**Instructions to Request that Lurie Children’s Serve as the IRB of Record**

1. ***Agree that serving as the IRB of Record is appropriate following email communication and exchange of study documents with Lurie Children’s IRB***

To initiate the reliance process please submit an email to IRBreliance@luriechildrens.org. In the email, please provide:

* + Source of funding for the study
	+ A copy of the proposed protocol
	+ The name(s) of the participating sites
* *Lurie Children’s IRB staff can assist in determining if reliance agreements with the identified sites already exist*
	+ Draft consent documents (as applicable)
	+ Draft recruitment materials (as applicable)
	+ Any other documents as applicable that will help Lurie Children’s assess the appropriateness of Lurie Children’s serving as the IRB of Record

If the study is a network or consortium funded study, the network will often name the IRB of Record. For NIH funded studies, the lead PI may request his/her institution to be the IRB of Record; however, the institutional official (IO) makes the determination of whether the institution will serve as IRB or Record or not. All requests should be submitted to IRB office for consideration via email at IRBreliance@luriechildrens.org.

1. ***Submit the study in Cayuse IRB for Lurie Children’s IRB approval***
2. ***Execute the IAA between Lurie Children’s IRB and any relying sites (can be done in parallel with review of study)***

Once established that Lurie Children’s will serve as the IRB of Record for a protocol, the Lurie Children’s IRB must enter into an IRB Authorization Agreement (IAA) with the relying site(s). The IAA (also called a reliance or cooperative agreement) defines the terms, scope and limits, and roles and responsibilities of the joint review arrangement and must be signed by the Institutional Official of each institution involved.

* 1. Determine whether Lurie Children’s has an existing agreement with the relying site(s). As of 8/1/2020, Lurie Children’s has reliance agreements with:

i. SMARTIRB – Lurie Children’s is a signatory to the SMART IRB master reliance agreement. Where possible, the SMART IRB agreement will be used as the basis for reliance.

ii. NCI IRB - The National Cancer Institute (NCI) funds an extensive national program of cancer research, including pilot, phase 1, phase 2 and phase 3 clinical trials in adults and children focused on cancer prevention, cancer care and delivery, and treatment. The NCI CIRB is an independent organization that provides review of NCI-funded clinical trials.

iii. CHAIRb - The Chicago Area IRB for studies funded and/or sponsored by PCORI (Patient-Centered Outcomes Research Institute) CAPRICORN (Chicago Area Patient-Centered Outcomes Research Network) group.

iv. Lurie Children’s/Northwestern University Reliance Agreement - For the review of research involving the Institution and Northwestern University (NU) and/or an NU Affiliate (Prentice Women’s Hospital, Shirley Ryan Ability Lab, etc.), investigators may request that the Lurie Children’s IRB serve as the IRB of record for NU or an NU affiliate under this reliance agreement. The agreement is per OHRP requirements and guidelines and defines the relationship between the IRBs and the responsibilities of each institution. The Lurie Children’s IRB reviews studies that involve research activity at both NU and the Institution or faculty of both institutions, and/or funding through NU with activity at the Institution.

* + - The PI, from either institution, will submit the study via Cayuse IRB indicating the nature of involvement of NU and/or requesting the Lurie Children’s IRB to serve as the IRB of Record.
		- The study will be routed for review by the Lurie Children’s IRB. ORIC staff will issue the review determination/approval documents to the PI via Cayuse IRB.
		- The PI will submit the study into the NU eIRB+ system indicating intent to rely on an external/central IRB.
		- The PI uploads the Lurie Children’s IRB review determination/approval into NU eIRB+.
		- Subsequent submissions (Renewals, Modifications, etc.) are to be submitted via Cayuse IRB for review. The PI is responsible for providing NU with any amended/approved documents and approvals.

v. Pediatric Practice Research Group (PPRG) - The Pediatric Practice Research Group is a well-established, regional practice-based research network founded in 1984 as a partnership of the Department of Pediatrics at Lurie Children’s and an enthusiastic group of over 50 pediatric practices across Chicagoland. Lurie Children’s has already executed IAA with many of these practices.

vii. Commercial IRBS (WIRB, Ethical and Independent Review services, Jaeb IRB...). Lurie Children’s IRB has several existing master reliance agreements with commercial IRBs; however, study-specific agreements must still be executed.

* 1. If a proposed relying site(s) is/are not listed above and the institution is NOT part of SMART IRB, an individual and study-specific authorization agreement will need to be established with that institution. The Single IRB Coordinator will work with the study team and study contacts at both sites to execute this agreement.

The Institutional Official (IO, Chief Operating Officer) is the final authority on whether Lurie Children’s will serve as the IRB of Record for a multi-site study. The IO has delegated authority to the Director, Office of Research Integrity and Compliance, as well as the Associate Director, Office of Research Integrity and Compliance to make ongoing determinations about IRB reliance arrangements under the SMART IRB or other master agreements.

All new reliance agreements are signed by the IO. The IO will consult with the Director, Office of Research Integrity and Compliance, the IRB Chair and General Counsel as necessary to make these decisions.

1. ***Collect applicable local context from relying site(s)***

Local context refers to applicable relying site institutional policies or state laws, study team member HSR/GCP training and qualifications, and information regarding any conflicts of interest for study personnel that apply to the proposed research. The Lurie Children’s single IRB coordinator will work with the relying IRB point of contact to collect local context information for each relying site. The Single IRB Coordinator will work with relying sites to modify the IRB approved Lurie Children’s consent forms and recruitment documents as needed to relying site informed consent requirements.

1. ***Provide Lurie Children’s IRB approval letter and approved study documents to relying site(s)***

Lurie Children's IRB will need to review and approve (and stamp) the relying site- specific parental permission, assent and adult consent forms as well as other supporting study documents.

6. ***Submit modification in Cayuse IRB to add relying sites and their local documents***​

7. ***Review of modification in Cayuse IRB (Lurie Children’s IRB Chair or Vice Chair)***

8. ***Issue Approval for relying sites including stamped consent forms***