Reliance Considerations

When is Reliance Required?
When is Reliance not Feasible?

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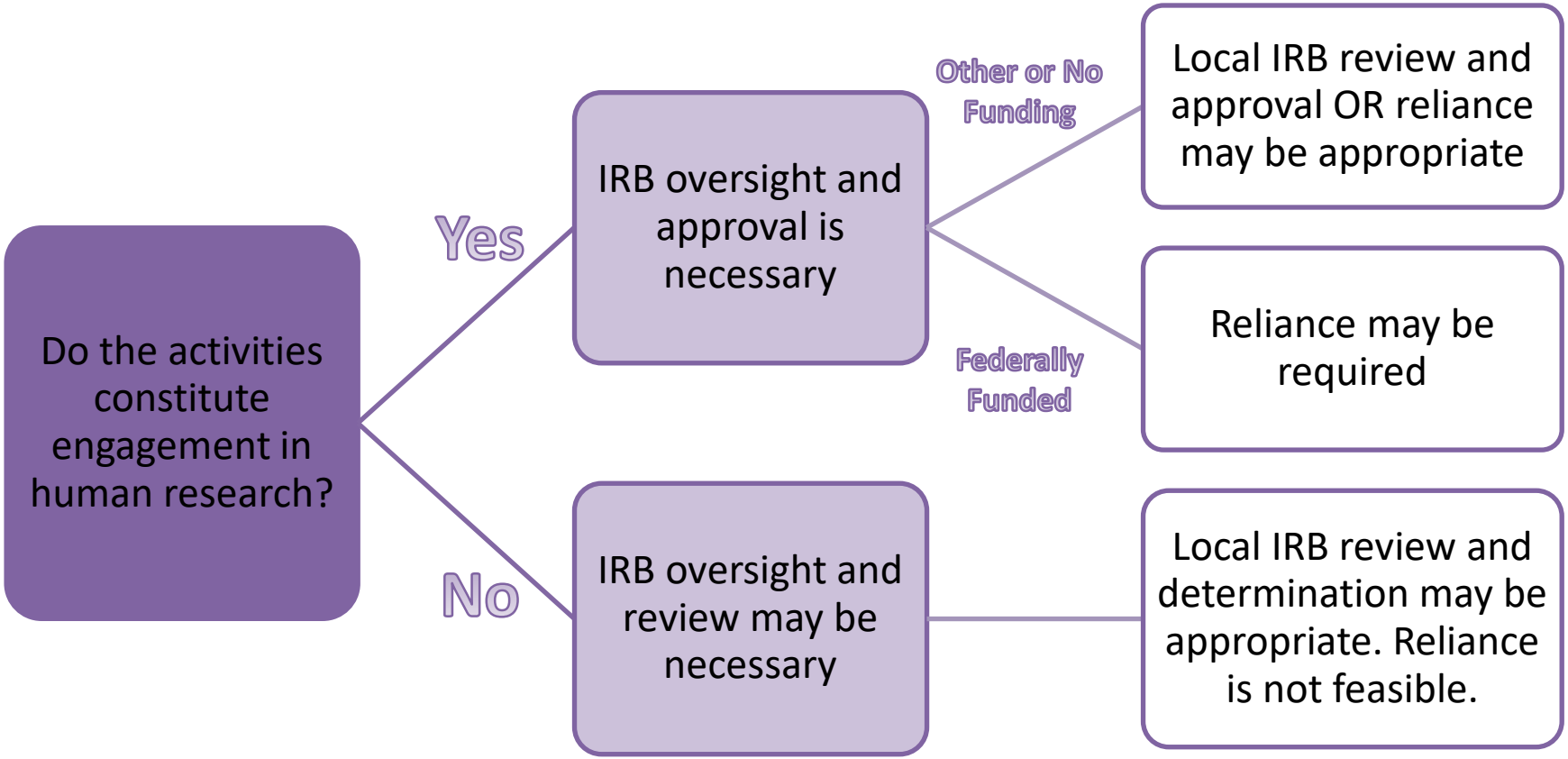
Key Concepts

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

IRB & Privacy Board

HRPP

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

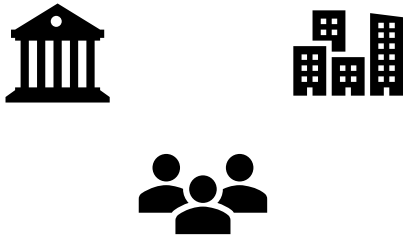
When reliance is preferred by the study team or IRB/site

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 outlines 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

