

Reliance Agreement Overview

Carilion Clinic IRB Reliance Agreements (Single IRB Review)

This overview is specific to research involving a Reliance Agreement/Single IRB process for multi-site research. Carilion Clinic frequently collaborates with external investigators and institutions. In an effort to reduce duplicate submission and oversight by multiple IRBs for the same project, Carilion Clinic IRB offers reliance opportunities.

To establish a reliance arrangement, the two IRBs must enter into a reliance agreement to document the arrangement for the Reviewing IRB (IRB of Record) and the Relying IRB.

Identifying the IRB of record starts with Carilion's specific engagement in research. When Carilion Clinic patients/data, Carilion staff (includes but is not limited to clinical providers, residents, and fellows), or facilities are involved then Carilion Clinic IRB must be involved in the IRB review process. Carilion Clinic IRB has local oversight authority.

Important factors when determining the IRB of Record for institutions engaged in multi-site research include the funding source, expertise required, participant population, risk level of the research, Conflict of Interest (COI), and logistical responsibilities.

Please refer to the following items when considering multi-site research:

- Please contact Carilion Clinic IRB at irb@carilionclinic.org during the early stages of planning.
- NIH funded under NIH sIRB policy OR federally funded under common rule (effective Jan. 20, 2020) require single IRB review. The lead PI/site/sponsor will be responsible for identifying the sIRB. This may involve consultation with other participating sites at the time of the grant submission.
- Carilion Clinic has a master IRB reliance agreement in place with VT IRB, VCOM IRB, Radford IRB, SMART IRB, and NCI CIRB.
- Use of a commercial IRB may be an option if approved and if funder agrees to be responsible for the fees. Carilion Clinic has master IRB reliance agreements with Advarra IRB and WCG IRB.
- Collaboration with an external individual (including a student) who is engaged in research due to the person's role/responsibilities will require an agreement to be put in place with Carilion IRB.
- Carilion Clinic Ancillary Department reviews are still necessary, as applicable.
- Carilion Clinic IRB does not execute IRB reliance agreements for exempt research studies unless submitted by a site that has a Master IRB reliance with Carilion.
- Decisions to rely on other IRBs are made on a case-by-case basis.
- A Request to Rely application must be submitted in PRISM, which is the Carilion IRB electronic submission system. (https://carilionclinic.imedris.net/). A Request to Rely submission includes the application, protocol, consent & associated consent materials as applicable, recruitment materials, R&D approval letter, documentation of IRB approval external site, and any other materials at the request of the IRB.