Northwestern | INSTITUTIONAL REVIEW BOARD

IRB Bulletin: October 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.

Evaluating Reports of Data Incidents: *A Streamlined Guide*

The IRB Office has updated our guidance to help researchers evaluate and report data incidents with clarity and confidence. You can access **Evaluating Reports of Data Incidents (HRP-1908)** on the **Human Research Policies & Guidance Page**.

Data Incident: An event that results in unauthorized access, use, or disclosure in violation of applicable data protection policies. This includes incidents that compromise the confidentiality, integrity, or privacy of sensitive information such as Protected Health Information (PHI) or Personally Identifiable Information (PII).

About the Guidance:
The revised document provides a step-by-step framework for responding to data-related events—whether the data involves Northwestern or an external institution. It defines key terms, explains regulatory context, and provides practical instructions so you can make informed decisions when an incident occurs.

What's Inside:
- **Evaluate:** How to determine whether an incident requires reporting
- **Document:** What to record and how to do it properly
- **Report:** Step-by-step instructions depending on the data source and IRB of Record
    - Using the Incident Assessment Tool (HRP-1207)
    - When to submit an RNI in eIRB+
    - How to document CAPA plans
    - When parallel reporting is required to Northwestern and/or external IRBs
- **Contacts:** Who to notify and when

Whether you're dealing with a minor issue or a significant breach, this guide is a valuable tool to help you respond appropriately and maintain compliance.

Keep this resource handy to stay prepared—before, during, and after a data incident.

10 Tips for Submitting to the IRB from the Social Behavioral Team

Submitting your study materials correctly the first time can significantly speed up the IRB review process. The Social-Behavioral Team has compiled a list of key tips to help ensure your submission is complete, consistent, and compliant with IRB requirements.

1. Make sure your **CITI Human Research Protections Training** is current and showing up in eIRB+.
2. **Check your documents for consistency**. Please read and compare all your documents to ensure information is accurate and aligned. We often send back clarifications when documents contain conflicting details.
3. Include all required elements in **recruitment documents**.
4. Any time you are sending back changes, always use **tracked changes in MS Word**.
5. For **modifications**, please accept all previously approved **tracked changes in MS Word** so that the only updates that appear are for the current modification only.
6. Use the **latest template versions** of the **protocol** and consent form documents downloaded from the IRB website. Do not reuse old templates.
7. Complete **all sections in your protocol** or address them with N/A. Do not delete sections from the protocol.
8. When completing your consent form, use the **consent signature block that matches your study procedures**. See the **Biomedical & Social Behavioral Consent Templates page**.
9. **All sections in eIRB+** need to be filled out with the information asked for in the section. Do not write “refer to the recruitment document” etc. for information.
10. During the review process, **avoid adding new procedures or documents** unless requested. Major changes can significantly delay the review process. If additional changes are necessary, communicate them to your IRB analyst and update the modification summary as necessary.

Feedback Requested! Incident Assessment Tool (IAT) Survey

The Northwestern University IRB Office launched the **Incident Assessment Tool (IAT)** in 2022 to help Principal Investigators and study teams document events and determine whether an event must be reported to the IRB via a Reportable New Information (RNI) submission.

Now that the tool has been in use for some time, we would like your feedback on its design, formatting, and content. Your input will help us refine the IAT so it is user-friendly, and aligned with your needs.

- The survey should take approximately 5–10 minutes to complete.
- Your responses are anonymous unless you choose to provide your contact information at the end.

Take the Survey Here

- We appreciate you!

UPCOMING IRB BROWN BAG

NUCATS Recruitment and Retention Consultation Service: Strategies to Improve Research Participation while Promoting Trust, Equity, and Reducing Fraud

Wednesday, October 15, 2025 | 12:00 - 1:00 PM

REGISTER HERE

Please join us for our monthly IRB Brown Bag Session on Wednesday, October 15, led by Andrés Alvarado Avila, MPH, Kathryn Macapagal, PhD, James Foran, and Bryant Norton, of the Impact Institute at Northwestern University.

Learn about the free Northwestern University Clinical Trials (NUCATS) **Recruitment & Retention Consultation** service that will help research teams and human research protections program (HRPP) members and staff:

1. Identify and implement innovative approaches to participant recruitment that enhance sample representativeness
2. Identify and implement strategies to improve retention while ensuring data integrity and participant trust and safety
3. Recognize and mitigate risks of fraud in recruitment and enrollment processes and learn about a multitiered approach to prevent fraud

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, Social Behavioral Research and IRB Review at Northwestern University, the presentation slides are now available on our **Brown Bag** webpage. This session highlighted the unique complexities of social-behavioral research and provided attendees with strategies for strengthening IRB submissions, a better understanding of review expectations, and tips for protecting participants while supporting ethical, compliant research.

UPDATED DOCUMENTS

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

- Supplemental Consent Language (HRP-1722)
  - Added GINA template language
- Parent Consent and Permission (HRP-1728)
- Parent Permission (HRP-1729)

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

- Guidance on Use of Investigational Medical Devices in Human Subjects Research (HRP-1918)

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

- Reportable New Information (HRP-024)
- NIH Genomic Data Sharing (GDS) Institutional Certification (HRP-064)

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

STAFF SPOTLIGHT

Meet Therese Brown!

Hi! I'm Therese and I joined the IRB as a Biomedical Analyst about 6 months ago. My role focuses on pre-reviewing submissions, providing approvals for expedited reviews and taking notes at IRB panel meetings. Prior to joining the IRB, I spent 3 years as a Clinical Research Coordinator at the Lurie Cancer Center here at Northwestern and a year in cardiovascular research. My experiences as a coordinator gave me insight into the challenges that study teams face and I enjoy working with study teams to understand necessary requirements for approvals. I have a BA in Biology and am currently pursuing an MS in Law, as I am very interested in areas in which science and law interact.

Outside of work, I enjoy reading, cooking, going to the gym, attending arts events and spending time with my husband and our two cats (Cleo and DJ).

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	---
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