IRB AUTHORIZATION AGREEMENT

This agreement allows The Children's Hospital of Philadelphia IRB (CHOP IRB) to act as the Reviewing IRB for another Institution.

Name of Designated Institution Providing IRB Review (Reviewing IRB)

Committees for the Protection of Human Subjects (CHOP IRB) The Children's Hospital of Philadelphia	
Assurance (FWA):	FWA00000459

Name of Institution Relying on the Designated IRB (Relying Institution)

Name of Relying Institution:	
Assurance (FWA):	

The Officials signing below agree that the Relying Institution may designate and rely on the CHOP IRB for review and continuing oversight of its human subjects research described below.

This agreement is limited to the following specific protocol(s):

CHOP IRB Number:	
Title of Study:	
CHOP Principal Investigator:	
Relying Site Principal Investigator:	
Sponsor or Funding Agency:	

By signing this agreement, both institutions have agreed that the CHOP IRB will serve as the Reviewing IRB and are agreeing to uphold their individual responsibilities as listed on page 2-3 of this document. The IRB at CHOP will follow written procedures for reporting its findings and actions to appropriate officials at the Relying Institution. Relevant minutes of CHOP IRB meetings will be made available upon request. The Relying Institution remains responsible for ensuring compliance with the CHOP IRB's determinations and with the Terms of its OHRP-approved FWA. This document must be kept on file by both parties and provided to OHRP upon request.

Signature of Signatory Official at CHOP:

Signature	Date
Print Full Name	Institutional Title

Signature of Signatory Official at the Relying Institution:

Signature	Date
Print Full Name	Institutional Title

Division of Responsibilities

A. The responsibilities of the CHOP IRBs are to:

1) Maintain a Federal Wide Assurance (FWA) with OHRP;

2) Maintain a Board membership that satisfies the requirements of 45 CFR 46, 21 CRF 56;

3) Make available to the Relying Institution upon request, the CHOP IRB Standard Operating Procedures;

4) Perform initial reviews, continuing reviews, reviews of submitted reportable events for the ceded research that involve risks to subjects or others, amendments, incidents of serious or continuing noncompliance, and reviews of any other documents as needed to be consistent with the applicable regulations;

5) Maintain and make accessible to the Relying Institution the CHOP IRB application, protocol reviews, letters to Principal Investigators, approvals and disapprovals, and minutes of the CHOP IRB meetings relevant to the protocol;

6) Notify the Relying Institution immediately in the event of a suspension or restriction of the CHOP IRB's authorization to review studies; and

7) Provide the Relying Site approved informed consent form(s). The consent from will indicate areas where the Relying Site may add language or otherwise customize the consent form for its own site. The changes are generally limited to the following areas: HIPAA, payment for research related injury, site-specific religious and cultural norms, and local contacts. Any modifications will be subject to approval by the Reviewing IRB, which will then provide a final approval consent form to the Relying Site for use;

8) Receive and review all conflict of interest determinations including management plans, which might need to include appropriate redactions, made by the Relying Site. The Reviewing IRB will ensure that any management plans are incorporated into its deliberations and that any mandated disclosures to subjects are included in the approved informed consent form. If the Reviewing IRB determines that a management plan requires modifications in order to ensure protection of Research participants, the Reviewing IRB will promptly notify the Relying Site. If the Relying Site is not willing to modify its management plan consistent with the Reviewing IRB's request, than the Research will not be eligible for review under this Agreement. The Reviewing IRB will not disapprove prohibitions or management plans that are more stringent or restrictive than what the Reviewing IRB would require. If the Reviewing IRB is unable to implement the Relying Site's prohibitions or management plans, the Research will not be eligible for review under this Agreement; and

9) Notify the Relying Institution of any CHOP IRB policy decisions or regulatory matters that might affect the institution's reliance on CHOP IRB reviews or performance of the research at the Relying Institution.

B. The responsibilities of the Relying Institution are to:

1) Maintain an FWA.

2) Maintain a human subjects protection program, as required by the DHHS OHRP;

3) Provide the CHOP IRB with the current the names and addresses of a local contact person who has the authority to communicate for the Relying Institution (e.g., the local IRB administrator);

4) Ensure that the Principal Investigators and other Research Personnel at the Relying Site who are involved in the Research are appropriately qualified and meet the Relying Site's standards for eligibility to conduct Research. This includes, but is not limited to, having the required professional staff appointments, credentialing, insurance coverage, and background checks for their assigned role in the Research;

5) Perform local analysis of any specific requirements of state or local laws, regulations, policies, standards (social or cultural) or other factors applicable to the Research, and notify the CHOP IRB of any relevant requirements or results of the analysis that would affect its conduct of the Research. Provide the applicable information to the Reviewing IRB as appropriate for consideration;

6) Perform local review by other local ancillary committee reviews (e.g. pharmacy, radiation safety, etc.) when required by the Relying Site's policies. The determinations should be provided to the Reviewing IRB when pertinent to its review and determinations;

7) Provide the Reviewing IRB with all specific wording needed to complete the identified site-specific sections - as enumerated in A.7 above. - of the study consent form(s) approved by the Reviewing IRB;

8) Maintain policies regarding the disclosure and management of conflicts of interest related to Research and share those policies with the Reviewing IRB when requested. Ensure that Relying Site Investigators and other Research Personnel involved in the Research disclose financial interests as required under the Relying Site policies. Ensure that conflicts of interest are reviewed and a management plan is implemented, if and as required under Relying Site policies. Provide all management plans to the Reviewing IRB for its review and consider modifications from the Reviewing IRB (as described in A.8 above). The Relying Site will ensure compliance of all management plans related to the Research.

9) Notify the CHOP IRB immediately if there is ever a suspension or restriction of the local IRB's authorization to review studies;

10) Notify the CHOP IRB immediately if there is a suspension or restriction of the investigator at the relying institution;

11) Ensure the safe and appropriate performance of the research at the Relying Institution. This includes, but is not limited to: monitoring study compliance; reviewing major protocol violations, and any unanticipated problems involving risk to subjects and others that occur at the institution; ensuring a mechanism exists by which complaints about the research can be made by local study participants or others.

12) Any actions taken as a result of problems that are identified in these areas should be shared with the CHOP IRB and the Principal Investigator at CHOP;

13) Require the PI at the Relying Institution to maintain appropriate copies of all approvals, and other correspondence documenting the review and approval of the research as required by the regulations;

14) Maintain compliance with any additional state, local, or institutional requirements related to the protection of human subjects;

15) The Relying Institution may, at any time, choose to change its decision to cede review for the research. In such cases the Reviewing IRB and Relying Site will work together to facilitate the transfer of IRB oversight with the goal of limiting the potential disruption to the Research. Until the IRB oversight is transferred, the Reviewing IRB will continue to assume oversight responsibility.