Northwestern | INSTITUTIONAL REVIEW BOARD

IRB Bulletin: April 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 page**. Please keep reading for this month's updates.

Reminder: NHSR vs. Human Subjects Research

The Northwestern University IRB Office reminds the research community that activities determined to be Not Human Subjects Research (NHSR) should not later be described in publications or presentations as human subjects research conducted with Northwestern University IRB approval.

To reinforce this, the following documents have been updated:

Protocol Templates Page

- Human Research Determination Form (HRP-503)
- Updates include:
  - Clarification regarding appropriate representation of activities determined to be NHSR in publications and presentations
  - Reinforced guidance that if data gathered from activities is intended to be "generalizable," then the project may be considered research.
  - Strengthened guidance around assessing whether the activity involves obtaining information about living individuals through intervention or interaction with those individuals.
  - Added reference to NMHC Privacy & Confidentiality Policy within the decedent HIPAA section

Policies & Guidance Page

- Quality Improvement and Program Evaluation Projects (HRP-1906)
- Updates include:
  - Clarification regarding appropriate representation of activities determined to be NHSR in publications and presentations.
  - Reinforced guidance that if data gathered from activities is intended to be "generalizable," then the project may be considered research.

CAPA CORNER

Building a Strong Corrective and Preventive Action (CAPA) Plan

A thoughtful, thorough, and well-documented **corrective and preventive action (CAPA) plan** is required when deviations, non-compliance, or unexpected events require

corrective and preventive action to protect: participant rights and welfare, data integrity, and/or regulatory compliance.

The CAPA plan should be maintained in the study regulatory record and be available for IRB or sponsor review.

If the event is reportable per the **Incident Assessment Tool**, the CAPA plan should be submitted with the **Reportable New Information (RNI).**

The Principal Investigator's (PI) role and oversight of the study and the CAPA plan should be detailed.

A strong CAPA includes:

- **Root Cause Analysis**
  - Use a structured approach to identify the underlying cause — not just the surface error.
  - Focus on systems and processes, not individuals.
- **Corrective Actions** taken to resolve the current issue.
  - What is being done?
  - Who (role) is taking part?
  - When will it be completed?
- **Preventive Actions** implemented to prevent recurrence.
  - Examples:
    - Creating or revising a standardized operating procedure (SOP)
    - Training (dates, topics covered, and attendance should be described)
    - Implementing checklists
    - Updating delegation logs
- **SMART Documentation**
  - CAPA plans must be:

Specific, **M**easurable, **A**chievable, **R**ealistic, **T**ime-bound

The IRB Office has updated our **Corrective and Preventive Action (CAPA) Plan** webpage where you can find additional guidance, examples, and new resources!

New Resources: Documenting and Assessing Corrective and Preventive Action (CAPA) Plans

The IRB Office is pleased to share new resources designed to support the research community in creating, documenting, and evaluating Corrective and Preventive Action (CAPA) plans.

These tools provide a clear, structured approach to identifying root causes, implementing corrective and preventive actions, and assessing effectiveness over time. By supporting thorough planning, documentation, and follow-up, these resources help protect research participants, support protocol compliance, and promote safe and responsible conduct of research.

New Resources:

- **CAPA Plan Form (HRP-1209)**
  - Helps investigators outline and document the root cause analysis, CAPA plan, and Principal Investigator (PI) oversight in a clear, organized format.
- **CAPA Plan Self-Assessment Form (HRP-1210)**
  - Supports investigators with documenting and reporting on CAPA plan implementation. The IRB Office recommends completing a CAPA plan self-assessment approximately 3–6 months after CAPA plan implementation to evaluate adherence and effectiveness.

Together, these resources, along with the updated **CAPA Plan** webpage, are intended to promote consistency, support research teams, and strengthen the overall quality of CAPA plans, evaluation, and follow-up.

These resources were developed in response to feedback from research teams and trends identified in IRB review and routine post-approval monitoring, to help investigators plan, document, and follow up on CAPAs more robustly and effectively.

For questions or additional guidance on these new tools, please contact the IRB Office Compliance Team at **irbcompliance@northwestern.edu**.

