investigators for initial and continuing review. Therefore, this material must provide IRB members with enough information about a study to assess if it adequately meets the IRB's criteria for approval. Submission requirements are detailed in SOP 1.01 *Continuing Review*, SOP 2.01 *Guidelines for New Protocol Submission*, SOP 2.03 *Proposed Amendments in Previously Approved Research Studies.* TCH IRB utilizes a web-based IRB management and submission system, Mentor IRB. The applications and submission forms within Mentor IRB use smart forms which require specific information based upon the responses of the applicant.

Communications and questions may also be sent to IRB_Office@thechristhospital.com.

The IRB Office mailing 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

5. Written Communications of IRB Decisions

Decisions of the IRB will be communicated to principal investigators in the Mentor IRB system through a written electronic 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.**