The Christ Hospital IRB
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STANDARD OPERATING PROCEDURE

The Christ Hospital Institutional Review Board Serving as IRB of Record

1 PURPOSE

1.1 This procedure establishes the workflow process when The Christ Hospital IRB serves as the Single IRB or IRB of Record for a Multi-Site Study or Collaborative Study.

1.2 The process begins when the Principal Investigator submits a study application and notifies the IRB Office in order for The Christ Hospital to consider serving as the Single IRB or IRB of Record.

1.3 The process ends when the Authorization Agreement is executed according to "SOP 1.21 Establishing Authorization Agreements", IRB Approval has been completed, and an IRB Approval Letter has been issued to The Christ Hospital Principal Investigator.

2 PREVIOUS VERSION

2.1 None.

3 POLICY

3.1 The Christ Hospital IRB Office:

3.1.1 Reviews and determines if it is appropriate to execute an Authorization Agreement for The Christ Hospital IRB to serve as the Single IRB or IRB of Record for a Multi-Site Study or Collaborative Study.

3.1.2 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.

4 RESPONSIBILITY

4.1 The executed Authorization Agreement delineates the roles and responsibilities of the institution and Participating Site Principal Investigator, including adhering to the Participating Site's required institutional approvals, notifications, and other reporting requirements.

4.2 The Christ Hospital Principal Investigator:

4.2.1 Submits a Single IRB Appropriateness Consultation form, at least 5 weeks before the NIH grant deadline to obtain a Letter of Support, if the request pertains to an NIH-funded Multi-Site Study that is mandated to use a Single IRB.

4.2.2 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 facilitates the submission of materials to TCH IRB on behalf of the Participating Site for subsequent submissions.

4.2.3 Obtains all appropriate institution/organization approvals prior to implementation of procedures at The Christ Hospital.

4.2.3.1 If, in reviewing a site that is relying on The Christ Hospital IRB:

4.2.3.1.1 a management plan is uploaded, or

4.2.3.1.2 a consent form is submitted that has disclosure information for an investigator at the site.

4.2.3.2 The IRB Analyst will notify The Christ Hospital Conflict of Interest Office via email or ancillary review.

4.2.4 Provides all The Christ Hospital IRB-approved study documents and other pertinent correspondence to the Participating Site.

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

4.2.6 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.

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

4.2.8 Maintains documentation of IRB approval and other study documentation.

5 PROCEDURE

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

5.1 Initial Review

5.1.1 The Principal Investigator includes the following documents in the Submission:

5.1.1.1 IRB Study Application

5.1.1.2 Study protocol

5.1.1.3 Draft consent form

5.1.1.4 Other documents for consideration (e.g. Investigator's Brochure, Instructions for Use, Advertising Materials)

5.1.1.5 Authorization Agreement template

5.1.2 The IRB Office staff and/or Chairman review the submission:

5.1.2.1 Using the procedures outlined in the Authorization Agreement Review worksheet, the IRB Office staff determines if it is appropriate for The Christ Hospital's IRB to serve as the Single IRB or IRB of Record. The IRB Office staff also assesses on a case-by-case basis whether

it is feasible for The Christ Hospital's IRB to serve in that capacity.

5.1.2.1.1 If appropriate and feasible, 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 and directly to the external institution, when appropriate.

5.1.2.2 Finalizes and issues approval letter along with all applicable IRB-approved documents.

5.1.3 The Christ Hospital Principal Investigator provides all IRB-approved study documents to the external institution(s) or Participating Site Principal Investigator.

5.2 Continuing Review and Modifications

5.2.1 The Christ Hospital Principal Investigator:

5.2.1.1 Facilitates submission of the Participating Site study modifications and continuing reviews to The Christ Hospital IRB Office.

5.2.1.2 Provides to the external institution contact or Participating Site Principal Investigator, any IRB determination letters, approval letters and other pertinent IRB correspondence.

5.2.1.3 Facilitates modification submission to the IRB Office for IRB approval of any new (additional) Participating Site. The modification should include details about the study procedures to be performed at the new Participating Site.

5.3 Reportable New Information

5.3.1 The Christ Hospital Principal Investigator:

5.3.1.1 Performs Reportable New Information Reporting to The Christ Hospital.

5.3.1.1.1 Submits Reportable Event forms for any Reportable New Information that involve The Christ Hospital or its affiliates' study participants.

5.3.1.1.2 Submits Reportable Event forms for any Reportable New Information that occur at any Participating Site.

5.4 Study Termination

5.4.1 The Christ Hospital Principal Investigator:

5.4.2 Provides the study closure documentation to the Participating Site Principal Investigator.

5.4.3 Maintains study records in accordance with record retention requirements.

6 DOCUMENTS

6.1 SOP 1.21 Establishing Authorization Agreements

6.2 Authorization Agreement Worksheet

6.3 Authorization Agreement TCH 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