

Northwestern University Relying on External IRBs

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Common Terms

- **IRB of Record** – General term for when an IRB is reviewing and making a determination on a study
 - IRBs will **serve** as the IRB of Record
 - Central IRB
 - **Single IRB or sIRB** – Specifically, IRB of Record for federally funded studies
- **Cede/Rely** – When one IRB allows another IRB to conduct the review of their site's activities
 - IRBs will **cede to** or **rely on** an **external IRB** (aka the IRB of Record)

Poll #1

If Northwestern is executing reliance with UChicago for a study where UChicago will conduct IRB review for all sites involved, which of the following are true?

- a. Northwestern is serving as the IRB of Record and UChicago is ceding review to Northwestern
- b. UChicago is serving as the IRB of Record and Northwestern is ceding review to UChicago
- c. Northwestern is relying on UChicago and UChicago is ceding review to Northwestern
- d. UChicago is serving as the IRB of record and Northwestern is serving as the Single IRB (sIRB)

What should you know about External IRBs (xIRBs)?

- When does the Northwestern IRB cede review to an external IRB? When will the NU IRB *not* cede review?
 - How do I determine if an external IRB is needed?
- Who are the most frequently used external IRB's?
- What does the process of ceding review to an external IRB look like?

When does the Northwestern IRB cede review to an external IRB? When will the NU IRB *not* cede review?

How do I determine if an external IRB is needed?

When does the Northwestern IRB cede IRB Review to an External IRB (xIRB)?

When justified or required.*

Justified:

- Sponsor request
- Merited on a case-by-case basis

Required:

