Northwestern | INSTITUTIONAL REVIEW BOARD

IRB Bulletin: August 2026

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 page**. Please keep reading for this month's updates.

Good Clinical Practice (GCP) Certification and ICH E6(R3)

The ICH E6(R3) Guideline for Good Clinical Practice (GCP) **is now in effect**, updating international expectations for the design, conduct, and oversight of clinical trials. There is *no requirement for Northwestern researchers to immediately retake GCP training.*

Current GCP certifications remain valid through their existing certification period, and the updated content will be incorporated into future CITI GCP enrollments and renewals.

Please note: Completion of GCP training does not meet Northwestern's **Human Research Protections Training** requirements. **Good Clinical Practice (GCP) training** is managed by the NUCATS Education Team, not the Northwestern University IRB Office. Questions about GCP training requirements or course enrollment should be directed to **nucats-ed@northwestern.edu**.

Read the full news story for additional information about the updated guideline and Northwestern training requirements: **Good Clinical Practice (GCP) Certification and ICH E6(R3)**

Updated Single IRB Consultation Intake Form

For all proposed research involving **federal** funding, **human** subjects, *and* **multiple** research locations, the Northwestern IRB requires you to obtain a 'Single IRB Letter of Support.' This letter is required for both projects where the Northwestern IRB cedes to an external Single IRB or serves as the Single IRB for a project.

We're happy to announce that we have significantly overhauled the intake form that community members use to request these letters of support. The new form is designed with more efficient information collection in mind and includes additional error checking to prevent unnecessary submissions. On the backend, we've also overhauled our administrative process for handling intake forms. So, while the overall process for community members has not changed, we're happy to report that our updates are already resulting in faster turnaround times for Letter of Support requests.

A link to the updated form is now live on the **Single IRB Planning** webpage

IRB EDUCATION

When a Principal Investigator Leaves Northwestern: What Research Teams Need to Know

When a Principal Investigator (PI) plans to leave Northwestern or one of its affiliates, research teams should begin planning early, before they leave, to ensure studies are appropriately managed and required IRB actions are completed.

Investigators should notify the IRB Office when they plan to leave Northwestern. Depending on the circumstances, research teams may:

- Transfer responsibility for the study to another eligible Northwestern researcher. See **Principal Investigator Transfer of Responsibility Guidelines**.
- Close the study at Northwestern University. See **Guidance on Study Closure**.
- Transfer IRB oversight to another institution, when appropriate.

The IRB Office recommends initiating these steps **at least 90 days before the planned departure date**. Additional information for navigating researcher offboarding is available on the **IRB Courses** Page.

Research teams should also remember:

- Active studies must have an **eligible** Northwestern PI. Study information and personnel should remain current in eIRB+.
- All open, non-exempt studies, including those without an expiration date, must be promptly closed upon completion. See **Continuing Review & Closure** for steps to close a study.
- Research records must be retained according to applicable regulatory, sponsor, and institutional requirements. See the **Research Document Retention Requirements for Principal Investigators**.
- Investigators who are no longer affiliated with Northwestern or its affiliates may not access Northwestern Medicine medical records as non-employees.
- *If a PI leaves unexpectedly or is no longer available to complete transition steps, the department is responsible for ensuring appropriate actions are completed and should notify the IRB Office.*

Learn more: Visit the **Office for Research Principal Investigator Resources** page and the IRB website for **Principal Investigator Responsibilities, Eligibility, and Permissions**.

UPCOMING BROWN BAG

Regulatory Aspects of Investigational Drug Service (IDS) Pharmacy

Wednesday, August 19, 2026 | 12:00 - 1:00 PM

REGISTER HERE

Please join us virtually for our monthly Brown Bag Session featuring Eunice Lee, Pharm D., JD., Protocol Management Pharmacist from the Investigational Drug Service (IDS) Pharmacy at Northwestern Memorial Hospital.

This session will provide an overview of IDS Pharmacy services and its role in supporting human research involving investigational products (IP). The presentation will cover the scope of IDS services, regulatory requirements, standard operating procedures (SOPs), and investigational product management, including licensing, preparation, handling, and shipping.

Speakers will highlight the role of IDS Pharmacy throughout the study lifecycle, including study feasibility, site selection, Site Initiation Visits (SIVs), corrective and preventive actions (CAPA), record keeping, and study closeout.

