

**The Christ Hospital IRB****Submitted By:** Erica Jones, CIP**Reviewed By:** John Kennedy, MD/Steve Roberts, MD**Approved By:** Steve Roberts, MD  
(I.I.D)**Number:** 3.04**Effective Date:** 01/09/09**Revised/Reviewed Date:** 04/21

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**STANDARD OPERATING PROCEDURE**

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**Policy Development and Communication for the Human Research Protections Program**

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**POLICY:**

The Christ Hospital (TCH) Institutional Official (IO) exercises overall supervision of the Human Research Protection Program (HRPP) and is responsible for its implementation. The Institutional Official will periodically, but no less than annually, arrange meetings with select representatives of various units of the Human Research Protection Program, to review existing policies and procedures, address the need for new or revised policies and/or procedures, and discuss new developments and information relevant to the Human Research Protection Program. An IRB sub-committee consisting of the Institutional Official, IRB Chairman and/or IRB Administrator are authorized to review policies and procedures for the Human Research Protection Program. The Institutional Official may delegate his/her authority to approve policies and procedures for the IRB and/or the HRPP to the IRB Chair or other appropriate individuals. All approvals, revisions of policies and procedures, and delegations of authority must be in writing, dated, and signed to be effective. All policies will be reviewed and revised or updated every 3 years or as necessary.

The IRB Office will maintain all policies and procedures of the Human Research Protection Program. A copy of applicable federal/state/local laws and regulations affecting human subject research can be found with the Risk Management Office and are made accessible to The Christ Hospital research community upon request.

**PROCEDURE:****INVESTIGATOR:**

- Reviews appropriate policies and procedures as requested by the IRB.
- Consults the IRB Office if any questions arise.

**IRB OFFICE STAFF:**

- Routinely reviews the OHRP and FDA web sites for issuance of new regulations, guidance and communications from these agencies.
- Attends staff meetings and IRB meetings to assess need for new or revised policies and procedures.
- Submits updated policies and procedures at a convened meeting for IRB review and acknowledgment.
- Provides regular input to the IRB Chair on the need for policy review and development.
- Relies on IRB policies and procedures when reviewing human research proposals.

- Maintains copies of all IRB policies and procedures on the [IRB page](#) on The Christ Hospital website or the [IRB SharePoint site](#).

**IRB MEMBER:**

- Reviews IRB policies and procedures when presented at IRB meetings.
- Provides input when requested for policy review and development.

**IRB CHAIR:**

- Brings the need for new and revised policies and procedures to the attention of the Institutional Official.
- Reviews and approves any updated policies and procedures

**INSTITUTIONAL OFFICIAL:**

- Meets periodically with the IRB Chair and legal counsel to address the need for updating policies and procedures.
- Ensures policies and procedures are reviewed and updated every 3 years or as necessary.

**REVISION HISTORY:**

Date Revised	Reason For Change	Revised By
06/08/15	Removal of HRCC and Risk Management	Becky
04/26/21	Minor Administrative Changes and Clarifications; Include Approval by Chair; Removed reference to CITI program	Erica