

# “Central IRBs”

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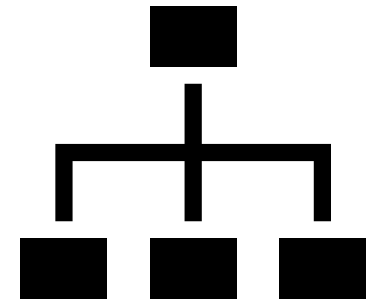
# Types of “Central IRBs”

- Studies where the Cooperative Research Requirement is Applicable (*Single IRBs*)
- Studies where the Northwestern IRB serves as the IRB of Record for an External Site or Sites
- Studies where the Northwestern IRB cedes IRB Review to an External IRB (*External IRBs*)

Studies where the Cooperative  
Research Requirement is  
Applicable (*Single IRBs*)

# What is a Single IRB?

The Single IRB mandate is a set of complementary federal policies that require certain types of federally-funded research, that involve multiple institutions, to use one IRB to accomplish IRB review and approval for all of the institutions/sites.



- [NIH - Single IRB Policy](#)
- [Common Rule - Cooperative Research Requirement](#)

# Which Studies Require a Single IRB?

If your proposed research involves:

- federal funding,
- human subjects,
- and multiple research locations,



please fill out our [Single IRB Pre-Consultation Intake Form](#) prior to submitting your proposal.

# The Pre-Consultation Process

- Single IRB Pre-Consultation is required when Northwestern IRB will *serve* as the IRB of Record for external sites (Single IRB), or *cede* IRB review to an external IRB.
- Please contact us *at least 5 weeks prior to the grant application due date.*
- We will issue a Letter of Support to serve (*subject to IRB fees*), or to cede, as appropriate.

Studies where the Northwestern IRB  
*Serves* as the IRB of Record  
for an External Site

# Northwestern as the IRB of Record

## *New Studies:*

- The initial review and onboarding of external site(s) could happen at the *same time*
- The initial review could include the overall study and Northwestern site *only*. The external site(s) would be onboarded in a *subsequent modification*.
  - If your study is subject to Single IRB fees, we will follow this route.



# Northwestern as the IRB of Record

## *Adding an External Site to a Study:*



- Is it appropriate to engage in reliance?
  - Will the external site be engaged in non-exempt research activities? *Answer must be yes*
- Is reliance federally mandated?
  - If **yes**, proceed with reliance agreements.
  - If **no**, is the external site willing to cede IRB review to Northwestern? Some sites will only engage in reliance if it is federally mandated

# Executing Reliance Agreements

- The IRB of Record or its study team typically choose the type of reliance agreement:
  - IRB Authorization Agreement (IAA)
  - SMART IRB (Online or Paper)
- The agreement is then drafted, reviewed by the external site, and signed by both of us. Then we will issue an *approval* and the external site will issue their *acknowledgement* of that decision.

Studies where the Northwestern  
IRB cedes IRB Review to an  
External IRB (*External IRBs*)

# External IRBs

- Two categories of IRBs we cede IRB review to:
  - Academic / Institutional IRBs 
  - Commercial / Independent IRBs 
- Prepare an “*External IRB Submission*” in eIRB+
  - This does **NOT** mean there is duplicated effort
  - The External IRB is responsible for IRB review of our site, but we are still responsible for ensuring all local requirements are met

# External IRBs

- As a relying IRB, we must make sure that:
  - The Northwestern activities are eligible for reliance,
  - The PI and study team members have completed Human Subjects Training,
  - COI review was conducted, and
  - HIPAA and local language are taken into consideration.
- Once reliance agreements are executed, the IRB of Record will *approve* our site and we will *acknowledge* that decision.

# Contact Us!

**Email:** [irbreliance@northwestern.edu](mailto:irbreliance@northwestern.edu)

**Website:** <https://www.irb.northwestern.edu/reliance/>

# Single IRB Review Process at Lurie Children's

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# Helpful definitions

**Reviewing IRB or Central IRB or Single IRB**: the IRB that is responsible for the review, approval and regulatory oversight of a multi-site research study. Also referred to as the **IRB of Record**.

