Human Research Protections Office (HRPO): Guidance for New Investigators

I am an investigator, where do I start?
Resources for investigators, such as education requirements, user guides, and information about IRB process and procedures can be on the HRPO & IRB website. For additional assistance, you can email irb@carilionclinic.org.

Am I required to have any training in research before starting my research project?
Yes. Individuals involved in the conduct of research must complete CITI training before their research will be approved by the IRB. The training requirements can be found on the Carilion Clinic IRB webpage by choosing "What are the required trainings for Carilion Clinic researchers?" button under the "Getting Started" section on the homepage. Updated CITI training is required every three years.

How do I submit a study to the Carilion IRB?
You will submit the Carilion IRB Research Application via the PRIS3M submission system. The Human Research Protections Office will then determine what type of review is required. All application types should be submitted through PRIS3M, including research submissions, Quality Assurance/Quality Improvement projects, case reports, and determination of human subjects research applications. Click the PRIS3M submission system to access it.

The first time you log onto PRIS3M you will use your Carilion Clinic, Active Directory, username, and password. This will alert us to create an account for you. When the account has been created you will be able to begin the application process. A helpful video and user guides for PRIS3M can be found here.

Before submitting to the IRB, you must first obtain an approval letter from either Research & Development (R&D) or the Department of Medicine (DoM). These departments are separate from the HRPO.

- For questions about the R&D eApplication, contact: research@carilionclinic.org
- For questions about the DoM eApplication, contact: DoMResearch@carilionclinic.org

For statistical support, you can contact the Health Analytics Research Team (HART) at HART@carilionclinic.org. They offer options for data storage through secure platforms such as Carilion share drives, REDCap, and SPARC. More information can be found on HART's website.

For Grant/Funding Information, please get in touch with research@carilionclinic.org. Their team is available to provide guidance and support throughout the grant application and management process.

What happens after my application has been submitted?
The IRB will determine the level of review for your project. More information about categories of review can be found at this link.

It is our intention to conduct preliminary reviews in a timely manner. For research that does not require full board review, submissions are typically reviewed between 10 and 15 business days. The submission may require additional information or clarification (stipulations). When stipulations are returned to the study team, the review timeline becomes dependent on the amount of time it takes for the study team to address the stipulations and return the application to the IRB. Upon return, the 10 to15 day business days review window opens again. There are times when we handle an increase in submissions and this timeline may be extended.

For full board review, please see the IRB submission schedule. This schedule provides the meeting dates, the deadline for preliminary review of new applications, and the final deadline for all application and applicable document revisions. IRB approval is dependent on the submission being satisfactory and complete with consistent information throughout the research documents.

What happens after my research application has been reviewed?

After review, one of the following actions will be taken:

- You will receive a written approval to begin your research. Please read all IRB communications carefully.
- The IRB may request stipulations. Once the stipulations have been fully addressed and verified by the IRB, your project will be approved, and you will receive an approval letter.
- The IRB, in a full board review, determines that substantive changes must be made to the submission before approval may be granted. In this case, the IRB will defer action. Once IRB concerns have been addressed, the full board will again review the research.
- The IRB, in a full board review, disapproves the project. Disapproval determines that the research cannot be conducted at Carilion or by employees or agents of Carilion. The research cannot be performed with the involvement or use of Carilion facilities or equipment. Carilion patients cannot participate in the research.