Reliance Demystified

Local Context Forms, Welcome Packet Updates, & More

Marcella Cooks, Monica Kane, Christina Spicer, Rita Knasel, Logan Clary
Institutional Review Board Office | Northwestern University

IRB Brown Bag
July 16, 2025

Agenda

- Meet your Presenters!
- What's Reliance?
- Reliance Welcome Packet Updates
- What are Local Context Forms?
  - How to Obtain and Use Local Context Forms
- External IRBs: Webpage Updates & New Resources
- External IRBs: eIRB+ and Ongoing Requirements

Meet your Presenters!

Logan

Marcella

Rita

Christina

Monica

What’s “Reliance”?

Key Concepts

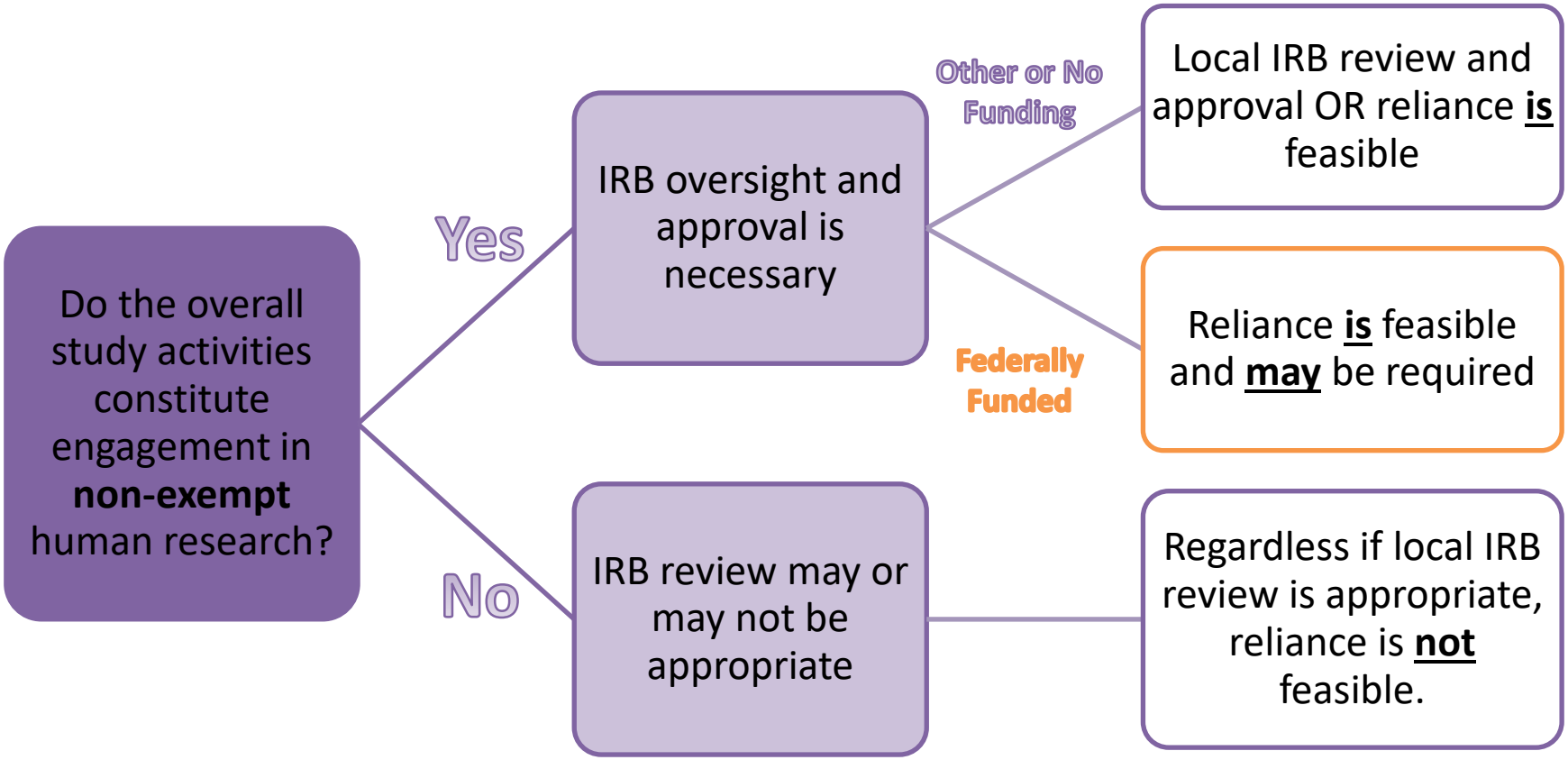
- **Reliance**
  - A relationship which allows one IRB to review and make determinations for another site's research activities (i.e., serve as the IRB of Record)
  - This relationship is established via **reliance agreements**

