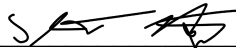


The Christ Hospital IRB

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Number: 1.05

Effective Date: 02/09

Revision Date: 03/21

STANDARD OPERATING PROCEDURE

Resource Allocation for Human Research Protection Program

1 PURPOSE

- 1.1 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 PREVIOUS VERSION

- 2.1 02/09- Original
- 2.2 03/26/15- Removal of IRB Manager
- 2.3 03/17- Reviewed
- 2.4 03/21- Template formatting change; clarifications of IO and VP/CMO; addition of IRB Administrator; removal of IRB Associate Chair; addition of virtual meeting space

3 POLICY

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

4 RESPONSIBILITY

- 4.1 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.
 - 4.1.1 IRB Chair oversees daily IRB operations reporting to the Institutional Official
 - 4.1.2 Oversight of the Regulatory Specialist is delegated to the IRB Administrator

5 PROCEDURE

- 5.1 Institutional Official (VP/CMO) ensures the IRB has the following-
 - 5.1.1 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.
 - 5.1.2 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:
 - 5.1.2.1 Staffing needs
 - 5.1.2.2 Regulatory agency expenses
 - 5.1.2.3 Continuing education expenses

5.1.2.4 General office operation expenses

6 DOCUMENTS

6.1 None

7 DEFINITIONS

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

8 REFERENCES

8.1 45 CFR 46.103(b)(2)

8.2 AAHRPP Standard I-2