CARILION CLINIC IRB Review

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Monthly updates from the Human Research Protections Office

Supportive Services: Research Education Session (RES)

Looking to strengthen your research practices? Consider participating in a Research Education Session (RES). These educational sessions are designed to support investigators and research teams across various study types, with particular emphasis on studies that may benefit from additional guidance and oversight:

- Investigator-initiated studies
- Research conducted by new investigators and research staff who may benefit from additional support
- Studies involving devices or drugs
- Studies that include a high degree of risk factors or include vulnerable populations

During a RES, Human Research Protections Office (HRPO) staff will work collaboratively with your team to review study files, discuss best practices for informed consent procedures, and provide guidance on maintaining research records in an audit-ready state. Contact Hilary Hedrick at hhhedrick@carilionclinic.org to schedule your Research Education Session.

What does "IRB Approval" *mean*?

IRB APPROVAL MEANS	
IRB Approval=Determination sent through outcome letter after thorough review that research meets **ethical standards** and **regulatory requirements**. Must be obtained **BEFORE** beginning research activities.	
Ethical Standards Met	**Professional & Regulatory Requirements**
✓ **Scientific merit**: Sound study design ✓ **Risk minimization:** Risks reduced as much as possible ✓ **Risk-benefit ratio:** Benefits justify risks ✓ **Participant safety:** Monitoring and privacy protections ✓ **Informed consent:** Clear information and proper documentation ✓ **Fair selection:** Equitable recruitment ✓ **Vulnerable populations:** Additional protections	✓ **Professional integrity:** Demonstrates ethical standards ✓ **Research credibility:** Enhances validity of findings ✓ **Clear research plan:** Provides structured path for research team ✓ **Publication requirement:** Needed for peer-reviewed journals ✓ **Regulations compliance:** Meets federal regulations and institutional requirements

Federal Agency Communications

FDA-NIH Release Clinical Research Terminology Glossary

The FDA and NIH have released the Modernizing Research and Evidence (MoRE) Consensus Definitions, a collaborative glossary featuring 40 clinical research terms focused on innovative study designs and real-world data applications for FDA-regulated medical products. This resource includes 20 additional contextual terms and aims to standardize terminology across the clinical research community.

The collaborative glossary serves as a reference tool and does not establish agency policy or regulatory requirements. The complete resource can be accessed **here**.

NIH GRANTS & FUNDING

NIH Public Access Policy

Effective July 1, 2025, the Public Access Policy requires Author Accepted Manuscripts to be submitted to PubMed Central immediately upon journal acceptance without embargo upon the official date of publication. This policy change aims to provide equitable accessibility to NIH-funded research findings for patients, healthcare providers, researchers, and public. To read more details and view full policy click here.

CoC

Notice about Certificate of Confidentiality

July 2025 Update: "The NIH CoC system is still undergoing renewal of its PRA approval and remains temporarily unavailable. [NIH] expect the system will be available by mid-September 2025. If necessary, NIH will provide another update at that time." Source
Reminder: NIH is currently undergoing a renewal of the Paperwork Reduction Act (PRA) approval for the NIH Certificate of Confidentiality (CoC) system. NIH will not be accepting requests to the CoC system or Institutional Official verifications for non-NIH funded research during this time. **Note that the CoCs for NIH-funded studies (i.e., deemed issued CoCs) and previously granted CoCs are not affected.**

Resources Center

August PRISM Class

Researchers can learn the basics of navigating PRIS3M 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 **Friday, August 22, 2025 from 12-1 PM.** You will need to use your Carilion Active Directory credentials to register for class.

Human Research Protections Office Personalized Services

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

- New to IRB study submission
- Consultations for studies
- Specific study questions
- In-service/training request
- 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.