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

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# STANDARD OPERATING PROCEDURE

## Establishing Authorization Agreements

## 1. PURPOSE

The Christ Hospital (TCH) policy on the use of a single Institutional Review Board (IRB) for multi-site research establishes the expectation that a single IRB of record will be used in the ethical review of non-exempt human subjects research protocols that are carried out at more than one site. The goal of this policy is to enhance and streamline the IRB review process in the context of multi-site research so that research can proceed as effectively and expeditiously as possible. Eliminating duplicative IRB review aids in reducing unnecessary administrative burdens and systemic inefficiencies without diminishing human subjects protections. Eliminating redundancy in reviews also allows IRBs to concentrate more time and attention on the review of single site protocols, thereby enhancing research oversight. (Ref. NOT-OD-16-094: Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research)

1.1 This procedure establishes the process to execute an Authorization Agreement with an external institution/organization.
1.2 The process begins when an External IRB has been identified by The Christ Hospital Institutional Review Board (TCH IRB) Office for a potential Authorization Agreement.
1.3 The process ends when the Authorization Agreement is fully executed.

## 2. POLICY

### 2.1 The Christ Hospital - SMART IRB

As applicable, TCH utilizes and maintains an agreement with SMART IRB, an integrated, comprehensive platform for multi-site studies. The "SMART IRB Master Common Reciprocal Institutional Review Board Authorization Agreement" supports Institutional Review Board reliance in facilitation of multi-site human subjects research, and allows Participating Institutions to cede IRB review (Relying Institution) to the IRB of another Participating Institution (Reviewing IRB). TCH strongly encourages the use of the SMART IRB Agreement. However, Participating Institutions may opt to use their own policies and procedures for the reliance relationship if doing so would not render the Participating Institutions in violation of any term of the SMART IRB Agreement. In such cases, Participating Institutions agree that if a

provision of their own policies or procedures conflicts with a term of the SMART IRB Agreement, then the SMART IRB Agreement will govern as to that term.

2.2 **The Christ Hospital IRB Office**

The IRB Office reviews and determines if it is appropriate to execute an Authorization Agreement to establish either:

2.1.1 The Christ Hospital IRB serving as the Single IRB or IRB of Record for a Multi-Site Study or Collaborative Study, or

2.1.2 The Christ Hospital IRB ceding IRB review to (i.e. relying on) an External IRB from another institution/organization.

## 3. PROCEDURE

3.1 **The Christ Hospital IRB Office**

Upon receiving a request to execute an Authorization Agreement with an external institution/organization, IRB Office staff will review the request to determine whether the request is appropriate by utilizing the Reliance Review Checklist in Mentor IRB. Next steps are determined by criteria either met or unmet as outlined in the checklist:

3.1.1 **Criteria Met**

If the criteria are met, complete the following:

3.1.1.1 Document terms and conditions under which either:

a. TCH IRB will serve as the IRB of Record using either the SMART IRB Master Common Reciprocal Institutional Review Board Authorization Agreement or the External IRB's Reliance Agreement Template, or

b. the External IRB will serve as the IRB of Record for The Christ Hospital using either the SMART IRB Master Common Reciprocal Institutional Review Board Authorization Agreement or the External IRB's Reliance Agreement Template.

3.1.1.2 Negotiate terms of the Agreement if not using the SMART IRB Master Common Reciprocal Institutional Review Board Authorization Agreement or the standard template. Any non-standard language may require additional review and approval from the IRB Chairman, Institutional Official, and/or Legal Counsel.

3.1.1.3 Determine responsibilities of (a) the Reviewing IRB and (b) the Relying Institution as outlined under **item 4.** (Responsibilities) below.

3.1.1.4 Following review and approval of the reliance agreement and application in Mentor IRB, forward the agreement to The Christ Hospital Institutional Official or designated signatory. Complete the execution of the agreement by ensuring all parties have signed the agreement and relevant parties have received the final executed copy.

3.1.2 **Criteria Not Met**

If the criteria have not been met, do not execute an Authorization Agreement. Notify the external institution/organization and the research team that the criteria are not met and work with all parties to resolve issues, as appropriate.

## 4. RESPONSIBILITIES

Unless otherwise specified in the Agreement, the following are standard responsibilities of the Reviewing IRB and the Relying Institution.

### 4.1 Reviewing IRB

4.1.1 **Federalwide Assurance**

The written Reliance Agreement shall include defining terms of The Federalwide Assurance in which a research institution commits to DHHS that it will comply with the Federal Policy. When serving as the Reviewing IRB, TCH IRB shall determine whether the Relying Institution applies its (the Relying Institution's) FWA to some or all research, and, in serving as the Reviewing IRB, TCH IRB shall satisfy the terms of the Relying Institution's FWA in IRB review and oversight of the research.

