IRB Authorization Agreement between CHOP & Penn

Determination Form

Use this form when both CHOP and PENN are engaged in the Research.

Please reference OHRP's Guidance on "Engagement of Institutions in Research" at http://www.hhs.gov/ohrp/humansubjects/assurance/engage.htm to determine if both CHOP and PENN are engaged in the research.

Submit this form to the Institution requested to serve as the IRB of Record.

Please note that IRB specific submission requirements still apply. If necessary, contact the respective IRB office for more information.

Protocol Title:	
Penn PI:	**CHOP PI:**
Penn IRB #:	**CHOP IRB #:**
IRB of Record: ☐ University of Pennsylvania IRB ☐ The Children's Hospital of Philadelphia IRB	**Hospitals Engaged:** ☐ HUP ☐ CHOP ☐ Pennsylvania Hospital
Provide a summary of the research activities that will be conducted at each Institution and the rationale for the choice of IRB of record.	

By signing this agreement, both institutions have agreed to uphold their individual responsibilities as listed on page 2 of this document. The IRB of Record will follow written procedures for reporting its findings and actions to appropriate officials at the relying institution. The relying institution remains responsible for ensuring compliance with the determinations of the IRB of Record 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 PI from Institution serving as IRB of record:	Date:
Signature CHOP IRB Chair or designee:	Date:
Signature Penn IRB Chair or designee:	Date:

Division of Responsibilities

The responsibilities of the IRB of Record 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 relying institution upon request, the IRB Standard Operating Procedures;

4) Perform initial reviews, continuing reviews, reviews of submitted unanticipated problems, reviews of protocol amendments, reviews of DSMB reports, reviews of single-subject exception requests, 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 relying IRB the application, protocol reviews, letters to Principal Investigators, approvals and disapprovals, and minutes of the IRB meetings relevant to the protocol;

6) Notify the relying institution immediately in the event of a suspension or restriction of the IRB of Record's authorization to review studies; and

7) Notify the local institution of any IRB policy decisions or regulatory matters that might affect the institution's reliance on IRB reviews or performance of the research at the relying institution.

The responsibilities of the relying 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 IRB of Record 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) Notify the IRB of Record immediately if there is ever a suspension or restriction of the local IRB's authorization to review studies;

5) 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;

6) Forward any Conflict of Interest management plans to the IRB of Record;

7) Notify the IRB of Record immediately if there is a suspension or restriction of 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 Principal Investigator at each institution and IRB of Record;

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.