

IRB Bulletin: December 2024

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.

IRB Office Shines at PRIM&R 2024: Leadership in Research Ethics and Oversight

We are excited to share that several of our IRB Office staff recently attended and presented at the 2024 Public Responsibility in Medicine and Research (PRIM&R) Annual Conference in Seattle, Washington. Presentation titles and authors are listed below. The IRB Office is proud to have a staff base so deeply committed to the rights and welfare of participants in research and engaged in their own professional development while actively participating in the evolving human research landscape as leaders in research ethics and oversight.

Consciously Uncoupling? When Institutions and Investigators Separate
Crista Brawley, Ph.D., CCRP, Associate Vice President, Office for Research

Are you Leaving Money on the Table? Ensuring IRB Fees Are Accounted for in a Single IRB World
Marcella Cooks, MS, CIP, IRB Reliance Manager

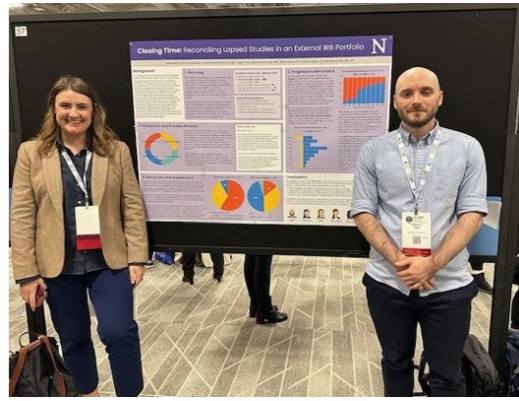
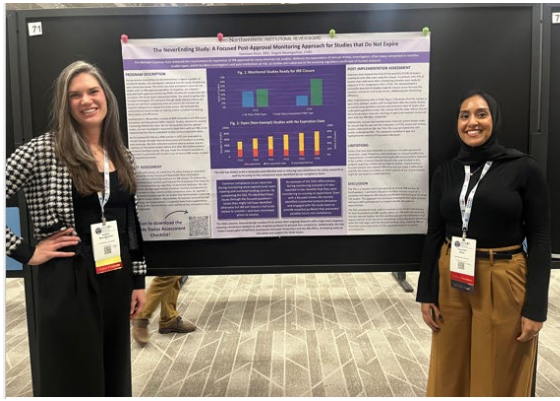
Pictured from left to right: (front) Yasmeen Khan, Marcella Cooks, Laura Loeb, (back) Logan Clary, Edeth Engel, Sheilah Graham, Angela Baumgartner, Monica Kane, and Crista Brawley. (Not pictured but also in attendance: Jennie Thai, Mila DeMarte, and Khrystyna Helner)



Showcasing Success: Innovative Approaches to Post-Approval Monitoring and Study Reconciliation at PRIM&R 2024

The IRB Office was accepted to present not one, but TWO posters for the PRIM&R24 Poster Presentation Program! The first poster was titled “The NeverEnding Study: A Focused PAM Approach for Studies that Do Not Expire” and detailed the success of a new post-approval monitoring checklist - **Study Status Assessment**. The second poster, “Closing Time: Reconciling Lapsed Studies in an External IRB Portfolio,” presented data from a novel clean-up program of studies in the Northwestern External IRB portfolio.

If you have any feedback or questions on either of these topics, reach out to IRBCompliance@northwestern.edu or irbreliance@northwestern.edu, respectively.



UPCOMING IRB BROWN BAG

IRB Office Winter Open House

[REGISTER HERE](#)

You are cordially invited to the [2024 IRB Office Winter Open House](#). Please join us as we gather in person to bid a warm farewell to 2024 with refreshments, games, prizes, and good cheer! The event is on [Friday, December 13th, 12:00 – 1:00 CST](#) in the [Simpson-Querrey Atrium](#) on the Chicago campus (303 E Superior Street). See our [Events page](#) for more information.

[Catch up on last month's Brown Bag session](#), "Streamlining Compliance: The New eIRB+ Compliance Workspace." The presentation slides and video recording are now available on our [IRB Brown Bag](#) webpage. This session highlighted the upcoming new Compliance Workspace within eIRB+. The IRB Compliance Team will conduct compliance activities, including routine post-approval monitoring (PAM) self-assessments, in the new Compliance Workspace within eIRB+ starting in early 2025. In this presentation, the IRB Compliance Team demonstrated system navigation, showcased effective communication strategies for the new compliance workspace, and engaged the research audience in a lively Q&A session.