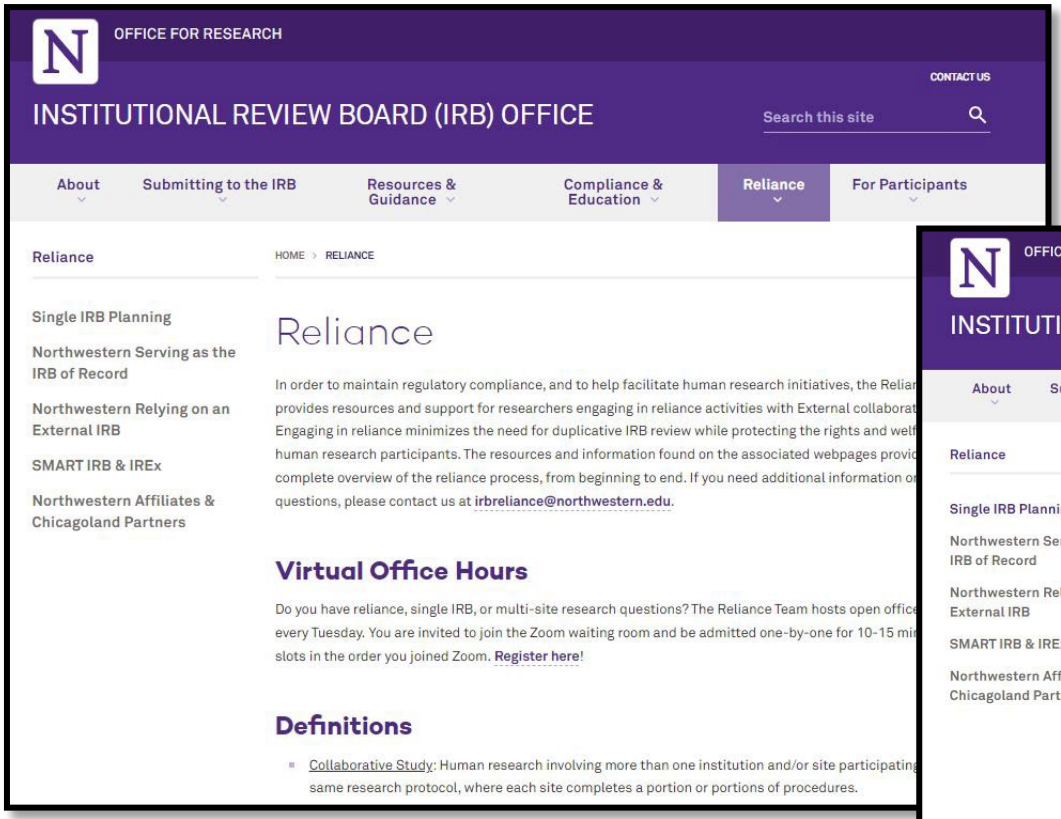
IRB & Privacy Board

HRPP

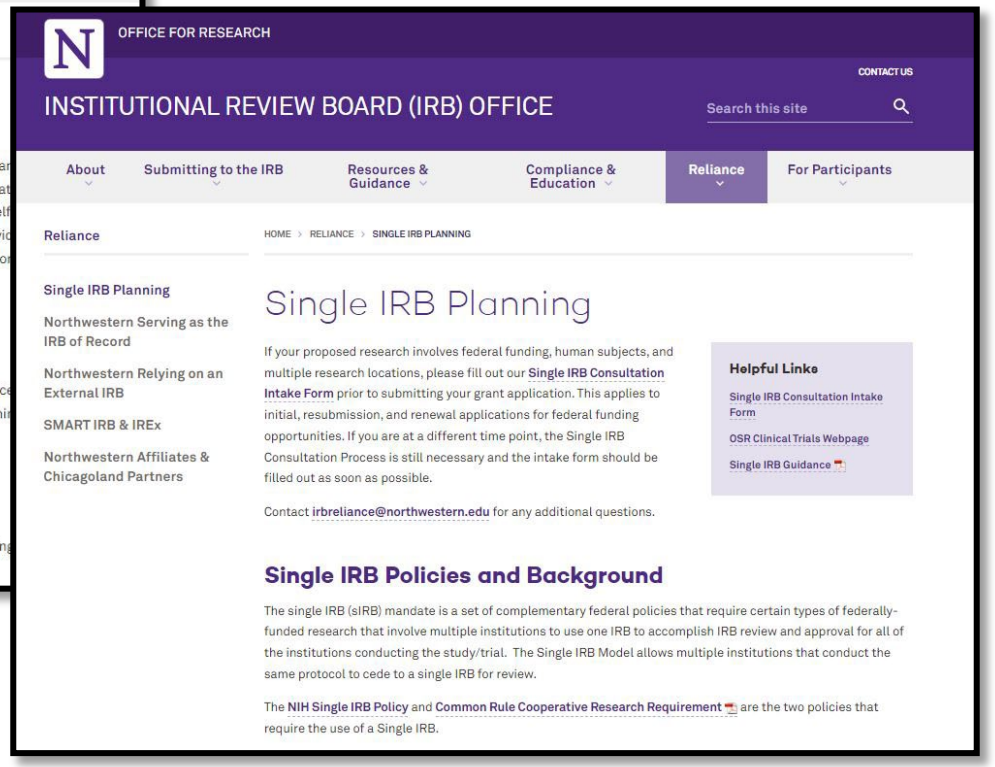
Ceding Review

- 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



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



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

Thank you for joining!

Email: irbreliance@northwestern.edu

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