CARILION CLINIC INSTITUTIONAL REVIEW BOARD
Standard Operating Guidelines

TITLE: 3.3: Reviews Requiring Special Consideration: Commercial IRBs (Advarra IRB and WCG IRB)	
Original Date: January 2006	**Date of Last Revision:** 3-10, 6-14, 3-18, 8-23
Primary Sponsor: Human Research Protections Office	**Approved By:** Director of the Human Research Protections Office

Objective:

Researchers wishing to open multi-center, industry-sponsored research utilizing commercial IRBs, Advarra IRB or WCG IRB (WIRB), shall submit the appropriate paperwork to the Carilion Clinic Institutional Review Board (IRB). If the Carilion IRB authorizes the commercial IRB review, the commercial IRB will then become the IRB of record. This guideline describes the process of interaction between the Carilion IRB and Advarra IRB or WCG IRB.

General Description:

Advarra IRB and WIRB Responsibilities

- Assumption of IRB oversight responsibility and performance of IRB functions in compliance with federal and state regulations for research studies to be conducted at Carilion
- Review and approval or disapproval of protocols
- Review and approval, disapproval or modification of consent forms
- Review and approval or disapproval of the investigator(s)
- Monitoring of adverse event reports
- Maintenance of required IRB records pursuant to 21 CFR §56.115 and 45 CFR §46.115
- Continuing review of research studies at least annually
- Notify Carilion of any Advarra IRB or WIRB termination or suspension of a study, instances of serious or continuing noncompliance with the federal regulations or the requirements and determinations of Advarra IRB or WIRB and any other matter that comes to the attention of Advarra IRB or WIRB that adversely affects Carilion's compliance with applicable regulations and laws
- Notify Carilion of its decisions to approve, disapprove or recommend modification of Carilion's research studies
- In addition, Advarra IRB or WIRB have agreed to provide the Carilion IRB with copies of meeting minutes relevant to any Carilion study, notification of study closures and copies of local serious adverse event forms for inclusion in Carilion IRB files.

Carilion IRB Responsibilities

- Ensure that investigators and other Carilion staff who are conducting studies are appropriately qualified and meet Carilion's standards for eligibility to conduct research
- Ensure that investigators receive proper initial education on the requirements related to human subjects' protection

- Notification to Advarra IRB or WIRB if any investigators conducting research have left Carilion, have had privileges revoked, or, with regard to the conduct of clinical research, have otherwise been disciplined or are under investigation by Carilion
- Notification to Advarra IRB or WIRB of all communications to and from the Food and Drug Administration (FDA), the Office of Human Research Protections (OHRP) and other applicable federal and state regulatory agencies regarding the studies that have been referred to Advarra IRB or WIRB and related IRB matters, and concerning investigators who have submitted studies to Advarra IRB or WIRB for review
- Notification to Advarra IRB or WIRB of any research requiring Advarra IRB or WIRB's review, and will follow Advarra IRB or WIRB's standard submission requirements to initiate the review process and/or transfer studies to Advarra IRB or WIRB
- Grant a partial HIPPA waiver and/or informed consent waiver for recruitment purposes if applicable.

In all research involving Advarra IRB or WIRB review and approval, the Carilion Clinic IRB shall have authority to review local protocol violations and local serious adverse events or unanticipated problems and to receive notification of any determinations of local serious non-compliance or continuing non-compliance. Additionally, the Carilion Clinic IRB shall have authority to 1) make its own determinations of local serious non-compliance or continuing non-compliance 2) require local investigators to develop and implement corrective action plans and 3) suspend or terminate local research activities.

Carilion Clinic IRB will also review the local recruitment plan to assess whether a partial HIPAA waiver and/or consent waiver for recruitment purposes is required. The Carilion Request to Rely application includes a recruitment question which asks about the local recruitment plan.

Procedure:

Approval Process

- Research and Development (R&D) approval must be obtained.
- Financial Conflict of Interest will be reviewed by the Carilion Clinic Organizational Integrity and Compliance (OIC) Office. Any potential conflicts of interests must be managed before the IRB will begin the review. The IRB office will be notified once OIC has completed their review.
- A copy of the packet that will be submitted to Advarra IRB or WIRB for approval shall first be submitted to the Carilion IRB using the IRB electronic submission system PRIS3M. This should include a copy of the Carilion Request to Rely Application, completed Advarra IRB or WIRB application, a copy of the consent form and a copy of the protocol, recruitment materials, as well as all study related materials.
- The Principal Investigator's current CV (within two years) should be emailed to irb@carilionclinic.org.
- An administrative review by Carilion IRB staff is conducted to look for local context issues, including verification of research staff training
- The Carilion IRB survey language has been added to the consent form (or attached as a separate document).
- The IRB Regulatory Affairs Administrator will notify the investigator that the submission is either eligible or not eligible for external review. If it is determined to be not eligible, the reason for that determination will be provided.

Carilion Clinic IRB Review

- Local investigators will be notified that they are required to submit copies to the Carilion Clinic IRB of any reports to Advarra IRB or WIRB of all local protocol violations and all local unanticipated problems or serious adverse events.
- Local investigators will be notified that they are required to submit copies of all monitoring visit reports or letters, including reports from sponsors, CROs and co-operative groups.
- Local investigators will be notified that they are required to submit notification to the Carilion Clinic IRB of any local personnel changes.
- The Carilion Clinic IRB will audit or investigate at its discretion any issues or concerns raised in reports it receives about Advarra IRB or WIRB studies according to the process outlined in its Standard Operating Guidelines.
- The Carilion Clinic IRB retains the authority to make institutional determinations of local serious and/or continuing noncompliance, unanticipated problems independent of the determinations made by an external IRB.