Northwestern **serves** as the **IRB of Record / Reviewing IRB / Single IRB** for Northwestern and external site(s)

or

Northwestern is a **Relying IRB / Relying Site** that **cedes review / relies** on an **External IRB / Reviewing IRB**

Engagement vs Reliance



Key Concepts

- **When is reliance required?**
  - Required by **federal regulations**
  - Required by sponsors
  - A site cannot review human research themselves

- **What is a reliance agreement?**
  - An agreement that allows an IRB to review human research on behalf of another entity.

Institutional Authorization Agreements(IAA)	SMART IRB Letter of Acknowledgement (LOA)
Individual Investigator Agreement (IIA)	SMART IRB Online Reliance System (ORS)

Key Concepts

- **What is a Single IRB (sIRB)?**
  - An sIRB is an IRB of Record for a study, with multiple relying sites, when reliance is **federally** required
- **When is a sIRB Required?**
  - **federal funding**, human participants, non-exempt activities, & multiple domestic research locations.
- **Why?**
  - Cooperative Research Requirement
  - NIH Single IRB Mandate

Key Concepts

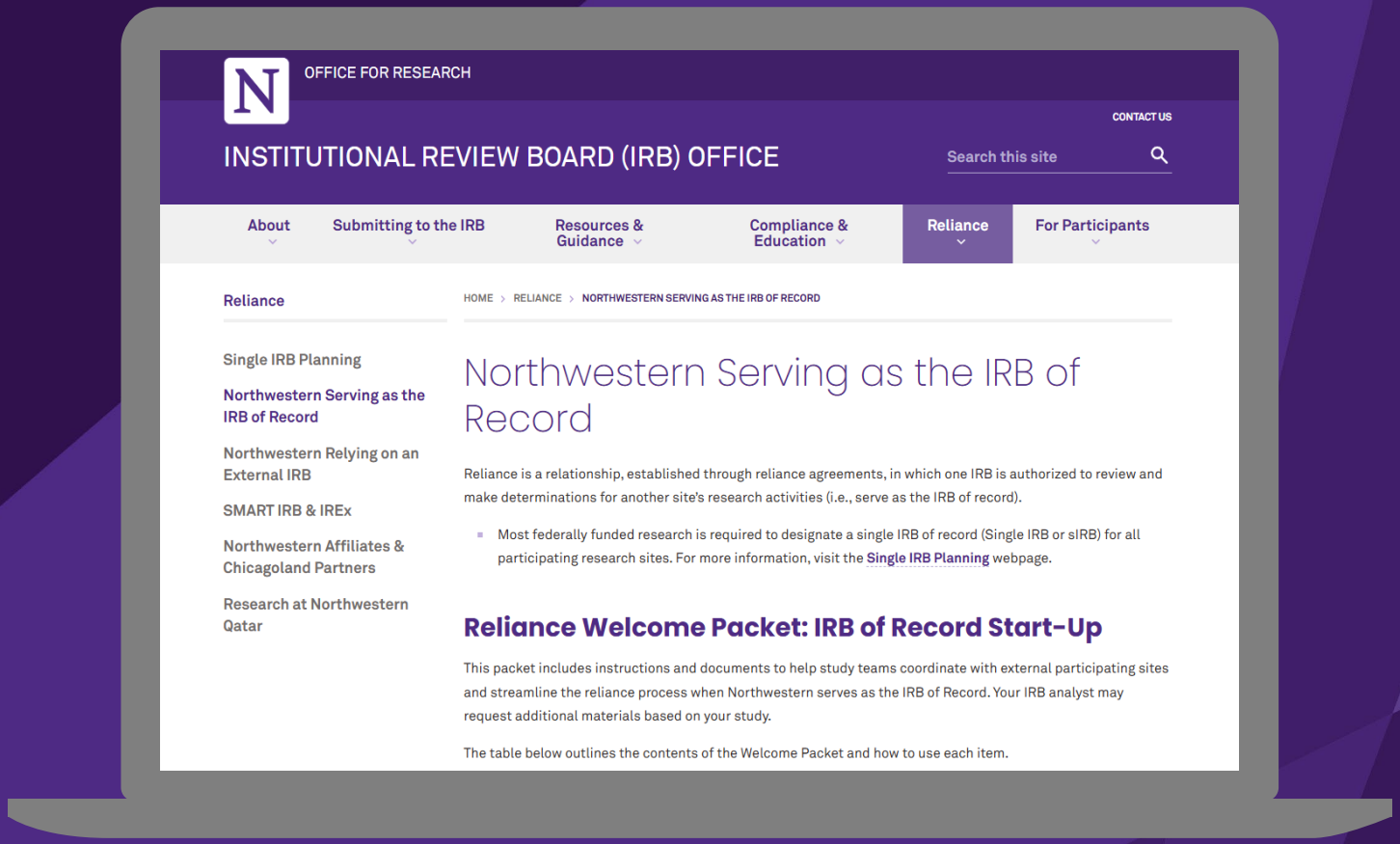
- **What is a sIRB Consultation Intake Form?**
  - Studies required to have a sIRB must submit a sIRB Consultation Intake Form, before grant applications are submitted. If appropriate, we will issue a sIRB Letter of Support (LOS) to serve or to cede.
    - Required if we will **serve as the sIRB** or **cede review**.
- **What is a sIRB Letter of Support (LOS)?**
  - The sIRB LOS is evidence of our willingness to serve or cede, but it is not an agreement nor is it binding.
    - It must be uploaded to eIRB+ as part of the initial application.
    - sIRB fees **only** apply when Northwestern is the sIRB.