4.1.2 **Review and Oversight**

The review and oversight of the research by the Reviewing IRB will be performed in accordance with the human subjects protection requirements of the Relying lnstitution's FWA, any applicable federal human subjects research regulations and ethical principles, and any other applicable federal human subjects research regulations or policies. The Reviewing IRB shall and perform reviews of:

4.1.2.1 Amendments

4.1.2.2 Complaints

4.1.2.3 Unanticipated problems that may involve risks to subjects or others

4.1.2.4 Potential non-compliance with applicable human subjects protection regulations, or with the requirements or determinations of the Reviewing IRB including protocol deviations and audit findings. Such review/oversight shall also include:

a. Determining whether an allegation of non-compliance has a basis in fact
b. Determining whether an incidence of non-compliance is serious or continuing
c. Reporting to the Relying Institution findings related to non-compliance

Additionally, oversight responsibilities of the Reviewing IRB shall include reviews of other documents, requests, or information related to the approval and continuing oversight of the Research and any corrective actions, as applicable.

4.1.3 **Audits**

As described in section 4.3.4 below (Joint Responsibilities, Monitoring), each Participating Institution is responsible for conducting and reporting on the results of for-cause and not-for-cause audits. Additionally, the Reviewing IRB may request that the Relying Institution conduct its own audit/investigation and report findings of fact back to the Reviewing IRB. Or, the Reviewing IRB and Relying Institution may work cooperatively to conduct a joint audit/investigation. In such cases, the Reviewing IRB will reasonably cooperate with the audit/investigation by the Relying Institution as necessary, including but not limited to, providing Research review records and related information, meeting with representatives from the Relying Institution, and helping to implement corrective actions, as applicable.

**Corrective Actions**: The Reviewing IRB shall inform the Relying Institution of any corrective actions in connection with an audit, investigation, or resolution of any matter of fact required by the Reviewing IRB, but shall not prevent the Relying Institution from adopting its own more stringent additional corrective actions.

4.1.4 **Vulnerable Populations**

The Reviewing IRB shall be responsible for obtaining any additional approvals from DHHS for research involving pregnant women, fetuses, and neonates; or children. Note: TCH does not engage in research involving prisoners.

4.1.5 **Scientific Review**

Scientific/scholarly review of the research shall be conducted upon initial review of the study. Such review includes, but is not limited to:

- 4.1.5.1 Assurance of scientific or scholarly validity
- 4.1.5.2 Confirming that proper scientific and department approvals have been obtained
- 4.1.5.3 Assurance that the hypothesis and procedures are consistent with generally accepted scientific principles in the discipline
- 4.1.5.4 Confirmation that the PI has appropriate training and expertise, adequate resources and sufficient time allocation to conduct the research
- 4.1.5.5 The research is pertinent to the needs and goals of the institution, department and community
- 4.1.5.6 The research has been found to be acceptable for IRB submission

4.1.6 **Additional Certifications**

The Reviewing IRB shall be responsible for confirming that Participating Institutions meet any additional certification requirements (e.g., Certificates of Confidentiality).

## 4.2 Relying Institution

4.2.1 **Audits, Investigations, Corrective Actions**

The Relying Institution shall cooperate, and require its research personnel to cooperate, with any audit or investigation by the Reviewing IRB. Such cooperation will include, but is not limited to, providing research records and related information, meeting with representatives from the Reviewing IRB/Institution and assisting in carrying out any corrective actions, as applicable.

If the Relying Institution is asked by the Reviewing IRB to conduct its own audit/investigation, or to work cooperatively with the Reviewing IRB to conduct an audit/investigation, then the Relying Institution will do so and will report its findings of fact to the Reviewing IRB within a reasonable timeframe.

The Relying Institution shall comply with and shall require its research personnel to comply with all corrective actions required by the Reviewing IRB, but nothing herein shall prevent the Relying Institution from adopting its own more stringent additional corrective actions.

4.2.2 **Noncompliance**

The Relying Institution shall promptly notify the Reviewing IRB of any discoveries of potential noncompliance with applicable human subjects protection regulations or with the requirements or determinations of the Reviewing IRB in connection with the research at the Relying Institution.

4.2.3 **Complaints**

The Relying Institution shall ensure that an institutional mechanism exists by which complaints about the research can be made by local research participants or others. Additionally, the Relying Institution shall promptly notify the Reviewing IRB of any complaints.

4.3 **Joint Responsibilities**

Each Participating Institution engaged in or conducing the Research agrees to be jointly responsible regarding the following:

4.3.1 **Education/Training/Qualifications**

Each Participating Institution shall agree to ensure that all research personnel have adequate education, training and qualifications to perform the research and safeguard the rights and welfare of research subjects. This includes, but is not limited to, the human subject research training requirement (CITI or acceptable equivalent) and understanding of the ethical standards and regulatory requirements governing research activities with human participants. A Participating Institution shall provide information and documentation regarding its research personnel's education, training, and qualifications in connection with a ceded review as requested by the Reviewing IRB.

4.3.2 **Monitoring**

Each Participating Institution shall agree that adequate access to a human subjects research **audit process** is in place to conduct and report on the results of for-cause and not-for-cause audits of the institution's and its research personnel's compliance with human subjects protections and other relevant requirements.

