Northwestern | INSTITUTIONAL REVIEW BOARD

IRB Bulletin: January 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.

FDA Updates Safety Reporting Guidance for Investigational Studies

The U.S. Food and Drug Administration (FDA) has issued two final guidances clarifying safety reporting safety reporting responsibilities for clinical research involving investigational drugs and devices. These updates **do not add new requirements** but emphasize reporting safety information that meaningfully changes participant risk, rather than large volumes of non-actionable adverse event reports.

The new guidances replace prior 2009 and 2012 documents and align with IND and IDE regulations.

Northwestern University investigators should continue to use the IRB Office's **Reportable New Information (RNI)** webpage and **Incident Assessment Tool (HRP-1207)** for guidance on what information must be submitted to the Northwestern IRB.

Key Updates for Investigators

Improved alignment with IND and IDE regulations

- The guidances clearly distinguish investigator responsibilities under Investigational New Drug (IND) and Investigational Device Exemption (IDE) studies

Clarified safety reporting obligations

Investigators remain responsible for promptly reporting safety information that may affect participant safety, including:

- Serious adverse events (SAEs)
- Unanticipated adverse device effects (UADEs)
- Other safety information that that may affect participant safety or study conduct

Focus on meaningful safety information

- Investigators are encouraged to report clinically significant and actionable safety information.

Streamlined reference material

- Content from multiple earlier FDA guidances has been consolidated into clearer, more accessible resources to support compliance.

Bottom Line for the Research Community

These updates reinforce a risk-based, meaningful approach to safety reporting, helping investigators and IRBs focus on information that truly impacts participant safety while reducing unnecessary administrative burden.

Access the FDA Guidance:

- **Investigator Responsibilities—Safety Reporting for Investigational Drugs and Devices**
- **Sponsor Responsibilities—Safety Reporting Requirements and Safety Assessment for IND and Bioavailability/Bioequivalence Studies**

NEW Process for Off-Campus Access to eIRB+

eIRB+ can be accessed off-campus through Northwestern's web VPN. To comply with University security policies, **Multi-Factor Authentication (MFA)** is required. If you have not yet set up MFA, you must do so first (smartphone authentication is recommended). Once MFA is enabled, you may log in through the web VPN, select the "eIRB Plus" tile, and sign in using your NetID and password.

What's changed: Submission of a support form is no longer required to gain off-campus access.

For step-by-step instructions please refer to the **Off-Campus Access (Web VPN) webpage**.

UPDATED DOCUMENTS

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

- Quorum and Expertise (HRP-305)
- Review Materials (HRP-301)
- Non-Significant Risk Device (HRP-418)

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

- Pre-Review (HRP-021)
- Not Otherwise Approvable Research, Not Federally Funded Nor Regulated (HRP-044)
- Not Otherwise Approvable Research, Federally Funded or Regulated (HRP-045)

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

UPCOMING BROWN BAG

Where Human Research Meets Integrity - *What You Need to Know*

Wednesday January 21, 2025 | 12:00 - 1:00 PM

REGISTER HERE

Please join us virtually for our monthly IRB Brown Bag Session led by Michelle Stalilonis, Associate Director of the Northwestern University Office for Research Integrity (ORI).

This session will introduce the office for Reseach Integrity and how their work overlaps with the IRB, and will highlight valuable resources and support available to researchers across the research lifecycle.

By the end of the session, attendees will:

- Be able to define research misconduct and understand its potential consequences.
- Recognize common red flags that may prompt follow-up review by the ORI and IRB.
- Review examples of alleged research misconduct through case-based discussions.
- Know where to find key resources and points of contact for research integrity questions.

Please view the **Events Page** for details and registration information for upcoming **Brown Bag** informational sessions. To access slides and recordings of previous Brown Bags, please visit our **IRB Brown Bag** webpage.

Upcoming IRB Brown Bag ✨🤔💭👤👤👤

Ask the IRB on Wednesday, February 18, 2026

Have IRB questions? Bring them! Experts from Northwestern University IRB Office's Biomedical, Social Behavioral, Compliance, Reliance, and Education teams will be on hand to answer your questions in real time. It's a great chance to connect directly with the IRB and get helpful guidance on processes and policies.