Reliance Welcome Packet Updates

Northwestern Serving as the IRB of Record

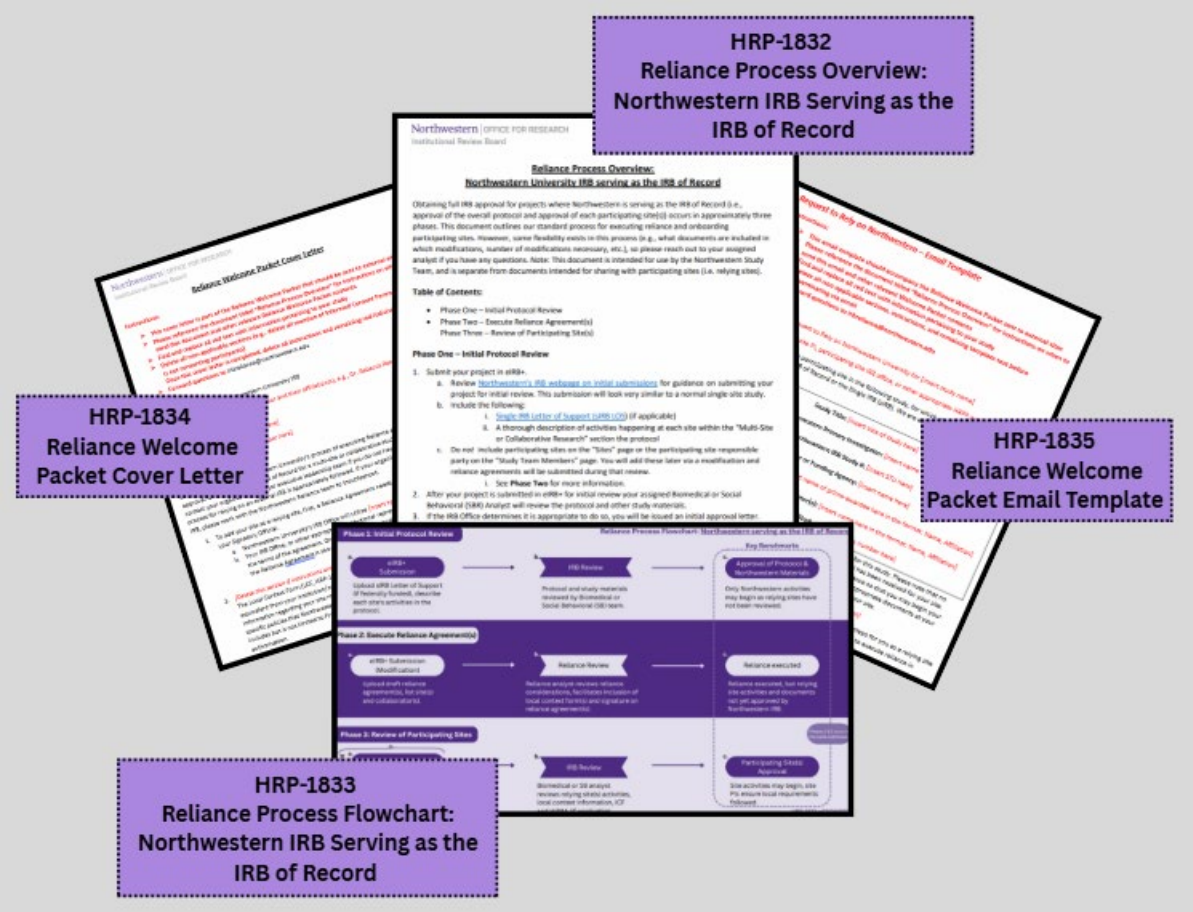
Submitting in eIRB+

- Once submitted our office reviews the protocol, documents, and Single IRB LOS (if applicable).
- If this is a new study, reliance agreements should be submitted in a modification.
  - This enables study teams to share approved documents *and* draft reliance agreements with proposed external relying sites.
- We can execute reliance and approve a relying site's documents all in one modification.



irb.northwestern.edu/reliance/nu-serving-as-the-irb-of-record.html

Reliance Welcome Packet



Local Context Forms

What is Local Context?

- **Local Context Language**
  - Site-specific required language. Example: HIPAA authorization, subject injury language, state law required language, etc.
- **Local Context Form**
  - A document that provides local context language, institutional information, state and local regulations, and factors relevant to research conduct at a site.
- **Local Context Review**
  - The review of a relying site's requirements, by an IRB, often aided by local context forms.

How to Obtain and Use Local Context Forms?

- **HRP-1825 Relying Site Local Context Form**
  - In some cases, we may already have a completed form for your proposed relying site. Our team will let you know if a new or updated form is necessary.
- **Incorporating LCFs**
