The Christ Hospital IRB
Submitted By: Erica Jones, CIP
Reviewed By: Steve Roberts, MD
Approved By: Steve Roberts, MD

Number: 1.22
Effective Date: 10/29/19
Revision Date: 09/22

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 IRB review to (i.e. rely on) 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.

2 RESPONSIBILITY

3.1 Principal Investigator at The Christ Hospital:

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

3.1.2 Follows procedures below to submit a new study application to TCH IRB, including the relevant study information in order for the IRB Office staff to make an initial assessment, and submits subsequent External IRB study updates/renewals to TCH IRB, as applicable.

3.1.3 Obtains all appropriate institution/organization approvals prior to implementation of 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 appropriated 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 Principal Investigator and IRB Office staff conduct the following procedures:

4.1 Initial Review

4.1.1 The Principal Investigator completes the reliance agreement e-application and includes the following with the submission in Mentor IRB:

4.1.1.1 Study protocol

4.1.1.2 Proposed consent form(s)

4.1.1.3 Reliance Agreement

4.1.1.4 Financial Conflict of Interest (FCOI) Disclosure

4.1.2 The appropriate TCCHN 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.

4.1.2.1 If approved, the submission is sent for review by the IRB Chairman.

4.1.2.2 If disapproved, the investigator is sent a letter outlining the reason(s) for disapproval.

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

4.1.2.2 Ensures that the consent form includes the required local context language (which includes, but is not limited to, conflict of interest, research costs, research injury and HIPAA language).

4.1.2.3 Ensures the Reliance Agreement e-application contains all study documents approved by the External IRB.

4.1.2.1 If reliance is determined to be 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.

4.1.2.1 If reliance is determined to be 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.

4.1.2.4 Finalizes and issues permission to proceed with submission to the External IRB.

5.2 Continuing Review and Modifications

5.2.1 The Principal Investigator is required to submit the External IRB approval letters to TCH IRB for study updates/renewals of the External IRB approved research that meet the following criteria:

5.2.1.1 Updates to Principal and Co-Investigators

5.2.1.2 Updates to protocol or consent forms

5.2.1.3 External IRB Continuing Review approval of The Christ Hospital study site

5.2.1.4 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 TCH IRB in writing within 24 hours of study expiration.

5.2.2 The IRB Office staff reviews the updated information

5.2.2.1 Verifies all applicable local context information is included.

5.2.2.2 Finalizes and issues acknowledgement letter.

5.3 Reportable New Information

5.3.1 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.

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

5.4 Study Termination

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

6 DOCUMENTS

6.1 None.

7 DEFINITIONS

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

8 REFERENCES

8.1 SOP 1.21 Establishing Authorization Agreements