Carilion Clinic Institutional Review Board (IRB) Reliance Agreements

Overview

An IRB reliance agreement is a formalized agreement that allows an institution engaged in non-exempt human research to entrust IRB review and approval to an external IRB. This agreement and process is also referred to as an IRB Authorization Agreement (IAA), single IRB review, collaborative research agreement, or ceding review in scenarios where research is conducted at two (or more) institutions and one is designated to serve as the reviewing IRB (IRB of Record) while the other serves as the relying IRB. Agreements are generally used to cover human subjects research under an organization's Federalwide Assurance (FWA). Funded and unfunded multi-site studies may enter into reliance agreements.

It is strongly recommended that researchers consult with the Carilion IRB early in the planning stage when they are considering requesting that a reliance agreement be established, and prior to a formal IRB submission. Please be aware that each institution has specific requirements that must be met, and this process can take a notable amount of time.

Several factors must be considered to assess whether a reliance agreement will be established on a case-by-case basis. Examples include: study funding, risks, procedures, population, location of research, personnel, institutional policies, IRB expertise.

NIH Single IRB Policy: On June 21, 2016, the National Institutes of Health (NIH) issued a policy on the use of a single Institutional Review Board (sIRB) for multi-site research to establish the expectation that a single IRB (sIRB) of record will be used in the ethical review of non-exempt human subjects research protocols funded by the NIH that are carried out at more than one site in the United States. The goal of this policy is to enhance and streamline the IRB review process in the context of multi-site research so that research can proceed as effectively and expeditiously as possible.

IRB Reliance Agreement Types

Participating research sites must enter into a reliance agreement to document the arrangements between the institutions. The most common type of reliance agreement is a study-specific reliance.

SMART IRB (Streamlined, Multisite, Accelerated Resources for Trials) Reliance Platform -

- Carilion IRB prefers to use the SMART IRB platform and agreement as the basis of reliance for all studies **where we rely on an external IRB or serve as the reviewing IRB.** This method is used for a **study-specific** reliance.

- In cases where an institution does not meet the eligibility criteria or prefers not to use the SMART IRB platform, Carilion IRB may use an IRB Authorization Agreement to establish a reliance relationship with an external institution.

Master Agreements (or "Memorandum of Understanding", MOU) exist between institutions which include established broad reliance arrangements for **multiple studies**. Study-specific reliance agreement processes do not need to be followed.

Carilion IRB has Master Agreements with the following IRBs:

- Advarra IRB (reviewing commercial IRB for multi-site, industry-sponsored research studies)
- WCG IRB (reviewing commercial IRB for multi-site, industry-sponsored research studies)
- NCI Central IRB (reviewing IRB for cooperative group oncology pediatric and adult research studies)
- Virginia Tech (VT) IRB (relying and reviewing)
- Radford University IRB (relying and reviewing)
- Edward Via College of Osteopathic Medicine (VCOM) (relying and reviewing)

Please see attachment titled, External IRB Reporting Requirements, for additional requirements.

Individual Investigator Agreements (IIA) are executed when an individual is engaged in human subjects research and is not affiliated with an organization that can provide IRB oversight. Carilion IRB can provide oversight of the conduct of the individual by executing an Individual Investigator Agreement. The study-specific IIA must be completed and returned to the Carilion IRB before the individual can conduct research.

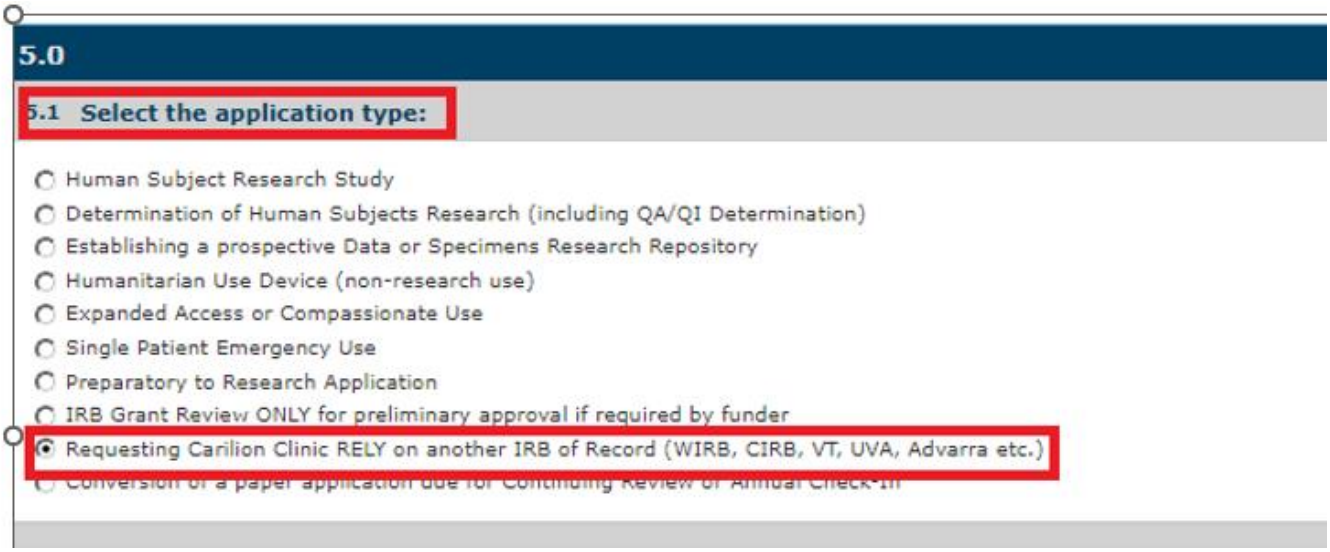
IRB Reliance Agreement Process

Request Carilion IRB to Rely on an External IRB:

Once researchers have consulted with Carilion IRB and it has been determined that Carilion is willing to rely on an external IRB, the Carilion researchers must:

STEP 1

Please submit a Request to Rely application in PRIS3M (aka PRISM or IMEDRIS) formally requesting the reliance. (https://carilionclinic.imedris.net).



