

Monthly Updates from the Human Research Protections Office

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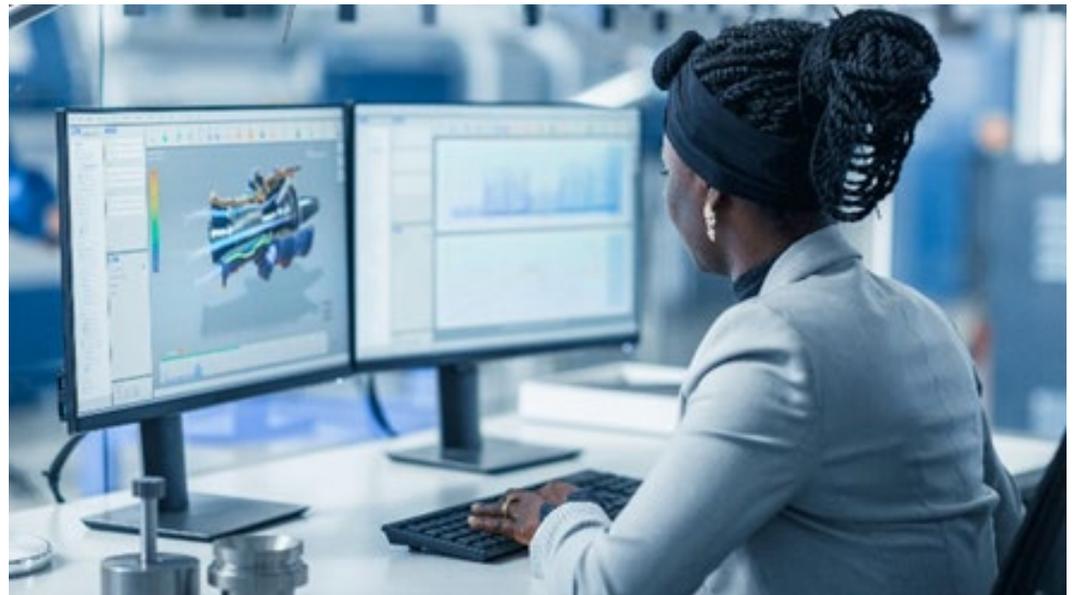
PRISM demonstration, training, and Q&A

NIH Updates 'Clinical Trial' Definition

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HRPO Customized Services

The HRPO offers a wide menu of customized services to support investigators and research teams. Contact IRB@carilionclinic.org to request support and consultation.



Post-Approval Monitoring Program

The Human Research Protections Office (HRPO) **Post-Approval Monitoring Program (PAM)** was developed to enhance the quality of research and maximize participant protections for human subjects research conducted at Carilion Clinic. The program provides education and oversight of human subjects research approved by or ceded to an external IRB by the Carilion Clinic IRB.

The post-approval monitoring program is an essential function of the HRPO, providing investigators and study teams support to ensure that studies are conducted in accordance with federal regulations, state law, and institutional policies. This is accomplished through study documentation reviews and tailored educational offerings. Post-approval monitoring is performed as a routine service, targeted service, or by request.

Demonstrating our continued commitment to research quality, the HRPO is pleased to announce the addition of a new position to support the post-approval monitoring program. **Megan Stuart, DHSc, MPH, will be joining the team at the end of February as the IRB Regulatory & Compliance Senior Specialist**, leading the post-approval monitoring program. Megan has an extensive background in human subjects research, program management and continuous quality improvement.



PRISM Class - March 2026

Researchers can learn the basics of navigating PRISM and beginning a study submission application. The first 30 minutes will 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, March 11, 2026 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 study submission
- Consultations for studies/study-specific guidance
- Schedule IRB training/assistance with regulatory requirements
- Guided help for PRISM
- General questions

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

NIH Updates Definition of 'Clinical Trial'

In an announcement released on January 26th, 2026, the NIH updated the scientific community to state that Basic Experimental Studies in Humans (BESH) are no longer subject to the requirements under the NIH definition of 'clinical trial'.

This notice serves as an update to the 2014 NIH definition of clinical trial, a *research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.* **In an effort to reduce administrative burden, NIH will no longer classify Basic Experimental Studies in Humans as clinical trials for submissions with due dates on or after May 25th, 2026.** NIH has narrowed the scope of clinical trials to studies with *"health-related biomedical or behavioral outcome(s) as having the potential for direct advancement of health. Although BESH research, which produces fundamental information about biology or behavior, might eventually inform advances in health, it is not conducted with the express intent of changing clinical practice or health but rather aims to understand fundamental aspects of phenomena without immediate clinical applications. Therefore, BESH research is no longer considered to meet the NIH definition of a clinical trial"*.

BESH applications submitted with due dates on or after May 25th, 2026 will not have to follow the requirements for clinical trials, including registration and reporting to ClinicalTrials.gov. BESH is still subject to all other applicable clinical research laws and regulations including but not limited to human subjects protections and NIH Data Management and Sharing Policy.

[NOT-OD-26-032: Basic Experimental Studies in Humans \(BESH\) Will No Longer Be Considered Clinical Trials by the NIH](#)