Northwestern | INSTITUTIONAL REVIEW BOARD

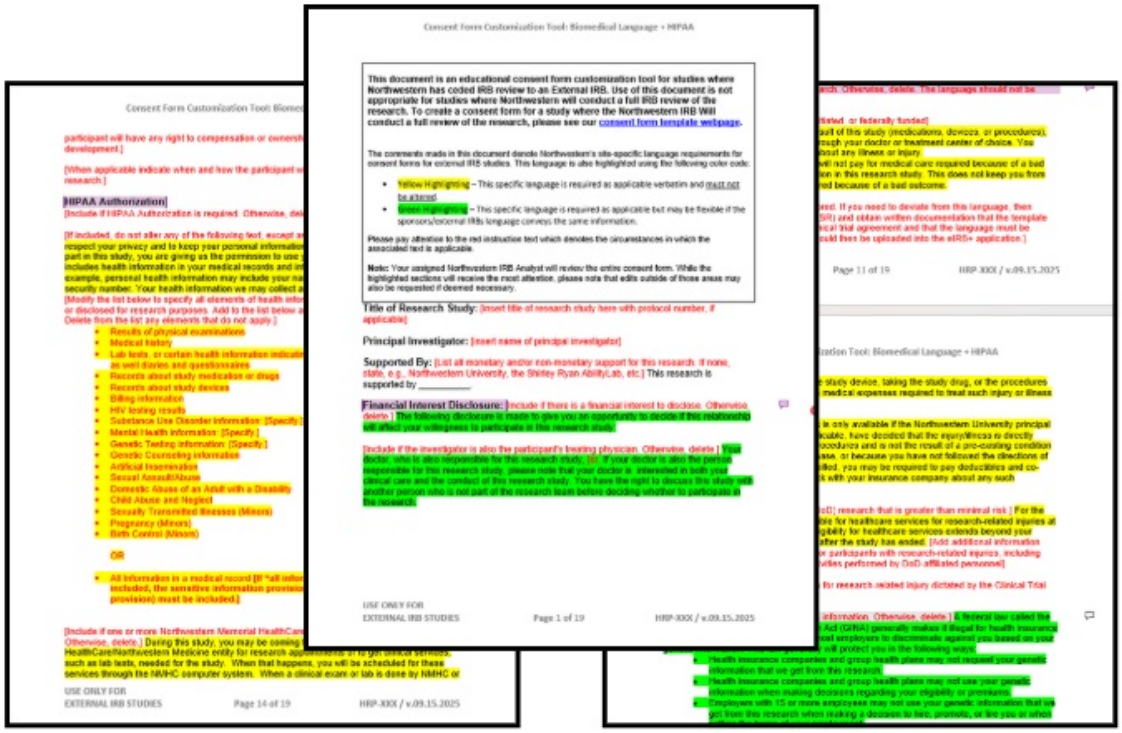
IRB Bulletin: November 2025

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.

Now Introducing: Consent Form Customization Tools for External IRB Studies!

The IRB Reliance team has developed three new tools to support researchers in customizing Northwestern-site specific consent forms for external IRB studies. These educational tools identify the required and flexible site-specific language for Northwestern-specific consent forms and can be found on our Northwestern Relying on an External IRB page under **Consent Form Customization Tools.**



Guidance on Use of Investigational Medical Devices in Human Subjects Research

The IRB Biomedical Team is excited to launch our updated "**Guidance on Use of Investigational Medical Devices in Human Subjects Research" (HRP-1918)**. Key updates include a new section about Software (artificial intelligence and machine learning) as a Medical Device and four new flowcharts to assist study teams in understanding device determinations and applicability of FDA regulations to their devices.

Other updates include improved searchability of the document, additional definitions, new examples of expedited study procedures, and references to IRB Worksheets and Checklists.

Contents

UPCOMING IRB BROWN BAG

Identifying and Managing Conflicts of Interest in Research

Wednesday November 19, 2025 | 12:00 - 1:00 PM

REGISTER HERE

Please join us for our monthly IRB Brown Bag Session, led by Emily Updegraff, PhD, Director of the Conflict of Interest Office at Northwestern University. This session will provide an overview of conflict of interest (COI) in research, from its historical roots to how COI is reviewed and managed at Northwestern. It will also highlight key policies, processes, and resources available to researchers.

By the end of the session, attendees will:

- Gain historical context for the development of COI regulations in research.
- Understand Northwestern's Policy on Conflict of Interest in Research and what it requires from investigators.
- Learn how COI reviews are conducted and how they intersect with IRB review.
- Know where to find institutional resources and points of contact for COI-related questions.

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, *NUCATS Recruitment and Retention Consultation Service: Strategies to Improve Research Participation while Promoting Trust, Equity, and Reducing Fraud,* the presentation slides, recording, and PDF information sheet are now available on our **Brown Bag** webpage. This session highlighted practical strategies to enhance participant recruitment and retention, strengthen data integrity, and reduce fraud in research, while promoting trust and equity across study populations.

UPDATED DOCUMENTS

The following forms are now available on the**Northwestern Relying on an External IRB** Page

- Biomedical Consent Form Customization Tool (HRP-1839)
- Social Behavioral Consent Form Customization Tool + HIPAA (HRP-1840)
- Social Behavioral Consent Form Customization Tool (HRP-1841)

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

- Neonates of Uncertain Viability (HRP-413)

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

STAFF SPOTLIGHT

Meet Meghan!

Hello!! I'm Meghan and have been with the IRB, serving as a Biomedical Analyst for just over 2

years now. In my role, I pre-review submissions, providing approvals for expedited reviews along with taking notes at IRB panel meetings. I also enjoy serving on several inter-office work groups where I get to collaborate with other IRB office staff. My passion for research started when I was an undergraduate, where I served as a student researcher in a biomechanics lab. Holding a role within the IRB office gave me the ability to see research from start to finish. I value safe and ethical research and have enjoyed learning how to best support the research community at Northwestern University.

When not working, I enjoy going to concerts, bopping around the city to find new restaurants, thrifting, and my most recent side quest of making sourdough

IRB Office - Contact Us

IRB Office Unit	Email/Phone	Virtual Office Hours
Biomedical Research/General	**irb@northwestern.edu** 312-503-9338	Monthly - Every 3rd 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**	---
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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