The Christ Hospital IRB
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STANDARD OPERATING PROCEDURE

Full Board Review Submission Guidelines

1.0 PURPOSE

This procedure establishes the process of The Christ Hospital Institutional Review Board (TCH IRB) review of proposed research activity involving human subjects protected under the institution's Human Research Protection Program, prior to the implementation of such research activity and determined to qualify for Full Board Review.

2.0 POLICY

The convened IRB meets monthly. Materials for IRB review are distributed to board members approximately two weeks prior to the meeting. A schedule of IRB meetings dates and deadlines for materials submission is available by contacting the IRB office by email at IRB_Office@thechristhospital.com, by visiting the IRB page on The Christ Hospital website or the IRB SharePoint site.

3.0 RESPONSIBILITY

3.1 Principal Investigator

3.1.1 Creates a new protocol submission in Mentor IRB, ensuring the submission contains all requirements as outlined in SOP 2.01, Guidelines for Protocol Submission

3.1.2 Submits through Mentor IRB in accordance with the corresponding IRB convened meeting deadline

3.1.3 For research initially approved with minor modifications, the Principal Investigator must address any requests for amendments or modifications in writing to the IRB before receiving an "activation letter" from the IRB office giving final approval for the trial to begin. The modifications must be approved prior to study initiation.

3.2 IRB Office Staff

3.2.1 Assigns any new greater-than-minimal-risk protocol, which is received in Mentor IRB, to the Full Board Panel. This action places the protocol on the next meeting agenda for review

3.2.2 Ensures that the submission is complete and is available in its entirety in Mentor IRB for IRB member review approximately two weeks prior to the convened meeting date

3.2.3 Communicates all IRB determinations through Mentor IRB in a notification letter sent to the Principal Investigator and any research coordinator(s) as outlined in SOP 1.04, IRB Meeting Minutes / Conducting IRB Meeting. If a protocol is initially approved with minor modifications, the modifications must be received and approved by the IRB Chair prior to study initiation.

3.2.4 Following receipt and approval of the IRB-requested modifications, a letter of study activation communicating final approval is sent to the Principal Investigator and any research coordinator(s).

3.2.5 New protocols are given a one-year approval, effective the date of the convened meeting, and expiring 12 months later on the first day of the 12th month. For example, new protocols approved by the convened IRB on March 9, 2021 will have an expiration date of March 1, 2022.

3.3 IRB Chair

3.3.1 Serves as a primary reviewer and/or delegates the responsibility to another qualified IRB member.

3.3.2 Reviews any IRB-requested minor modifications to the research and, if approved, grants final approval of the changes.

3.4 Convened IRB

3.4.1 Reviews any new proposed research that is greater than minimal risk.

3.4.2 Makes its determination.

4.0 PROCEDURE

4.1 The investigator creates and submits a new research protocol in Mentor IRB.

4.2 The IRB Office reviews and places the submission on the next scheduled convened IRB meeting agenda.

4.3 The IRB Office assigns the appropriate primary reviewer in Mentor IRB.

4.4 The IRB Office ensures materials are available for IRB member review approximately two weeks prior to the convened meeting date.

4.5 The convened IRB reviews the submission and makes its determination.

4.6 The IRB Office communicates IRB determinations to the investigator in Mentor IRB.

4.7 The Principal Investigator submits any IRB-requested minor modifications for review and approval by the IRB Chair.

4.8 The IRB Chair reviews any submitted IRB-requested minor modifications.

4.9 Following approval of any minor modifications, a letter of study activation conveying final approval is sent to the Principal Investigator.

4.10 New protocols receive a one-year approval effective the date of the convened meeting, unless otherwise specified by the convened IRB. This approval period expiration is 12 months later on the first day of the 12th month.

5.0 DOCUMENTS

Not Applicable.

6.0 DEFINITIONS

Not Applicable

7.0 REFERENCES

7.1 Standard Operating Procedures: SOP 1.04 IRB Meeting Minutes/Conducting IRB Meeting; SOP 2.01 Guidelines for Protocol Submission

7.2 Reference Manuals: RM 02 IRB Review of Proposed Research Studies

7.3 Web Links: The Christ Hospital IRB page (Documents and Forms for Protocol Submission); The Christ Hospital IRB SharePoint site; Mentor IRB (TCH Users); Mentor IRB Log-in (External Users)

7.4 AAHRPP Standards: II.2.E.1