CARILION CLINIC IRB Review

Monthly updates from the Human Research Protections Office (HRPO) Issue 27/ November 2025

What's that reference at the bottom of your IRB approval letter?

Have you ever noticed **HRP-800 Investigator Obligations** at the bottom of your IRB approval letter? This document outlines your responsibilities as a Principal Investigator throughout your research project. Here are some points we want to highlight:

Before Starting

Obtain IRB approval. Please ensure all ancillary approvals are in place.

During your Study

- Conduct research exactly as approved; modifications require IRB approval
- Use only IRB-stamped consent form
- Do not enroll vulnerable populations (children, pregnant women, prisoners, adults unable to consent, non-English speakers) without explicit approval from IRB
- Submit continuing reviews on time (if approval expires, stop all research immediately)
- Report problems immediately
- Disclose conflicts of interest for all team members and update within 30 days of changes

Ending your Study

Submit study closure when enrollment is concluded, all interventions completed, and identifiable data collection/analysis finished.

Record retention: Keep records for at least 3 years (6 years for PHI, longer for FDA-regulated studies)

Take a moment to review HRP-800 when you see it in your approval letter. You can also read the full HRP-800 document on the IRB website.

Artificial Intelligence (AI) added to HRP-800

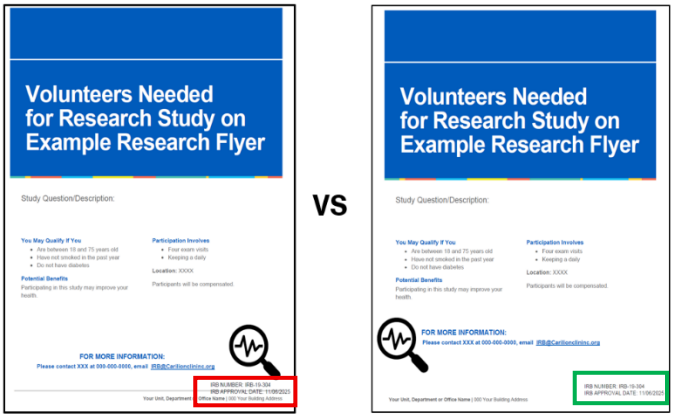
NEW language in HRP-800 regarding Artificial Intelligence (AI):

Investigators and research team members must use Artificial Intelligence (AI) tools responsibly and in accordance with Carilion Clinic policies. Specifically:

- AI may be used to support efficiency (e.g., drafting documents, summarizing information, or assisting with analysis), but cannot replace investigator judgment, oversight, or compliance obligations.
- Do not input identifiable private information, protected health information (PHI), or confidential data into AI tools unless expressed approved and securely configured by Carilion Clinic. Use of AI tools to process identifiable/confidential data for research is permitted only through approved workflows using Carilion managed devices and must be reviewed and approved by the IRB, Compliance, and Privacy in coordination with HART. Public or open-access AI tools must never be used for identifiable private information, protected health information, or business confidential data.
- All outputs generated by AI must be critically reviewed and verified for accuracy, completeness, and appropriateness before use in research activities.
- AI must not be used in ways that could introduce bias, compromise subject safety, or conflict with ethical principles and regulatory requirements.

Quick Tip: Flyer Design Considerations

When you are creating recruitment flyers or other materials for your study, keep in mind that the IRB approval stamp goes in the bottom right corner. We recommend leaving the bottom right corner clear so you do not cover up important details. This can also ensure your flyer looks professional and eye-catching while meeting all the requirements. Also important to note, you cannot distribute any materials until they have the official IRB approval stamp on it. So, plan your design around this requirement from day one!



2026 IRB Meeting Schedule

The 2026 IRB Meeting schedule through June 25, 2026, is now available on our website. Please note these dates as you plan your research activities for the coming months. Access the schedule by clicking **here**.

Human Subjects Research Ethics and Education Manager

Deliver education and training to support the ongoing needs of the research community, including physicians, leaders, IRB members, clinical research team members, VTCSOM students, and other employees. For full job description and to apply, click here.

Resources Center

PRISM Class

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, December 17, 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.