  - Once obtained, information from the site-specific LCF should be reviewed and any applicable local site requirements addressed in the protocol and study materials as appropriate.
  - Relying site LCFs need to be uploaded to eIRB+.

FORM: Relying Site Local Context Form

NUMBER	APPROVED BY	EFFECTIVE DATE	PAGE
HRP-1825	Executive Director, IRB Office, Northwestern University	10/18/2024	Page 1 of 2

To be filled out by relying site Human Research Protection Program (or equivalent office) personnel:
The purpose of this form is to provide the Northwestern University IRB Office staff with local context information for external sites that rely on the Northwestern University IRB to serve as their IRB of Record. At a minimum, this form must be completed every three years. If there are significant changes to local context information before every three years, the form should be updated as soon as possible.

1 Site Information

1. Legal name of Site:
   1a. List all other names by which this Site is known:
2. Federal Wide Assurance (FWA) number:
   2a. FWA expiration:
   2b. Does this Site's FWA ext
   2c. List all institutions or affili
   2d. Describe any institutiona
3. Does this Site have an interna
   3a. Is the Site's IRB AAHRP
      a. If "no," describe the Sit
4. Is this Site a covered entity*?
   4a. Provide any relevant info
5. Site HRPP (or equivalent offic
   Name:
   Email:
   Phone #:
6. Are there any investigations,
   relevant to the conduct of hu
   6a. If "yes", provide additiona

