

IRB Bulletin: July 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.

HIPAA Authorization Language for Consent Templates for Studies Involving Children

Investigators using any of the consent and permission templates for studies involving children listed below should ensure that the appropriate HIPAA Authorization language is included **if the study involves the collection, use, or disclosure of HIPAA-protected health information (PHI)**.

This requirement applies to the following **templates**:

- Parent Consent and Permission with Child Assent (HRP-1711)
- Parent Permission with Child Assent (HRP-1712)
- Parent Consent and Permission (Parent and Child Participate Without Assent) (HRP-1728)
- Parent Permission (Parent's Permission Without Assent) (HRP-1729)

When HIPAA Authorization is required, investigators should incorporate the appropriate HIPAA Authorization language from these documents, as appropriate for the study.

- **Social & Behavioral Consent Document with HIPAA Authorization (HRP-1721), or**
- **Biomedical Consent Template (HRP-592)**

Please review your consent documents carefully to ensure the required HIPAA Authorization language is included before submission to the IRB.

EDUCATION EXCHANGE

Looking Ahead: IRB Education Opportunities

The Northwestern University IRB Office is committed to fostering a culture of shared learning and collaboration across our research community. Our IRB Brown Bag sessions bring together researchers, IRB staff and members, and institutional partners as partners in advancing high-quality, ethical, and compliant human research.

Held generally on the third Wednesday of each month from 12:00–1:00 PM CST, these sessions offer



opportunities to discuss emerging topics, regulatory updates, and research best practices in an open and collaborative setting.

Upcoming Sessions

- **July 15, 2026:** Featuring members of the IRB Office Compliance Team discussing Documenting, Executing, and Evaluating Corrective and Preventive Action (CAPA) Plans. Complete session details are available in the Brown Bag section below.
- **August 19, 2026:** Featuring the Investigational Drug Services Pharmacy, Northwestern Memorial Hospital
- **September 16, 2026:** Featuring Export Controls & International Compliance, Northwestern University

Stay Connected & Keep Learning

Can't make a session or interested in revisiting past discussions? Explore presentation materials, including slides and recordings, on the [IRB Brown Bag](#) page.

Registration details for upcoming sessions are available on the IRB [Events](#) page and on the [Northwestern Events Calendar, PlanIT Purple](#).

Have an idea for a future topic? We'd love to hear from you—email irbtraining@northwestern.edu.

UPCOMING BROWN BAG

Documenting, Executing, and Evaluating Corrective and Preventive Action (CAPA) Plans

Wednesday, July 15, 2026 | 12:00 - 1:00 PM

REGISTER HERE

Please join us virtually for our monthly Brown Bag Session featuring members of the Northwestern University IRB Office Compliance Team: Senior IRB Compliance Analysts Jennie Thai and Brittanë Garyet.

This session provides an overview of Corrective and Preventive Action (CAPA) Plans and introduces new and updated resources available on the IRB Office [CAPA Plans Page](#), including the CAPA Plan Form (HRP-1209) and CAPA Plan Self-Assessment Form (HRP-1210). Attendees will learn how to conduct a root cause analysis, develop and implement a CAPA plan, document CAPA activities, and evaluate the effectiveness of actions taken to prevent recurrence of the deviations or unexpected events.

By the end of the session, attendees will be able to:

- Locate and utilize the CAPA Plan Form (HRP-1209) and CAPA Plan Self-Assessment Form (HRP-1210).
- Conduct a root cause analysis to identify underlying causes of research deviations and unexpected events.
- Develop and implement a CAPA plan that addresses the root causes of the deviations or unexpected events and reduce the likelihood of recurrence.
- Document CAPA activities and maintain supporting records.
- Evaluate the effectiveness of the actions taken using the CAPA Plan Self-Assessment Form.



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, *Before You Submit: A Practical Guide to Nuclear Medicine and Radiation Safety Review in Human Research*, the slides and recording are now available on our [IRB Brown Bag](#) page. This session highlighted the role Nuclear Medicine and Radiation Safety play in supporting human research at Northwestern.

