	The Children's Hospital of Philadelphia Committee for the Protection of Human Subjects Policies and Procedures	SOP 305 Page: 1 of 8
	Title: Cooperative Agreements	Effective Date: 6/19/2006 Version Date: 2/26/2013

I. PURPOSE

This standard operating procedure describes the IRB's procedures for review and oversight of research conducted under a cooperative agreement with an external (outside) IRB.

It is permissible under 45 CFR 46.114 for an institution to rely on an IRB of another OHRP-approved institution for protocol review. Cooperative research projects include those where more than one institution is engaged in human subjects research activities. During the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy.

II. POLICY STATEMENT

When participating in a cooperative project with another institution, the CHOP IRB may enter into a joint review arrangement, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort.

III. SCOPE

These policies and procedures apply to all research submitted to the IRB.


IV. DEFINITIONS

External IRB: means the IRB at another institution. An external institution must hold an FWA issued by OHRP in order to be qualified (approved) to serve as the IRB of record or to serve as a relying institution.

Local or Internal IRB: are referred to in OHRP's guidance documents and for the purposes of this policy, mean CHOP's IRB.

IRB Authorization Agreement (also referred to as a Cooperative IRB Agreement): means an agreement between two IRBs, that designates one IRB to be the IRB of record for human subjects research taking place at both institutions and the other institution(s) to be the relying institution(s). The IRB of record is responsible for the regulatory oversight of the protocol.

Relying Institution: means the institution that has assigned another IRB to serve as the IRB of record under an IRB Authorization Agreement.

	The Children's Hospital of Philadelphia Committee for the Protection of Human Subjects Policies and Procedures	SOP 305 Page: 2 of 8
	Title: Cooperative Agreements	Effective Date: 6/19/2006 Version Date: 2/26/2013


V. PROCEDURES

A. Serving as the IRB of record for another institution

1. When appropriate, the CHOP IRB may serve as the IRB of record for a relying institution. Examples of appropriate circumstances include, but are not limited to the following:
 - (a) multi-center research studies where a CHOP principal investigator (PI) is the overall study PI or steering committee chair;
 - (b) multi-center research studies where a CHOP PI serves as the PI for multiple regional sites;
 - (c) research studies where greater than minimal risk study interventions or procedures occur at CHOP and where follow-up procedures that are performed at external sites are not greater than minimal risk.
 - (d) other compelling circumstances where, due to the nature and location of the research activities, CHOP is best situated to safeguard the rights and welfare of research subjects.
2. Reliance on CHOP's IRB as the IRB of record will be governed by a signed Cooperative Agreement.
 - (a) The Cooperative Agreement will define the terms, scope and limits, and roles and responsibilities of the joint review arrangement. (see Appendix A for standard terms)
 - (b) Cooperative Agreements may apply to multiple studies between institutions or may be developed on a case-by-case basis for a single study. If the latter, the Director, Human Subjects Research, will work with an IRB Administrator at the external IRB to establish an IRB Authorization Agreement.
3. The Institutional Official, or designee, will serve as the signatory authority for IRB Authorization Agreements negotiated with other IRBs.

B. Reliance on another IRB


1. When appropriate, the CHOP IRB may rely on an external IRB to serve as the IRB of record. Examples of appropriate circumstances include, but are not limited to the following:
 - (a) multi-center research where a specialized central IRB has been established for the sole purpose of reviewing a category of investigative studies (e.g., the NCI CIRB);

	The Children's Hospital of Philadelphia Committee for the Protection of Human Subjects Policies and Procedures	SOP 305 Page: 3 of 8
	Title: Cooperative Agreements	Effective Date: 6/19/2006 Version Date: 2/26/2013

- (b) multi-center research where a cooperative study group has designated an IRB to serve as the IRB of record for a study or group of studies.
 - (c) research where the sole involvement of CHOP is the participation of a CHOP investigator, but where all subject-related activities will take place at an external institution;
 - (d) research where greater than minimal risk study interventions or procedures occur at an external institution and where the follow-up procedures performed at CHOP are not more than minimal risk;
 - (e) other compelling circumstances where, due to the nature and location of the research activities, an external IRB is equally situated to safeguard the rights and welfare of research subjects at CHOP.
2. This reliance on an external IRB will be governed by a signed IRB Authorization Agreement that will define the terms, scope and limits, and roles and responsibilities of the joint review arrangement. The agreement may apply to multiple studies between the institutions or may be developed on a case-by-case basis for a single study.
 3. The Director, Human Subjects Research, will work with the IRB Administrator at the other site to establish an IRB Authorization Agreement.
 4. The Institutional Official, or designee, is the signatory authority for IRB Authorization Agreements negotiated with other IRBs.

