The Christ Hospital IRB
Submitted By: Erica Jones, CIP
Approved By: Steve Roberts, MD

Number: 1.02
Effective Date: 02/09
Revised/Reviewed Date: 04/26

STANDARD OPERATING PROCEDURE

HRPP Statement of Ethical Principles and Assurance of Compliance with Department of Health and Human Services Policy on the Protection of Human Subjects Federalwide Assurance and IRB Registration

1.0 PURPOSE

This procedure establishes:

1.1 The application of The Belmont Report to all non-exempt human subjects research, regardless of source of support;

1.2 The application of the U.S. Federal Policy for The Protection of Human Subjects (45 CFR Part 46 Subpart A or the "Common Rule") to all non-exempt, federally funded human subjects research;

1.3 The application of Food and Drug Administration (FDA) regulations to all FDA regulated research; and

1.4 The registration of the IRB for review of research involving human subjects conducted or supported by the Department of Health and Human Services and/or clinical investigations regulated by the FDA.

2.0 POLICY

The Christ Hospital (TCH) Human Research Protection Program (HRPP) is committed to advancing the ethical treatment of research participants, promoting the responsible conduct of research, and ensuring and protecting the rights of every human research participant. It is The Christ Hospital's policy to protect the rights, dignity, welfare, and privacy of the human subjects in all research conducted on behalf of the institution (regardless of funding) by adhering to the principles outlined in the *National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research* report titled, "Ethical Principles & Guidelines for the Protection of Human Subjects of Research" (i.e., the "Belmont Report"). TCH adheres to the regulations of the Department of Health and Human Services (HHS) (ref. 45 CFR Part 46 Subpart A or the "Common Rule") for any human subjects research supported by any U.S. federal department or agency that has adopted the Policy through a written assurance (Federalwide Assurance or FWA) with the Office for Human Research Protections (OHRP), Food and Drug Administration (FDA) for any human subjects research subject to FDA regulation, and any other agencies, as applicable.

The Christ Hospital holds the FederalWide Assurance #FWA00000702, Organization Registration (IORG) #ORG0001054, and IRB Registration #IRB00001448.

3.0 RESPONSIBILITY

3.1 IRB Office

Updates and maintains the assurance and IRB registration via the OHRP electronic submission system.

3.2 IRB Chair

Reviews updates and renewals to the assurance prior to submission by the IRB office.

3.3 Institutional Official (IO)

Serves as the Human Protections Administrator (HPA) or Human Subjects Contact Person for the FWA.

3.4 The Christ Hospital President and CEO

Serves as Signatory Official (SO) for the FWA.

4.0 PROCEDURE

4.1 IRB Office

4.1.1 Submits FWA renewals and updates to OHRP after discussion and review by the Human Protections Administrator and/or IRB chair;

4.1.2 Submits IRB Registration updates and renewals to OHRP after discussion and review by the Human Protections Administrator and/or IRB chair; and

4.1.3 Maintains record of all updates and renewals.

4.2 IRB Chair

Reviews updates and renewals to the assurance prior to submission by the IRB office.

4.3 Human Protections Administrator

Serves as the Human Subjects Administrator on an as-needed basis.

4.4 Signatory Official

Serves as signatory for updates and renewals of the FWA.

5.0 REFERENCES

5.1 U.S. Department of Health and Human Services (HHS)

5.1.1 45 CFR Part 46 Subpart A

5.1.2 45 CFR 46.103

5.1.3 Federalwide Assurance (FWA)

5.2 U.S. Food and Drug Adminstration: 21 CFR 56.106

5.3 National Research Act of 1974, National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research: Belmont Report

5.4 AAHRPP Domains and Elements: I.1.A