After attending this session, participants should be able to:

1. Describe the role and scope of Investigational Drug Service (IDS) Pharmacy services in supporting human research.
2. Identify key regulatory and operational considerations for investigational product management, including licensing, preparation, handling, and shipping.
3. Recognize the role of IDS Pharmacy throughout the study lifecycle, from feasibility and site selection through study closeout.
4. Understand key study activities involving IDS Pharmacy, including SIVs, CAPA, and record keeping.

Please view the **Events Page** for details and registration information for upcoming **Brown Bag** informational sessions.

In case you missed last month's Brown Bag session, *Documenting, Executing, and Evaluating Corrective and Preventive Action (CAPA) Plan*, the slides and recording are now available on our **IRB Brown Bag** page. This session provided an overview of CAPA Plans and introduced new and updated resources available on the IRB Office **CAPA Plans Page**. Attendees learned how to conduct a root cause analysis, develop, document, and implement a CAPA plan, and evaluate the effectiveness of actions taken to prevent recurrence of the deviations or unexpected events.

UPDATED DOCUMENTS

The following **Reliance Agreement templates** have been updated and are now available on their respective pages. *Please ensure these versions are utilized for new reliance submissions.*

- IRB Authorization Agreement (NU IRB of Record) Reliance Agreement (HRP-1808)

    - **Northwestern Serving as the IRB of Record**
- Authorization Agreement (NU IRB NOT IRB of Record) Reliance Agreement (HRP-1807)
    - **Northwestern Relying on an External IRB**
- Advarra Master Agreement Acknowledgment Letter (HRP-736)
    - **Northwestern Relying on an External IRB**
- Western Copernicus Group (WCG) Master Agreement Acknowledgment Letter (HRP-735)
    - **Northwestern Relying on an External IRB**
- SMART IRB LOA Reliance Agreement (HRP-1806)
    - **SMART IRB & IREx**
- GU-Q Clearance Letter Reliance Agreement (HRP-739)
    - **Research at Northwestern Qatar**

The following was updated and is now available on the **SOPs** Page:

- Emergency Use (HRP-023)
- Compassionate Use (Device Only), and IRB Waiver for Individual Patient Expanded Access (Drug Only) (HRP-031)

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

STAFF SPOTLIGHT

Meet Braden Van Buskirk!

Hello! I'm Braden Van Buskirk the IRB Manager for the Social and Behavioral research team. I've been with the Northwestern University IRB Office for 19 years. I was on the Social and Behavioral research IRB team for three years, then worked with the Biomedical IRB team for 10 years before returning to the SB IRB in late 2019. It has been a great experience to work in multiple capacities and to collaborate with study teams across multiple disciplines.

It has been awesome to see all of the growth in research and innovation through the years and be able to work with the research community and our clinical affiliates. I often say the thing that keeps me at the Northwestern University IRB Office is the people! I've made countless friends and colleagues in the IRB Office, in the research community, and within the Office for Research.

I'm a transplant to Chicago but consider it home. What an amazing city we live in! I like to bike ride, explore neighborhoods, and love good concerts. I also love TV shows, movies, music, and playing games with friends (all of which are perfect on a frigid winter day)!

IRB Office - Contact Us

IRB Office Unit	Email/Phone	Virtual Office Hours
Biomedical Research/General	**irb@northwestern.edu** 312-503-9338	**Monthly** - Every Second Wednesday 11:00 AM - 12:00 PM **Register**
Social and Behavioral Research	**sbirb@northwestern.edu** 847-467-1723	Weekly - Every Wednesday 2:30 - 3:30 PM **Register**

Compliance	**irbcompliance@northwestern.edu** 312-503-1376	Appointment Available Upon Request **Email Compliance**
Reliance	**irbreliance@northwestern.edu**	Weekly - Every Tuesday 3:00 - 4:00 PM **Register**
Training and Education	**irbtraining@northwestern.edu**	Appointment Available Upon Request **Email Training/Education**
eIRB+ Technical	**eIRB+ Support Form**	---

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

Northwestern | RESEARCH

Northwestern University IRB Office | 750 N. Lake Shore Drive Rubloff Hall, 7th Floor | Chicago, IL 60611 US