The Christ Hospital IRB
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STANDARD OPERATING PROCEDURE

Institutional Official Delegation

1.0 PURPOSE

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

1.1. Act for and on behalf of the institution, and obligate the institution to the Federalwide Assurance (FWA) Terms of the Assurance, and
1.2. Assume operational authority for the institutional Human Research Protection Program (HRPP).

2.0 POLICY

It is The Christ Hospital's policy that the Institutional Official is an individual of sufficient standing and authority within the institution whose role includes:

2.1 Operational authority for The Christ Hospital's HRPP, and
2.2 Assuring that the program is functional, adequately staffed and funded, and respected within the research community.

3.0 RESPONSIBILTY

The Institutional Official is responsible for ensuring that the HRPP functions effectively within the institution by:

3.1 Providing the resources and necessary support to comply with all requirements applicable to research involving human subjects;
3.2 Exercising appropriate administrative oversight to assure that The Christ Hospital's policies and procedures designed for protecting the rights and welfare of human participants in research are effectively applied in compliance with its Federalwide Assurance (FWA), including:
  3.2.1 Representing the institution in the Federalwide Assurance (FWA), and
  3.2.2 Serving as the Human Protections Administrator (HPA) on the FWA, and the institution's point of contact for the Department of Health and Human Service's official for the Office of Human Research Protections (OHRP);

3.3 Ensuring that The Christ Hospital Institutional Review Board (IRB) functions independently and that its chair and members have direct access to the IO for appeal if they experience undue influence or have concerns about the function of the IRB;
3.4 Promoting an institutional culture supporting the ethical conduct of human subjects research;
3.5 Ensuring that investigators fulfill their responsibilities;
3.6 Assuring training and educational opportunities are available for the IRB and investigators; and
3.7 Determining what external IRBs the Institution will rely upon.

4.0 PROCEDURE

The Institutional Official:

4.1 Performs all duties in accordance with the responsibilities outlined under section 3.0 Responsibility above.
4.2 Shall assume authority to disapprove research approved by The Christ Hospital IRB if the research does not suit the needs of the institution for any reason deemed appropriate. However, the IO cannot approve of research that has been disapproved by the IRB.
4.3 Delegates to the IRB Chair the following duties:
  4.3.1 IRB policies and procedure creation,
  4.3.2 Reliance Agreements with external IRBs, and
  4.3.3 Delegates to the IRB Office duties of providing education and training to researchers.

5.0 REFERENCES

5.1 Code of Federal Regulations
  5.1.1 U.S. Department of Health and Human Services (HHS): 45 CFR 6.103(b)
  5.1.2 U.S. Food and Drug Administration: 21 CFR 56.106(b)(1)
5.2 AHRPP Domains and Elements
  5.2.1 I.1.B
  5.2.2 I.1.C