

CARILION CLINIC INSTITUTIONAL REVIEW BOARD

Standard Operating Guidelines

Title: 2.10: Review of Research: APPEAL PROCESS	
Original Date: March 2006	Date of Last Revision: 1-08, 8-23
Primary Sponsor: Human Research Protections Office	Approved By: Director of the Human Research Protections Office

Objective:

To provide principal investigators with a process for appealing decisions made by the Carilion Institutional Review Board (IRB).

General Description:

Principal investigators shall have the right to appeal a decision of the IRB by notifying the IRB chair, in writing, of their decision to appeal. Decisions of the IRB that may be appealed include, but are not limited to, major determinations or actions of the IRB such as the disapproval of a study, the IRB's assessment of the risks and benefits of a proposed research project or sanctions imposed on a researcher for research misconduct. This guideline does not apply to decisions made by the IRB staff. Any request for an appeal must be considered by the convened IRB. No institutional official may approve a research activity that has been disapproved by the IRB.

Procedure:

A principal investigator shall have the right to appeal a decision by the IRB. The appeal must be initiated within 30 days of the investigator receiving notification of the decision. It must be made in writing and sent to the IRB Chair or to the staff. An appeal cannot be considered unless there is new or additional material available relevant to the IRB's decision. The Chair and the staff will review the appeal and decide whether additional information is necessary to present at the IRB meeting.

Once received by the staff, the appeal will be placed on the next meeting agenda of the committee that originally reviewed the protocol. The IRB Regulatory Affairs Administrator or other staff member will notify the principal investigator of the date and time of this meeting. The principal investigator should be prepared to attend that meeting in order to answer any questions.

Requests for appeals of decisions made by the convened IRB must be heard by the convened IRB. In order to reverse the original decision of the IRB, the majority of the voting members attending the meeting must vote in favor of the reversal of the decision.

The board will notify the principal investigator of its decision on the appeal within 60 days. The IRB shall document in the minutes for the meeting and in a letter to the principal investigator the IRB's decision and the rationale for its decision regarding the request to appeal.

The determination made by the full-board regarding the appeal of a decision is final.