2 State Law and Site Policy Requirements

1. Provide any state or local laws that the Northwestern University IRB may need to consider when reviewing this Site. For example, this may include but is not limited to: state privacy laws, laws related to sensitive data collection, age of majority, legally authorized representative(s), etc. Provide descriptions and/or brief summaries of relevant laws:
2. What is the age of majority for research in this Site's state? (i.e., age when one is considered an adult in your state):
3. Provide any site policies that the Northwestern University IRB may need to consider when reviewing this Site. For example, this may include but is not limited to: data retention, e-Consent, consent processes for minors, consent processes for those with Impaired Decision-Making Capacity, use of short forms for non-English speaking individuals, translation of consent forms, etc. Provide descriptions and/or brief summaries of relevant policies:
4. Provide information on any ancillary reviews that the Northwestern University IRB must verify are completed before studies can begin. This excludes ancillary reviews or processes that the relying site is responsible for:
5. Will this Site verify that all Site personnel engaged in human research are appropriately qualified and up-to-date on this Site's institutionally-required training (e.g., human subjects protections or HIPAA training)? Yes ☐ No ☐
6. If an individual or institutional financial conflict of interest is present, will this Site provide a management plan? Yes ☐ No ☐
7. Does this Site conduct administrative or institutional reviews of all ceded studies to ensure state and local laws and institutional policies are adhered to before activities at this Site begin? Yes ☐ No ☐

https://irb.northwestern.edu/reliance/nu-serving-as-the-irb-of-record.html

3 Informed Consent Requirements

1. Is the Site agreeable to Northwestern University serving as the HIPAA Privacy Board? Yes ☐ No ☐ Other ☐
   1a. If "No" or "Other," provide further information:
2. If the answer to Question 1 is "Yes", can HIPAA authorization language be included in the consent form? Yes ☐ No ☐
   2a. Provide this Site's required HIPAA authorization language:
3. If the answer to Question 1 is "Yes", does this Site require unique waivers of authorization under HIPAA (e.g. accessing medical records for recruitment purposes)? Yes ☐ No ☐
   3a. If "Yes," elaborate when this Site would require a unique waiver, partial waiver, or alteration:
4. Provide this Site's required informed consent language, verbatim, in the spaces below:
   4a. Subject Compensation:
   4b. Research Related Injury:
   4c. Provide any other consent form language required by state and local laws and institutional policies: 4d. Other:
5. Are there additional informed consent considerations that the Northwestern IRB should be aware of (e.g. inclusion of logos in headers)?:
6. Will this Site conduct an administrative or institutional review of its site-specific informed consent form(s) to ensure all state and local laws and institutional policies are adhered to before activities at this Site begin? Yes ☐ No ☐

4 Community Considerations

1. Identify any special characteristics and/or concerns of your community which the reviewing IRB should be aware for this Site. Please also outline any steps that are recommended to be taken to address these concerns:

5 Signatures and Attestations

By signing below, the signatory affirms that they attest to the accuracy and completeness of the information provided herein.

The Site is solely responsible for consulting with its own legal counsel to determine whether research reviewed by the Northwestern IRB (including but not limited to any consent process, participant documentation, or HIPAA documentation) meets all other applicable federal, state, and local legal and policy requirements, including but not limited to HIPAA compliance.

