Northwestern | INSTITUTIONAL REVIEW BOARD

IRB Bulletin: March 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.

Mental Health and Developmental Disabilities Confidentiality Act (MHDDCA) Updates

Effective January 2025, the Illinois Mental Health and Developmental Disabilities Confidentiality Act (MHDDCA) was amended to no longer require the following when obtaining informed consent for human research: a calendar expiration date, a statement regarding the right to inspect records, and a witness signature.

The IRB Office updated the Biomedical Consent Document (HRP-592) and the Social Behavioral Consent Document with HIPAA authorization (HRP-1721) to align with the amendments. Please use the new templates for all new study submissions. Existing approved informed consent documents using the previous templates remain compliant and do not require changes unless the study team chooses to update them. However, informed consent documents following the previous template must continue to adhere to the previous MHDDCA provisions. For a full list of updated IRB documents reflecting this change, see the Updated Documents section below.

Make an Impact: Join the Northwestern IRB as a Non-Scientist Reviewer!

The Northwestern IRB is seeking non-scientists from our community to join our review panels! Non-scientists bring unique perspectives shaped by their diverse life experiences and backgrounds outside the scientific field. These members - who may come from fields such as law, ethics, education, business, or the general public - play a vital role in evaluating research from a broader perspective. Their input ensures that research is ethically conducted and upholds the rights and welfare of all participants.

Interested in becoming a panel member? **Visit the IRB Member Panel** page or register for this month's Brown Bag to learn more about the role and how to apply. Your voice is essential in shaping the future of research at Northwestern!

UPCOMING IRB BROWN BAG

IRB Panel Operations and Membership

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

Please join us for our monthly IRB Brown Bag Session, where the IRB Office is excited to present a session led by Lucas Sikorski and Heather Yates, who will provide a comprehensive description of IRB panel operations and IRB panel membership.

During this presentation, attendees will learn about the lifecycle of an IRB submission that requires panel review, with an in-depth look into each step of the process from pre-review to approval. We will also describe the responsibilities of being an IRB panel member, with one of our own IRB panel members joining the presentation to describe their experience as a panel member and participate in a Q&A about IRB processes from the perspective of an IRB member. Please join us in furthering the research community's knowledge about IRB panel operations and the vital role of IRB panel members.

REGISTER HERE

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, Navigating Continuing Reviews - Submission Guidelines & Key Considerations, the presentation slides are now available on our **IRB Brown Bag** webpage. This session's content includes how to submit a continuing review and best practices for a smooth submission.

UPDATED DOCUMENTS

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

- Local Protocol Addendum (HRP-508)
  - Reliance related edits to the final section, "Multi-Site or Collaborative Research," clarifying language added to other sections

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

- Establishing Authorization Agreements (HRP-801)
- Post-Approval Monitoring - Recruitment Materials and Process (HRP-097)

MHDDCA Updated Documents:

- Biomedical Consent (HRP-592)
  - Updated HIPAA language per MHDDCA, Removal of references to Stored Value Card language (See **Office of the Controller Program Updates**)
- Social Behavioral Consent with HIPAA Authorization (HRP-1721)
  - Updated HIPAA language per MHDDCA
- Data and Specimen Analysis Protocol (HRP-1704)
  - Removed language related to MHDDCA and statement regarding the uploading of Data Use Agreements/Material Transfer Agreements (DUA/MTA)
- Northwestern University Local Context Information (HRP-1822)
- Informed Consent for Research (HRP-090)
- Legally Authorized Representatives, Children, and Guardians (HRP-013)
- HIPAA Authorization (HRP-330)

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

STAFF ANNOUNCEMENTS

Tadé Ogungbadero joined the biomedical team of the Northwestern IRB Office on March 10, 2025, in the role of IRB Analyst. Tadé has been involved in research for the past 8 years, including 2.5 years of experience as a Regulatory Compliance Officer for the Ohio State University cancer clinical trials office. In her new role, Tadé will be a valuable resource for the Northwestern research community. Congratulations Tadé!

STAFF SPOTLIGHT

Meet Sierra Willis!

Hello! I am one of the new Lead IRB Analysts within Northwestern's expanding Biomedical IRB team. I recently joined the office in December. Prior to joining Northwestern, I spent the last 10 years in smaller human research protection programs as an IRB analyst, IRB specialist, and research conflict of interest program manager. While working in smaller programs has been great in developing operational and regulatory knowledge of HRPPs and IRBs, opportunities to grow in leadership were limited.

Here at Northwestern, I oversee and foster the growth of associate analysts and IRB analysts within the biomedical team, act as a key resource for regulatory and procedural guidance in the daily operations of the biomedical team, ensure consistency in IRB panel reviews, as well as conduct study reviews within the biomedical research portfolio. I hold a Master's and Bachelor of Science in Exercise Science with specializations in Physiology and Sports Medicine, and I have also extensively studied Rehabilitation Science.

I live and work remotely from a small mountain town located high in the Rockies of Colorado. Outside of the IRB, I enjoy trail running, skiing, camping, and making pottery with my family.

Please use the Northwestern University IRB Office Website
as your primary source of information and resources on human research protections