The submission will be reviewed for compliance with institutional polices, and federal and state regulatory requirements.

Required documents to be submitted in PRIS3M:

- Request to Rely Application; Data management plan is included
- Completed External IRB Application
- Protocol, Consent, Carilion QA/QI Consent addendum (if industry-sponsored), R&D approval letter, all applicable research and documents
- If study-specific reliance: finalized reliance agreement documents and external IRB approval letter

Carilion IRB must complete the following tasks:

- Consent- ensure appropriate injury language and LAR signature boxes included
- Act as Privacy Board to ensure HIPAA requirements met (separate HIPAA Auth required if the Consent does not meet the requirements)

- Verify the Principal Investigator (PI) is qualified and has appropriate privileges to conduct the research; Department Chair approval
- Verify the PI and all research personnel have completed human subjects protection training on CITI (citiprogram.org).
- Verify COI review has been completed & COI management plan is addressed
- PIs CV should be emailed to irb@carilionclinic.org

STEP 2
SMART IRB (Streamlined, Multisite, Accelerated Resources for Trials) Reliance Platform

- Carilion IRB prefers to use the SMART IRB platform and agreement as the basis of reliance for all studies **where we rely on an external IRB.** This method is used for a study-specific reliance.
- In cases where an institution does not meet the eligibility criteria or prefers not to use the SMART IRB platform, Carilion IRB may use an IRB Authorization Agreement to establish a reliance relationship with an external institution.
- **If the collaborator has an established Master Agreement with Carilion, this step does not need to be followed.**

Carilion IRB will provide an approval letter to the PI to document the finalized reliance agreement. The PI should provide the Carilion IRB approval letter, reliance agreement, and research documents to the external IRB, as applicable.

Request Carilion to IRB Serve as the Reviewing IRB:

STEP 1

The full IRB Application should be completed and submitted in the Carilion IRB electronic submission system PRIS3M. https://carilionclinic.imedris.net. Detailed information about the external collaborators must be described in the Collaboration Section within the IRB Application. Carilion IRB will communicate with the external site for additional site-specific requirements and collaborating personnel approvals. If the involvement of the external collaborators is limited to only receiving de-identified data, then additional requirements may not be applicable.

STEP 2
SMART IRB (Streamlined, Multisite, Accelerated Resources for Trials) Reliance Platform

- Carilion IRB prefers to use the SMART IRB platform and agreement as the basis of reliance for all studies **where Carilion serves as the reviewing IRB.** This method is used for a study-specific reliance. If

the collaborator has already entered into a Master Agreement with Carilion, this process does not need to be followed.

- In cases where an institution does not meet the eligibility criteria or prefers not to use the SMART IRB platform, Carilion IRB may use an IRB Authorization Agreement to establish a reliance relationship with an external institution.
- **If the collaborator has an established Master Agreement with Carilion, this step does not need to be followed.**

Carilion IRB will provide an approval letter to the PI to document the finalized reliance agreement. The PI should provide the Carilion IRB approval letter, reliance agreement, and research documents to the external IRB, as applicable.

PI Responsibilities After Approval to Rely on External IRB

When a study is approved by an external IRB, researchers are responsible for following all of the requirements of the reviewing IRB.

Additionally, if relying on an external IRB, Carilion IRB will continue to have local oversight authority and responsibilities as outlined in the approval letter and reliance agreement.

Carilion IRB submission requirements:

- Local site personnel changes. New research personnel also need to be cleared by the Carilion Compliance Department for financial disclosures. Associated documents that will be revised due to the personnel changes do not need to be submitted to Carilion IRB. If the PI is changed, please upload an acknowledgement document (letter or email) from the PI indicating that he/she accepts the responsibilities as PI, as well as the Dept Chair approval. (Please use PRIS3M Change/Update Form)
- Local site reportable events which can include local protocol deviations, local serious adverse events, local serious or continuing non-compliance (Please use PRIS3M Promptly Reportable Information Form)
- Local site audit reports and monitoring reports (Please use PRIS3M Promptly Reportable Information Form)
- Please consult with staff member if a partial HIPAA waiver for a recruitment activity at the local site has not been granted (see Carilion approval letter for HIPAA waiver reference). Please consult with a staff member if a recruitment method is changing significantly from what was originally indicated. (e.g., external patients approached, etc) Further guidance will be provided.
- Please conclude the study in PRIS3M when all local research activities are completed, including identifiable data analysis. (Please use PRIS3M Conclusion Form)

Every institution is responsible for research conducted by its own personnel, regardless of where the research occurs. Carilion IRB personnel may not conduct human subjects research until approval has been obtained**.**

See Attachments for Additional Guidance:
-Smart IRB Guidance
-External IRB Reporting Requirements (WCG, Advarra, NCI CIRB, Virginia Tech IRB, Radford University IRB, Edward Via College of Osteopathic Medicine (VCOM)
-Decision Matrix for IRB Reliance

Contact Information:
For questions, please email irb@carilionclinic.org