The Christ Hospital IRB
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STANDARD OPERATION PROCEDURE

Policy Development and Communication for the Institutional Review Board and Human Research Protections Program

1.0 PURPOSE

This procedure establishes the process of developing and maintaining the policies and procedures of The Christ Hospital Institutional Review Board (IRB) and Human Research Protection Program (HRPP) including regular review of existing policies and procedures and addressing needs for new or revised policies and/or procedures.

2.0 POLICY

The Christ Hospital (TCH) Institutional Official (IO) exercises overall supervision of the Institutional Review Board (IRB) and Human Research Protection Program (HRPP) and is responsible for its implementation. All policies and procedures of the IRB and HRPP are maintained by the Christ Hospital Institutional Review Board (TCH IRB). Documentation of applicable federal/state/local laws and regulations affecting human subject research are held by the Department of Risk Management.

3.0 PROCEDURE

3.1 Review of Policies and Procedures

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 needs for new or revised policies and/or procedures, and discuss new developments and information relevant to the Human Research Protection Program.

3.2 Authorization for Review

Authorization to review policies and procedures for the Institutional Review Board and Human Research Protection Program is appointed to a sub-committee of the Institutional Review Board. The sub-committee consists of the Institutional Official and the IRB Chairman and/or IRB Administrator. 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.

3.3 Approvals and Revisions

All approvals and/or revisions of policies and procedures, and delegations of authority, must be in writing, dated, and signed in order to be effective.

3.4 Frequency of Review

All policies will be reviewed and revised or updated every 3 years or as necessary.

4.0 RESPONSIBILITY

4.1 Study Investigator

4.1.1 Reviews appropriate policies and procedures as requested by the IRB

4.1.2 Consults with the IRB office as needed regarding any questions that may arise

4.2 IRB Office Staff

4.2.1 Maintains all policies and procedures of the Institutional Review Board and Human Research Protection Program

4.2.2 Routinely reviews the OHRP and FDA web sites for issuance of new regulations, guidance, and communications from these agencies

4.2.3 Attends staff meetings and IRB meetings to assess needs for new or revised policies and procedures

4.2.4 Submits updated policies and procedures at convened meetings for IRB review and acknowledgment

4.2.5 Provides regular input to the IRB Chair regarding needs for policy review and development

4.2.6 Relies on IRB policies and procedures when reviewing research proposals involving human subjects

4.2.7 Maintains copies of all IRB policies and procedures on Mentor IRB, The Christ Hospital's IRB webpage and/or the IRB SharePoint platform.

4.3 IRB Member

4.3.1 Reviews IRB policies and procedures when presented at IRB meetings

4.3.2 Provides input when requested for policy review and development

4.4 IRB Chair

4.4.1 Brings needs for new and revised policies and procedures to the attention of the Institutional Official

4.4.2 Reviews and approves any updated policies and procedures

4.5 Institutional Official

4.5.1 Periodically meets with the IRB Chair and legal counsel to address the need for updating policies and procedures

4.5.2 Ensures policies and procedures are reviewed and updated every 3 years or as necessary

4.6 Department of Risk Management

Documentation of applicable federal/state/local laws and regulations affecting human subject research are held within the Risk Management office and accessible to The Christ Hospital research community upon request.

5.0 DOCUMENTS

5.1 IRB Policy Template

6.0 DEFINITIONS

6.1 SOP 3.23 Definitions (definitions of double underlined terms)

7.0 REFERENCES

7.1 AAHRPP Standards: I.1.D

7.2 Web Links: Institutional Review Board Written Procedures: Guidance for Institutions and IRBs (2018)