COMMUNICATION PLAN

Purpose of the form: To identify and document how the CHLA Study Team will communicate with Relying Site Study Teams for a multi-site study when CHLA is the Reviewing IRB. A good communication plan involves initial study start-up discussions and regularly scheduled meetings, calls, presentations, etc. to discuss oversight of the conduct of the study. Sufficient administrative resources are required to implement this process. This form must be completed and submitted to the CHLA IRB for review and approval. Once approved by the CHLA IRB, this document should be shared with all Relying Site Study Teams.

CHLA IRB Number:	
Study Title:	
CHLA Principal Investigator:	
Version Date:	

CHLA Study Team Responsibilities – Please review the responsibilities below and indicate the CHLA Study Team's agreement to comply with the following requirements by placing a check in the box next to "CHLA Study Team Acceptance" for each item:

Initial Application to the CHLA IRB:	Preparing and submitting the study-wide application for initial CHLA IRB review and any study-wide amendments to the CHLA IRB via iStar. **CHLA Study Team Acceptance:** ☐
Financial Conflicts of Interest Management:	Providing and ensuring implementation of required financial conflict of interest management plans required for the Relying Site Study Team members to the CHLA IRB. *Note: This information should be captured in the Institutional Profile Sheet completed by the Relying Site.* **CHLA Study Team Acceptance:** ☐
Training & Qualifications Documentation:	Providing confirmation to the CHLA IRB that the Relying Site Study Teams have completed relevant training and are qualified to conduct the proposed research. *Note: This information should be captured in the Institutional Profile Sheet completed by the Relying Site. CVs of the site study team members (PI and co-investigators only) should also be submitted in the reliance packet. CHLA study teams should keep training certifications with the study regulatory documents.* **CHLA Study Team Acceptance:** ☐
Consent/Assent Templates & Recruitment Templates:	Providing the CHLA IRB approved master consent/assent form templates and any approved master recruitment material templates to the Relying Site Study Teams. Ensuring that the Relying Site Study Teams properly incorporate site-specific language into the templates and send them to the CHLA Study Team. *Note: The CHLA Study Team is responsible for submitting these site-specific consent/assent forms and any recruitment materials to the CHLA IRB for review and approval prior to use.* **CHLA Study Team Acceptance:** ☐
Local Context Information from Relying Sites:	Providing local context information to the CHLA IRB regarding state laws and institutional requirements that pertain to the review of Relying Sites. *Note: This information should be captured in the Institutional Profile Sheet completed by the Relying Site.* **CHLA Study Team Acceptance:** ☐

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Adding Relying Sites to the Study:	Preparing and submitting the site-specific applications and site-specific amendments to the CHLA IRB that address site variations in study conduct, informed consent language, HIPAA Privacy Rule requirements, subject identification and recruitment processes (including recruitment materials), and any other applicable components of the research. *Note: This information should be captured in the Institutional Profile Sheet completed by the Relying Site.* Refer to the CHLA HSPP website under, "External Sites Relying on the CHLA IRB for Review and Oversight" for more information about adding Relying Sites. **CHLA Study Team Acceptance:** ☐
CHLA IRB Determinations & CHLA IRB-Approved Documents – Relying Sites:	Providing documentation of all CHLA IRB determinations and copies of the most current versions of CHLA IRB-approved study materials to Relying Site Study Teams in a timely manner. **CHLA Study Team Acceptance:** ☐
Continuing Review Information & Submission to the CHLA IRB:	Obtaining and collating study-wide enrollment and study progress information for continuing review from all Relying Site Study Teams. Submitting the continuing review application to the CHLA IRB via iStar. **CHLA Study Team Acceptance:** ☐
New Information that Requires Prompt Reporting to the CHLA IRB:	Reporting new information that requires prompt reporting to the CHLA IRB (e.g., new or increased risks, unexpected harm to subjects or others, or new safety information; noncompliance with federal regulations or the determinations of the CHLA IRB). **CHLA Study Team Acceptance:** ☐
Closure Reports to the CHLA IRB:	Providing the CHLA IRB with required information from all Relying Site Study Teams when the study is closed (or when a Relying Site is closed). **CHLA Study Team Acceptance:** ☐

Plans for Communication with Relying Site Study Teams - Relying Sites Study Teams must be familiar with the CHLA HSPP website and CHLA investigator guidance documents, including but not limited to:

1. Obtaining and Documenting Consent and Assent
2. New Information that Requires Prompt Reporting
3. Amendments to CHLA IRB Approved Research
4. Continuing Review Requirements and Submission of Closure Reports

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CHLA IRB Review and Oversight: Describe the plan for communicating with Relying Site Study Teams about CHLA IRB review requirements, policies, procedures and guidance.
CHLA Prompt Reporting Requirements: Describe the plan for ensuring Relying Site Study Teams understand CHLA IRB requirements for prompt reporting of new information to the CHLA Study Team.
Dissemination of CHLA IRB Approved Study Documents: Describe the plan for providing documentation of CHLA IRB determinations and the most current approved versions of CHLA IRB-approved materials to Relying Site Study Teams in a timely manner.

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Continuing Review Information: Describe the plan for ensuring Relying Site Study Teams provide site enrollment and study progress information to the CHLA study team.
Closure Report Information: Describe the plan for ensuring Relying Site study teams provide the CHLA study team with the required information when a study is closed (or if a site is closed prior to study closure).