The Christ Hospital IRB **Number:** 1.05
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STANDARD OPERATING PROCEDURE

Resource Allocation for Human Research Protection Program

1.0 PURPOSE

This procedure establishes the process to ensure that The Christ Hospital has sufficient resources to support the operation of its IRB and Human Research Protection Program.

2.0 POLICY

The Christ Hospital provides financial resources, space, and personnel to support the operations of its IRB and Human Research Protection Program.

3.0 RESPONSIBILITY

3.1 Vice President for Medical Affairs/Chief Medical Officer

The Vice President for Medical Affairs/Chief Medical Officer serves as the Institutional Official and maintains responsibility for overall management of the IRB staff and budget.

3.2 IRB Chair and IRB Administrator

The IRB Chair and IRB Administrator oversee daily IRB operations and report to the Institutional Official.

4.0 PROCEDURE

The Institutional Official ensures:

4.1 Appropriate IRB Staffing

The Christ Hospital IRB staff consists of a contracted IRB chair, one full-time IRB Administrator, and one full-time Regulatory Coordinator. The IRB is housed on the 3rd floor of the main hospital and includes a 2-office suite of approximately 400 sq. feet where it manages daily operations. In-person IRB meetings are held in a conference room on the main campus of The Christ Hospital. Virtual IRB meetings are held via the Microsoft Teams platform.

4.2 Appropriate IRB Budget

The Christ Hospital IRB budget is established by the Institutional Official, the IRB Chair, and the IRB Administrator. The budget is reviewed annually to ensure that appropriate resource allocations are in place to provide a quality research program. When establishing the annual IRB budget, the following considerations are made:

4.2.1 Staffing needs,
4.2.2 Regulatory agency expenses,
4.2.3 Continuing education expenses, and
4.2.4 General operational expenses of the IRB office.

5.0 REFERENCES

5.1 Code of Federal Regulations

5.1.1 45 CFR 46.108(a)(1), and 21 CFR Parts 50 and 56

Require IRBs to have adequate resources to review and monitor biomedical research

5.1.2 45 CFR 46.111

Common Rule criteria for IRB approval: An IRB must determine that risks to subjects are minimized and are reasonable in relation to anticipated benefits. This review requires significant resources, including qualified staff and expert consultants.

5.2 AAHRPP Domains and Elements: Standard I-2