

# Reliance Considerations

*When is Reliance Required?*  
*When is Reliance not Feasible?*

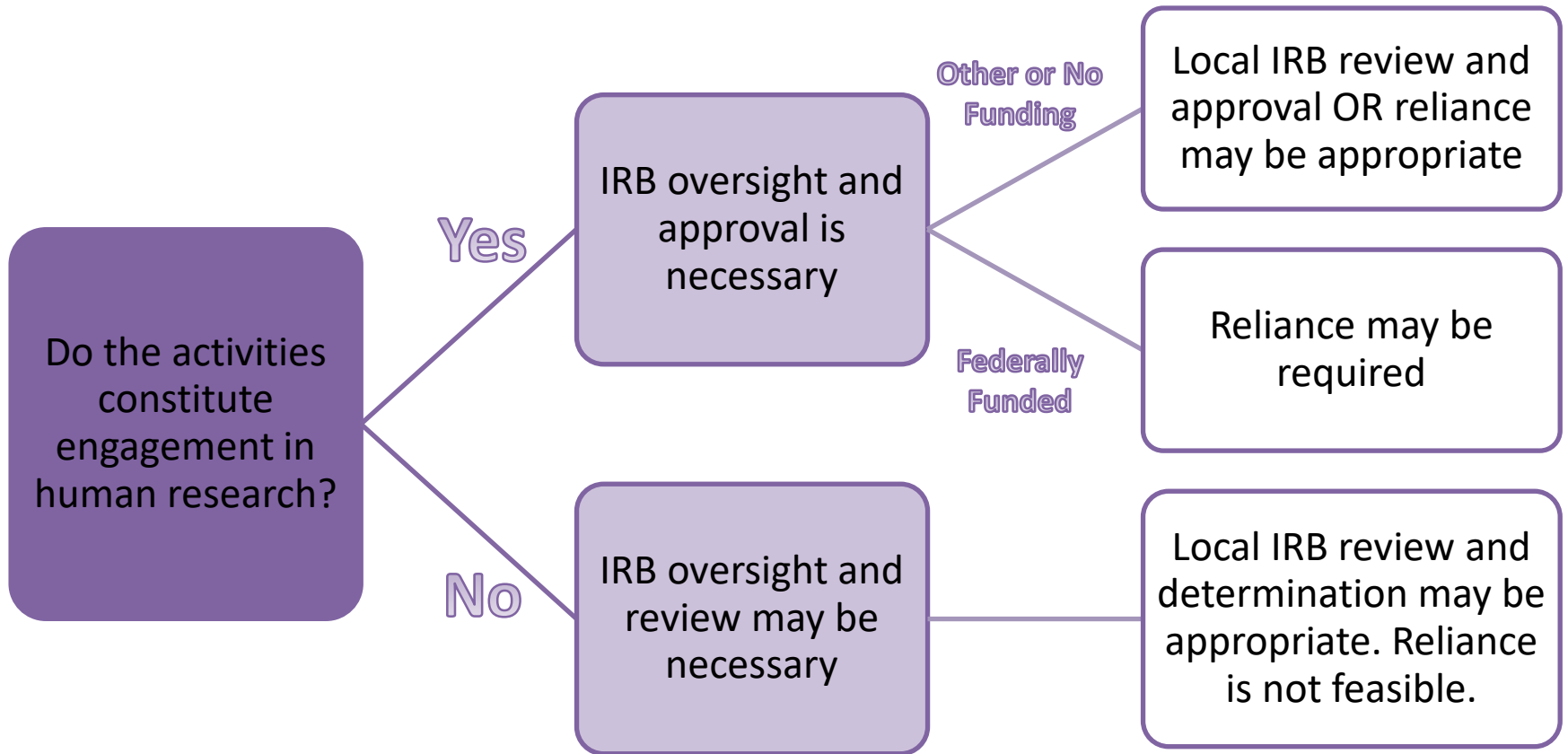
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# Key Concepts

# Engagement ≠ Reliance



# Research at Multiple Sites

- Local IRB Review
  - All sites obtain their own separate IRB review and approval of the activities happening at their site
- Reliance
  - An IRB serves as the IRB of Record / Reviewing IRB / Single IRB for their site and external site(s)
  - An IRB/site cedes review / relies on an external IRB
  - These roles are established via reliance agreements

# Roles and Responsibilities



# When is Reliance Required?

# When is Reliance Required?

## Required

When reliance, or a Single IRB, is required by the federal regulations

When reliance is a prerequisite for participation

## Optional

When reliance is preferred by the study team or IRB/site

When it is appropriate and feasible for an IRB to serve



# When is a Single IRB Required?

When the research involves :

- federal funding,
- human participants,
- non-exempt activities,
- & multiple domestic research locations.



