

The Christ Hospital IRB

Number: 3.05

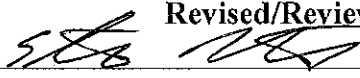
Submitted By: Erica Jones, CIP

Effective Date: 03/27/09

Reviewed By: Michael Jennings, MD/Steve Roberts, MD

Revised/Reviewed Date: 03/17

Approved By: Steve Roberts, MD
(covered in application)



STANDARD OPERATING PROCEDURE

Activities Subject to IRB Jurisdiction

POLICY:

It is the policy of The Christ Hospital that the Institutional Review Board has jurisdiction over all research involving human participants as determined by its Assurance.

- I. Review and Approval of Human Participant Research.
 - A. All research involving human participants, and all other activities, which in part involve such research, regardless of sponsorship, must be reviewed and approved by TCH IRB.
 1. No intervention or interaction with human participants in research, including advertising, recruitment, and/or screening, may begin until the IRB has reviewed and approved the research.
 2. It is the responsibility of the IRB Chairperson or his/her designee or the full IRB Committee to determine what activities constitute "research" involving "human subjects" as defined by the Federal regulations and in accordance with the policy and procedure Determining Whether an Activity Represents Research Involving Human Subjects.
 3. Certification to the appropriate supporting Department or Agency will be made via the PI.
 - B. The Christ Hospital's Assurance with the Federal government defines its jurisdiction over the review of research activities involving human participants. Regardless of sponsorship, the IRB must review all research involving human subjects research when any of the following apply:
 1. The research is sponsored by The Christ Hospital;
 2. The research is conducted by or under the direction of any investigator, employee, staff, or student of The Christ Hospital in connection with his/her institutional responsibilities;
 3. The research is conducted by or under the direction of any investigator, employee, staff, or student of this institution using any of its property or facilities;
 4. The research involves the use of non-public information maintained by The Christ Hospital to identify or contact human participants or prospective participants;

5. The Christ Hospital receives a direct Federal award to conduct human participant research, even where all activities involving human participants are carried out by a subcontractor or collaborator; and/or
6. The research is conducted in accordance with an Assurance filed with the Office of Human Research Protections (OHRP) in which The Christ Hospital IRB is designated as the IRB of record through an established Memorandum of Understanding.

PROCEDURE

This procedure provides guidance on types of research activities that are subject to review and approval by The Christ Hospital Institutional Review Board.

IRB Responsibilities:

- A. The IRB Chair or staff will conduct an initial review of the research proposal to verify that The Christ Hospital IRB has jurisdiction.
- B. If TCH IRB has jurisdiction, the IRB Chair will process the research proposal in accordance with applicable Human Research Protections Program and/or TCH IRB policies and procedures. If TCH IRB does not have jurisdiction, the research proposal will be returned to the PI with notification of such.

Cross References / Resources:

45 CFR 46.102(d), 45 CFR 46.102(f), 45 CFR 46.102(f)(1), 45 CFR 46.102(f)(2), 45 CFR 46.103(f), 45 CFR 50.603
 21 CFR 50.3(g)
 45 CFR 46
 21 CFR 50 and 56
 FDA Information Sheets: Non-Local IRB Review
 IRB Management and Function; Amdur, R. and Bankert, E.; 2002 Jones and Bartlett Publishers, Inc.

REVISION HISTORY:

Date Revised	Reason For Change	Revised By