UPDATED DOCUMENTS

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

- Template: Data and Specimens Analysis Protocol (HRP-1704)
 - Revisions include added prompts for AI use, updates for IRB gender inclusion standards, and minor administrative changes.
- Template: Biomedical Protocol (HRP-593)

- Revisions include inclusive language updates (e.g., "pregnant persons"), added justifications for PHI in the HIPAA section, new guidance on assent requirements, international research, and the applicability of PIPL (Personal Information Protection Law) and FERPA (Family Educational Rights and Privacy Act), along with AI usage instructions in the Procedures section.

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

- Media Relations Permission Form (HRP-1704)
- Mobile Apps and Mobile Medical Apps Guidance (HRP-1922)
 - Updates to align with current FDA guidance, policy, and regulatory oversight. Delineates between Mobile Apps and MMAs and the distinctions of FDA regulatory oversight (i.e., IDE Exempt; Non-Significant Risk device (NSR)-abbreviated IDE; and SR requiring an IDE).

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

- Engagement Determination (HRP-311)
- Children (HRP-416)

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

- NIH GDS Institutional Certification (HRP-064)
- IRB Formation (HRP-080)
- Informed Consent Process for Research (HRP-090)
- Pre-review (HRP-021)

The following Form was updated and is now available on the [Northwestern Serving as the IRB of Record](#) Page:

- Relying Site Local Context Form (HRP-1825)
 - Revisions include rephrased questions for clarity, reorganized sections to better collect topic specific information such as Informed Consent requirements, and overall optimization of the Form to support IRB review when the Northwestern IRB serves as the IRB of Record for relying sites (i.e. sites external to Northwestern University and its affiliates).
 - Note: A completed Local Context Form is now required when onboarding external sites that will rely on Northwestern via reliance agreements. Please review the [Reliance Welcome Packet](#), and once you submit in eIRB+ wait for our guidance regarding Local Context Forms. Do not obtain or complete this form in advance, unless directed, since we may already have a completed form for your proposed relying site.

STAFF ANNOUNCEMENTS

Yeletza Solano, BA, has joined the Northwestern University IRB Office as Biomedical IRB Analyst Associate. Yeletza started her career at Northwestern University for the *All of Us* Research Program as a Research Study Assistant, where she developed a growing curiosity and passion for protecting human research participants, ultimately deciding to pursue a career with the IRB office at Northwestern that began just a few weeks ago.

She is excited to engage with the Northwestern research community as the IRB's first point of contact. Welcome Yeli!

Sierra Willis, MS, CIP will be joining the Northwestern IRB team, as a Biomedical IRB Lead Analyst, effective December 16th, 2024. With nearly a decade of experience in IRB and Research COI oversight, Sierra is a skilled IRB professional who joins us from the Vail Health hospital in Vail, Colorado. In her new role, Sierra will be a valuable resource and leader for the Northwestern research community. Congratulations Sierra!

Heather Yates, MPH, CIP has been promoted to Biomedical IRB Lead Analyst, effective December 16th, 2024. She has been with Northwestern University IRB for over 4 years. She looks forward to continuing to serve as an excellent resource and leader to the research community in her new role. Congratulations Heather!

STAFF SPOTLIGHT

Meet Jennie Thai!

Hello! I started my career with the Northwestern University Institutional Review Board (IRB) Office Compliance Team two years ago. My primary responsibilities include ensuring that research compliance activities and programs performed at the institution adhere to research regulations and policies. In my role as an IRB Compliance Analyst, I conduct routine IRB post-approval monitoring assessments; attend IRB panel meetings where I serve as a subject matter consultant to the IRB in their review of unanticipated problem reports and non-compliance submissions; conduct for-cause audits; investigate allegations of non-compliance and participant complaints; and assist in developing and revising standard operating procedures for the compliance component of the IRB Office.



I am also a member of the **Fostering Accessibility and Inclusivity in Research (FAIR)** Workgroup within the Office of Research, working to encourage inclusive and equitable practices across the Northwestern University human research landscape in alignment with the Belmont Principle of Justice by creating and sharing resources across the University. Outside of the Office for Research, I am pursuing a Master of Science in Regulatory Compliance at Northwestern. I enjoy kickboxing, rock climbing, hanging out with my 9-year-old rescue pup, and exploring Chicago's incredible restaurant scene with friends.

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