IRB Review

Monthly updates from the Human Research Protections Office (HRPO) Issue 26/ October 2025

Understanding Stipulations

When investigators and research teams receive IRB feedback requesting revisions to their research protocols, it is natural to feel a moment of frustration or concern. However, these stipulations serve a vital purpose in the research ecosystem, and understanding the "why" behind them can help improve the review process.

Protecting all Stakeholders: IRB analysts and committee members issue stipulations primarily to ensure that research meets ethical standards and regulatory requirements. This is about safeguarding research participants, investigators, research teams, Carilion Clinic, and the integrity of scientific research itself.

Common Categories of Stipulations

Understanding the types of revisions frequently requested can help research teams anticipate and address potential issues proactively:

- **Clarity and completeness issues** arise when protocols lack sufficient detail for IRB analysts to assess risks and benefits thoroughly.
- **Risk-benefit imbalances** occur when protocols don't adequately justify risks to participants or fail to minimize risks through study design modifications.
- **Equity and inclusion concerns** ensure that participant selection is fair and that vulnerable participants receive appropriate additional protections.
- **Data protection gaps** have become increasingly important as technology evolves and data breaches are more common nationwide.

HRPO & IRB Support

IRB analysts bring expertise in research ethics, regulatory requirements, and risk assessment that complements investigators' and research teams' scientific expertise. Stipulations represent careful consideration of how to make good research even better while safeguarding participants, who make research possible. Our analysts are available for appointments to walk you through any questions. You may also access our **user guide** and **training video** to help you address stipulations in PRISM.

We want your feedback!

To help us better serve you, I am seeking your input on our HRPO/IRB training programs, educational materials, and support services. What's working well? What could be improved? Your feedback will directly shape our future educational offerings and resources. Please take a moment to scan the QR code below to share your thoughts with Hilary Hedrick, Human Subjects Research Ethics and Education Manager. We appreciate your time and valuable insights!

Introducing the National Advisory Committee on Human Research Protections

The research community has a new resource—the National Advisory Committee on Human Research Protections (NACHRP). This independent organization was formed by former members of Secretary's Advisory Committee on Human Research Protections (SACHRP) and Office for Human Research Protections (OHRP) who are now volunteering to support the research community following SACHRP's termination in March 2025.

NACHRP is not affiliated with the U.S. Federal Government but aims to provide ethical and practical guidance for human research protections. The committee welcomes new perspectives on ethical issues in human subjects research and plans to expand membership based on community interest.

For IRB professionals, research administrators, and investigators navigating complex ethical questions, NACHRP offers access to experienced professionals who understand the practice challenges of implementing research protections. Learn more at https://nachrp.org/.

One of the inaugural members of NACHRP is Benjamin Silverman, MD, who was a featured speaker at our January webinar. Dr. Silverman presented, "How Does the Use of AI in Research Test the Notions of Personal Privacy and Identifiability of Data?" To access the recording and his presentation slides, click here.

Federal Agency Communications

NIH Operations during Federal Funding Lapse

The National Institute of Health (NIH) issued guidance for the federal funding lapse beginning October 1, 2025. For more information, visit NIH guidance document.

Helpful Document for Research Teams

Anyone involved in human subjects research must complete **CITI training** *before* submitting their project to the IRB. Click and save this user guide about "How to Enroll in CITI Training."

Resources Center

PRISM Class

Researchers can learn the basics of navigating PRISM and beginning a study submission application. The first 30 minutes will be led by Hilary to take you through an overview of PRISM. The remaining 30 minutes will be dedicated to questions and addressing specific needs from attendees. You must register to attend.

Register here for **Wednesday, October 22, 2025 from 8-9 AM.** Click here to register for **Thursday, November 13, 2025 from 12-1 PM.** You will need to use your Carilion Active Directory credentials to register for class.

HRPO Personalized Services

Contact our office at irb@carilionclinic.org for the following:

- New to IRB study submission
- Consultations for studies
- Specific study questions
- Schedule IRB training
- Guided help for PRISM
- Assistance with IRB regulatory requirements
- General questions

We tailor our support to each researcher's schedule and expertise level, ensuring they receive exactly the assistance they need.