Why? Due to two complementary federal policies:

- [Cooperative Research Requirement](#)
- [NIH Single IRB Mandate](#)

# Single IRB Consultation

- [Single IRB Consultation](#) is required for all federal funding proposals (both Prime and Sub-Award) involving two or more domestic sites.
  - Required for requests to serve and cede.
- Submit our consultation intake form before your grant application due date.
- We will issue a Letter of Support to serve (subject to IRB fees), or to cede, as appropriate.

# Single IRB Scenarios

## Scenario 1

- Northwestern is the prime awardee and will conduct de-identified data analysis. A subcontract site (University of Chicago) will conduct informed consent, interviews, and data collection.

If a subcontract site is engaged in human research, then the prime awardee is automatically engaged – regardless of the prime’s local activities. All sites engaged in human research must have a Single IRB.

# Single IRB Scenarios

## Scenario 2 - *Advanced*

- 1) NIH notifies you that you have a fundable score and that you are in JIT. You are the prime and your sub-k plans to conduct **exempt** Human Research. You submit and obtain a Not Human Research determination from the Northwestern IRB, which you send to NIH.
- 2) Your sub-k submits its work to its IRB, which reviews the activities under **expedited** review.

# Single IRB Scenarios

## Scenario 2 - *Advanced*

3) The sub-k's **expedited** determination makes Northwestern engaged in Human Research and requires that Northwestern and the sub-k site rely on a Single IRB.

- You **must** notify the Northwestern IRB Office, which will work with you to identify the Single IRB and update its previous Not Human Research determination.
- You **must** notify Sponsored Research and the NIH.

# When is Reliance Feasible?

# When is Reliance Feasible?

## Feasible

When the study and site(s) activities are non-exempt

When the scope of activities and number of sites match the capabilities and expertise of the IRB/IRB Office

## Not Feasible

When the study or site(s) activities are exempt

When the scope of activities or number of sites exceed the capabilities and expertise of the IRB/IRB Office

# Feasibility Scenarios

## Scenario 1

- Northwestern investigators intend to add a new biostatistician to their study. The study involves informed consent, medical examinations, and data collection. This new biostatistician is a professor at another local university and will conduct de-identified data analysis.

The proposed biostatistician's activities do not constitute engagement in human research. Reliance is **not** feasible. The biostatistician should follow any/all institutional policies for IRB oversight at their local university.



# Feasibility Scenarios

## Scenario 2

- Northwestern investigators are interested in conducting a study that will involve 20 domestic sites, a drug intervention covered under an IND, and an enrollment goal of approximately 5,000 participants at each study site.

Presently a study of this scope and number of study sites exceeds the capabilities of the Northwestern IRB and IRB Office. The Northwestern IRB Office will work with you to identify an appropriate IRB.

# Feasibility Scenarios

## Scenario 3

- Northwestern investigators are collaborating with individuals at a tech company. That company is the recipient of a Small Business grant from NIH and Northwestern is a subcontract. Engaged human research activities will only occur at Northwestern and only be conducted by Northwestern staff.

If a subcontract site is engaged in human research, then the prime awardee is thus engaged, and all sites must have a Single IRB. It is not standard practice for Northwestern to serve as the IRB for corporate entities. The Northwestern IRB Office will assist in identifying an appropriate IRB.

# How is Reliance Executed?

# Reliance Agreements

- An agreement between two or more entities that allows an IRB to review human participants' research on behalf of another institution or site.
- Types of reliance agreements include:
  - Institutional Authorization Agreements (IAA)
  - Individual Investigator Agreement (IIA)
  - Master Reliance Agreement (MRA)
  - Memorandum of Understanding (MOU)

# Serving as the IRB of Record

- If your study involves federal funding, a Single IRB Letter of Support is required to proceed with IRB review and approval.
  - If you don't have a Single IRB Letter of Support, please submit a Single IRB Consultation intake form as soon as possible.
- The Single IRB Letter of Support should be uploaded within the eIRB+ application under “Supporting Documents”

# Serving as the IRB of Record

- Whether you are submitting a new study, or adding a new site to an existing study, the protocol should detail all proposed multi-site or collaborative activities for Northwestern and any external site(s) as part of a reliance plan.

**Multi-Site Study:** Non-exempt Human Research involving more than one institution and/or site participating in the same research protocol, with each site completing all research activities outlined in the protocol.

