The Christ Hospital IRB
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STANDARD OPERATING PROCEDURE

Reliance on External IRBs

1. PURPOSE

1.1 This procedure establishes the process when The Christ Hospital IRB cedes IRB review to (i.e., relies on) an External IRB.

1.2 The process begins when the Principal Investigator submits an Authorization Agreement requesting the use of an External IRB.

1.3 The process ends when the Authorization Agreement is executed according to SOP 1.21 Establishing Authorization Agreements.

2. POLICY

2.1 The Christ Hospital IRB Office

2.1.1 Reviews and determines if it is appropriate to execute an Authorization Agreement to cede (i.e., rely on) IRB review to an External IRB

2.1.2 Performs routine post-approval monitoring activities or conduct directed (for cause) reviews of study records. These oversight activities may be accomplished remotely, in collaboration with the external institution's IRB/Compliance team located at the participating research site.

3. RESPONSIBILITY

3.1 The Christ Hospital Principal Investigator

3.1.1 Complies with all submission and reporting requirements of the External IRB

3.1.2 Follows procedures listed below (item 4.) to submit a new study application in Mentor IRB including relevant study information in order for the IRB Office staff to make an initial assessment, and submits subsequent External IRB study updates/renewals to The Christ Hospital IRB, as applicable

3.1.3 Obtains all appropriate institutional/organizational approvals prior to implementation of study procedures at The Christ Hospital

3.1.4 Complies with applicable Ohio laws, regulations, and The Christ Hospital policies

3.1.5 Ensures that all collaborators and study staff are appropriately qualified, have completed Human Subjects Protections training (CITI Course), and have been adequately trained to conduct the study in alignment with the IRB approved protocol

3.1.6 Promptly reports any Unanticipated Problems Involving Risk to Subjects or Others (UPIRSOs), termination or suspension of the study to TCH IRB.

3.1.7 Maintains documentation of External IRB approval and other study documentation.

4. PROCEDURE

The Christ Hospital Principal Investigator and IRB Office staff shall conduct the following procedures:

4.1 Initial Review

4.1.1 Principal Investigator

The Christ Hospital Principal Investigator shall complete the reliance agreement e-application and includes the following with the submission in Mentor IRB:

a. Study protocol
b. Proposed consent form(s)
c. Reliance Agreement
d. Financial Conflict of Interest (FCOI) Disclosure (see item 4.3 "Conflicts of Interest" below for additional information)

4.1.2 The Christ Hospital Health Network (TCHHN) Department Head

The appropriate TCHHN department head reviews the submission in Mentor IRB to ensure appropriate resources are available at the institution for the study to proceed through IRB review.

a. If approved, the submission is sent for review by the IRB Chairman.
b. If disapproved, the investigator is sent a letter outlining the reason(s) for disapproval.

4.1.3 The Christ Hospital IRB Chairman

The IRB Chairman reviews the submission utilizing the Reliance Agreement checklist to:

a. Ensure that the consent form includes the required local context language, including, but is not limited to, conflict of interest, research costs, research injury and HIPAA language
b. Ensure that the Reliance Agreement e-application contains all study documents approved by the External IRB
c. Determine that if reliance is appropriate, the IRB Office staff follows the process outline in SOP 1.21 Establishing Authorization Agreements, and forwards the partially

executed Authorization Agreement to the local research team to proceed with the External IRBs processes

d. Finalize and issue permission to proceed with submission to the External IRB

4.2 Continuing Review and Modifications

4.2.1 The Principal Investigator

The Christ Hospital Principal Investigator shall submit the External IRB approval letters to The Christ Hospital IRB for study updates/renewals of the External IRB approved research which meets the following criteria:

a. Updates to Principal and Co-Investigators
b. Updates to protocol or consent forms
c. External IRB Continuing Review approval of The Christ Hospital study site
d. Compliance with the External IRB expiration date. In the event that the Principal Investigator has failed to renew the study with the External IRB by the expiration date, the Principal Investigator must notify The Christ Hospital IRB in writing within 24 hours of study expiration.

4.2.2 The Christ Hospital IRB Office

The IRB Office staff reviews the updated information

a. Verifies that all applicable local context information is included
b. Finalizes and issues the acknowledgement letter

4.3 Conflicts of Interest

4.3.1 Review of COIs

When an investigator, or any other key personnel, on a proposed research project discloses that they (or their spouse or dependent children) have significant financial or management interests in a sponsored project, further review by an IRB is required including determination of what, if any, management plan is necessary to minimize the risk of imparting bias into the research (ref. SOP 2.13 Investigator Disclosure of Financial Interest). When The Christ Hospital IRB relies on IRB review by an external IRB, The Christ Hospital maintains responsibility for review of any conflicts of interest disclosures and development of COI management plans, as necessary. The convened IRB shall review any COI disclosures upon receipt at the time of initial review and during annual status updates. Additionally, the IRB shall develop and approve plans to manage the conflict of interest, as appropriate.

4.3.2 Management Plans

Management plans are typically tailored to the specific study and/or sponsor, and the researcher’s financial interests.

4.3.3 Reporting to the External IRB

The Christ Hospital IRB shall report findings and determinations of COI reviews and development of management plans to the external IRB through direct communication with the external IRB.

Ref. SOP 2.13 Investigator Disclosure of Financial Interest; TCH Policy 1.05.104 Human Research Protections Program Conflict of Interest

4.4 **Reportable New Information**

4.4.1 Unanticipated Problems Involving Risk to Subjects or Others (UPIRSOs) that do not involve The Christ Hospital or its affiliates' study participants are not required to be submitted to The Christ Hospital IRB.

4.4.2 The Principal Investigator is required to submit a Reportable Event form for any Reportable New Information that involves The Christ Hospital or its affiliates' study participants.

4.5 **Study Termination**

The Christ Hospital IRB Office considers study closure a change in status. The Principal Investigator is therefore required to submit the External IRB closure documentation to The Christ Hospital IRB.

5. **DOCUMENTS**

None

6. **DEFINITIONS**

For definitions of double underlined terms, see SOP 3.23 Definitions

7. **REFERENCES**

- SOP 1.21 Establishing Authorization Agreements
- SOP 2.13 Investigator Disclosure of Financial Interest
- The Christ Hospital Administrative Policy 1.05.104 Human Research Protections Program Conflict of Interest