

The Christ Hospital IRB

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STANDARD OPERATING PROCEDURE

Establishing Authorization Agreements

1 PURPOSE

- 1.1 This procedure establishes the process to execute an Authorization Agreement with an external institution/organization.
- 1.2 The process begins when an External IRB has been identified by The Christ Hospital Institutional Review Board (TCH IRB) Office for a potential Authorization Agreement.
- 1.3 The process ends when the Authorization Agreement is fully executed.

2 PREVIOUS VERSION

- 2.1 None.

3 POLICY

- 3.1 The IRB Office reviews and determines if it is appropriate to execute an Authorization Agreement to either:
 - 3.1.1 The Christ Hospital IRB to serve as the Single IRB or IRB of Record for a Multi-Site Study or Collaborative Study, or
 - 3.1.2 The Christ Hospital IRB to cede IRB review to (i.e. rely on) an External IRB from another institution/organization.

4 RESPONSIBILITY

- 4.1 An IRB Office staff member carries out these procedures.

5 PROCEDURE

- 5.1 Upon receiving a request to execute an Authorization Agreement with an external institution/organization, an IRB Office staff member will review the request to determine if it is appropriate by utilizing "Authorization Agreement Review Worksheet" to verify all relevant criteria has been met.
- 5.2 If the criteria have been met, complete the following:
 - 5.2.1 Document in the agreement the terms and conditions under which:
 - 5.2.1.1 TCH IRB will serve as the IRB of Record using either the IRB of Record Reliance Agreement template or the External IRBs Reliance Agreement Template, or
 - 5.2.1.2 The External IRB will serve as the IRB of Record for The Christ Hospital using either the TCH IRB Not IRB of Record Reliance Agreement template or the External IRBs Reliance Agreement Template
 - 5.2.2 Negotiate the terms of agreement, if different from the standard template.

Any non-standard language may require additional review and approval from the IRB Chairman, Institutional Official, and/or Legal Counsel.

- 5.2.3 If the external institution/organization participates in SMART IRB and requests the use of the SMART IRB documentation, then determine if the SMART IRB agreement may be utilized in lieu of the standard Authorization Agreement template.
- 5.2.4 Forward the Agreement to The Christ Hospital Institutional Official or designated signatory. Complete the execution of the agreement by ensuring all parties have signed the agreement and relevant parties have received the final executed copy.
- 5.3 If the criteria have not been met, do not execute an Authorization Agreement. Communicate this to the external institution/organization and the research team, and work with all parties to resolve the issues, as appropriate.

6 DOCUMENTS

- 6.1 SOP 1.22 External IRBs
- 6.2 Authorization Agreement Review Worksheet
- 6.3 Authorization Agreement TCH IRB of Record template
- 6.4 Authorization Agreement TCH IRB Not IRB of Record template

7 DEFINITIONS

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

8 REFERENCES

- 8.1 NOT-OD-16-094: Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research