

The Christ Hospital IRB
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STANDARD OPERATING PROCEDURE

Resource Allocation for Human Research Protection Program

1.0 PURPOSE

This procedure establishes the process to ensure 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 personnel, space, and financial resources to support the operations of its IRB and Human Research Protection Program.

3.0 RESPONSIBILITY

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

3.1.1 IRB Chair and IRB Administrator oversee daily IRB operations reporting to the Institutional Official

4.0 PROCEDURE

4.1 Institutional Official (VP/CMO) ensures the IRB has the following:

4.1.1 Appropriate Staffing- TCH IRB staff consists of: a contractor IRB Chair; 1.0 FTE IRB Administrator; 1.0 FTE Regulatory Specialist. TCH IRB is housed on the 3rd floor of the Hospital, and includes a 2-office suite (approximately 400 sq. ft) for daily operations. In-person IRB meetings are held in a conference room in the Administrative Suite of the main campus and virtual IRB meetings are held via the Microsoft Teams platform.

4.1.2 Appropriate Budget: Maintains a designated budget for its IRB. Budgets are reviewed and established by the IRB Chair, IRB Administrator, and VP/CMO annually to ensure appropriate resource allocations are in place to provide a quality research program. The following are considered when establishing a budget for the IRB:

4.1.2.1 Staffing needs

4.1.2.2 Regulatory agency expenses

4.1.2.3 Continuing education expenses

4.1.2.4 General office operation expenses

5.0 DOCUMENTS

Not Applicable.

6.0 DEFINITIONS

Not Applicable.

7.0 REFERENCES

7.1 45 CFR 46.103(b)(2)

7.2 AAHRPP Standard I-2