

IRB Bulletin: January 2025

Announcements

As a part of the Northwestern University IRB Office's initiative to share timely resources and information with the research community, the IRB publishes the Bulletin at the beginning of each month, which contains relevant updates from the IRB Office. You can also find the IRB Bulletin on the [IRB News & Announcements webpage](#). Please keep reading for this month's updates.



Crafting Clear and Accessible Consent Forms

Are you working on an informed consent form and striving to make it clear, simple, and easy to understand?

The IRB's [Fostering Accessibility and Inclusivity in Research \(FAIR\)](#) Team has released a brand-new guide to help you write more accessible consent documents using plain, lay-friendly language.

Key Fact: informed consent is more than just a form—it's an ongoing, interactive process with your participants.

Explore the [Quick Guide for Writing Consent Forms in Lay Language](#) for practical tips, helpful examples, and additional resources to craft consent forms for your research participants.

Highlighting Northwestern University's HRPP Excellence



We are thrilled to announce that Northwestern University has been awarded **Full Reaccreditation for five years** by the Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP)! This achievement reflects the collective efforts and dedication of everyone involved in our Human Research Protection Program (HRPP). As a vital part of our program, we are excited to share this positive feedback with you and celebrate this milestone together. Thank you for your continued commitment to advancing research excellence and human subject protection!

Areas of Distinction identified by AAHRPP:

- **Community Engagement and Accessibility Initiatives:** The HRPP supports diverse activities to engage and educate research participants and communities, such as the FAIR initiative, Community Engagement Coordination Council, and partnerships like ARC and NP3. These programs promote inclusivity and accessibility in research.
- **Comprehensive Education Programs:** Robust training is offered to IRB staff, members, and researchers through initiatives like I-STOP, I-POEM, and Navigating Human Research & Regulatory Review with the IRB through MyHR Learn, ensuring all HRPP community members are equipped with the knowledge and expertise to protect research participants.
- **Responsive and Collaborative IRB Practices:** The IRB is recognized for its proactive communication, responsiveness, and integration within the HRPP. IRB staff are trusted resources, regularly soliciting and acting on feedback to improve processes.
- **Streamlined Post-Approval Monitoring (PAM):** Northwestern's innovative use of PAM checklists empowers researchers to self-assess compliance, reducing administrative burden while improving efficiency. This approach has facilitated faster closure of minimal-risk projects and allowed compliance staff to focus on strategic priorities, such as developing the *eIRB+ Compliance Workspace!*

Reliance Radar

Reliance Welcome Packet Turns 1!

One year ago, the Reliance Welcome Packet debuted on the [Northwestern Serving as the IRB of Record](#) webpage. To celebrate its first anniversary, we're recapping the key documents included in the [Reliance Welcome Packet](#) and reintroducing Local Context Forms—*now a required component*. The instructions and documents included in this packet have been designed to help study teams communicate with their collaborators and streamline the reliance process when Northwestern is serving as the IRB of Record.

HRP-1832 Reliance Process Overview	Outlines standard process for executing reliance and onboarding participating sites
HRP-1833 Reliance Process Flowchart	A visual representation of our standard process for executing reliance and onboarding participating sites
HRP-1834 Cover Letter	An optional template study teams can use to communicate with participating sites
HRP-1835 Reliance Welcome Email Template	An optional template study teams can use to communicate with participating sites
HRP-1825 - Relying Site Local Context Form	This form solicits background information regarding participating sites and their site-specific consent language and policies

Collaborative vs Multi-site: What's the Difference?

In eIRB+, the distinction between multi-site and collaborative research is important because it documents whether Northwestern will conduct the entire protocol from start to finish (i.e., **Multi-site**) or if Northwestern will only be conducting a portion of the protocol (i.e., **Collaborative**). Let's break it down further to help you navigate these classifications!

Multi-Site: Each site engaged in Human Research will conduct the entire study

Example: 5 sites are conducting a clinical trial. Each site will be recruiting, enrolling, and conducting follow-up activities exactly as specified in the protocol.

Whether the study is **collaborative** or **multi-site**, the selection informs the IRB Office of what else might be required in your submission (e.g., consent forms, recruitment materials, surveys etc.)

Ensure you are only selecting **multi-site** under Q7 of the basic information page of the STU if your study is truly a multi-site study (i.e., all sites will be conducting the entire protocol).

Collaborative: Each site engaged in Human Research will conduct a portion of the study

Example: Participants are recruited from site A, and they will go to site A to provide consent and receive the study intervention. They will then go to site B for assessments of the intervention's effectiveness.

When a study is identified as **collaborative** (i.e., Northwestern will be conducting a portion of the protocol), your eIRB+ submission should document which portion of the protocol will be conducted at Northwestern or by Northwestern personnel at other research locations.

If your external IRB study is **collaborative**, the best place to document which portion of the activities will be conducted at Northwestern or by Northwestern personnel is in the description of local activities on the IRBSITE (i.e., IRBSITE Basic Information page, Q3).

Contact irbreliance@northwestern.edu or drop by Reliance Office hours with any questions.

UPCOMING IRB BROWN BAG

Ask the IRB!

Please join us **Wednesday, January 15**, for our monthly IRB Brown Bag Session, where representatives from Northwestern IRB's Biomedical, Social Behavioral, Compliance, Reliance, and Education teams will answer your human research protection-related questions! This is a great opportunity to engage with subject matter experts and receive real-time feedback on all things IRB. We look forward to seeing you there!

Please view the [Events Page](#) for details and registration information for upcoming [Brown Bag](#) informational sessions.

[REGISTER HERE](#)

UPDATED DOCUMENTS

The following was updated and is now available on the Policies & Guidance Page:

- Investigator Manual (HRP-103)
- Several sections were revised including investigator and study team roles, financial disclosure requirements, reliance on external IRBs, study management processes (such as submitting continuing reviews and study closures, and record retention), handling unexpected events, PI departures, and guidance for using unapproved drugs, biologics, or devices.

The following was updated and is now available on the Checklists & Worksheets Page:

- Payments (HRP-316)
- Criteria for Approval for HUD (HRP-323)
- Non-Significant Risk Device (HRP-418)
- Pregnant Persons (HRP-412)
- Post Approval Monitoring Participant File (HRP-428)

The following was updated and is now available on the IRB's Fostering Accessibility and Inclusivity in Research (FAIR) Diversity, Equity, and Inclusion (DEI) Resources Page:

- Research Design Considerations DEIJ Perspective (HRP-1921)
- Members of the research community and the FAIR team have reassessed this document to provide more clarity including elaborated definitions, more specific questions, and administrative changes for readability.

For more information on updated documents reach out to irb@northwestern.edu

STAFF EVENT SPOTLIGHT

Celebrating Community and Connection: The 2024 Winter Open House

Each year, the IRB office hosts colleagues from across campus at our annual Winter Open House. The event is in place of our monthly Brown Bag sessions and offers an opportunity for our Northwestern community to connect, build community, collaborate, and reflect on the year gone by.

The event grew significantly from last year's gathering, where we welcomed nearly 200 members of the Northwestern research community and their friends to enjoy catered refreshments, lively conversation and a bit of friendly competition. Attendees participated in engaging activities, including research bingo and a scavenger hunt with chances to win IRB-branded "swag," all while enjoying festive tunes and great company.

We look forward to welcoming you to the 2025 Winter Open House this December! Until then, on behalf of the Northwestern IRB Office team, we wish you a joyful and prosperous year ahead!



Please use the [Northwestern University IRB Office Website](#) as your primary source of information and resources on human research protections