

IRB Bulletin: April 2024

Announcements

As a part of the Northwestern University IRB Office's initiative to share timely resources and information with the research community, the IRB Bulletin is released at the beginning of each month and contains relevant updates from the IRB Office. The IRB Bulletin is also posted monthly on the [IRB News & Announcements webpage](#). Please keep reading for this month's updates.

5 Tips for submitting updated Protocols and Investigator Brochures (IB)

1. Provide a redline or tracked changes version, a clean version if it's a sponsor-sent PDF copy, a summary of changes document, and the most current package insert.
2. In the modification description, outline the major changes **and** identify where the updates to study documents originate.
3. Read the eIRB+ checkboxes carefully to ensure you provide the most up-to-date and accurate information.
4. Make the appropriate updates to all study documents (such as the Informed Consent Form)
5. If there is updated risk or other information that might affect participants' willingness to continue in the study, provide the plan to notify or re-consent participants per [Guidance on Re-Consent/Notification of Study Participants \(HRP-1097\)](#), as applicable.

Enhancing the quality of IRB submissions is paramount to maintaining the integrity and effectiveness of the review process. The outlined strategies aim to reduce common problems, assist investigators in navigating the IRB process, and ultimately contribute to advancing ethical and responsible research practices.

Reliance Ready: Northwestern Local Context Information

For studies where Northwestern cedes IRB review, the external IRB may request the study team to fill out a form that gathers important information about the Northwestern site. These forms often have different names (e.g., Local Context Form, Relying Site Information Sheet, Relying Site Survey, Relying Site Application, etc.). The external IRB will use the information gathered in this form to ensure their review meets our local requirements.

The "Northwestern Local Context Information" document may help you complete these forms. Please visit our [IRB Information](#) page for a link to this document and other IRB information. Local Context Forms (i.e., Relying Site Information Sheet, Relying Site Survey, Relying Site Application) should be submitted with your external IRB eIRB+ submission for review before sending them to the external IRB. If your Local Context Form requires a signature, the IRB Office will work to obtain the relevant signature at that time.

FOSTERING ACCESSABILITY AND INCLUSIVITY IN RESEARCH (FAIR) NEWS

Be the Source for Better Health: Improving Health Outcomes Through Our Cultures, Communities, and Connections

April is National Minority Health Month! This is a time to increase awareness about the health disparities facing racial and ethnic minorities and American Indian/Alaska Native (AI/AN) populations and to encourage action to end these inequities.

This is also a time to discuss the importance of working to reduce health disparities and improve the health of racial and ethnic minority communities. As an example, Asian Americans and Pacific Islanders experience higher rates of gastric cancer; and Hispanic and American Indian/Alaska Natives experience higher rates of cervical cancer, yet in clinical trial participant populations these communities are underrepresented. ([National Cancer Institute Cancer Disparities](#)).

Annually, the U.S. Department of Health and Human Services (HHS) [Office of Minority Health](#) (OMH) chooses a theme and 2024's theme is **Be the Source for Better Health: Improving Health Outcomes Through Our Cultures, Communities, and Connections**. For additional information see the page [National Minority Health Month 2024](#), including useful such as the [National Minority Health Month 2024 Reading List](#).

Community-engaged research is increasingly recognized as a vital strategy towards reducing and eliminating health disparities. As detailed on [FAIR's Community-Engaged Research Page](#), Northwestern University Feinberg School of Medicine's [Center for Community Health \(CCH\)](#) has resources to help research teams develop and implement projects involving patient and community stakeholders, including a free consultation to involve patients and stakeholders in research.

UPDATED DOCUMENTS

The following compliance document was updated and is now available on the [Checklist and Worksheets](#) page:

- Waiver or Alteration of Consent Process HRP-410

Updated for consistency with the Common Rule and DoD regulation 10 USC 980

UPCOMING IRB BROWN BAG



Interconnectedness of Animal and Human Research

Please join Northwestern University IRB Analyst, Mila DeMarte and Northwestern University IACUC Analyst Lead, Jeremiah Dunlap as they present the April 2024 Brown Bag on the interconnectedness of animal and human subjects' research. This presentation will cover a background of the regulatory and historical framework that has led to Institutional Review Boards (IRBs) and Institutional Animal Care and Use Committees (IACUCs) and will dive more deeply into an example highlighting the animal research foundations leading to one of the major medical advancements in human medicine. We look forward to shedding some light on how our Northwestern University IRB and IACUC's teams work to promote ethical research at Northwestern and its affiliates

Please view the [Events page](#) for details and registration information for upcoming [Brown Bag](#) informational sessions

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

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