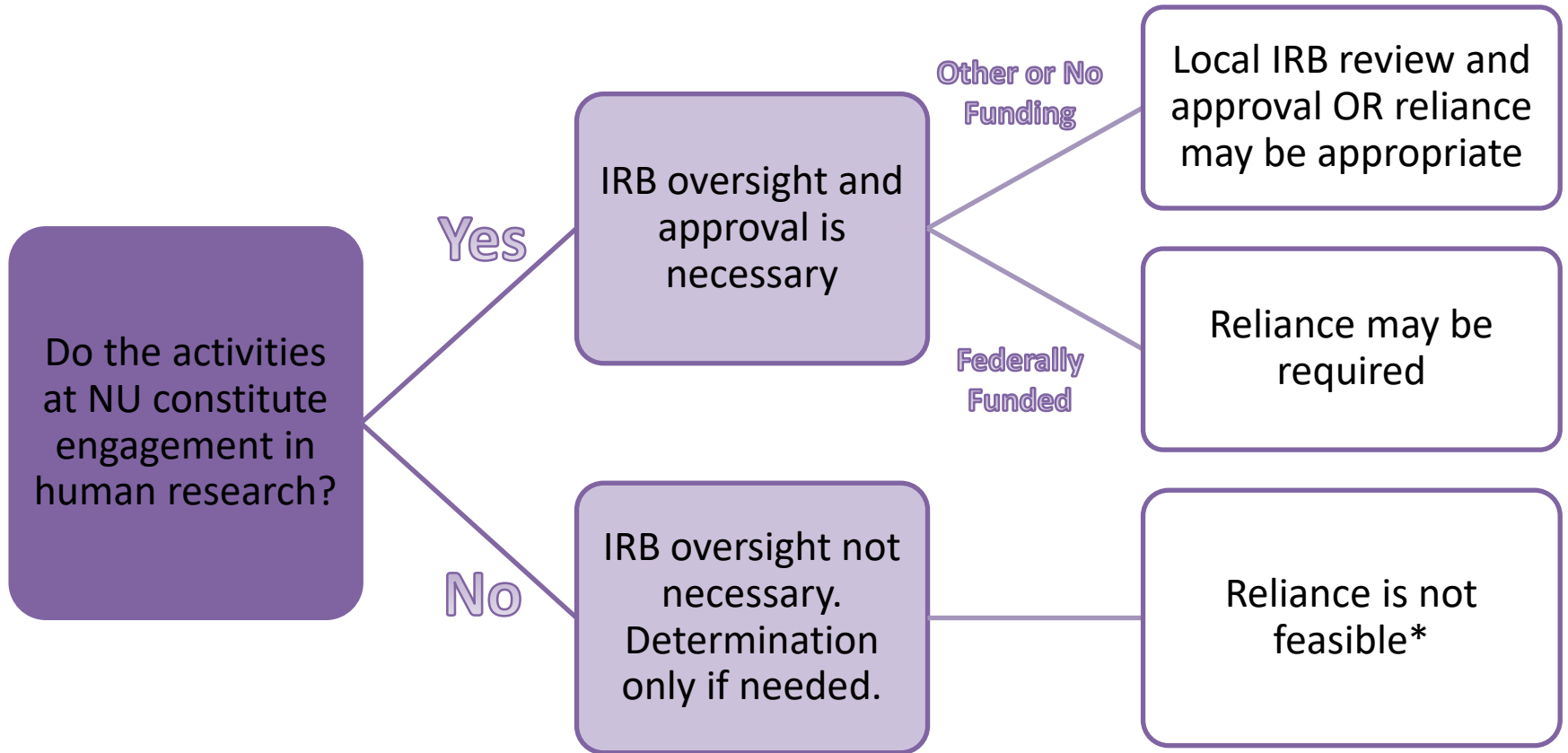
- Cooperative Research Requirement

* The reliance team will still review all xIRB requests to ensure that proposed reliance is appropriate and feasible. Per our SOP, we reserve the right to not cede when it is not mandated or justified.

Cooperative Research Requirement

- Federally funded projects, involving non-Exempt human subjects research *and* multiple research sites.
 - In the context of what is happening at *all* research sites working on the specific research protocol.
 - Depending on the layout of federal funds, reliance will be *required* in many situations.
 - NU has its own local process for navigating these scenarios along side study teams.

Engagement ≠ Reliance



In what situations will the NU IRB *not* cede review to an external IRB?

- If sufficient justification for reliance is not provided.
- If the research was reviewed as exempt at the proposed IRB of Record*
- If the proposed IRB of record...
 - Is themselves relying on another institution for review of the research (aka daisy-chaining)
 - Is an international institution
 - Does not appear to have sufficient capacity, expertise, or qualifications to serve as the IRB of Record

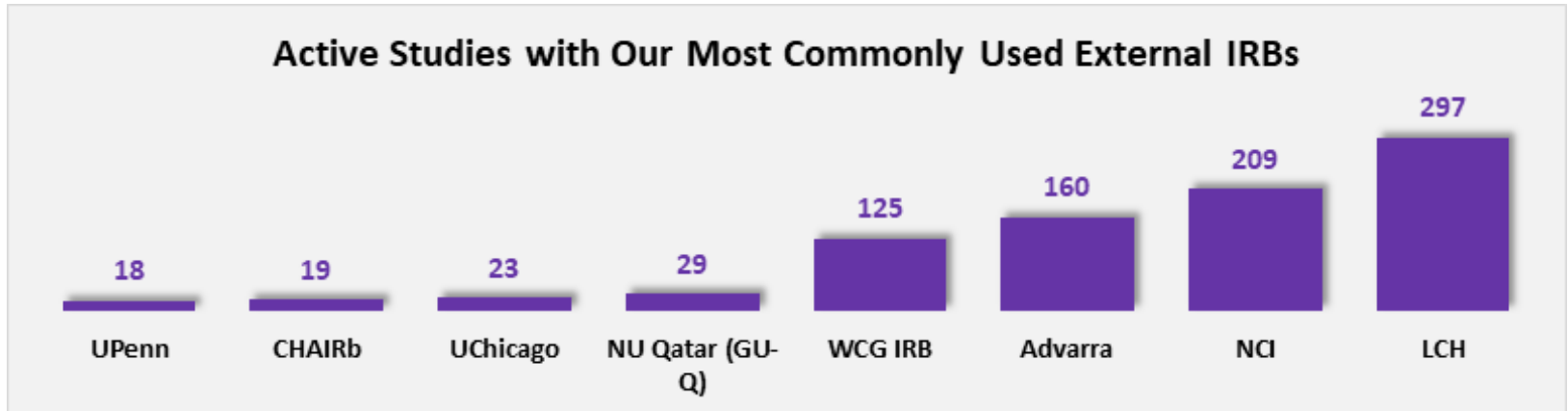
Poll #2

A Northwestern PI and her collaborators at UCLA and Florida State are starting a new study that is being funded by a grant from the National Science Foundation (NSF). The PI at UCLA is listed as the prime awardee of the grant and has decided they want the UCLA IRB to be the IRB of Record. The UCLA IRB has already reviewed the project with consideration for activities across all sites and has made an Exempt determination. Would reliance be appropriate?

- a. Yes, because there is federal funding involved
- b. Yes, because there is more than one site involved in the research
- c. No, because the project was reviewed as exempt
- d. No, because UCLA should not have already reviewed the project

Who are our most commonly used external IRBs?

Commonly used xIRBs and our Relationships



- Academic / Institutional IRBs 
 - Lurie Children's Hospital (LCH)
 - National Cancer Center (NCI)
 - Other Chicagoland Universities (e.g. UChicago, UIC)
- Commercial / Independent IRBs 
 - WCG
 - Advarra

What does the process of ceding review to an external IRB look like?