UPCOMING BROWN BAG

Incorporating AI into your Research Responsibility

Wednesday, April 15, 2026 | 12:00 - 1:00 PM

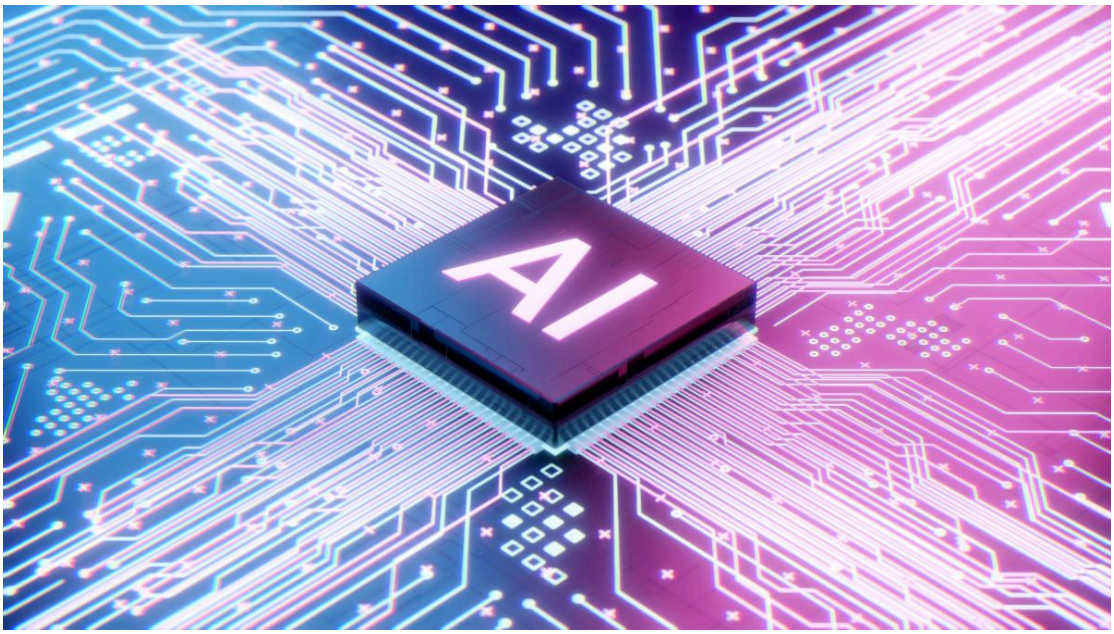
REGISTER HERE

Please join us virtually for our monthly IRB Brown Bag session, featuring Christina Maimone, Associate Director, Research Data Services, and Daniel Schneider, Director, Research Analytics. During the session, we will explore how to integrate artificial intelligence into research in a responsible and secure way. Attendees will gain practical guidance on mitigating risks to human research data, while also learning how AI tools can enhance research workflows.

By the end of the session, attendees will:

- Understand the risks AI poses for human research data and learn best practices to keep research data secure when using Artificial Intelligence (AI).
- Identify opportunities to use AI tools to support research workflows.
- Know where to find key resources and points of contact for further guidance.

We'd love to see you there!



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, Keeping Up with Compliance: Post-Approval Resources & Quality Assurance, the slides and recording are now available on our **IRB Brown Bag** page. This session highlighted tools available to researchers

designed to support internal Quality Assurance (QA) reviews and help research teams keep studies compliant with IRB and regulatory requirements.

UPDATED DOCUMENTS

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

- Compassionate Use Request Form for the Investigational Devices Form (HRP-1201)

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

- Determining and Processing When Continuing Review is Required (HRP-033)

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

- Engagement Determination (HRP-311)

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

STAFF ANNOUNCEMENTS

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

Meghan Haser, **MS** has been promoted to Senior Biomedical Analyst. Meghan has been with the IRB Office since October of 2023. She quickly learned our HRPP and grew to review more complicated submissions. She's been a gracious and conscientious leader and contributor to the eIRB workgroup. Meghan has also served as document champion and has contributed to the IRB bulletin and website updates. She's demonstrated wonderful collegiality by working with others in the office with their submissions. Meghan has a background in scientific research and has impressive working knowledge of the regulations. Congratulations Meghan!

Yasmeen Khan, MSL, CHRC has been promoted to Senior IRB Compliance Analyst. Yasmeen joined the IRB Office in July of 2022 as an IRB Compliance Analyst. Since then, she has expertly managed the Compliance Team email inbox, established Study Status Assessments for efficient post-approval monitoring of studies without an expiration date, and helped to create and manage the monthly IRB Office Bulletin, among numerous other initiatives she has championed to enhance compliance policies and processes. She has demonstrated exceptional initiative, a collaborative mindset, passion and talent for communication, and an investment in improving human research compliance at Northwestern. In her senior role, Yasmeen will continue to support the Northwestern research community and protect research participants through compliance oversight, education, and outreach. Congratulations Yasmeen!

Yeli Solano, BA has been promoted to Biomedical IRB Analyst. Yeli has been with the IRB Office since November of 2024. She has shown diligence and resourcefulness in assisting the research community with difficult questions sent through the IRB inbox and supporting Panel Q. Congratulations Yeli!

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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