C. Working with Other IRBs

1. The School District of Philadelphia and other school districts
 - (a) The IRB Office works closely with the IRB of the School District of Philadelphia and other school districts on studies where research will be conducted at these other sites.
 - (b) A copy of the IRB approval letter from the School District of Philadelphia, or other school district, must be provided to the CHOP IRB office prior to the CHOP IRB granting final approval for a research study.
2. External IRBs with which CHOP has established Cooperative Agreements for multiple studies: (see attachments for links to the agreements)
 - (a) The University of Pennsylvania
 - (b) The National Cancer Institute's Central IRB (CIRB)

	The Children's Hospital of Philadelphia Committee for the Protection of Human Subjects Policies and Procedures	SOP 305 Page: 4 of 8
	Title: Cooperative Agreements	Effective Date: 6/19/2006 Version Date: 2/26/2013

D. Required Documentation when CHOP is the IRB of Record

1. In addition to the submission requirements outlined in SOP 301, the following must be submitted to the IRB when CHOP is the IRB of record:
 - (a) The accreditation status of the outside IRB;
 - (b) Conflict of Interest management plans of all investigators at the outside institution (when applicable); and
 - (c) The role of the investigators at the outside institution in the research.

E. Required Documentation when CHOP is Not the IRB of Record


1. Initial Approval
 - (a) A copy of the initial approval letter from the IRB of record
 - (b) A copy of the protocol
 - (c) A copy of the informed consent document(s) and any recruitment materials that will be used at CHOP.
2. Continuing Review and Modifications
 - (a) A copy of the following
 - (1) Approval letters for each continuing approval and approved modifications issued by the IRB of record
 - (2) Current version of the approved protocol
 - (3) Current version of the approved consent form

VI. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.114

VII. REFERENCES TO OTHER APPLICABLE SOPS

IRB SOP 306: Facilitated Review Procedures
 For Studies Approved by the NCI CIRB

	The Children's Hospital of Philadelphia Committee for the Protection of Human Subjects Policies and Procedures	SOP 305 Page: 5 of 8
	Title: Cooperative Agreements	Effective Date: 6/19/2006 Version Date: 2/26/2013

VIII. RESPONSIBILITIES

Title	Responsibility
Director, Human Subjects Research	Responsible for negotiating IRB Authorization Agreements, maintaining complete files on all research reviewed via an IRB Authorization Agreement negotiated with another IRB and for all applicable regulatory compliance requirements.
Institutional Official, or designee	Responsible for approving and signing Cooperative Agreement Determination forms for studies conducted at CHOP and UPenn.


IX. ATTACHMENTS

The IRB website at <https://intranet.research.chop.edu/display/cmtirb/IRB+Forms> contains forms for IRB authorization agreements including:

1. Penn-CHOP Authorization Agreement and current Determination Form
2. NCI CIRB Authorization Agreement
3. CHOP Authorization Agreement (when CHOP will be the Primary IRB for an external institution)

X. REVISIONS:

- 2/14/2007 Revised to incorporate changes in IRB office staff responsibilities.
- 11/10/08 Revision includes provision to permit CHOP to serve as the IRB of record for other institutions. Specific additional submission requirements when CHOP is the IRB of record and when CHOP is not the IRB of record were added (Sections V.D and V.E).
- 6/9/10 Revised attachment section to reflect updates to the documents available on the IRB website. This revision also authorizes the Director, HSR to negotiate IRB and sign authorization agreements.
- 1/13/2013 Remove reference to facilitated review with the NCI Central IRB and clarified who may sign authorization agreements.

	The Children's Hospital of Philadelphia Committee for the Protection of Human Subjects Policies and Procedures	SOP 305 Page: 6 of 8
	Title: Cooperative Agreements	Effective Date: 6/19/2006 Version Date: 2/26/2013


XI. APPROVAL:

Director, Human Subjects Research

Date

Chair, Committees for the Protection of Human Subjects

Date

	The Children's Hospital of Philadelphia Committee for the Protection of Human Subjects Policies and Procedures	SOP 305 Page: 7 of 8
	Title: Cooperative Agreements	Effective Date: 6/19/2006 Version Date: 2/26/2013


XII. APPENDIX A

Division of Responsibilities When CHOP is the IRB of Record

(terms contained in the CHOP Cooperative Agreement)

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 Children's Hospital of Philadelphia Committee for the Protection of Human Subjects Policies and Procedures	SOP 305 Page: 8 of 8
	Title: Cooperative Agreements	Effective Date: 6/19/2006 Version Date: 2/26/2013

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 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.