Carilion Clinic IRB Review

Monthly updates from the Human Research Protections Office (HRPO) Issue 25/ September 2025

Advancing Research Excellence through Enhanced IRB Collaboration

Our Institutional Review Board has recently undertaken comprehensive reviews of several cutting-edge research proposals that represent the forefront of scientific innovation. These studies have encompassed groundbreaking device technologies and advanced genetic research methodologies.

Recognizing the complexity in these research areas, our IRB enhanced collaborative communication strategies with both internal institutional partners and external research collaborators. This proactive approach has fostered more effective dialogue between the research team and IRB throughout the approval process.

The improved communication channels facilitated clearer research objectives and more comprehensive risk-benefit assessments. We encourage all researchers to leverage these enhanced communication pathways and continue engaging with the IRB team to support the advancement of research within our institution.

Post-Approval Monitoring Questionnaire Now Available

The Human Research Protections Office (HRPO) is pleased to announce a new tool designed to support ongoing research compliance and participant safety. The Post-Approval Monitoring Questionnaire is now available to help research teams proactively identify and address potential compliance issues in their ongoing studies.

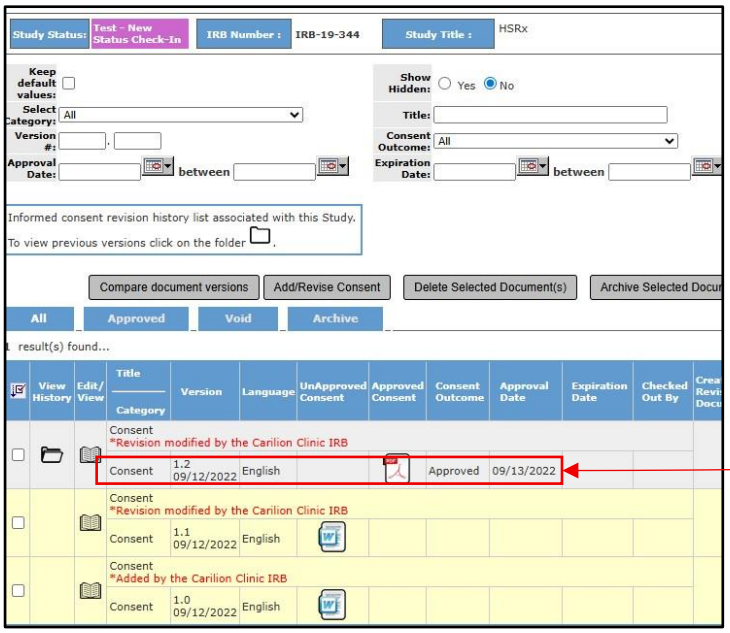
What is the Post-Approval Monitoring Questionnaire? This new tool serves as a systematic approach to monitor research activities and regulatory responsibilities after study approval. The questionnaire helps researchers assess their current practices and identify areas that may require attention or improvement.

Key Features:

- Proactive identification of potential compliance issues
- Opportunity for researchers to document planned corrective actions
- Follow-up guidance provided by HRPO staff
- Confidential process with information restricted to HRPO support staff
- Editable submissions for updates after initial completion

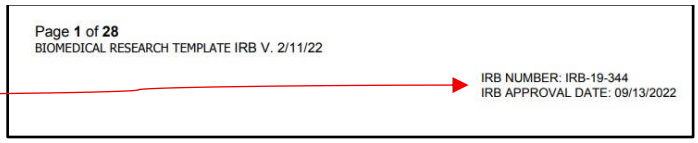
The questionnaire represents a collaborative approach between HRPO and investigators to maintain the highest standards of research integrity and participant protection.

For questions about this new service or to access the questionnaire, email IRB@carilionclinic.org.



Reminder: Most Recent Informed Consent Form

Please ensure you are using the most recent approved consent form, which can be found in PRISM under the "Informed Consent" document section in your Study Dashboard. The currently approved version date should match the IRB approval date in the stamp on the Informed Consent Form.



Federal Agency Communications

NIH Certificate of Confidentiality (CoC) Update

NIH Online Certificate of Confidentiality (CoC) system is available. Visit the NIH website to read and review "CoCs for Research Not Funded by NIH" that was updated on August 22, 2025.

Researcher Documents Organization Checklist

The checklist will guide research teams through creating and maintaining appropriate study documentation for all studies, regardless of the level of IRB review or funding source. Click here to download the Researcher Documents Organization Checklist.

Resources Center

October 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.** 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.