

IRB Bulletin: July 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 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.

2024 AAHRPP Reaccreditation Site Visit: Information & Expectations

The IRB Office is preparing for the Association for the Accreditation of Human Research Protection Program's [AAHRPP Reaccreditation](#) site visit from Thursday, August 22, 2024, through Friday, August 23, 2024.

The AAHRPP site visitors will conduct virtual interviews with investigators, research study team members, IRB members, IRB Office staff, key research offices, and institutional and organizational officials regarding the Northwestern Human Research Protection Program. The interviews will be individual or group sessions and are expected to last 20-45 minutes.

To ensure everyone is ready for the visit, the IRB Office provides information and resources on our [AAHRPP Accreditation Page](#) and will also hold informational sessions for the research community before the site visit.

The IRB Office staff are here to support you! If AAHRPP selects you to be interviewed, IRB Office staff will e-mail you for scheduling and support. Kindly respond to these requests at your earliest opportunity to facilitate reaccreditation.

During the AAHRPP site visit, the research community may experience longer-than-typical wait times for a response, but rest assured, all staff members are monitoring voice and e-mail and will respond to any urgent items as soon as possible.

Key Facts

- The **Association for the Accreditation of Human Research Protection Programs, Inc.** is an independent, non-profit accrediting body that uses a voluntary, peer-driven, educational model to ensure that the HRPP meets rigorous standards for quality and protection.
- AAHRPP evaluates Northwestern's **Human Research Protection Program (HRPP)**, including our policies and procedures. As part of AAHRPP Reaccreditation, the site visit is a mechanism AAHRPP uses to re-evaluate the implementation of our policies and procedures.
- The Northwestern University HRPP received Initial Accreditation on December 19, 2016, and achieved reaccreditation on December 15, 2019.

Stay tuned for future announcements with links to resources and educational opportunities!

eIRB Legacy Retiring Soon

The IRB Office will retire and remove its first electronic submission system, [eIRB Legacy](#), from service in August 2024. If investigators require any documents in eIRB Legacy for their files, including those for studies that transitioned to eIRB+, download the study materials immediately and save them in a secure location. Guidance on accessing the system or downloading materials can be found on the [eIRB Legacy Retirement webpage](#). If you have any questions about the retirement of eIRB Legacy, contact the IRB Office at irb@northwestern.edu.

IRB Staff Picks

We're excited to showcase insightful articles bookmarked by our IRB staff. These pieces provide valuable perspectives on the latest in research compliance, ethical considerations, and best practices in the field.



**Upcoming OHRP Livestream:
Commemorating the 50th
Anniversary of the National
Research Act**

INFORMED
CONSENT



**Informed Consent in Cluster
Randomised Trials: a Guide
for the Perplexed**
Picked by Edeth Engel,

*Picked by Monica Kane,
IRB Reliance Analyst Lead*

July 12, 2024, marks the 50th anniversary of the enactment of the National Research Act. The National Research Act was a response to public outcry regarding the actions of the federal government withholding syphilis treatment from hundreds of Black men in rural Alabama for the so-called purpose of “research”. This OHRP commemorative event will reflect on what happened following the passage of the National Research Act, showcase the diverse role research participants play in contemporary research, and consider what future scientific advances may mean for research participants and public trust in research. Watch the livestream at [hhs.gov](https://www.hhs.gov).

Lead IRB Analyst

Navigating informed consent in Cluster Randomized Trials (CRTs) of individual-level interventions is a complex topic that baffles both researchers and IRBs. Generalizability can't justify waiving consent—respecting autonomy is key. Cost should prompt alternatives, not waivers. Even standard care interventions may pose risks, demanding informed consent for participant clarity. Ethical frameworks guide these decisions, emphasizing early consent and adapting to local regulations for sound research practice. Read more about it in the article by clicking [here](#).

UPDATED DOCUMENTS

The following SOP was updated and is now available on the [SOPs](#) page:

- Written Documentation of Consent and Assent (HRP-091)

The following general document was updated and is now available on the [About](#) IRB Page:

- Northwestern University Local Context Information (HRP-1822)

UPCOMING IRB BROWN BAG

University Compliance as a Partner

July 17, 2024 | 12:00 – 1:00
PM

[REGISTER HERE](#)

Join us as Lucas Christain, Associate Director of University Compliance, outlines the intentionality behind recent changes in the Northwestern University Compliance Office and how those changes position this small team to partner with the many compliance owners at our institution.



Please visit our [Events page](#) for details and registration information on this and upcoming [Brown Bag](#) sessions.

STAFF EVENT SPOTLIGHT

IRB Staff represents at AAHRPP Annual Conference

Representatives from the Northwestern University IRB Office attended the Association for the Accreditation of Human Research Protection Programs' (AAHRPP) Annual Conference in San Diego, which focused on Science and Standards.

Not content with honing their skills at the accreditation-focused conference, members of the IRB Office also gave presentations on contemporary topics germane to human research protections.

Piper Hawkins-Green, Associate Director of IRB Compliance and Reliance, presented *A Journey to Corrective Action Plan (CAPA) Verification*, which instructed attendees on the tools and mechanisms they could implement at their institutions to evaluate and ensure the completion of CAPA plans.

Nathalia Henry-Whitely, Executive Director, IRB Office, delivered a plenary talk, *Where We Are and Where We Are Going*, in which she shared her vision for the future of Human Research Protections Programs (HRPPs), focusing

on the challenges and complexities of the issues we face today as an HRPP Community. Nathalia followed her presentation with a break-out session where she led robust discussions and shared her visionary approach to culture change and leadership.

The IRB Office team left sunny San Diego full of enthusiasm for Northwestern's HRPP's future and dedicated to returning and sharing lessons learned and innovative ideas.



Piper Hawkins-Green (right) presenting A Journey to Corrective Action Plan (CAPA) Verification at the AAHRPP Annual Conference

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

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