CARILION CLINIC INSTITUTIONAL REVIEW BOARD
Standard Operating Guidelines

Title: 2.2: Review of Research: COMPONENTS OF PROTOCOL	
Original Date: March 2006	**Date of Last Revision:** 8-11, 8-23
Primary Sponsor: Human Research Protections Office	**Approved By:** Director of the Human Research Protections Office

Objective:

To help investigators develop a complete protocol for the research they are proposing for Carilion Institutional Review Board (IRB) review.

General Description:

Depending on the nature of the research, some of the elements of this outline may not be necessary. Investigators who are conducting studies sponsored by industry, not-for-profit groups or governmental agencies may have a protocol already developed for them. These industry-sponsored protocols may vary somewhat from the protocol structure outlined below. The Carilion IRB will accept applicable variations in the protocol structure. However, it reserves the right to ask that a protocol be changed or amended to provide more complete or accurate information. The Carilion IRB does not require a separate protocol document in addition to the IRB application. The IRB Application includes all protocol details. If the principal investigator prefers to submit a separate protocol, all details must be completely reflected in both documents accurately. After initial approval, only the protocol document will reflect revisions going forward without the need to duplicate the revisions in the IRB application to reduce administrative burden.

Procedure:

Recommended components to be included in the protocol:

Title Page

- Full title
- Sponsor of protocol
- IND# or IDE# for investigational drugs or devices
- Principal investigator's name, professional qualifications, phone numbers, address and departments
- Original date of protocol and any revision dates
- Name of responsible departmental chairperson, phone number and address

Study Abstract

- Brief description of the methods
- Potential benefits
- Potential risks
- Risk management procedures

Background

- History of the disease
- The current treatment
- Literature supporting rationale for the proposed research, including animal research
- The relevance of this research to the contribution of this field of study

Objectives

- Major and secondary objectives
- Questions to be answered by this research
- Hypotheses to be tested
- Data to be gathered
- Expected outcomes

Patient Selection

- Patient characteristics - number, age, gender, ethnic characteristics and health status of subjects
- Patient criteria - inclusion and exclusion criteria along with how this is determined and by whom
- Special populations - provide rationale for using special populations
- Recruitment - define methods to be used, where this will take place and by whom. If access to medical records provides the recruitment, then provide authorization to the access. Provide supporting media such as advertisements, radio spots, flyers and telephone scripts if that will be used.
- Informed consent process - describe how informed consent will be obtained to ensure that it is voluntary, and who will obtain it. Include all elements of the informed consent document.
- Potential problems - address any problems that may arise during the study with patient identification, recruitment, or data collection

Research Procedures

- Research design - give a description of the research design including use of placebo, randomization, and an explanation of what is experimental. Include type of study: descriptive, retrospective, cross-sectional (surveys), prospective observational, pilot, experimental, etc.
- Research procedures - provide information on pre-treatment tests and medications, tests and medications during therapy and forms to be filled out just for the research. Include the length of time subject will be on the study and the expected amount of time required for each study visit. Include follow-up information.
- Data collection - describe how labs will be submitted and how data will be compiled for assessment
- Management of adverse events
- Compensation for participation or injury

Benefits

- To the subject
- To the group of individuals with this disease process

- To society/science

Risks

- Identification of risks - include physical, psychological, social, economic and legal harm that may result from participation. Define the level of risk (no risk, minimal risk, risk but with potential benefit to patient, risk but no benefit to patient).
- Management of risk - describe how the risk will be minimized, what safeguards are in place and alternatives that may be incorporated into the research to accommodate those risks
- Confidentiality - describe how records will be maintained
- Assess risk - provide compelling evidence that benefits of study outweigh risks
- Additional costs subjects may incur

Statistical Considerations

- Includes information on variables, sample size needed and discussion of end points

References

- Include any references to previous studies or articles

Appendices

- Forms to be used
- Recruitment materials
- Calendars
- All other study related materials as applicable