The Christ Hospital IRB
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Number: 2.04
Effective Date: 11/08
Revision Date: 03/26

STANDARD OPERATING PROCEDURE

Complying with IRB Decisions

1.0 PURPOSE

The purpose of this policy is to describe investigator responsibility for compliance with the decisions of The Christ Hospital (TCH) Institutional Review Board (IRB).

2.0 POLICY

When implementing research activities, the investigator must comply with the IRB's decisions, conditions, and requirements as described in this policy. After final IRB approval has been granted, the investigator must submit the proper certification to the sponsor/funding agency. The IRB office staff will provide necessary signatures when provided with certification forms.

3.0 RESPONSIBLITES

3.1 Principal Investigator

When implementing research activities, the investigator is responsible for complying with IRB decisions, conditions, and requirements as described in Section 4.0 below. After final IRB approval has been obtained, it is the investigator's responsibility to submit the proper certification to the sponsor/agency.

3.2 IRB Office

The IRB office staff will provide necessary signatures when provided with certification forms.

4.0 PROCEDURE

4.1 IRB Submissions

IRB members generally rely solely on the documentation submitted by investigators for initial and continuing review. Therefore, material provided to the IRB must include enough information about the study to assess if it adequately meets the IRB's criteria for approval. Submission requirements are detailed in IRB Standard Operating Procedures:

4.1.1 SOP 1.01 Continuing Review
4.1.2 SOP 2.01 Guidelines for New Protocol Submission
4.1.3 SOP 2.03 Proposed Amendments in Previously Approved Research Studies.

Submissions are made through TCH IRB's electronic record management system, Mentor IRB. Application and submission forms within Mentor IRB use smart forms which require specific information based upon the responses of the applicant.

Related communications and questions may be sent to the IRB office:

The Christ Hospital Institutional Review Board
2139 Auburn Avenue - Room 3140 (3 North)
Cincinnati, OH 45219
Phone (513) 585-2298
Fax (513) 585-2107
IRB_Office@thechristhospital.com

4.2 IRB Review Types

4.2.1 **Full Board Review** (Ref. SOP 1.07 - Full Board Guidelines)
Under the full review mechanism, the IRB may take one of the following actions regarding the submitted new protocol:

4.2.1.1 Approved: The investigator is sent an approval letter noting the date of required continuing review (at least annually).

4.2.1.2 Approved with Minor Modifications: In some instances, approval may be granted while, at the same time, asking for minor modifications to an informed consent or the protocol. 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 as a tracked copy 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.

4.2.1.3 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 including a description of the revisions or clarifications requested. For some studies, one or more members of the IRB may be designated to

discuss the rationale for the revisions 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.

4.2.1.4 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.

4.2.1.5 Disapproved: A letter is sent to the investigator describing the reasons for disapproval of the protocol. Disapproval 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.

4.2.2 **Expedited Review** (Ref. SOP 1.17 - Expedited Review Procedures)
Under certain circumstances, the expedited review mechanism of TCH IRB may be utilized. 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 designated reviewer(s) may exercise all the authorities of the IRB, except that it may not disapprove research. All actions of expedited review are reported to the convened IRB at its next regularly scheduled meeting where quorum is present.

Under the expedited review mechanism, the reviewer(s) may take one of the following actions regarding the submitted new protocol and the subsequent procedures are identical to those described above:

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

4.2.2.2 Additional Information Requested: A letter is sent to the investigator, explaining the additional information requested.

4.2.2.3 Protocol Requires Full Board Review: The investigator is notified that a full review is needed and any necessary revisions or clarifications are outlined and are required with the submission of the protocol for review by the full board. The decision to require full review is made if:

4.2.2.3.1 The protocol fails to meet the expedited review categories specified by federal regulations;

4.2.2.3.2 The designated reviewer(s) is unable to satisfy its concerns regarding the rights and wellbeing of the subjects; and/or

4.2.2.3.3 Crucial aspects of the protocol or consent statement

require significant clarification.

4.2.3 **Exempt Review** (Ref. SOP 1.16 Exempt Research)
Unless otherwise required by federal regulations, certain research may be deemed exempt from full IRB review. Criteria for exemption (exemption categories) are outlined in SOP 1.16. Exempt review is conducted by the IRB chairman and/or a designated IRB reviewer. The reviewer may take one of the following actions:

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

4.2.3.2 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.

4.2.3.3 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.

4.2.4 **Limited IRB Review** (Ref. SOP 1.16 Exempt Research)
Limited IRB Review is a process required for research projects qualifying for certain Exempt Categories as described in SOP 1.16, and that do not require consideration of all approval criteria described in federal regulations 45 CFR 46.111. 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 reviewer(s) may take one of the actions described in Section 4.2.3, Exempt Review.

4.3 Written Communications of IRB Decisions

Decisions of the IRB will be communicated to principal investigators through a written letter in Mentor IRB outlining the study's approval status and any concerns, questions, and/or comments of the IRB. Decisions from a full board meeting will be verbally available the day following the convened IRB meeting; however, written communications are not released until the meeting minutes of the relevant IRB meeting are reviewed and approved by the IRB chair. Such written communications typically necessitate a period of three (3) working days from the IRB meeting date.

Note: Initiation of the research study may not proceed until a written notification of final approval has been received from the IRB office.

5.0 REFERENCES

5.1 IRB Standard Operating Procedures

- 5.1.1 SOP 1.01 - Continuing Review
- 5.1.2 SOP 1.07 - Full Board Guidelines
- 5.1.3 SOP 1.16 - Exempt Research
- 5.1.4 SOP 1.17 - Expedited Review
- 5.1.5 SOP 2.01 - Guidelines for New Protocol Submission
- 5.1.6 SOP 2.03 - Proposed Amendments/Modifications in Previously Approved Research Studies

5.2 IRB Reference Manual: RM 2.0 - IRB Review of Research

5.3 Code of Federal Regulations

- 5.3.1 U.S. Department of Health and Human Services (HHS)
  - 5.3.1.1 Definition: Human Subject 45 CFR 46.102(e)
  - 5.3.1.2 Assuring compliance - research conducted or supported by any Federal department or agency 45 CFR 46.103
- 5.3.2 U.S. Food and Drug Administration (FDA): IRB Review of Research 21 CFR 56.109

5.4 AAHRPP Domains and Elements: II.5.B