Northwestern | INSTITUTIONAL REVIEW BOARD

IRB Bulletin: March 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 webpage**. Please keep reading for this month's updates.

NIH Clarifies the Definition of a Clinial Trial

The National Institutes of Health (NIH) recently issued **NOT-OD-26-032** clarifying that Basic Experimental Studies Involving Humans (BESH) will no longer be considered clinical trials under the NIH definition. This takes effect May 25, 2026.

What is a Basic Experimental Study Involving Humans (BESH)?
BESH studies involve human participants and are designed to understand fundamental aspects of biological or behavioral phenomena, rather than to test an intervention intended to directly improve health outcomes.
BESH studies aim to advance basic scientific knowledge and do not have a direct application toward clinical processes or products. NIH defines "processes or products" as the application of biomedical or behavioral research intended to affect a health-related outcome.

Under this updated clarification, NIH does not consider BESH studies to be clinical trials. Researchers who are unsure whether their project is a clinical trial, a BESH study, or an observational study involving humans can review NIH's decision tool: **Is My Project a Clinical Trial, Basic Experimental Study Involving Humans (BESH), or an Observational Study Involving Humans?**

📣 Free Webinar: CITI Webinar Symposium

CITI Program's first Webinar Symposium will showcase five prior webinars delivered in CITI Replay format. The webinars present various topics from across the CITI Program catalog.

Register for the individual sessions today!

March 24, 2026 at 8:30 AM

- **Artificial Intelligence: The Impact on Academic and Research Integrity** 8:30 a.m. CST
- **Service Dogs in Science: Barriers to Inclusion** 9:45 AM CST
- **Qualitative Data Analysis: Eight-Step Basic Process** 11:30 a.m. CST
- **Generative AI and Science Communication** 1:00 p.m. CST
- **A Recovering IRB Chair's Guidance to Students who want to do Research** 2:30 p.m. CST

IRB Website Spotlight

✨**We've updated the IRB Education website to make it easier for researchers to find the resources they need:**

- **Education** is now a top-level tab, your hub for training, outreach, and learning opportunities across the Northwestern HRPP community.
- **For Participants** is now under the **About** page, for access to participant-focused resources.

Explore IRB Education Resources
Our educational offerings are designed to build regulatory knowledge and foster dialogue, collaboration, and connection among researchers and research professionals.

- **IRB Brown Bag:** Monthly live sessions highlighting current human research protection topics; open to all HRPP community members.
- **IRB Courses**: (MyHR Learn): Introductory and advanced courses, including onboarding, offboarding, and human research protections fundamentals.
- **Human Research Protections CITI Training:** Required every three years for all personnel engaged in human research.
- **Special Event Training:** Tailored live sessions for departments or teams. Requests must be submitted at least five weeks in advance.
- **Optional CITI Course: Software as a Medical Device & Clinical Decision Support Systems (SaMD & CDSS)** – Recommended for investigators and teams working with digital health technologies, AI/ML-enabled tools, or device trials with software components.
- **IRB Bulletin:** Monthly newsletter keeping the research community informed and connected. Subscribe via the IRB Listserv and explore past issues on the **News & Announcements** page.

Explore all offerings on the **IRB Education Page** and take advantage of resources to strengthen human research protections across the Northwestern research community.

✨**The IRB Office is excited to unveil a new webpage: Post-Approval Resources & Quality Assurance!**

This page is designed to support the research community with post-approval monitoring by providing guidance and tools to help research teams conduct their own internal post-approval monitoring - also known as quality assurance (QA) reviews.

The Compliance Team recommends using the **post-approval monitoring checklists** *outside of routine IRB reviews* to help ensure studies remain compliant with applicable federal regulations, state laws, institutional policies, and best practices.

You will find a detailed list of each type of post-approval monitoring checklist, along with its intended scope. This information is designed to help research teams determine which checklists may be most beneficial and applicable based on a study's design and risk profile.

Lastly, the Compliance Team has compiled examples of common observations that may arise during monitoring activities, along with best practice recommendations for addressing them. We hope this page is helpful, practical, and informative, as you prepare for a QA review or a routine post-approval monitoring activity.

Thank you for Keeping Up with Compliance!

UPDATED DOCUMENTS

The following was updated and is now available on the **Biomedical & Social Behavioral Consent Templates** Page:

- Biomedical Consent Document (HRP-592)
    - Added the Illinois Department of Public Health (IDPH) reportable disease language in the HIPAA authorization. Examples of applicable infectious reportable diseases have been added, along with a reference link to the IDPH website. Additionally, the optional elements section of the informed consent has been revised for clarity.
- Emergency Use Consent Document (HRP-506)
    - Added the Illinois Department of Public Health (IDPH) reportable disease language in the HIPAA authorization.

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

- Suicidality in Human Research Protocols (HRP-1915)

The following Reliance Agreement templates have been updated and are now available on their respecive webpages:

- **Advarra Master Agreement Acknowledgement Letter**
- **Western Copernicus Group (WCG) Master Agreement Letter**
- **SMART IRB Letter of Acknowledgement (LOA)**
    - Ensure the newest version is downloaded and utilized when submitting new reliance requests in eIRB+.

