The Christ Hospital IRB **Number:** 1.07
Submitted By: Erica Jones, CIP **Effective Date:** 02/09
Reviewed By: Steve Roberts, MD **Reviewed/Revised Date:** 03/21
Approved By: Steve Roberts, MD Date: 05/10/21
(II.2.E)

STANDARD OPERATING PROCEDURE

Full Board Review Submission Guidelines

POLICY:

The IRB meets monthly, and materials for IRB review are distributed to IRB members approximately 2 weeks prior to the meeting. A schedule of IRB meetings dates and deadlines for materials submission is available by contacting the IRB Office either by phone at 513-585-2298 or by email at IRB_Office@thechristhospital.com or by going to the IRB page on The Christ Hospital website or the IRB SharePoint site.

PROCEDURE

INVESTIGATOR:

1. Review of new protocols requires the investigator/research staff to contact the IRB office to obtain a protocol number. This number must be listed on all submission documents where it is required.

2. The protocol submitted must contain all requirements as outlined in SOP 2.01, "Guidelines for Protocol Submission". These materials must be received in the IRB office before noon at least 21 days prior to the scheduled IRB meeting.

3. The investigator is required to include (but not limited to) a Study Application, HIPAA Partial Waiver form, Disclosure of Financial Interest Forms, Consent Form(s), protocol, Investigator Brochure, recruitment materials for each study with the protocol submission as applicable. The IRB Office provides these documents in the IRB packets to each IRB member for review prior to the convened meeting.

4. The Principal Investigator, Sub-Investigator(s), and key research personnel must provide a copy of their CITI Course transcript (which must have been taken within the last three years)

5. The Principal Investigator must provide a signed PI Assurance and Responsibilities form.

6. The Principal Investigator and all Sub-Investigators (that have direct physical contact with Human Subjects) must be credentialed by TCH Medical Staff Office prior to study activation.

7. The investigator must address any requests for amendments or modifications in writing to the IRB before receiving an "activation letter" from the IRB office giving approval

for the trial to begin.

IRB OFFICE STAFF:

1. All investigator requests submitted to the IRB requiring full board review are distributed to all IRB members approximately 2 weeks prior to the meeting date, and therefore must be received in the IRB Office by that time for distribution.

2. IRB decisions are communicated to the investigator as outlined in SOP 1.04 "IRB Meeting Minutes / Conducting IRB Meeting." Additionally, receipt of IRB required study amendments for approval must be received and approved by the IRB Chair prior to study initiation. This information is communicated to the investigator in the notification letter sent to the Principal Investigator.

3. Following receipt and approval of the amendments for approval, a letter of study activation is sent to the investigator.

4. New protocols are given a 1-year approval, effective the date of the convened meeting, and expiring on the 1st day of the month, 12 months later. For example, new protocols approved by the convened IRB on March 9, 2021 will have an expiration date of March 1, 2022. The IRB maintains a fixed anniversary date for the expiration of annual IRB approvals thereafter to keep the IRB approval period constant from year to year throughout the life of a research project.

5. The contents of study file are made available to IRB members upon request during the IRB meeting.

REFERENCE:

SOP- 1.04 IRB Meeting Minutes / Conducting IRB Meeting
SOP- 2.01 Guidelines for Protocol Submission

REVISION HISTORY:

Date Revised/Reviewed	Reason For Change	Revised By
12/15/10	Change in submission forms	Becky
07/18/19	Updated IRB website and Investigator Responsibilities	Emily
01/13/20	Changed # of copies needed from 17 to 15	Emily
01/29/20	Corrected hyperlink address	Emily
03/17/21	Updated hyperlink addresses and added IRB email contact information; minor administrative changes and clarifications; added Reference section	Erica
05/10/21	Added fixed anniversary date procedure	Erica