CARILION CLINIC INSTITUTIONAL REVIEW BOARD
Standard Operating Guidelines

Title: 3.4: Reviews Requiring Special Consideration: RECIPROCAL IRB REVIEW (RELIANCE AGREEMENTS)	
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Primary Sponsor: Human Research Protections Office	**Approved By:** Director of the Human Research Protections Office

Objective:

To describe the processes that are used when more than one Institutional Review Board (IRB) is involved in the review of a research protocol that involves Carilion facilities, patients or employees who conduct research.

General Description:

In some cases research protocols are developed that may require the review of the Carilion IRB as well as the IRB of another institution. In all of these instances, a written memorandum of understanding executed between the Carilion IRB and the IRB of the outside institution will give clarity to the IRB oversight process.

Procedure:

Carilion IRB Standard Operating Procedures allow for reciprocal review and approval arrangements with another IRB in which one IRB relies on the review of another IRB. This relieves an investigator of obtaining the independent approval of two IRBs. Reciprocal review and approval can be implemented through a written Memorandum of Understanding (MOU) between the Carilion IRB and the IRB of another facility. An MOU also can be executed to provide for joint IRB review of a research protocol. The purpose of the MOU is to establish a written understanding that defines the responsibilities of each IRB.

There are four scenarios in which the Carilion IRB and another IRB could be involved in the review of research. Below is a description of those four scenarios and guidance on the type of MOU that should be executed. In general, the Carilion IRB prefers to execute a Reciprocal IRB Review MOU whenever the research involves enrollment of subjects at a Carilion facility or site.

1) A Carilion investigator seeks to conduct research at a non-Carilion facility or site that has an IRB. The Carilion IRB will defer review of the research to the IRB of the outside facility under a Reciprocal IRB Review MOU.
2) An investigator from an outside institution with an IRB seeks to conduct research at Carilion. The Carilion IRB will execute a Reciprocal IRB Review MOU in which the IRB of the outside institution defers review of the research to the Carilion IRB. If the IRB of the outside institution declines to execute a Reciprocal IRB Review MOU, then a Joint or Split IRB Review MOU must be executed.
3) A Carilion investigator and an investigator from an external institution with an IRB jointly seek to conduct research at both of their sites or at a site that does not have an IRB. The Carilion IRB will execute a Reciprocal, Joint or Split IRB Review MOU with the IRB of the external institution.

4) A Carilion investigator seeks to conduct research at a Carilion facility or site as part of a requirement for a degree program of an educational institution that has its own IRB. The Carilion IRB may review the study or may execute an agreement with the IRB of the educational institution.

When a protocol involving one of the four above-mentioned scenarios is brought to the attention of the Carilion IRB, the Director of the Human Research Protections Office, or the Carilion IRB Regulatory Affairs Administrator will take the appropriate steps to execute reciprocal review with the outside IRB or institution. Any of these Carilion IRB officials should contact a representative with the outside IRB and inform the representative about the reciprocal review requirements in this guideline. Appropriate reciprocal review arrangements must be in place before a research study can be conducted.

Please note that Carilion IRB is a member of the SMART IRB platform. Please also note that a reliance agreement will not be executed for studies meeting the Exempt research criteria unless there are special circumstances. (i.e. A Master IRB Reliance Agreement for the review of multiple studies has already been established with the external institution.)

Reference: IRB Reliance Agreement Guidance Documents