

The Christ Hospital IRB
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STANDARD OPERATING PROCEDURE

Reliance on External IRBs

1.0 PURPOSE

This procedure establishes the process for The Christ Hospital (TCH) ceding Institutional Review Board (IRB) review to (i.e., reliance on) an external IRB.

2.0 POLICY

When The Christ Hospital relies upon an external IRB for non-exempt human subjects research, a reliance agreement will be established between TCH and the reviewing IRB. Prior to the initial submission to the external IRB for review, the request for external reliance is submitted in TCH IRB's electronic record management system Mentor IRB, a local institutional administrative review is completed, and TCH IRB provides clearance via the "TCH IRB External IRB Reliance and Local Context Review Approval" letter indicating that the required materials may be submitted to the external IRB for approval.

Investigators do not have the authority to sign or otherwise commit to any reliance agreement, nor make an initial submission to the external IRB for review, until after TCH IRB provides clearance via the TCH IRB External IRB Reliance and Local Context Review Approval letter indicating that the required materials may be submitted to the external IRB.

Following external IRB approval of The Christ Hospital as a research site, the fully executed reliance agreement and all approval documentation must be submitted into the main protocol page in Mentor IRB for final institutional approval by TCH IRB. Research activities may not commence at TCH until final approval is issued by TCH IRB.

For research studies overseen by an external IRB, TCH IRB shall provide post-approval monitoring and/or directed (for cause) reviews of study records on an ongoing basis, as applicable. TCH IRB oversight activities may be accomplished remotely in collaboration with the external institution's IRB/compliance team located at the participating research site.

3.0 RESPONSIBILITY

3.1 The Christ Hospital (local) Principal Investigator

- 3.1.1 Complies with all submission and reporting requirements of the External IRB;
- 3.1.2 Follows procedures outlined below for submitting a new study application in Mentor IRB, including relevant study information in order for TCH IRB to make an initial reliance determination, and submitting all final reliance documents received after external IRB approval into the main protocol page in Mentor IRB;
- 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 state and federal laws and regulations, as well as institutional policies of The Christ Hospital;
- 3.1.5 Ensures that all collaborators and study staff are appropriately qualified including completion of (1) Human Subjects Protections training (CITI course), and (2) adequate training required to conduct the study in alignment with the IRB-approved protocol;
- 3.1.6 Following receipt of permission to submit to the external IRB, submits all required documentation to the external IRB for site approval.
- 3.1.7 Submits the fully executed reliance agreement, all other approval documentation of External IRB approval of The Christ Hospital as a research site, and any other applicable study documentation, to TCH IRB for final approval;
- 3.1.8 Submits a Status Update to TCH IRB through Mentor IRB following external IRB renewals including uploading the current consent form(s) and protocol with the submission; and
- 3.1.9 Promptly reports any Unanticipated Problems Involving Risk to Subjects or Others (UPIRSOs) and other reportable events, and/or termination or suspension of the study, to TCH IRB.

3.2 IRB Office Staff

- 3.2.1 Facilitates the review of requests for reliance and the process of ceding IRB review to an External IRB; and
- 3.2.2 Performs routine post-approval monitoring activities or conducts directed (for cause) reviews of the study records of research studies in which TCH relies on an external IRB.

3.3 IRB Chair

- 3.3.1 Reviews requests for reliance;
- 3.3.2 Executes reliance agreements on behalf of The Christ Hospital;
- 3.3.3 Issues final approval for commencement of the research study at TCH;
- 3.3.4 Reviews and approves status updates; and
- 3.3.5 Reviews any reportable events.

4.0 PROCEDURE

4.1 Initial Reliance Review

4.1.1 Principal Investigator/Authorized Designee

The Christ Hospital Principal Investigator (or designee) completes the reliance agreement e-application including the following with the submission in [Mentor IRB](#):

- 4.1.1.1 Study protocol;
- 4.1.1.2 Proposed consent form(s), as applicable;
- 4.1.1.3 FDA documentation, as applicable;
- 4.1.1.4 Reliance Agreement (study specific); and
- 4.1.1.5 Clinical trial agreement or research services agreement, as applicable.

4.1.2 The Christ Hospital Health Network (TCHHN) Department Head

The appropriate TCHHN Department Head reviews the submission in Mentor IRB to ensure that appropriate resources are available at the institution for the study to proceed through IRB review. This is documented on The Christ Hospital Department Approval Checklist.

- 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.

4.1.3 The Christ Hospital Legal Counsel

The Christ Hospital Legal Counsel reviews clinical trial agreements (CTA), if applicable, for consistency between [AAHRPP Elements 1.8.A – 1.8.E](#), as applicable, and the research. Legal Counsel also ensures that the language regarding research-related injury is consistent with the local consent form.

- 4.1.3.1 If confirmed, the submission is sent for review by the IRB chairman;
- 4.1.3.2 If not confirmed, the IRB office staff sends the investigator (or designee) a letter requesting revisions to the agreement and/or local consent form.

4.1.4 The Christ Hospital Pharmacy

The Christ Hospital Pharmacy reviews any protocol involving the use of an investigational new drug (IND) to ensure that appropriate resources are available at the institution for the study to proceed through IRB review. This is documented on The Christ Hospital Pharmacy Utilization Review Checklist.

