CARILION CLINIC INSTITUTIONAL REVIEW BOARD
Standard Operating Guidelines

Title: 1.5: General Administration: PROCEDURE FOR PLANNING AND IMPLEMENTING IRB MEETING AGENDAS	
Original Date: January 2006	**Date of Last Revision:** 2-07, 01-08, 8-23
Primary Sponsor: Human Research Protections Office	**Approved By:** Director of the Human Research Protections Office

Objective:

To provide a detailed guide to be used when preparing the Carilion Clinic Institutional Review Board (IRB) meeting agenda.

General Description:

IRB members shall be provided sufficient time to review submissions before the actual meeting takes place. An agenda for the meeting is prepared and the submissions copied and sent to each member.

Procedure:

The IRB Regulatory Affairs Administrator will create and distribute the agenda to board members. Agenda packets will be sent via email and shall include: the agenda; minutes from the previous meeting; educational materials; a spreadsheet containing the non-voting items completed since the last meeting; and any other material that may be relevant to any of the items scheduled for a particular meeting. All relevant study documents including IRB applications, Protocols, Continuing Review Forms, consent forms, flyers, and other pertinent information for the submissions will be available to members via the online e-system PRIS3M. The agenda and administrative meeting materials shall be emailed to members at least one week before the date of the meeting.

The agenda shall be one of two categories:

- Category I: items requiring action by the full board (examples: new study submissions, continuing reviews of open protocols, amendments or revisions with major changes)
- Category II: information items, actions not requiring full board review (examples: items meeting expedited review criteria such as new studies, continuing reviews and amendments; NCI facilitated reviews; exempt studies; QA/QI studies; emergency uses of drugs/devices; and study closures and conclusions)

The agenda must include the date, time, and location of the meeting. If the meeting is being conducted remotely, details of how to connect to the meeting will be included. Each item on the agenda shall be listed under an appropriate category, i.e., New Protocols, Continuing Reviews, etc., and must be identified by study title and investigator name. A short summary of the action shall be given. If the action requires full board review, the name of the reviewer(s) will be listed as well. If any new information becomes available before the meeting, the agenda shall be updated and resent to the members along with a notification of the changes.