Whether you're navigating submissions, compliance questions, or IRB policies, this session offers real-time insights and direct access to IRB expertise. Don't miss this opportunity to connect with the IRB. We'd love to see you there!

Register and submit your questions to the IRB here!

STAFF ANNOUNCEMENTS

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

Marcella Cooks, MS, CIP, will assume the role of IRB Director, effective December 15, 2025. Marcella has been an esteemed member of the Northwestern University community for over 19 years, holding several human research–focused positions and demonstrating a longstanding commitment to the protection of research participants. Marcella joined the IRB Office in 2006 as a Department Assistant. In 2007, she transitioned to the Northwestern University Clinical and Translational Sciences (NUCATS) Institute as a Project Coordinator. She remained with NUCATS for nine years in roles of increasing responsibility, honing her regulatory knowledge and human research expertise throughout her tenure. Her culminating role with NUCATS was Research Project Manager. In 2016, Marcella returned to the IRB Office as the IRB Education Specialist, where she was integral to the design and implementation of the IRB Office's education and training program. In 2017, her responsibilities expanded when she became the IRB Reliance and Education Lead. In this role, Marcella implemented numerous education-focused initiatives and deployed several reliance-focused operations, including liaising between organizations, supporting more than 1,000 active studies, facilitating the negotiation of over 650 reliance agreements, and developing and implementing the Human Research Protection Program's (HRPP) Single IRB workflow and fee schedule. In 2022, Marcella was selected as the inaugural IRB Reliance Manager, tasked with the design, implementation, and management of a robust IRB Reliance program. In this role, she oversaw legal and institutional requirements related to reliance agreements, served as a primary liaison between organizations and agencies, and applied her leadership and communication skills to support and guide team members as the Reliance Unit grew from 2 to 5 FTEs. Following an extensive national search for a new IRB Director, Marcella was selected based on her depth of experience, comprehensive knowledge of IRB operations, demonstrated leadership, and proven ability to build sustainable programs that support both regulatory compliance and institutional priorities. As a member of the Office of Research leadership team, Marcella will work closely with colleagues across the University to advance the mission of Northwestern University's Human Research Protection Program, strengthen collaborative partnerships, and support a culture of ethical, compliant, and high-quality research. Please join us in congratulating Marcella on this well-deserved appointment. Congratulations, Marcella!

Logan Clary, MS has been promoted to IRB Reliance Analyst Senior effective December 15, 2025. Logan has been a member of the IRB Office since August 2022, where he has played an integral role in supporting the University's reliance activities. In his time at Northwestern, Logan has worked closely with investigators, study teams, and internal and external partners to manage single IRB and reliance determinations, facilitate cede and serve requests, and ensure compliance with institutional policies and federal regulations, including Single IRB requirements. In the Senior role, Logan will continue to support the Northwestern research community by leading and enhancing reliance operations, compiling metrics, maintaining compliance with institutional policies and federal regulations, and serving as a liaison for key internal and external stakeholders. Congratulations, Logan!

Sheila Graham, MPH, CIP has been promoted to the role of Lead Biomedical Analyst effective January 12, 2026. Sheilah joined the IRB Office at Northwestern in October of 2017 as a Senior Analyst. During that time she has worked as the leading analyst for panels Q and D. She's also played a key role in the development of the I-STOP training and onboarding program for IRB Staff as well as the I-POEM workgroup for onboarding board members. Prior to coming to Northwestern, Sheilah worked as an IRB Coordinator at the University of Illinois Chicago from 2004 to 2017 and at Rush University from 2000 to 2004, steadily mastering the regulations, supporting panels, and reviewing all types of IRB submissions. Sheilah has a Master in Public Health (MPH) degree from the University of Illinois Chicago, concentrating on health policy and administration. In the role, Sheilah will continue to support the research community and the IRB office with

her communication and training skills and her wide breadth of knowledge. Congratulations, Sheila!

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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