**IRB Authorization Agreement (IAA)**: The responsibilities of each IRB is detailed and are agreed upon within the IAA. It may be referred to as a Cooperative Agreement, Single IRB Agreement, or IRB Reliance Agreement. Agreements can be study or investigator specific.

**Master Reliance Agreement**: An IAA designed to cover all multi-center studies involving two or more sites.

**Overall PI**: The principal investigator with ultimate responsibility for the overall conduct, safety, regulatory oversight and data integrity for a multi-site research study.

**Site PI**: A principal investigator who is responsible for the conduct of the research at their Participating Institution.

**Relying Site**: A hospital, clinic, or doctor's office where research will take place and which will rely on an external IRB for a multi-site study.



# Increase in Use of Single IRBs

- Using a Single IRB is now a requirement for federally funded multi-site research per the following mandates:
  - **NIH Policy:** Effective January 25, 2018, the NIH requires use of a Single IRB [sIRB] for the review of NIH-funded multi-site studies where each site will conduct the same protocol involving non-exempt "human subjects research," whether supported through grants, cooperative agreements, contracts, or the NIH Intramural Research Program.
  - **Revised Common Rule:** Effective January 20, 2020, the Common Rule federal policy regarding Human Subjects Protection requires government funded cooperative non-exempt human subjects research studies also require sIRB review.
- Some consortiums or industry sponsors also request the use of a Single IRB

## Prior to Single IRB Mandate

### IRB A

- Institution A

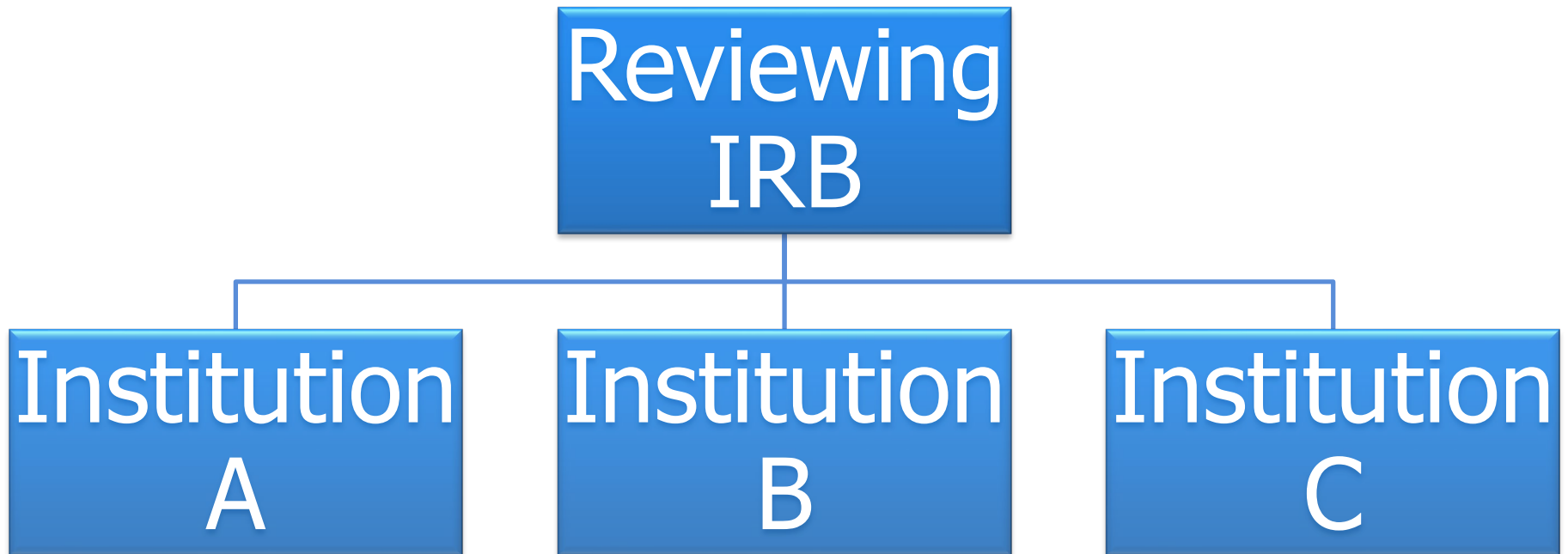
### IRB B

- Institution B

### IRB C

- Institution C

## Post Single IRB Mandate



# Reliance Agreements

When executing reliance agreements, Lurie Children's tries to be flexible with how reliance is negotiated and documented, and accepts it from several different sources, including:



If an agreement with an IRB already exists, Lurie Children's IRB staff can determine if the agreement can be utilized for a study reliance request.

