CARILION CLINIC INSTITUTIONAL REVIEW BOARD
Standard Operating Guidelines

Title: 6.2: Conduct of Research: PROCEDURE FOR COMPLAINTS REGARDING HUMAN SUBJECTS RESEARCH	
Original Date: April 2006	**Date of Last Revision:** 01-08, 04-08, 11-25
Primary Sponsor: Human Research Protections Office	**Approved By:** Director of Human Research Protections Office

Objective:

To describe the procedure the Carilion Institutional Review Board (IRB) will use for addressing complaints received from patients, research participants, investigators or research staff involved in human subjects research under the jurisdiction of the Carilion IRB.

General Description:

The Carilion IRB staff will seek to investigate and resolve written and verbal complaints concerning the conduct of human subjects research studies. Complaints may come from any source including IRB members, investigators and their staff, participants in the research and their families, institutional personnel, other institutional committees, the media and anonymous sources. Complaints may come from any category of research reviewed and may include anyone involved or not directly involved in the research study. The confidentiality of the individual filing the complaints and of the individual(s) about whom the complaint is made will be protected to the greatest extent possible.

Procedure:

Research participants are encouraged to express their concerns to the Principal Investigator (PI) or a member of the research team. Research participants may also speak with the Carilion Clinic IRB Chair or the Human Subjects Protections Administrator to resolve existing concerns. The Carilion Clinic IRB external website includes information about the IRB and contact information is included for participants to submit comments. All consent documents must contain a telephone number for participants to voice concerns or questions to the PI, research team member, or IRB office.

If the complaint is received by the PI or research team member, it is the responsibility of the investigator to notify the IRB of any individual's complaint regarding the research as soon as possible, but no later than seven business days after the investigator first learns of the complaint. The PI may also assess the complaint to determine if actions are necessary to protect the safety or welfare of the participant(s). The IRB Office should be consulted if there is any question regarding whether to report the complaint or not, and to be advised about potential necessary actions.

Complaints should be directed to the Carilion Clinic IRB Chair or the Human Protections Administrator (HPA). Initial reviews of new participant questions or complaints are to be completed within sixteen work hours of receipt. Complainants are to be contacted within 48 hours of receipt of their question or complaint. The responsible individual will investigate the

complaint and make a determination of whether the complaint relates to the conduct of a research study. If the substance of the complaint is not directly related to a research study, it will be referred to an appropriate institutional official. If the complaint is directly related to a research study, the individual will further investigate the complaint. The level of investigation will depend on the seriousness of the situation and the potential risk to subjects, and may involve the Compliance Office, Legal Department, and other institutional officials as deemed appropriate.

A brief written report will be created and will include the name and contact information of the individual making the complaint, the date the complaint was received, a copy of the written complaint, if any, or a written description of the verbal complaint, and a copy of written responses or verbal summaries of responses from others contacted about the complaint. The IRB Chair and the HPA will decide if the complaint can be resolved and, if so, take the appropriate steps to do so.

If the complaint cannot be resolved at this stage, the IRB Chair and/or HPA will conduct a further investigation or audit. The IRB Chair and/or the HPA will work collaboratively with other appropriate officials to resolve the complaint. These officials may include the Carilion Institutional Official, Carilion Compliance Office, and the Carilion Legal Department. Appropriate research team members may be included. At the completion of the investigation or audit, the findings, if warranted as determined by the IRB Chair and HPA, will be referred to the appropriate IRB for review. A determination will be made by the IRB of any further actions that are to be taken.

Investigators are to cooperate with the IRB by making documents accessible, responding to written requests within a designated timeframe and being available for questions by the IRB.

The Standard Operating Guidelines (SOG) for Reporting Unanticipated Problems, including Adverse Events (SOG 2.9) and Non-compliance, Suspension, and Termination (SOG 6.4) will be followed, as applicable. If scientific misconduct is suspected, the Research Misconduct Policy will be followed.