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 (TCH 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. POLICY

2.1 The Christ Hospital IRB Office

2.1.1 Reviews and determines if it is appropriate to execute an Authorization Agreement for TCH IRB to serve as the Single IRB or IRB of Record for a Multi-Site Study or Collaborative Study

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

3. RESPONSIBILITY

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.

3.1 The Christ Hospital Principal Investigator

3.1.1 Follows procedures below to submit a new study application in Mentor 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

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

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

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), or termination or suspension of the study to TCH IRB

3.1.7 Maintains documentation of 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 Principal Investigator or his/her representative submits the following through Mentor IRB, as applicable, for IRB consideration:

a. Application, including requests for the following as applicable to the research:
   - Request for Full or Partial Waiver of HIPAA Authorization
   - Waiver of Informed Consent
   - Waiver of Documentation of Informed Consent
b. Protocol, if applicable
c. Informed consent documents, if applicable
d. CITI completion certificates
e. Other documents for consideration (e.g. Investigator's Brochure, Instructions for Use, Advertising Materials)
f. Reliance Agreement

4.1.2 IRB Office Staff and/or Chairman

The IRB Office Staff and/or Chairman review the submission including:

a. Use of the procedures outlined in the Authorization Agreement
b. Review of the checklist, determining if it is appropriate for The

Christ Hospital's IRB to serve as the Single IRB or IRB of Record; the IRB Chairman also may assess, on a case-by-case basis, whether it is feasible for The Christ Hospital IRB to serve in such a capacity

c. Following the process outlined in SOP 1.21 Establishing Authorization Agreements, if appropriate and feasible, and forwarding the partially executed Authorization Agreement to the local research team and directly to the external institution, when appropriate (IRB Office staff)
d. Performing the initial review of any Financial Conflict of Interest disclosed by a member of the research personnel at the Participating Site, and making a determination as to whether the disclosure constitutes a significant financial interest (The IRB Chairman); if yes, a management plan must be provided and the disclosure will be assigned to the Full Board Panel for convened IRB review as described in SOP 2.13 Investigator Disclosure of Financial Interest.
e. Finalizing and issuing the approval letter along with all applicable IRB-approved documents

4.1.3 The Christ Hospital Principal Investigator

TCH Principal investigator provides all IRB-approved study documents to the Principal Investigator of the external institution(s) or Participating Site(s).

4.2 Research Conducted in Another State or Country

4.2.1 Interstate Research

The Christ Hospital IRB is committed to assuring that research approved by the IRB is conducted in accordance with state and local law, in addition to federal law. Ref. 45 CFR 46.101(e), 21 CFR 56.103(c), SOP 1.15 State and Local Laws in Human Subjects Research

When relying on TCH IRB, relying institutions must agree to provide the following important information to help the TCH IRB conduct its review:

a. The requirements of any applicable state or local laws, regulations, institutional policies, standards, or other local factors, including local site ancillary reviews, relevant to the research that would affect the conduct or approval of the research at your institution
b. Site-specific consent information for this study using the template provided by the TCH IRB

The Christ Hospital IRB becomes aware of any such information on applicable state or local laws, regulations, institutional policies, standards or other local factors including local site ancillary reviews through completion of TCH IRB Local Context Questionnaire.

4.2.2 **International Research**
TCH does not engage in international research.

4.3 **Continuing Review and Modifications**
The Christ Hospital Principal Investigator shall:

4.3.1 Facilitate submission of the Participating Site study modifications and continuing reviews through the web-based IRB submission system Mentor IRB

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

4.3.3 Facilitate modification submissions through Mentor IRB for IRB approval of any new (i.e., additional) Participating Site(s) including details about the study procedures to be performed at the new Participating Site(s)

a. Review of Additional Research Sites: The IRB may review requests to add research sites as **modifications to previously approved protocols**.

- **Minor Modification/Minimal Risk:** The addition of an investigative site will be considered to be a minor modification when:
  1) The research conducted at the site is considered minimal risk research, and
  2) The site will follow the same protocol as has already been reviewed and approved by the convened IRB. Such cases of minor modification requests may be reviewed through the Expedited Review procedure.
- **Greater Than Minimal Risk:** For modification requests involving greater than minimal risk, when serving as the reviewing IRB TCH requires that the convened IRB consider the modification request through full-board review in order to approve the modification and any associated materials (e.g., template consents, recruitment materials, etc.)

4.4 **Reportable New Information**
The Christ Hospital Principal Investigator performs Reportable New Information Reporting to The Christ Hospital by submitting Reportable Event forms for any:

4.4.1 Reportable New Information that involves The Christ Hospital or its affiliates' study participants

4.4.2 Reportable New Information that occur at any Participating Site

4.5 **Study Termination**
The Christ Hospital Principal Investigator shall:

4.5.1 Facilitate a closure request for the Participating Site and through Mentor IRB

4.5.2 Provide the study closure documentation to the Participating Site Principal Investigator

4.5.3 Maintain study records in accordance with record retention requirements

5. **DOCUMENTS**

5.1 SOP 1.21 Establishing Authorization Agreements

5.2 Authorization Agreement Worksheet

6. **DEFINITIONS**

For definitions of double underlined terms above, refer to SOP 3.23 Definitions.

7. **REFERENCES**

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