Reliance Agreements

- What are they?
 - Definition
- Types
 - Master Agreements
 - (LCH/NCI)
 - (WCG/Advarra)
 - Study specific agreements
 - SMART IRB
 - Institutional Authorization Agreement

Federal Funding?

- When federal funding is involved in multi-site non-exempt projects, the first step is submitting a **single IRB Consultation intake form**
- We strongly advise that this occurs as early as possible, at least 5 weeks prior to the grant *application* due date.

Responsibilities of a Relying Site

- 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
 - HIPAA and local language requirements are taken into consideration.
- How do we make sure all of these local requirements are met?

The eIRB+ Submission

- The “*External IRB Submission*” in eIRB+
 - This is an application to *cede IRB review*
 - This submission allows us to...
 - Review the protocol and funding to determine whether reliance is justified and or required
 - If appropriate, sign reliance agreements
 - Track which Northwestern personnel are involved and ensure they have appropriate credentials (i.e., CITI training, PI permissions, COI)
 - Review consent and HIPAA forms to ensure appropriate local language is included

The STU and IRBSITE Pages

Local Submissions in eIRB+
[NU serving as IRB of Record]

STU
Basic Information
Funding Sources
Study Team Members
Study Scope
<i>Drugs</i> (as applicable)
<i>Devices</i> (as applicable)
Local Site Documents
Sites
Study-Related Documents ¹
Final Page and RSS

versus

External IRB (xIRB) Submissions in eIRB+
[NU ceding to an External IRB]

STU ²	IRBSITE ³
Basic Information	Basic Site Information
External IRB	Funding Sources
Funding Sources	Study Team Members
Study Scope	Local Site Documents
<i>Drugs</i> (as applicable)	Final Page and RSS
<i>Devices</i> (as applicable)	
Study-Related Documents	
Final Page and RSS	

Resources at Your Disposal

eIRB+ Tutorials for Relying on an External IRB

[Submitting a New Study Tutorial – External IRB Requiring a Signed Reliance Agreement - HRP - 1829](#)

- This tutorial is intended for use when Northwestern will cede IRB review to an external IRB via an IRB Authorization Agreement (IAA) or another reliance pathway like SMART IRB.
- If your study involves Northwestern ceding IRB review to WCG or Advarra please follow this tutorial and the corresponding Master Agreement Acknowledgement Letter in lieu of another reliance pathway.

[Submitting a New Study Tutorial – External IRB with a Master Reliance Agreement - HRP - 1830](#)

- This tutorial is intended for use when Northwestern will cede IRB review to entities like Lurie Children's Hospital IRB.

[Submitting a External IRB Modification and/or Continuing Review Tutorial](#)

- This tutorial is intended for use when submitting a modification for studies where Northwestern has ceded review to an external IRB.
- If you have continuing review or study closure documentation to submit for Northwestern's acknowledgement, please use this tutorial.

Resources for Relying on an External IRB

- [HRP-092 – SOP External IRBs](#)
- [HRP-801 – SOP Establishing Authorization Agreements](#)
- [HRP-1801 – Worksheet Authorization Agreement Review](#)
- [HRP-1802 - Reliance Workflows](#)
- [HRP-1812 – Local Context Form](#)
- [HRP-1828 – Where to upload documents for External IRB Studies](#)

Study Acknowledgement

- Once reliance agreements are executed, the IRB of Record will review and *approve* our site and the Northwestern IRB will *acknowledge* that decision.
- Research activities at Northwestern may only begin once:
 1. Approval has been granted by the IRB of Record.
 2. Acknowledgement has been granted by the Northwestern IRB.
 3. There are no other holds imposed by the IRB of Record or outstanding ancillary reviews.

NU Study Team Obligations *after* acknowledgement.

- Ensure all external IRB approved study updates are promptly* submitted to eIRB+
 - Study modification (e.g., changes to consent forms)
 - Continuing reviews
 - Personnel changes
 - Co-Investigator and study team member updates do not require external IRB approval BUT PI changes do
 - Study closures
- Investigator Manual (HRP-103)

*Per our SOP, study updates should be submitted within 2 weeks of external IRB approval

Poll #3

A new Northwestern PI will be replacing the previous Northwestern PI on an external IRB study. With consideration for the PI change that will need to occur, when can the new PI begin research activities?

- a. As soon as the new PI is identified by the study team.
- b. Once the IRB of Record has approved the new PI.
- c. Once the NU IRB has acknowledged the PI change.
- d. 2 weeks after being named in eIRB+.

Questions?

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

Office Hours: Every Tuesday, 3pm CST

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