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

UPCOMING BROWN BAG

Keeping Up With Compliance: Post-Approval Resources & Quality Assurance

Wednesday March 18, 2026 | 12:00 - 1:00 PM

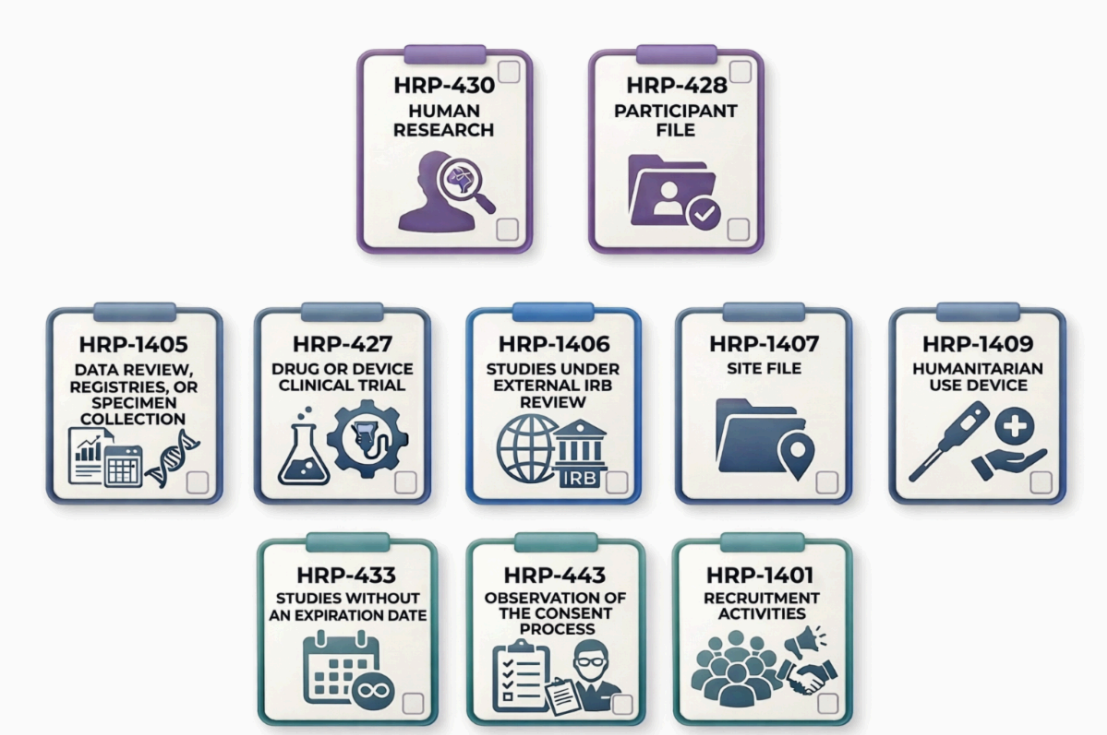
REGISTER HERE

Please join us virtually for our monthly IRB Brown Bag session, led by Yasmeen Khan, MSL from the IRB Office Compliance Team.

This session will introduce the IRB Office's new post-approval webpage – **Post-Approval Resources & Quality Assurance**! The page features Post-Approval Monitoring (PAM) checklists designed to support internal Quality Assurance (QA) reviews and help research teams keep studies compliant with IRB and regulatory requirements. We'll explore when QA reviews can be most helpful throughout the study lifecycle, highlight our comprehensive suite of PAM checklists available to research teams, and share common observations along with recommendations for addressing them.

Attendees will leave with:

- An understanding of the purpose of post-approval monitoring and internal QA reviews
- Knowledge of when and how to conduct internal QA reviews
- Ability to apply Post-Approval Monitoring (PAM) checklists
- Awareness of common QA observations and recommendations



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, Where Human Research Meets Integrity - What You Need to Know, the slides and recording are now available on our **IRB Brown Bag** webpage. This session highlighted the office for Research Integrity and how their work overlaps with the IRB.

STAFF SPOTLIGHT

Meet Kevin Puyleart!

Hello! I am a Senior IRB Analyst in my seventh year with the Northwestern Institutional Review Board (IRB) Office and have been at Northwestern for over 31 years. I started as a Program Assistant in the Center for Comparative Medicine (CCM) and then worked my way up to Assistant Director in the Office for the Protection of Research Subjects (OPRS). Due to the number of changes in OPRS in which the department was split up to IACUC and IRB, I transferred to a Senior Regulatory Coordinator position in the Clinical Trials Office (CTO) of the Robert H. Lurie Comprehensive Cancer Center (RHLCCC) for over 17 years.

As a Senior Biomedical IRB Analyst my main responsibilities are conducting pre-reviews and processing initial new studies and modification submissions within eIRB+. I am also the Lead Analyst for Panel C, which meets on the second Friday every month. My goal is to ensure consistency in the panel member reviews and decrease processing times of panel determination letters. This position gives me the opportunity to work with the research community and offer guidance obtained in the many years at Northwestern. I hold a Bachelor of Science degree in Psychology from Northwestern University.

Outside of the IRB Office, I enjoy traveling to Mexico to visit family and experience the amazing people, weather and food of Mexico. I am working on my Spanish and hope to some day retire in Mexico.

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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