Northwestern | INSTITUTIONAL REVIEW BOARD

IRB Bulletin: August 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.

Northwestern University Human Research Protection Program Prepares for Important AAHRPP Reaccreditation

The IRB Office is preparing for the Association for the Accreditation of Human Research Protection Program (AAHRPP) Reaccreditation site visit on Thursday, August 22, and Friday, August 23, 2024.

Please visit our **AAHRPP Reaccreditation webpage** for information and resources, including **AAHRPP Interview Guides**, for this important process, which strengthens protections for participants in Northwestern-led human research while elevating the caliber of our institution and research enterprise.

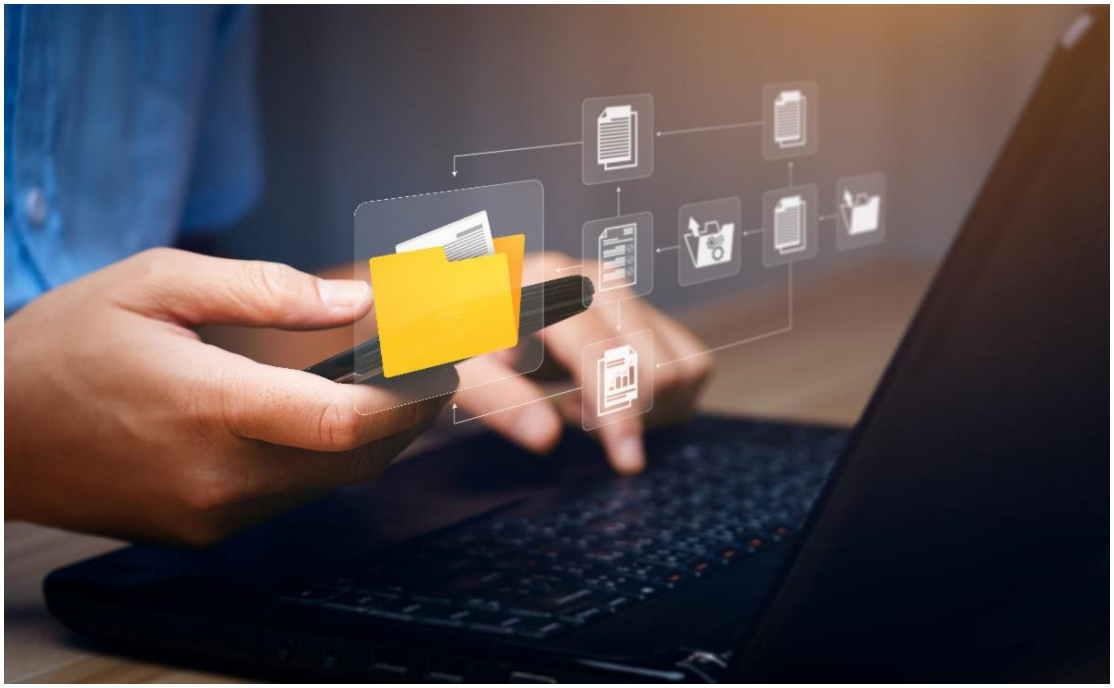
Please contact the IRB Office at **IRBCompliance@northwestern.edu** with any questions about AAHRPP Accreditation. If you have been selected as an AAHRPP interviewee and have any urgent concerns on the day of your meeting, please call the IRB Office at 312-503-9338.

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

eIRB Legacy Entering Retirement

The IRB Office will retire its first electronic submission system, **eIRB Legacy**, from service on August 30, 2024. You can find guidance on accessing the system and downloading materials on the **eIRB Legacy Retirement webpage**. If you have any questions about the retirement of eIRB Legacy, please contact the IRB Office at **irb@northwestern.edu**.

As a reminder, the Principal Investigator's records are considered the official research file. According to **Document Management and Record Retention of Institutional Review Board Records (HRP-072),** the IRB Office maintains copies of documents sent to the investigator (e.g., eIRB+; legacy eIRB), but these do not constitute the PI's official record. The PI is responsible for maintaining adequate documentation of research procedures/processes. In the event of a request to review a research record, such as an audit or routine monitoring, all information must be readily available to be reviewed by the appropriate entity or individual in a responsible manner. Review the IRB's **Research Document Retention Requirements for Principal Investigators** for further guidance**.**



UPDATED DOCUMENTS

The following were updated and are now available on the **SOPs Page**:

- Incoming Items (HRP-020)
- Directed Review (For Cause) Audits (HRP-025)
- Compassionate Use (Device Only), and IRB Waiver for Individual Patient Expanded Access (Drug only) (HRP-027)

- Conflicting Interests of IRB Members (HRP-050)
- Post Review (HRP-052)

The following were updated and are now available on the **Checklists & Worksheets Page**:

- Devices (HRP-307)
- Additional Federal Agency Criteria (HRP-318)

UPCOMING IRB BROWN BAG

Human Research in the Global Sphere: Export Controls & Research Security Including Foreign Influence

September 18, 2024 | 12:00 – 1:00 PM

REGISTER HERE

This IRB Brown Bag session will cover export controls, international travel and shipping, and malign foreign influence. It will use case studies and scenarios to provide a framework to: (1) understand how key federal regulations intersect with campus and global activities, (2) identify export control and international compliance red flags, and (3) when to contact the Export Controls & International Compliance team. We hope you join us!

Please visit our Events page for details and registration information on this and upcoming Brown Bag sessions.

TIPS & TRICKS

Draft FDA Guidance on Facilitating Understanding in Informed Consent

In March 2024, the FDA released Draft Guidance, **Key Information and Facilitating Understanding in Informed Consent Guidance for Sponsors, Investigators, and Institutional Review Boards**. The document includes recommendations about informed consent in FDA-regulated and HHS-supported or conducted research and provides considerations on how to present key information to prospective participants.

The key information section in informed consent helps to facilitate discussions between a potential participant and a researcher about whether the participant should join the study. This section is also a useful ongoing resource for enrolled participants and should be viewed as a tool by those drafting particularly complex consent documents.

Below is a summary of tips and tricks from this draft guidance:

- Improve accessibility by tailoring the key information section to study design, participant population, condition, and other relevant factors.
- Use innovative methods and technology to help prospective participants understand why they may or may not want to join the research; consider using alternative media (e.g., pictures, video, electronic tablets) to improve clarity and increase prospective participants' understanding.
- Consider consulting with patient advocacy groups, prospective participants, or those unfamiliar with the research about their views on developing key information and understandability; this may be particularly helpful for forms translated into additional languages.
- Ask questions from potential participants' perspectives when preparing the key information section (e.g., *What aspects of research participation or this particular study are likely to be unfamiliar to a prospective participant, to diverge from their expectations, or to require special attention?)*
- Make the consent form document easier to read by formatting text into two columns, using bullet points, and including empty space around distinct sections.
- Use a combination of text and pictures or diagrams; organize information with the most important points first and break complex information into understandable groups.
- NOTE: When using the short consent form with oral presentation, the key information must be presented at the beginning of the consent process, before other information.

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

Northwestern | RESEARCH

Northwestern University IRB Office | 750 N. Lake Shore Drive Rubloff Hall, 7th Floor | Chicago, IL 60611 US