

The Christ Hospital IRB

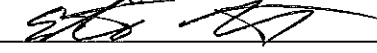
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Submitted By: Erica Jones, CIP

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Reviewed By: S. Roberts, MD & M. Jennings, MD

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Approved By: Steve Roberts, MD 

(IL.3.F)

STANDARD OPERATING PROCEDURE

Guidelines for Protocol Submission

POLICY:

In order to submit a study to The Christ Hospital IRB (TCH IRB), the following documents must be prepared for submission: (See Guidelines that follow to help in preparing #1-4 below)

1. TCH IRB New Protocol Cover Sheet (1 original)
2. Study Application (*original plus 17 copies*)
3. Informed Consent in TCH format, Waiver of Informed Consent form, or Waiver of Documentation of Informed Consent form, whichever is applicable (*original plus 17 copies*)
4. Protocol (*original plus 2 copies*)
 - The DHHS-approved sample consent document (when one exists) (original plus 2 copies)
 - The complete DHHS-approved protocol (when one exists) (original plus 2 copies)
5. HIPAA Request for Partial Waiver to Individual Authorization Form, if applicable (1 original)
6. Investigational Drug Data Form or Investigator Device Data Form, if applicable, signed by the PI (original plus 2 copies)
7. Disclosure of Financial Interest Form on PI and all co-investigators (*1 original for each investigator, or copy of completed Financial Disclosure form required by the sponsor for each investigator, but ONLY if the sponsor COI is \$5,000 or under.*)
8. Certificate of completion from the CITI course for the Principal Investigator and all Co-Investigators (*the course must be taken every three years*)
9. Advertising Materials, if any (*original plus 17 copies*)
10. Investigator's Brochure, if applicable (*original plus 2 copies*)
11. Any relevant grant applications (1 original)

NOTE: Templates for #1-4, above, and the forms listed in 6-9, above, can be obtained by visiting www.thechristhospital.com/IRB/ or by calling the IRB office at 513-585-2298. Also, contact the office staff for instructions on taking the CITI course.

NOTE: If applicable, all Principal Investigator's must be credentialed by the Medical Staff Office. Co-Investigator's or research staff that have direct physical contact with subject's (i.e. Consenting) must also be credentialed through the Medical Staff Office. All other Co-Investigator's or research staff must complete a SARF form. Please contact Erica Jones or Emily Humbert at 513-585-2298 for further information.

To be placed on the agenda of a meeting of the Institutional Review Board, the above items must be provided to the Coordinator or Chairman 21 days prior to the scheduled meeting. There is a one-time fee of \$2,500 for each protocol submitted for full board review. You will be billed for this by The Christ Hospital Accounting Department. Please do not send checks with your protocol submission. If the study is a non-funded study, please call 513-585-2298 and request an "IRB Fee Appraisal" to be completed to request funding from hospital research funds or be exempt from the fee. (Administrative policy 4.20.178)

REFERENCE:

45 CFR 46.109(b); 45 CFR 46.116; 21 CFR 50.25; 21 CFR 56.109(b)

PROCEDURE:

GUIDELINES FOR PREPARATION OF REQUIRED DOCUMENTS (for Items 1-4):

1. Cover Sheet -- 1 original

A cover sheet is available from the IRB to aid the investigator in assuring all documents are prepared appropriately. This serves as a check list when gathering documents for submission.

2. Study Application- 1 original plus 17 copies

3. Informed Consent, Waiver of Informed Consent, or Waiver of Documentation of Informed Consent, *whichever is applicable*- 1 original plus 17 copies

Refer to the Informed Consent Template at www.thechristhospital.com/irb/ for guidelines.

THE FOLLOWING FORMS MUST ALSO BE SUBMITTED:

4. Protocol – 1 original plus 2 copies

5. Financial Disclosure Form – 1 original for each investigator

This form must be completed on all investigators involved in the study. Investigators may choose to submit a copy of their financial disclosure form required by the sponsor in lieu of submitting the TCH IRB COI form, but **ONLY** if the sponsor COI is \$5,000 or under.

6. HIPAA Request for Partial Waiver to Individual Authorization signed by the PI (when applicable) – 1 original

The HIPAA Privacy Rule establishes the conditions under which protected health information (PHI) may be used or disclosed by covered entities for research purposes, without specific patient authorization. In order to recruit individuals into research studies using PHI from The Christ Hospital, and contact the patient to seek informed consent and authorization for use and disclosure of PHI, the principal researcher must obtain Partial Waiver to Individual Authorization from the IRB.

7. Investigational Drug Data Form (when applicable) – 1 original plus 2 copies

This form must be completed, signed by the PI and submitted for new protocols using any non-FDA approved drug. (A copy of the completed form will be sent to the Pharmacy Director by the IRB Coordinator.)

8. Advertising Materials (when applicable) – 1 original plus 17 copies

9. Investigators Brochure (for IND Studies) – 1 original plus 2 copies

10. CITI Course Transcript – 1 original for each investigator

A transcript for each investigator must be included in the submission, unless it is already on file with the IRB Office. The CITI Course is required to be taken every three years.

REVISION HISTORY:

Date Revised	Reason For Change	Revised By
08/16/10	Revised Certificate of Investigator Responsibilities	Becky
12/14/10	Revised COI section	Becky
04/09/15	Updated sponsor COI to \$5000	Becky
03/15/17	Removed Becky from NOTE	Emily