4.3.3 **Termination**

Termination of a reliance agreement may occur only upon the mutual agreement of all then-Participating Institutions. Should termination occur, TCH will be responsible for continued oversight of the studies until closure or a mutually agreed upon transfer of the studies.

4.4 **Conflicts of Interest Management Plans**

The convened Christ Hospital IRB reviews any disclosures of significant financial interest upon receipt of, and at the time of initial and continuing review. TCH IRB develops and approves plans to manage such interest, as appropriate, to minimize the risk of imparting bias into the research. TCH IRB Administrator shall be responsible for providing management plans to the Reviewing IRB.

## 5. AAHRPP Accreditation

Except under special circumstances, TCH relies only upon external IRBs that are AAHRPP accredited. AAHRPP accreditation, the "gold seal" standard for HRPPs, ensures that an institution meets a rigorous set of human protection standards aligned with ethical principles protecting research participants. TCH may, however, consider relying on a non-AAHRPP accredited institution if it is determined that appropriate human subject protections are in place given the potential risks to participants.

If TCH relies on a non-AAHRPP accredited IRB, TCH IRB office will conduct an administrative review of the reliance submission to ensure compliance with TCH's ethical standards and applicable laws and regulations. The extent of the review may vary depending on the level of risk to research participants. AAHRPP outlines in Standard I-9 requirements to ensure that, when sharing oversight of research with another organization, the rights and welfare of research participants will be protected. Therefore, any Authorization/Reliance Agreement with a non-AAHRPP accredited IRB shall establish and delineate roles and responsibilities of each party, and clearly outline the responsibilities and requirements under this standard. Considerations in the review shall include, but not be limited to, the following:

5.1 **Minimal Risk Research**

For minimal risk research, TCH IRB may:

- 5.1.1 Obtain an assurance from the non-accredited IRB that it will conduct its review consistent with the applicable ethical standards and regulations, and that it will report any regulatory violations or investigations of the reviewing IRB by regulatory agencies (e.g., OHRP, FDA, or other regulatory agency)
- 5.1.2 Request that the Reviewing IRB attest to completion of its own internal quality review process. Examples of self-assessment tools include:
  - 5.1.2.1 FDA Checklists for IRBs
  - 5.1.2.2 OHRP QA Self-Assessment Tool
  - 5.1.2.3 AAHRPP Evaluation Instrument for Accreditation Reliance

5.2 **Greater Than Minimal Risk Research**

For greater than minimal risk research, TCH IRB may require additional oversight such as:

5.2.1 Reviewing relevant portions of the minutes of the IRB meeting in which the study is reviewed

5.2.2 Reviewing IRB records of the study being reviewed (e.g., requesting access to the reviewing IRBs electronic system)

5.2.2.1 Evaluating relevant policies and procedures of the reviewing IRB

5.2.2.2 Confirming that IRBs in other locales/states have completed relevant certifications, as applicable

5.2.2.3 Observing a portion of an IRB meeting when the study is reviewed

5.2.2.4 Appointing someone from the Relying Institution to serve as a consultant to the non-accredited IRB for the purposes of reviewing the study

5.2.2.5 Conducting not-for-cause monitoring of the IRB

## 6. NIH SINGLE IRB POLICY

An NIH funded study being conducted at more than one U.S. site involving non-exempt human subjects research may be subject to the NIH Single IRB (sIRB) policy and/or the revised Common Rule cooperative research provision (45 CFR 46.114). NIH-supported studies conducting multi-site or cooperative research may need to have a single IRB as outlined at Single IRB for Multi-Site or Cooperative Research.

Note: As of January 20, 2020, studies subject to the Revised Common Rule Cooperative Research Provision (45 CFR 46.114(b)) must use a single IRB as required by the terms and conditions of award including studies not subject to the NIH sIRB policy (e.g., domestic, multisite career development (K) and fellowship (F) awards).

**Exceptions** to the use of a single IRB in studies being conducted at more than one site are rare. However, exceptions may be granted under certain circumstances. Questions about or requests for an exception should be directed to the appropriate NIH Program Official. Offerors should consult with their Contracting Official. Exception requests not based on a federal/state/tribal law, regulation, or policy, and exception requests to the revised Common Rule Cooperative Research sIRB Mandate during the COVID-19 Public Health Emergency, require the review and approval of the NIH Office of the Director.

Justification: Exception requests to the NIH Single IRB policy must provide sufficient information which demonstrates a compelling justification for an exception to the NIH Single IRB policy. **TCH IRB shall document rationale for not relying upon a single IRB review in accordance with NIH policy on exceptions from single IRB review**.

7. **DOCUMENTS**
   7.1 SMART IRB Master Common Reciprocal Institutional Review Board Authorization Agreement

8. **DEFINITIONS**
   See SOP 3.23 Definitions for definitions of double underlined terms.

9. **REFERENCES**
   9.1 SOP 1.22 External IRBs
   9.2 NOT-OD-16-094: Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research