CARILION CLINIC INSTITUTIONAL REVIEW BOARD
Standard Operating Guidelines

Title: 1.7: General Administration: DOCUMENTATION OF IRB MEETING MINUTES	
Original Date: January 2006	**Date of Last Revision:** 02-07, 01-08, 8-23
Primary Sponsor: Department of the 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 minutes of the Carilion Clinic Institutional Review Board (IRB) meetings.

General Description:

Federal regulations mandate that minutes of IRB meetings be kept in sufficient detail to show attendance at meetings, actions taken by the IRB along with the vote on these actions, the basis for requiring changes or disapproving research and a written summary of the discussion of controverted issues and their resolution. The Carilion IRB fully encompasses these regulations by adhering to this guideline.

Procedure:

Detailed minutes of each IRB meeting shall be kept on file in the IRB office, under the supervision of the IRB Regulatory Affairs Administrator. They are distributed in advance and brought before the board members for approval at the next scheduled meeting. Minutes are approved by the IRB. The format and subject matter comply with the federal regulations and include the following:

- Date of meeting, time started, and time ended
- Attendance at each meeting, including members and attendees (investigators, coordinators, advisors, visitors and their reason{s} for visiting, etc.) along with a listing of absent board members
- Documentation that all board actions included at least one scientist in the review and vote
- Documentation that all board actions included at least one non-scientist in the review and vote
- Notation when a member enters or leaves the room during the convened meeting. When a member declares a conflict of interest and leaves the room, and whether or not the member returns to the meeting.
- Documentation reflecting the convened IRB, with quorum, reviewed, deliberated, and voted for each action requiring a vote, and that at least a majority of the IRB members present voted on all actions requiring a vote
- The vote on actions taken including the number of members voting for, against (with reason for the against vote), to defer, and abstaining (including member name and reason for choosing to abstain)
- The vote on approval of the minutes from the prior meeting
- All actions taken by the board, including the length of time for any approval, the basis for requiring any modification, the basis for tabling a study, and the basis for any disapproval

- When approval of a study is dependent upon minor modifications, minutes will state who will review and confirm that the investigator has completed the modifications requested by the IRB. Subsequent minutes will state that this review was done.
- Listing of all protocols, continuing reviews and emergency uses of drugs/devices that were approved by expedited review since the prior meeting
- Listing of all new modifications/amendments to protocols that were approved by expedited review since the prior meeting
- Review of adverse events and unanticipated problems
- Review of protocol violations or deviations
- For protocols in which the board waived the requirement of informed consent, documentation of the justification for the waiver in accordance with 45 CFR 46.116(d)
- For research involving pregnant women and/or fetuses, documentation of the findings required under Subpart B of 45 CFR 46
- For research involving children, documentation of board findings in accordance with Subpart D of 45 CFR 46
- Documentation of consideration of additional safeguards for vulnerable subjects when appropriate
- A written summary of the discussion of controverted issues and their resolutions
- Educational articles
- Any other business appropriate for board meetings
- All submissions approved outside of the convened IRB will be referenced in a separate document.