# Determining Reliance

- If the study is federally funded and/or there is a requirement for a single IRB
- If the study is not federally funded and single IRB review is not otherwise required, Lurie will review reliance requests on a case by case basis.

Several factors are considered when reviewing requests, including:

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whether the study is part of an existing network, consortium, or agency which encourages or mandates single IRB review

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whether the proposed reviewing IRB has already reviewed the study or a similar study

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consideration of the proposed reviewing IRB expertise (e.g., special subject population, atypical research design, sensitive topics)

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efficiency considerations, especially for collaborating research

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considerations of the ability of Lurie Children's to conduct study activities at Lurie Children's

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the level of risk as determined by the reviewing IRB

# Lurie Children's Process for Relying On an External IRB

To initiate the reliance process please submit an email to [IRBreliance@luriechildrens.org](mailto:IRBreliance@luriechildrens.org).

In the email, please provide:

- The name of the IRB of record
  - Lurie Children's IRB staff can assist in determining if a reliance agreement with the identified reviewing IRB already exists
- A copy of the approved protocol
- A statement of the status of the study with the reviewing IRB (e.g. whether the IRB at the reviewing site has approved the study or whether it is still in development)
- Source of funding for the protocol
- Draft/approved consent documents (as applicable)
- Draft/approved recruitment materials (as applicable)
- Any other documents that will help Lurie Children's assess the appropriateness of the reliance request

# Lurie Children's Process for Relying On an External IRB

1. Agree that reliance is appropriate following email communication and exchange of study documents with IRB
2. Execute the IAA between Lurie Children's IRB and the reviewing IRB
3. Provide applicable local context to reviewing IRB
  - ❖ Local context refers to applicable institutional policies or state laws, study team member training and qualifications, and any conflicts of interest for study personnel
4. Obtain overall IRB approval letter and approved study documents from the reviewing IRB
  - ❖ The reviewing IRB will need to review and approve (and stamp) the Lurie - specific parental permission, assent and adult consent forms as well as other supporting study documents
5. Submit study in Cayuse IRB – abbreviated application
  - ❖ Not a duplicate IRB review
6. Review of study in Cayuse IRB (Lurie Children's IRB Chair or Vice Chair)
7. Issue External IRB of Record Acknowledgment letter in Cayuse IRB

# Lurie Children's Process for Relying On an External IRB


Execute the IAA between Lurie Children's IRB and the reviewing IRB




Provide applicable local context to reviewing IRB



Obtain IRB approval and approved study documents from the reviewing IRB



Submit study in Cayuse IRB – abbreviated application (signed IAA, approved protocol, approved and stamped consent forms (as applicable) from the reviewing IRB, supporting documents (IB, etc))



Study is reviewed by the Lurie Children's IRB Chair or Vice Chair and External IRB of Record Acknowledgement letter issued in Cayuse




# Lurie Children's Process to be the IRB of Record

- To initiate the reliance process please submit an email to [IRBreliance@luriechildrens.org](mailto:IRBreliance@luriechildrens.org)
- Requests are reviewed on a case by case basis
- In the email, please provide:
  - The name(s) of the participating site(s)
    - Lurie Children's IRB staff can assist in determining if reliance agreements with the identified sites already exists
  - A copy of the proposed protocol
  - Source of funding for the protocol
  - Draft consent documents (as applicable)
  - Draft recruitment materials (as applicable)
  - Any other documents that will help assess the appropriateness of Lurie Children's serving as the IRB of record


