Northwestern | INSTITUTIONAL REVIEW BOARD

IRB Bulletin: June 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.

New CITI Course Now Available: Essentials of Software as a Medical Device & Clinical Decision Support Systems

We're pleased to share that a new training course is now available to the Northwestern and affiliate research community, with valid Northwestern NetID, through the CITI (Collaborative Institutional Training Initiative) Program: ***Essentials of Software as a Medical Device (SaMD) & Clinical Decision Support Systems (CDSS).***

About the Course
This course helps learners navigate the regulatory landscape related to Software as a Medical Device (SaMD) and Clinical Decision Support Systems (CDSS) in clinical research.

Topics include:

- How to identify SaMD and CDSS
- Regulatory obligations for investigators developing SaMD or CDSS
- Considerations for artificial intelligence/machine learning (AI/ML)-enabled and combination medical devices
- Key factors in design, development, and deployment
- Investigator obligations when designing or using CDSS/SaMD

Who Should Take This Course?
This course is recommended (not required) for:

- Investigators developing or using digital health technologies in research
- Clinician-researchers involved in software-enabled interventions
- Research teams conducting studies that include medical software or AI/ML tools
- Individuals working on device trials involving decision support or software components

How to Add the Course:

1. Log in to your CITI Program account using "Log in Through My Organization" and select Northwestern University.
2. Under Learner Tools, choose “Add a Course.”
3. Scroll down to Question 11, and select: *Essentials of Software as a Medical Device & Clinical Decision Support Systems*

Beyond IRB Approval: Updated Guidance on Additional Reviews

In addition to IRB approval, some studies may require additional approvals or notifications before research can begin. The **Additional Reviews** page outlines common examples, such as radiation safety, imaging services, and conflict of interest. This list is not exhaustive, and requirements may vary based on the specifics of your study.

What’s New:

- Revised content for the Research Imaging Collaboration Office (RICO) section, now moved to the top of the page for easier visibility. Key steps for studies using Radiology services include:
  - Researchers must contact RICO and complete their dedicated study intake and review process before requesting the Radiation Dosimetry Form or submitting an eIRB+ application.
  - This step helps ensure appropriate coordination and feasibility review for imaging-related services.
  - A direct link to the RICO website and contact email is included to support this process.
- New contact information for the Nuclear Medicine Research Review Committee.
- Reorganized layout so the RICO, Radiation Safety Officer (RSO), and Nuclear Medicine sections appear next to each other, making imaging-related reviews easier to locate.

We encourage researchers to review the updated content and incorporate these steps into your research submissions as applicable. This page is a helpful reference when planning your research submissions—bookmark it for easy access!

UPCOMING IRB BROWN BAG

Paper Trails and Digital Details: Records Retention Made Simple

Wednesday June 18, 2025 | 12:00 - 1:00 PM

REGISTER HERE

Please join us for our monthly IRB Brown Bag Session led by Kim Rowan, Senior Education and Communication Analyst from the IRB office**.**

Whether you're navigating the early stages of a study or preparing to close one out, understanding what research records to keep, how to store them, and for how long can feel overwhelming. This session will break it all down: covering what makes up a research record, when to start thinking about retention, when the official retention timeline begins, and managing research records in electronic and hard copy formats.

Attendees will walk away with helpful tools, resources, and 🏆 best practices for records retention to make the process easier to navigate, more organized, and aligned with institutional and regulatory requirements.

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, Resources for Research Faculty transition, the presentation slides are now available on our **IRB Brown Bag** webpage. This session highlighted a collaborative effort led by Human Research Protection Program (HRPP) Offices across Northwestern University to improve support for research faculty transitions and the development of two new MyHR Learn courses: Researcher Onboarding and Researcher Offboarding.

UPDATED DOCUMENTS

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

- Engagement Determination (HRP-311)
- Post Approval Monitoring: Drug or Device Clinical Trial (HRP-427)
- Post Approval Monitoring: Participant File (HRP-428)

- Post Approval Monitoring: Humanitarian Use Device (HRP-1409)

The following was updated and is now available on the **SMART IRB & IREx** Page:

- SMART IRB Letter of Acknowledgment (LOA) (HPR-1806)
  - The SMART IRB LOA template, a reliance agreement template, was updated to reflect that Northwestern is now signed on to SMART IRB version 3. Please use this template for any new studies requiring reliance agreements (re-execution of previous agreements is not required).

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

STAFF SPOTLIGHT

Meet Katie Wright!

Hello! I'm Katie Wright (they/them) and I am an IRB Analyst for the social and behavioral team. I've been with the Northwestern IRB for three years and really love the work we do here. I particularly enjoy working collaboratively with study teams to help both meet their goals while ensuring research participant safety. Students are my fave but faculty members, I love y'all too.

Prior to working at Northwestern, I worked as a research coordinator at Howard Brown Health. My focus was in social and behavioral research with sexual and gender minority populations. I have a continued fondness for research in this area and with these populations.

When I'm not reading your protocols, you might find me reading in the sunshine with iced coffee, quilting or knitting on my couch, listening to podcasts on the Fullerton bus, or engaging in any sort of horror-themed activity - TV shows/movies, books, and videogame related. Shoot me an email with movie and book recs…or questions about your study.

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