The Christ Hospital IRB **Number:** 1.18
Submitted By: Erica Jones, CIP **Effective Date:** 03/09
Approved By: Steve Roberts, MD_____ **Revised/Reviewed Date:** 11/20

STANDARD OPERATING PROCEDURE

Institutional Official Delegation

1. PURPOSE

1.1. This procedure outlines the responsibilities of the Institutional Official (IO) the individual authorized by The Christ Hospital President/CEO to:

1.1.1. Act for the institution and, on behalf of the institution obligates the institution to the Federalwide Assurance (FWA) Terms of the Assurance, and

1.1.2. Assume operational authority for the institutional Human Research Protection Program.

2. PREVIOUS VERSION

2.1. 03/17- administrative changes made to upgrade to new template

3. POLICY

3.1. It is The Christ Hospital's policy that the Institutional Official is the Vice President for Medical Affairs, an individual of sufficient standing and authority within the institution, who role includes:

3.1.1. Operation authority for TCH's HRPP, and

3.1.2. Assuring that the program is functional, adequately staffed and funded, and respected in the research community.

4. RESPONSIBILITY

4.1. The Institutional Official is responsible for ensuring the HRPP functions effectively with the institution by:

4.1.1. Providing resources and support necessary to comply with all requirements applicable to research involving human subjects;

4.1.2. Exercising appropriate administrative oversight to assure that TCH's policies and procedures designed for protecting the rights and welfare of human participants are effectively applied in compliance with its Assurance;

4.1.2.1. Represents the institution in the Federalwide Assurance (FWA);

4.1.2.2. Serves as the Human Protections Administrator (HPA) on the Federalwide Assurance, the hospitals point of contact with DHHS's official for Human Research Protections (OHRP);

4.1.3. Ensuring that the IRB functions independently and its chair and members have direct access to the IO for appeal if they experience undue influence or if they have concerns about the function of the IRB;

4.1.4. Promoting an institutional culture for the ethical conduct of human subjects' research.
4.1.5. Ensures investigators fulfill their responsibilities
4.1.6. Assuring training and educational opportunities are available for the IRB and investigators;
4.1.7. Determining what IRBs the Institution will rely upon;
4.1.8. Cannot approve research disapproved by TCH IRB; however, may disapprove research approved by TCH IRB.

5. PROCEDURE

5.1. The Institutional Official performs the following duties:
5.1.1. Provides resources and support necessary to comply with all requirements applicable to research involving human subjects; and welfare of human participants are effectively applied in compliance with its Assurance;
5.1.2. Ensures institutional policies and procedures designed for protecting the rights and welfare of human participants are effectively applied in compliance with its Assurance;
5.1.3. Represents the institution in the Federalwide Assurance (FWA);
5.1.4. Serves as the Human Protections Administrator (HPA) on the Federalwide Assurance, the hospitals point of contact with DHHS's official for Human Research Protections (OHRP);
5.1.5. Ensures that the IRB functions independently and its chair and members have direct access to the IO for appeal if they experience undue influence or if they have concerns about the function of the IRB;
5.1.6. Ensure investigators fulfill their responsibilities;
5.1.7. Assumes authority to disapprove research approved by TCH IRB, if the research does not suit the needs of the institution for any reason deemed appropriate.
5.1.7.1. However, cannot approve research that has been disapproved by the IRB.
5.2. The Institutional Official delegates to the IRB Chair the following duties:
5.2.1. IRB policies and procedure creation
5.2.2. Reliance Agreements with External IRBs
5.3. The Institutional Official delegates to the IRB Office the following duties:
5.3.1. Providing education and training to researchers

6. DOCUMENTS

6.1. None.

7. DEFINITIONS

7.1. See SOP 3.23 Definitions for definition of double underlined terms.

8. REFERENCES

8.1. 45 CFR 46.103(b)
8.2. 21 CFR 56.106(b)(1)
8.3. AAHRPP Standard I.1.B and I.1.C