The Children's Hospital of Philadelphia®

Institutional Review Board, Committees for the Protection of Human Subjects

IRB AUTHORIZATION AGREEMENT

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

Name of Designated Institution Providing IRB Review

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

Name of Relying Institution:	
Assurance (FWA):	

The Officials signing below agree that 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):

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

By signing this agreement, both institutions have agreed that the CHOP IRB will serve as the IRB of record and are agreeing uphold their individual responsibilities as listed on page 2 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 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

The responsibilities of the CHOP IRBs are to:

1) *Maintain an FWA with OHRP and the registration of its IRBs with both OHRP and the FDA;*

2) Maintain a Board membership that satisfies the requirements of 45 CFR 46, 21 CRF 56 and provide special expertise as needed from Board members or consultants to adequately assess all aspects of the study;

3) Make available to the local institution upon request, the CHOP IRB Standard Operating Procedures;

4) Perform initial reviews, continuing reviews, reviews of submitted Serious Adverse Events, reviews of protocol amendments, reviews of DSMB reports, and reviews of any other documents submitted by the Principal Investigator of the research study subject to this agreement;

5) Maintain and make accessible to the local IRB at 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) Notify the local 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 local institution.

The responsibilities of the local institution are to:

1) *Maintain a Federal Wide Assurance (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 IRB at the relying institution (e.g., the local IRB administrator);

4) Maintain a local IRB whose membership satisfies the requirements of 45 CFR 46 and 21 CRF 56;

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

6) Ensure that the investigators and other staff at the relying institution who are conducting the research are appropriately qualified and meet the institution's standards for eligibility to conduct research;

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

8) 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.

   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;

9) 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;

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