- 4.1.4.1 If approved, the submission is sent for review by the IRB chairman.
- 4.1.4.2 If disapproved, the IRB office staff sends the investigator (or designee) a letter outlining the reason(s) for disapproval and/or any required modifications.

4.1.5 The Christ Hospital IRB Office Staff

The IRB office staff reviews the submission utilizing the IRB Office Reliance Review Checklist to ensure that:

- 4.1.5.1 All ancillary reviews have been completed;
- 4.1.5.2 The Reliance Agreement e-application contains all required fields;
- 4.1.5.3 All required documentation has been uploaded;
- 4.1.5.4 The consent form includes the required local context language including, but not limited to, conflict of interest, costs to the research subject, research injury, and HIPAA language; and

- 4.1.5.5 Key research personnel have valid credentials, training, and Annual Financial Conflict of Interest (FCOI) disclosure forms (required for funded/sponsored research) uploaded to their Mentor Accounts.

If the IRB chair indicates reliance in Mentor, the IRB office:

- 4.1.5.6 Sends a copy of the reliance agreement for local execution to the IRB chair through DocuSign after the IRB chair indicates reliance in Mentor, and
- 4.1.5.7 Finalizes and issues permission to proceed with submission to the External IRB through Mentor IRB, and forwards the partially executed Reliance Agreement to the local research team to proceed with the External IRB's processes.

4.1.6 **The Christ Hospital IRB Chairman**

The IRB chairman reviews the submission utilizing the Reliance Agreement Checklist to:

- 4.1.6.1 Confirm 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;
- 4.1.6.2 Confirm that the Reliance Agreement e-application contains all required information; and
- 4.1.6.3 Determine that if reliance is appropriate, the IRB office staff follows the process outlined in SOP 1.21 - Establishing Authorization Agreements, and forwards the partially executed Authorization Agreement to the local research team to proceed with the External IRB's processes.

4.2 **Final Reliance Review**

4.2.1 **The Christ Hospital IRB Office Staff**

The IRB office staff reviews the final submitted documentation indicating External IRB reliance utilizing the "IRB Office: Final Reliance Document Review Checklist" to ensure that all final reliance documents are received after external IRB approval, such as the:

- 4.2.1.1 External IRB approval letter;
- 4.2.1.2 HIPAA Waiver approval regulatory letter, if applicable;
- 4.2.1.3 Fully-executed reliance agreement;
- 4.2.1.4 Fully-executed CTA/research services agreement, if applicable;
- 4.2.1.5 Approved consent document(s), if applicable; and
- 4.2.1.6 Approved protocol, if applicable.

After the Chairman reviews and approves the final reliance submission, IRB office staff issues final approval to proceed with the research at the TCH site.

4.2.2 **The Christ Hospital IRB Chairman**

The IRB chairman reviews the final submitted documentation indicating External IRB reliance utilizing the "IRB: Chair Final Reliance Document Review Checklist" to

confirm that all final reliance documents have been received after external IRB approval and issue final approval at the site.

4.3 **Continuing Review and Modifications**

4.3.1 **The Principal Investigator**

- 4.3.1.1 Submits any proposed changes to local key research personnel (i.e., addition or removal of principal investigator, sub-investigator, research coordinator, or research staff);
- 4.3.1.2 Maintains compliance with the External IRB’s set expiration date;
- 4.3.1.3 Submits a status update submission in Mentor IRB, which includes a copy of the following documents:
 - 4.3.1.3.1 External IRB continuing review approval letter;
 - 4.3.1.3.2 Current approved consent form(s); and
 - 4.3.1.3.3 Current approved protocol.

4.3.2 **IRB Office**

The IRB office staff:

- 4.3.2.1 Reviews the updated information;
- 4.3.2.2 Verifies that all applicable local context information is included; and
- 4.3.2.3 Finalizes and issues the acknowledgement letter.

4.4 **Conflicts of Interest (COI)**

When The Christ Hospital relies on an external IRB for human subjects protection oversight, The Christ Hospital maintains responsibility for review of any conflicts of interest disclosures of their research personnel under their policies, development of COI management plans (as necessary), and reporting to the external IRB. Note that the reviewing external IRB has the right to impose additional prohibitions or conflict management requirements.

4.4.1 **Review of COI**

When an investigator or any other key personnel on a proposed research project discloses that he/she (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). 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 (ref. SOP 1.28 - Review of Financial Conflicts of Interest).

4.4.2 **Management Plans**

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

4.4.3 **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.

4.5 **Reportable New Information**

4.5.1 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.

4.5.2 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.

4.6 **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.

In the event that the Principal Investigator has failed to renew the study with the External IRB by the External IRB's expiration date, the Principal Investigator must notify The Christ Hospital IRB in writing within 24 hours of study expiration.

5.0 **REFERENCES**

5.1 [IRB Standard Operating Procedures](#)

5.2.1 IRB SOP 1.21 - Establishing Authorization Agreements

5.2.2 IRB SOP 1.28 - Review of Financial Conflicts of Interest

5.2.3 IRB SOP 2.13 - Investigator Disclosure of Financial Interest

5.2 The Christ Hospital Administrative Policy

1.05.104 - Human Research Protections Program Conflict of Interest

5.3 AAHRPP Domains and Elements

[Elements I.8.A – I.8.E](#)