UPDATED DOCUMENTS

The following was updated and is now available on the [Consent Templates](#) Page:

- Social Behavioral Consent Document (HRP-582)
- Verbal Consent (HRP-1710)
- Parent Consent and Permission with Child Assent (HRP-1711)*
- Parent Permission with Child Assent (HRP-1712)*
 - *Updated to include guidance for studies using Shirley Ryan AbilityLab participant payments, with a reference to the Supplemental Social Behavioral Consent Language document for the required compensation language. Updated HIPAA and National Institute of Justice (NIJ) content
- Social Behavioral Consent Document with HIPAA Authorization (HRP-1721)
- Parent Consent and Permission (HRP-1728)
- Parent Permission (HRP-1729)

The following was updated and is now available on the [SOPs](#) Page:

- Observation of the Consent process (HRP-012)
- Non-Committee Review Preparation (HRP-031)
- Principal Investigator Permission (HRP-096)
- Annual HRPP Evaluations (HRP-060)

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

STAFF ANNOUNCEMENTS

We are pleased to share the following IRB Office staff announcement:

Angela Baumgartner has been promoted to IRB Compliance Manager effective June 22, 2026. Angela has over twelve years of experience in human research at Northwestern University, the past 7 years of which have been spent within the IRB Office. Most recently serving as Lead IRB Compliance Analyst, Angela has assisted in managing the daily operations of the Compliance Team, including the post-approval monitoring program, and has served as a primary resource to the IRB Office and research community for regulatory and procedural guidance on the compliant conduct of human research. Before joining the IRB Office, Angela served as a Senior Regulatory Coordinator and Regulatory Coordinator within NUCATS, where she managed regulatory submissions and documentation across dozens of concurrent studies, providing human research regulatory guidance, and developed SOPs and training. As IRB Compliance Manager, Angela will lead the Compliance Team within the IRB Office, overseeing its operations and continuing to advance the compliance program in support of Northwestern University's HRPP. Angela will work closely with the IRB Office leadership to further the office's strategic goals and ensure the highest standards in research compliance. Angela holds a Bachelor of Arts, summa cum laude, with majors in Biology and Pre-Medicine from Augustana College. Angela is also a Certified Healthcare Research Compliance (CHRC)® professional. **Congratulations, Angela!**

Monica Kane has been promoted to IRB Reliance Manager effective June 22, 2026. Monica has over nine years of experience in human research, including the past 6 years within the Northwestern IRB Office, where she began as the first 100% dedicated reliance position and most recently served as IRB Reliance Analyst Lead. In that role, Monica continued to lead efforts to enhance reliance resources for the research community and IRB staff and oversee the processing of countless reliance reviews in eIRB+. She also continues to serve as a wellness representative for the office, supporting IRB staff in day-to-day activities and fostering opportunities for continued engagement. As IRB Reliance Manager, Monica will now lead the Reliance Team, overseeing its day-to-day operations and supporting the continued growth of Northwestern's reliance portfolio. As a member of the IRB Office leadership team, she will work closely with colleagues to support the mission of Northwestern University's HRPP and share in the responsibility for the success of the IRB Office in accomplishing its strategic goals. Monica holds a Bachelor of Arts, with a major in Chemistry and a minor in Art History from Case Western Reserve University, and a Master of Public Health with a major in Epidemiology from the University of Illinois at Chicago. Monica also obtained a Pharmacoepidemiology certification from the University of Illinois at Chicago. **Congratulations, Monica!**

STAFF SPOTLIGHT

Meet Mila DeMarte!

Hi! I'm a Senior IRB Analyst on the Biomedical Team in the IRB Office. I joined the IRB Office in December 2022 after working as a research coordinator in the Division of Gastroenterology and Hepatology for two years. I earned my bachelor's degree in Health Sciences from Boston University and I spent a few years working in research in Boston before moving back to Chicago.

At the IRB Office, I lead Panel M, our newest biomedical review panel. We meet on the fourth Friday of each month and review a wide range of submission types. One of my favorite parts of my role is working with our IRB panel members, the research community, and my colleagues in the IRB Office. I also enjoy reviewing biomedical studies and learning about the research taking place at Northwestern across the biomedical and social-behavioral sciences.

Outside of work, I love swimming, reading, cooking, and trying new creative hobbies. Ballet is one of my favorite hobbies, and I have performed in *The Nutcracker* with a small



ballet company for the past two holiday seasons. I am also an avid reader, and in the summer, you can often find me reading a novel by the lake.

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

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