# Lurie Children's Process to be the IRB of Record

1. Agree that Lurie Children's can act as the IRB of record following email communication and exchange of study documents
2. Submit study in Cayuse IRB for Lurie Children's IRB approval
3. Execute the IAA between Lurie Children's IRB and any relying sites (can be done in parallel with review of study)
4. Collect applicable local context from relying sites
  - ❖ Local context refers to applicable institutional policies or state laws, confirmation of study team member training and qualifications, and any conflicts of interest for study personnel
5. Provide Lurie Children's IRB approval letter and approved study documents to relying sites
  - ❖ 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 study in Cayuse IRB (Lurie Children's IRB Chair or Vice Chair)
8. Issue Approval for relying sites including stamped consent forms


## Request Submitted

- The request is reviewed by the reliance coordinator
  - If appropriate, Lurie Children's can agree to act as the IRB of record
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## Study Reviewed

- The study should be reviewed at Lurie Children's per the local process and approved in Cayuse
  - Other sites will be added later via modifications in Cayuse
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## Agreements Executed

- Agreements with the other study sites are executed
  - Consent form templates are created with the Lurie Children's reliance coordinator and provided to the other sites with the Lurie Children's approved study documents
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## Submit Documents to Lurie Children's IRB

- Once the other sites agree to rely, a modification should be submitted to add the other sites' documents
- Consents for other sites are stamped and returned to the study team with the modification approval.

# Lurie Children's and Northwestern University Master Agreement



# Lurie Children's and Northwestern University Master Agreement

- Lurie Children's and Northwestern University have an Institutional Authorization Agreement (IAA) which allows the Northwestern University IRB to rely on the Lurie Children's IRB for the review of human subjects research under the following circumstances:
  - Studies that involve research activity at Lurie Children's and Northwestern University or an affiliate (Prentice Hospital, Northwestern Medicine, Shirley Ryan Ability Lab, etc.) (i.e. investigators/staff at both institutions are engaged in the research).
  - Studies with funding through Northwestern University, but research activity will be conducted at Lurie Children's
  - Studies conducted only at Northwestern University which enroll minors (i.e., participants < 18 years of age).

# Institutional Responsibilities

## • Lurie Children's Responsibilities:

- Serve as the IRB of record
- Lurie Children's IRB will review the entire study, including research activity that involves both adults and children taking place outside Lurie Children's
  - IRB expertise is made up of both pediatric and adult specialties (i.e., maternal-fetal medicine, neonatology, dermatology, etc.)
- Lurie Children's IRB will have oversight authority to correct non-compliance and/or suspend research

## Northwestern's Responsibilities:

- Ensure Northwestern researchers comply with University policies and procedures regarding the conduct of human subject research.
- Conduct post-approval monitoring of research activities within Northwestern or its affiliated entities.
- Report any non-compliance or conflict of interest to Lurie Children's IRB.

# Northwestern Engagement

- Examples of when Northwestern is engaged and IRB approval at both institutions is required:
  - Participants will have study visits/activity at a Northwestern site
  - Identified data and/or samples will be sent to investigators at Northwestern
  - Non-Lurie Children's Northwestern faculty or staff will be engaged in some aspect of the research
  - Some or all of the funding will be coming through the Northwestern Office of Sponsored Research
  
- Examples of when Northwestern is involved, but not engaged:
  - Data will be collected or stored using REDCap
  - Sharing de-identified data/specimens only
  - Providing standard of care services only (e.g. radiation therapy that is only being done for standard of care)
  - Performing commercial service (e.g. statistical analysis, lab analysis, etc.)

Questions?





# Resources

- Lurie Children's IRB website has step by step instructions with screen shots and who to contact for help: <https://www.luriechildrens.org/en/research/toolkit/irb-resources/studies-involving-lurie-childrens-and-northwestern/>
- SMART IRB: <https://smartirb.org/>
- NIH sIRB Policy: <https://grants.nih.gov/policy/humansubjects/single-irb-policy-multi-site-research.htm>
- Common Rule sIRB Policy: <https://www.hhs.gov/ohrp/regulations-and-policy/single-irb-requirement/index.html>
- More resources to come! Watch for announcements from the Lurie Children's IRB on new forms, policies, and templates for single IRB.