**Collaborative Study:** Human Research involving more than one institution and/or site participating in the same research protocol, where each site complete a portion or portions of procedures.

# Serving as the IRB of Record

- The initial review will proceed, and reliance agreements can be submitted for review and execution in subsequent modification(s).
  - This allows external sites to provide approved study documents to their IRB, which increases the speed of deciding whether they will cede review.
- We encourage our study teams to select the type of reliance agreement. Common types:
  - IRB Authorization Agreement (IAA)
  - SMART IRB ORS or LOA
    - *SMART IRB is not an IRB*

# Serving as the IRB of Record

- Include a drafted reliance agreement with your submission, when you are ready for us to review and sign it.
  - If Northwestern will be the IRB of Record, we prefer to review reliance agreements before external site signatures are acquired.
- If reliance is feasible, the agreement will be sent for signature. Once both sites sign the agreement it is considered fully executed.
  - It is the responsibility of the study teams to shuttle this document between sites/IRBs.



# Roles and Responsibilities



# Serving as the IRB of Record

- Once the agreement is fully executed, the IRB of Record can conduct IRB review of the relying site, their documents, and issue an approval.
- The approval letter should be shared with the external site so they can issue their acknowledgement.
  - Many sites conduct an administrative review, after IRB of Record approval, to ensure local requirements are met. Local activities cannot begin until that local site provides acknowledgment or official sign off.

# Ceding Review

- Prepare an “External IRB Submission” in eIRB+
  - Include a description of NU activities, an approved protocol, a draft or partially executed reliance agreement, and completed STU and IRBSITE pages
- NU IRB and COI Offices will review the request
  - The IRB Office makes sure NU activities are eligible for reliance, that the study is a good fit for our site, and that the NU PI and study team are qualified and trained Human Subjects Research.
  - The COI Office makes determinations and provides management plan(s).

# Roles and Responsibilities



# Ceding Review

- If ceding review is appropriate the reliance agreement will be signed.
  - The NU study team must work with the external IRB (or their study team) to acquire the external IRB signature.
- The fully executed agreement should be shared with both NU IRB and the External IRB.
- The NU study team next obtains approval of the NU site and site-specific documents by the External IRB.

# Roles and Responsibilities



# Ceding Review

- The NU IRB then reviews any site documents and ensure required local language is included:
  - Financial Interest Disclosure
  - Investigator / Treating Physician Conflict of Interest
  - Financial Responsibility for Research Related Injury
  - Research Costs
  - HIPAA Authorization
- Once acknowledgement is provided, the research may begin at Northwestern.

# Resources



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## Reliance

In order to maintain regulatory compliance, and to help facilitate human research initiatives, the Reliance provides resources and support for researchers engaging in reliance activities with External collaborat

Engaging in reliance minimizes the need for duplicative IRB review while protecting the rights and well human research participants. The resources and information found on the associated webpages provid

complete overview of the reliance process, from beginning to end. If you need additional information o

questions, please contact us at [irbreliance@northwestern.edu](mailto:irbreliance@northwestern.edu).

### Virtual Office Hours

Do you have reliance, single IRB, or multi-site research questions? The Reliance Team hosts open office every Tuesday. You are invited to join the Zoom waiting room and be admitted one-by-one for 10-15 mi

slots in the order you joined Zoom. [Register here!](#)

### Definitions

- **Collaborative Study:** Human research involving more than one institution and/or site participating same research protocol, where each site completes a portion or portions of procedures.

<https://irb.northwestern.edu/reliance/index.html>

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Reliance

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## Single IRB Planning

If your proposed research involves federal funding, human subjects, and multiple research locations, please fill out our **Single IRB Consultation Intake Form** prior to submitting your grant application. This applies to initial, resubmission, and renewal applications for federal funding opportunities. If you are at a different time point, the Single IRB Consultation Process is still necessary and the intake form should be filled out as soon as possible.

Contact [irbreliance@northwestern.edu](mailto:irbreliance@northwestern.edu) for any additional questions.

**Helpful Links**

- [Single IRB Consultation Intake Form](#)
- [OSR Clinical Trials Webpage](#)
- [Single IRB Guidance](#)

### Single IRB Policies and Background

The single IRB (sIRB) 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 conducting the study/trial. The Single IRB Model allows multiple institutions that conduct the same protocol to cede to a single IRB for review.

The NIH [Single IRB Policy](#) and [Common Rule Cooperative Research Requirement](#) are the two policies that require the use of a Single IRB.

<https://irb.northwestern.edu/reliance/single-irb-planning.html>

# Thank you for joining!

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

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