

CARILION CLINIC INSTITUTIONAL REVIEW BOARD

Standard Operating Guidelines

Title: 1.3: General Administration: THE INSTITUTIONAL REVIEW BOARD	
Original Date: January 2006	Date of Last Revision: 01-08, 04-08, 4-14, 8-23, 1-24
Primary Sponsor: Human Research Protections Office	Approved By: Director of the Human Research Protections Office

Objective:

To provide information on the main components of the Carilion Clinic Institutional Review Board (IRB).

General Description:

The Carilion Clinic IRB must review and approve any human subject research activity that is conducted involving Carilion patients, personnel, or facilities.

Carilion Clinic maintains an active Federalwide Assurance (FWA) with the Department of Health and Human Services (FWA00000392). Carilion Clinic extends the Federal Policy for the Protection of Human Subjects (The Common Rule) and the Belmont Principles to all human subjects research conducted at Carilion Clinic.

The primary goal of the Carilion IRB is to protect human subjects involved in research. To achieve this goal, the Carilion IRB reviews research prior to the research being initiated. It approves research that meets established criteria and monitors approved research to ensure the continuing protection of human subjects.

Procedures:

Rosters

The IRB consists of three committees to review all research under its jurisdiction. Rosters of Committee A, Committee B, and Committee C will be updated periodically. They are stored on the IRB secure Carilion server. IRB membership with the Office for Human Research Protections (OHRP) will also be maintained.

Meeting Times

Committee A meets on the second Wednesday of every month at 7:00 am. Committee B meets on the fourth Thursday of every month at 11:30 am. Committee C meets as needed. The meeting may be held remotely or in person.

Submission Schedule

The IRB submission schedule can be found on the Carilion IRB website or can be requested from the Human Research Protections Office. The submission schedule shows the meeting dates for one year, along with the deadline dates for submitting required documentation to the IRB. The primary deadline indicates the day submission materials need to be received in the IRB office. The secondary deadline indicates the day that the final submission is needed to be received in the IRB office. Information must be submitted electronically to the IRB via PRISM or by email. All items received after the deadline (even if by one day) may be placed on the next meeting's agenda.

Submission Guidelines

To submit research to the IRB for review, the IRB Application and research documents must be complete. These documents and the requirements for submission are explained in detail in other IRB guidelines. Any documents that are not complete will be returned to the investigator to be corrected. Corrected forms need to be received by the deadline. The applications are available in the Carilion IRB electronic submission system, PRIS3M.

Physician and Nursing Members

Each IRB committee shall have at least one physician member and at least one nurse member from Carilion Clinic (CC). Whenever a protocol with a CC physician serving as Principal Investigator is reviewed at a convened meeting, at least one CC physician member shall vote on the protocol. Whenever a protocol with a CC nurse serving as Principal Investigator is reviewed at a convened meeting, at least one CC nurse member shall vote on the protocol.

Compensation of Members

Affiliated IRB members do not receive direct monetary compensation for participation on the board. Non-Carilion affiliated community members are paid a stipend for each study review or for each meeting they attend if they do not review a study. If meeting in person, parking during attendance at a meeting will be provided in a designated parking garage, and a light meal may be served. A reasonable stipend may also be provided to consultants and/or ad hoc reviewers at the discretion of the IRB Chair or designee.

Attendance of Members

Members of the IRB are expected to attend and participate in all scheduled board meetings. However, it is recognized that circumstances may occur that interfere with a member's ability to attend every meeting. While an occasional missed meeting is understandable, missing excess meetings may hinder the ability of the board to review research.

If there are significant concerns of any nature, the Chair will assess the need for suspension or dismissal from the board.

Consulting Reviewers

The IRB, at its discretion, may use individuals with competence in special areas to assist in the review of research issues that require additional expertise. Qualified individuals may include

those with previous IRB experience, CITI training, and/or related educational background. Outside consultants (those not affiliated with Carilion) will receive a stipend appropriate for the service performed. Consulting reviewers are not voting members of the IRB.

Attendance of Guests

At their discretion, the Chair, Vice-chair, Human Protections Administrator, or IRB Regulatory Affairs Administrator may invite:

- Scientists or non-scientists who have special expertise to function as consultants and ad hoc reviewers of a study. These individuals may have access to all documents submitted to the IRB relevant to the specific study under review and participate in the deliberations and make recommendations on the study.
- Investigators, coordinators and/or advisors for the purpose of additional clarification or discussion regarding their study. These individuals are required to leave the meeting for the final discussion and voting.
- Other guests may attend a meeting for educational purposes, to observe while considering board membership or other appropriate reasons. The reasons for attendance will be stated at the beginning of the meeting and in the minutes.

None of the guests outlined above are included in determining or establishing a quorum at the meetings. They do not vote. Guests may be required to sign a Confidentiality Statement prior to attendance of a meeting. The IRB meeting minutes will reflect the presence of all guests.