_____
Signature of Site's Human Research Protection Program (or equivalent office) Authorized Individual

_____ _____
Printed Name and Title of Authorized Individual Date

https://irb.northwestern.edu/reliance/nu-serving-as-the-irb-of-record.html

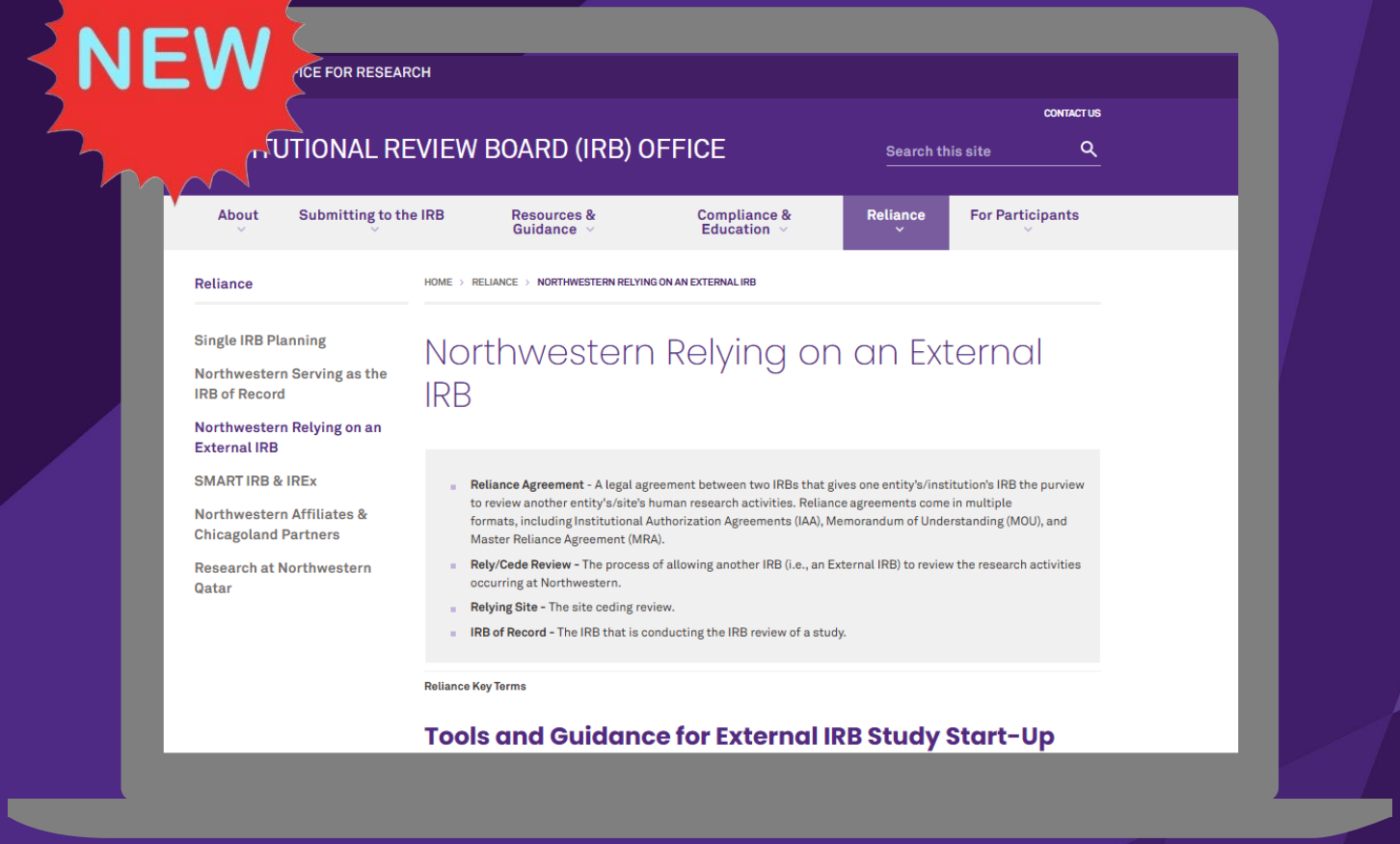
Local Context Review

- The assigned analyst and/or IRB will use the Local Context Form to ensure that local and state laws, institutional policies, and community considerations are accounted for with respect to:
  - Relying site activities
  - Relying site consent form(s)
  - Recruitment materials for use at/by the relying site
  - Other documents for use at/by the relying site

External IRBs

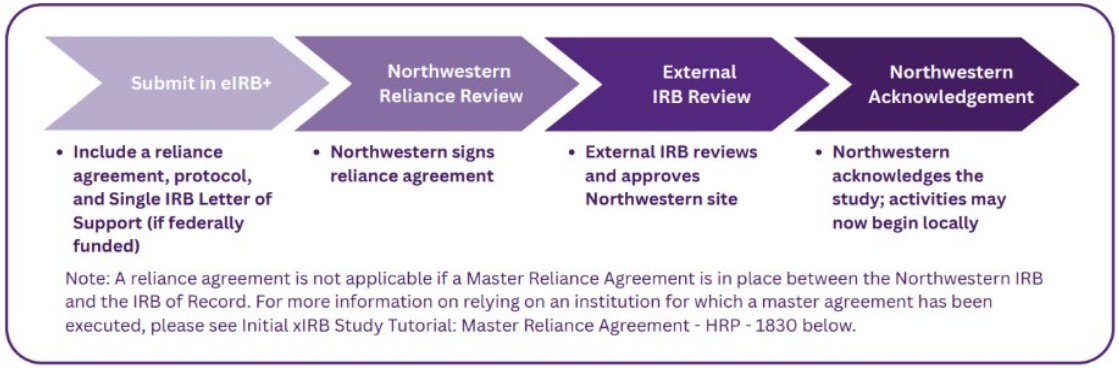
https://irb.northwestern.edu/reliance/nu-relying-on-an-external-irb.html

