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 IRB's review of proposed human subjects research, prior to the implementation of such research activities, which has been determined to meet requirements for Full Board (convened) IRB Review.

2.0 POLICY

The convened IRB meets monthly. Materials for IRB review are distributed to board members approximately one week prior to each meeting. A schedule of IRB convened meetings and materials submission deadlines are provided to each board member, and may also be found on the IRB page of The Christ Hospital website and the IRB SharePoint site. The list may also be obtained by contacting the IRB Office.

3.0 RESPONSIBILITY

3.1 Principal Investigator or Designee

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

3.1.2 Submits the new protocol through Mentor IRB in accordance with the corresponding IRB convened meeting deadline; and

3.1.3 Addresses any requests for amendments or modifications, to research approved with minor 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 received in Mentor IRB to the Full Board Panel, thus placing 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 one week 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, "Conducting IRB Meetings/IRB Meeting Minutes"; (Note: If a protocol is

initially approved with minor modifications, the modifications must be received and approved by the IRB chair or designee prior to study initiation.);

3.2.4 Sends a letter of activation to the principal investigator and any research coordinators through Mentor IRB following receipt and approval of any IRB-requested minor modifications; and

3.2.5 Sets expiration date in Mentor following review and approval.

3.3 **IRB Chair**

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

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, and

3.4.2 Makes its determination.

4.0 PROCEDURE

4.1 The investigator or designee 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 reviewer checklist to the appropriate primary reviewer in Mentor IRB.

4.4 The IRB office ensures that materials are available for IRB member review approximately one week 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 IRB office sets expiration date in Mentor following review and approval. New protocols receive a one-year approval effective the date of the convened meeting, unless otherwise specified by the convened IRB. The approval-period expiration is 12 months later, on the first day of the 12th month, unless otherwise specified by the convened IRB.

4.8 The principal investigator or designee submits any IRB-requested minor modifications for review and approval by the IRB chair or designee.

4.9 The IRB chair reviews any submitted IRB-requested minor modifications.

4.10 Following approval of any minor modifications, a letter of study activation conveying final approval is sent to the principal investigator and any research coordinator(s).

7.0 REFERENCES

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

7.2 IRB Reference Manual: RM 02 - IRB Review of Proposed Research Studies

7.3 The Christ Hospital IRB website: IRB webpage/Submissions

7.4 The Christ Hospital SharePoint site: IRB SharePoint pages

7.5 Mentor IRB: TCH Users; External Users

7.6 AAHRPP Domains and Elements: Element II.2.E.1