CARILION CLINIC INSTITUTIONAL REVIEW BOARD
Standard Operating Guidelines

Title: 1.4: General Administration: DEVELOPMENT, APPROVAL AND MAINTENANCE OF IRB STANDARD OPERATING GUIDELINES and STANDARD OPERATING PROCEDURES	
Original Date: January 2006	**Date of Last Revision:** 1-10, 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 creating, maintaining and distributing the Standard Operating Guidelines (SOGs) and Standard Operating Procedures (SOPs) for the Carilion Clinic Human Research Protections Office and the Institutional Review Board (IRB).

General Description:

21 CFR 56.108 and 45 CFR 46.108 require an IRB to follow specific written procedures when its institution is engaged in human subjects research. 45 CFR 46.103(4) & (5) note what written procedures must be in place. 45 CFR 46.103(c) requires the execution of an assurance with the federal oversight office that gives an institutional official the responsibility for implementing the obligations imposed by 45 CFR 46. Carilion's Federal Wide Assurance document states "The institution and designated IRB(s) have established . . . written procedures . . ." The regulations and the assurance document note that the institutional official has ultimate responsibility for ensuring procedures are in place. However, the assurance document, by stating that the institution and IRB must have established written procedures, suggests that the two should work together.

The SOG/SOPs developed under the process outlined here cover the operations of the Carilion Clinic Institutional Review Board (IRB) committees and staff. These procedures are described in detail to ensure efficient and consistent functioning among the committees of the Carilion Clinic IRB and to serve as a resource for investigators.

Procedure:

SOG/SOP Development

The Director of the Human Research Protections Office (director) shall develop and establish appropriate IRB SOG/SOPs. In establishing these SOG/SOPs, the director and his/her designee must comply with all applicable federal, state and local regulations and must consider the impact on investigators.

IRB SOG/SOPs are produced by computer and follow a standard format. The following information is required:

- SOG/SOP Title
- Page numbering utilizing appropriate format (category: SOG: Page ___ of ___)
- Original Date: the date on which the content of the SOG first became official
- Revision Date: the date that this revision became effective (if applicable)

Input from the IRB Chair, Vice-Chair, IRB members, HRPO staff, and research colleagues may be obtained as deemed necessary. The director may also solicit input from other institutional officials as appropriate.

It is the responsibility of the director to assure all proposed SOG/SOPs conform to the above format and have followed the above procedure prior to approving its use as an official SOG/SOP.

The approved version of the SOG/SOPs will be made available on the Carilion Clinic IRB website. Approval occurs internally prior to posting on the IRB website. Approvals are documented by official posting the IRB website. The Director of Director of the Human Research Protections Office will grant final approvals.

SOG/SOP Revision and Maintenance

The IRB Regulatory Affairs Administrator will review SOG/SOPs for continuing suitability at least once every three to five years. Revisions may be made at this time or at any other time deemed necessary. Approval and posting of revised SOG/SOPs shall follow the process outlined above.

SOG/SOP Designee

Throughout all Carilion IRB SOG/SOPs, unless otherwise stated, the designees for the IRB Chair will be the IRB Vice-chair, Human Protections Administrator, or IRB Regulatory Affairs Administrator. The designees for the Vice-chair will be the Human Protections Administrator or IRB Regulatory Affairs Administrator. The designee for the Human Protections Administrator will be the IRB Regulatory Affairs Administrator.