NEW



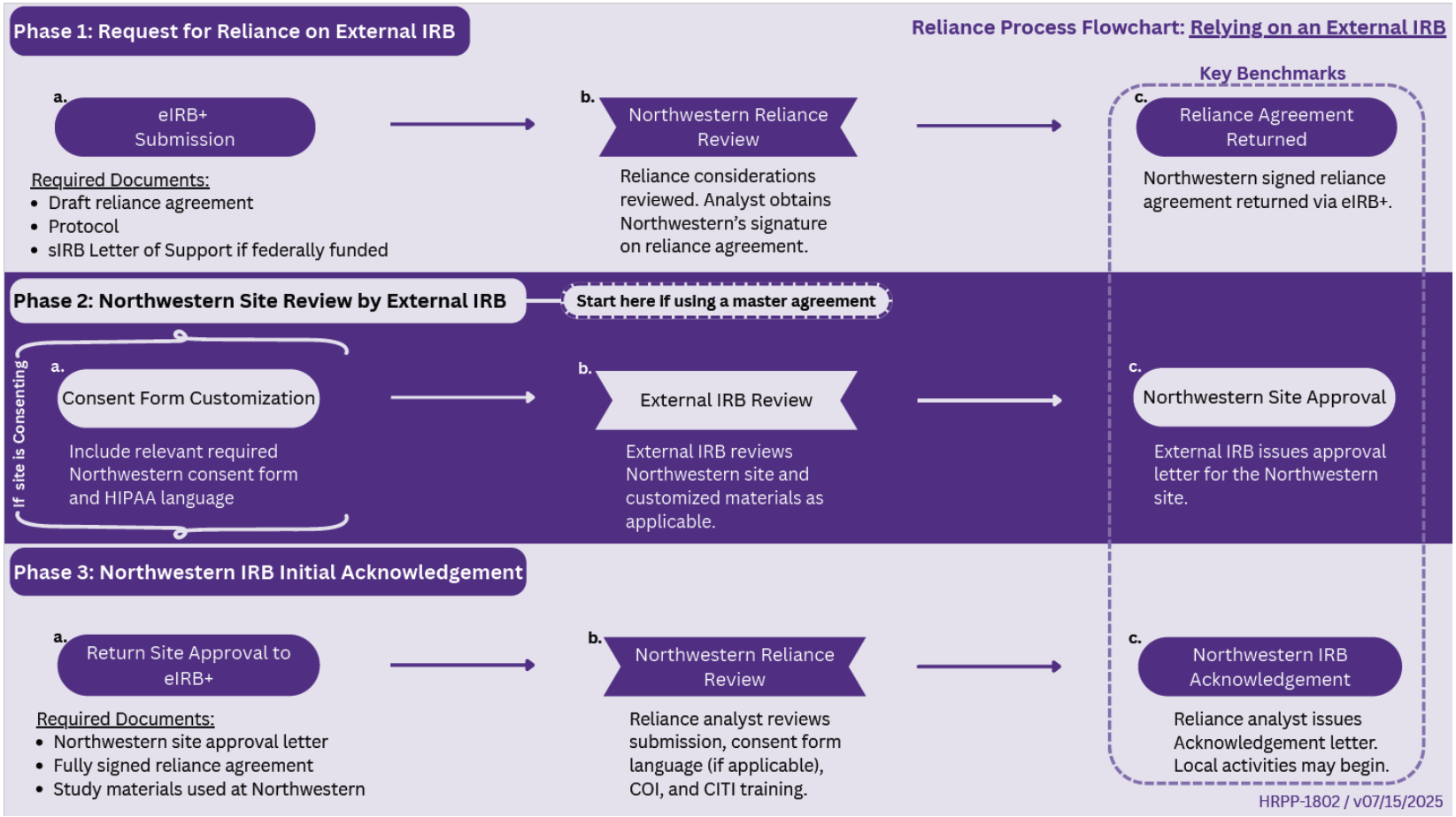
Updates to the External IRB Webpage

- Reorganization of content to resemble the lifecycle of a study
  - Main content is organized by study-start up, study maintenance, and other tools and guidance
- Addition of a detailed FAQ section
- Addition of two external IRB workflow resources



Northwestern Relying on an External IRB

A New Resource!



