

**National Pediatric Research Alliance  
Master Common Reciprocal Institution Review Board Authorization Agreement  
Determination Form**

**PURPOSE OF THIS FORM**

This form should be completed and signed in collaboration with Reviewing IRB and Relying Institution. It should be completed for each protocol utilizing the Master IRB Authorization Agreement, with fully executed copies maintained by both sites.

Protocol Information

Protocol Title:

Overall Study Principal Investigator:

Reviewing IRB:

Relying Site Principal Investigator:

Reviewing IRB Protocol #:

Relying Site

<input type="checkbox"/> Boston Children's Hospital	<input type="checkbox"/> Lurie Children's Hospital of Chicago
<input type="checkbox"/> Cincinnati Children's Hospital Medical Center	<input type="checkbox"/> Dayton Children's Hospital
<input type="checkbox"/> Children's Hospital of Philadelphia	<input type="checkbox"/> Children's Healthcare of Atlanta
<input type="checkbox"/> Children's Hospital of Colorado	<input type="checkbox"/> Indiana University
<input type="checkbox"/> University of Colorado, Denver	<input type="checkbox"/> Children's Mercy Kansas City
<input type="checkbox"/> Nationwide Children's Hospital	<input type="checkbox"/> Children's Hospital Los Angeles
<input type="checkbox"/> The Nemours Foundation	<input type="checkbox"/> Stanford University
<input type="checkbox"/> Seattle Children's Hospital	<input type="checkbox"/> University of Kentucky
<input type="checkbox"/> Washington U., St. Louis Children's Hospital	<input type="checkbox"/> University of California, Davis
<input type="checkbox"/> Children's National Medical Center	<input type="checkbox"/> Massachusetts General Hospital

Notes:

Local Ancillary Reviews

Each Relying Site is responsible for obtaining any required local institutional ancillary reviews (radiation safety/MRI review, nursing review, pharmacy review, Clinical Trials/Sponsor Agreements, Biomechanical Engineering review, etc.) that apply to the conduct of this research protocol.

Please check here that all required ancillary reviews have been conducted (or that reliance can be executed while ancillary reviews are pending, per local policies/procedures, with protocol not being initiated until all required reviews are completed).

Notes:

Conflicts of Interest

Each Relying Site is responsible for reviewing the protocol and determining whether a conflict of interest exists in accordance with their institutional policies. It is the Relying Site's responsibility to manage or eliminate any

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conflict. The conflict and the management plan must be disclosed to the Reviewing IRB, who will have the final determination whether it is appropriate for the Reviewing IRB to assume IRB review responsibilities given any disclosure and management plan.

Does the protocol present any potential conflicts of interest as defined in the relying Site's institutional policies?

Yes    No

If yes, list investigators with a conflict of interest and attach a full description of the conflict of interest and associated management plan:

Notes:

**Research Investigators/Staff Training**

Each Relying Site is responsible for ensuring their Principal Investigators and Research Personnel have appropriate training requirements.

Please check here that investigators and staff involved in the protocol have satisfied local training requirements.

Notes:

**Signatures/Approvals**

By signing this determination form (1) the Reviewing IRB indicates that it has agreed to serve as the single IRB for one or more of the institutions listed in the Master Reliance Agreement; (2) the Relying Institution agrees to cede review and oversight of the study to the Reviewing IRB; and (3) both institutions agree to uphold their individual responsibilities as listed in the Master Common Reciprocal Institutional Review Board Authorization Agreement.

This document must be kept on file by both institutions and provided to the Office for Human Research Protections (OHRP) upon request.

Signature of Reviewing IRB Designee

Date

Signature of Relying Site Designee

Date