STU vs. IRBSITE

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

STU
Basic Information
Funding Sources
Study Team Members
Study Scope
Drugs (as applicable)
Devices (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]
Basic Information
External IRB
Funding Sources
Study Scope
Drugs (as applicable)
Devices (as applicable)
Study-Related Documents
Final Page and RSS

IRBSITE [3]
Basic Site Information
Funding Sources
Study Team Members
Local Site Documents
Final Page and RSS

STU vs. IRBSITE

STU
(aka Study)

IRBSITE/SITE
(aka Site)

HRP-1828 – Where to upload documents for External IRB Studies

Where to upload documents for External IRB Studies: Study vs. Site Submissions in eIRB+

Study Document	STU or IRBSITE?	Page Name
Protocol	Study Submission ("STU")	Basic Information
Local Protocol Addendum	Study Submission ("STU")	Basic Information
Consent Form(s) - Northwestern specific language*	Site Submission ("IRBSITE" a.k.a. "Site")	Site-Specific Documents
Consent Form Template(s)	Study Submission ("STU")	Study-Related Documents for non-NU Research Sites
Investigator Brochure	Study Submission ("STU")	Drugs
Package Insert	Study Submission ("STU")	Drugs
Device Manual	Study Submission ("STU")	Devices
Recruitment Material - Overall Study	Study Submission ("STU")	Study-Related Documents for non-NU Research Sites
Recruitment Material - Northwestern Site	Site Submission ("IRBSITE" a.k.a. "Site")	Site-Specific Documents
Questionnaires - Overall Study	Study Submission ("STU")	Study-Related Documents for non-NU Research Sites
Questionnaires – Northwestern Site	Site Submission ("IRBSITE" a.k.a. "Site")	Site-Specific Documents
External IRB Approval Letter - Initial Site Approval	Study Submission ("STU")	External IRB
External IRB Approval Letters – Post-Initial Approval**	Site Submission ("IRBSITE" a.k.a. "Site")	Site-Specific Documents
Reliance Agreement***	Site Submission ("IRBSITE" a.k.a. "Site")	Site-Specific Documents

*E.g., Northwestern PI contact information, HIPAA, subject injury, financial disclosures, etc.
**Continuing review approvals, modification approvals, RNI determinations, closure letters
***Institutional Authorization Agreement (IAA), Master Agreement Acknowledgement Letters (Commercial IRBs), SMART IRB Letter of Acknowledgement (LOA)

Crafting Consent Forms

- Use the template of the IRB of Record
- Add site-specific language (local language requirements)
  - Financial Interest Disclosure
  - Investigator / Treating Physician Conflict of Interest
  - Research Related Injury*
  - Research Costs and Compensation
  - Institutional Policy/State Law Requirements
  - Local Study Team Contact Information
  - HIPAA Authorization*

*Edits are not allowed

Ongoing Study Requirements

When the External IRB is the IRB of Record

- What to Submit to the External IRB
  - All changes/modifications to NU site protocol and materials
  - Change in PI
  - Reportable New Information

- What to Submit to Northwestern IRB
  - Any Change to Key Study Documents (i.e., Protocol, Consent, etc.) once approved by External IRB
  - CRs and Closure, once approved by External IRB
  - Northwestern Study Team Member Updates
  - Reportable New Information*

Final Reminders

- Your assigned analyst is your key point of contact
- All studies must undergo institutional reviews (COI*, SRC*, OSR, NMHC, NMH Device Committee, etc.)
  - * These reviews are required before initial acknowledgment
- External IRB-approved consent forms must include the required Northwestern template language
- All approved study documents listed on the External IRB approval letter should be uploaded into the submission
- All study team members must have Human Subject Protections training completed within the last 3 years.
- Documents should be uploaded into the appropriate sections of the eIRB+ application (STU vs. IRBSITE)

Northwestern IRB Reliance

Email: irbreliance@northwestern.edu

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

Office Hours: Tuesdays @ 3pm CT