GUIDELINES FOR WRITING A RESEARCH PROTOCOL

The primary responsibility of the IRB is to safeguard the rights and welfare of human research participants. For that reason, the principal investigator must provide sufficient information for the IRB to determine that research participants will be adequately protected and that the research will be conducted in full compliance with Mount Carmel’s Federal-Wide Assurance. In order to approve a research activity involving research participants, the IRB must assure that all of the following requirements are satisfied:

1. Risks to research participants are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose research participants to risk. Whenever possible, research should employ procedures already being performed on participants for diagnostic or treatment purposes.
2. Risks to research participants are reasonable in relation to (1) anticipated benefits, if any, to the research participants, and (2) the importance of knowledge that may reasonably be expected to result.
3. The selection of the research participants is equitable. In making this assessment, the IRB must take into account the purpose of the research and the setting in which the research will be conducted. It must pay particular attention to the special problems which may arise in research involving vulnerable populations, such as children, pregnant women, prisoners, mentally disabled persons, or economically or educationally disadvantaged persons. If any of the research participants is likely to be vulnerable to undue influence or coercion, the IRB may require additional safeguards to protect such research participants.
4. Informed consent will be sought from each prospective research participant, or the participant’s legally authorized representative, generally by means of a written consent document that the IRB has carefully reviewed to assure that it contains the required elements of informed consent and that it is understandable to the layperson. The informed consent document should be written at an eighth grade reading level.
5. The research plan makes adequate provisions for ensuring the safety of research participants.
6. There are adequate provisions to protect the privacy of research participants and to maintain the confidentiality of data.

Required Elements of the Protocol

1. **Background and Rationale for the Study** – State the problem and provide justification and rationale for the proposed research. Provide a summary of prior experience and/or history important for understanding the proposed study and procedures. Include any relevant research literature.

2. **Objectives** – Specify objectives and hypotheses to be tested in the research project.

3. **Eligibility** – Identify the patient population being evaluated by the protocol. List the inclusion and exclusion criteria and the source of prospective research participants.

4. **Study Design and Methods** – Describe the involvement of research participants (section 7 below) including initial evaluation procedures and screening tests, phase, procedures and sequence of the study. Separate standard and experimental aspects of the study as much as possible. Describe alternatives to experimental therapy if they exist. Give detailed procedures for treatment, dose adjustments, etc. Describe the randomization procedures, if applicable. Address the experience of investigators if procedures are to be performed for which the investigators have been specifically credentialed.
For Record Review Studies:
1. What is the source of the medical information?
2. Does the chart information to be used in the study already exist?
3. Will some or all of the chart information to be used come from data sources created in the future (e.g. after the date of IRB approval)?
4. What is the time period of the medical information under review?
5. Who will have access to this collected information?
6. How long will the information be kept and what are the plans for destroying it once the study is completed?
7. Is there a list of variables that will be used from the medical record/chart?
8. What are the plans for maintaining the privacy and confidentiality of the information?
9. Are there any plans for coding or de-identifying the information to be collected?

5. Monitoring Participants and Criteria for Withdrawal of Participants from the Study – Consider specifying a monitor if the study involves a blinded design. Define stop points and criteria for withdrawing subjects from the study.

6. Analysis of the Study/Statistical Considerations – This section should clearly outline three topics, (1) how the data will be evaluated in relation to each of the objectives, (2) summarize the statistical approach to the analysis of the data gathered, and (3) sample size justification.

Sample size justification literally means, “to justify the sample size” or to “justify the number of participants you are enrolling in your study.” In particular, this is important anytime you have to write a research proposal that is going to be reviewed by a committee (e.g. dissertation committee, IRB, granting agency). The “committee” wants to rest assured that your study design (one aspect of study design being “sample size”) is adequate to address your research questions.

*****See the reference section on the last page of the guidelines for websites to provide statistical assistance. *****

7. Human Subject Protections: Protocols without this section will not be accepted for IRB review.

a. Rationale for Participant Selection: The protocol must include (a) a rationale for research participant selection based on a review of gender/ethnicity/race categories at risk for the disease/condition being studied; (b) strategies/procedures for recruitment (including advertising, if applicable); and (c) justification for exclusions, if any. If the protocol is a Phase III or IV clinical trial, a discussion of how the trial will be carried out to conclude valid result analyses of differences by gender and ethnicity must be included. If the protocol involves participant enrollment at multiple sites, describe plans for ensuring appropriate IRB review and approval at each site.

Explain the rationale for the involvement of special classes of subjects, if any, such as fetuses, pregnant women, children, cognitively impaired individuals, prisoners or other institutionalized individuals, or others who are likely to be vulnerable. Reference the appropriate Federal Regulations Subparts as necessary when discussing the research involvement of these participants. Discuss what, if any, procedure or practices will be used in the protocol to minimize their susceptibility to undue influences and unnecessary risks (physical, psychological, etc.) as research participants.

b. Evaluation of Benefits and Risks/Discomforts: Describe the potential benefits to research participants or to others that may reasonably be expected from the research. If paid healthy volunteers are involved, or if participants are to be paid, specify the amount of compensation.

Describe any potential risks – physical, psychological, social, legal, or other and assess their likelihood and seriousness. Where appropriate, describe alternative treatments and
procedures that might be advantageous to the research participants. Describe the procedures for protecting against or minimizing any potential risks, such as violations of confidentiality, and assess their likely effectiveness. Where appropriate, discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the research participants.

Discuss why the risks to the subjects are reasonable in relation to the anticipated benefits and in relation to the importance of the knowledge that may reasonably be expected to result.

8. **Adverse Event Reporting and Data Monitoring** – Provide a plan for reporting adverse events to the IRB. Also, describe the provisions for monitoring the data collected to ensure the safety of subjects.

9. **Consent Process** – In accordance with FDA regulations, it is the investigator’s responsibility to obtain written informed consent from the prospective participant or the participant’s legally authorized guardian/representative after adequate explanation of the aims, methods, anticipated benefits, and potential hazards of the study and before any study related procedures begin. The research participant must be given a copy of the signed informed consent document. The original signed copy of the informed consent document must be retained in the principal investigator’s study binder. If the patient is hospitalized, a copy of the signed research consent document must also be placed in the medical record.

If a waiver of informed consent or a waiver of documentation of informed consent will be requested, you must address the request in this section. Consider the following:

1. Does the research involve no more than minimal risks to the participants?
2. How will the waiver or alteration **not** adversely affect the rights and welfare of the subjects?
3. Why the research could not practicably be carried out without the waiver or alteration?
4. If appropriate, will the subjects be provided with additional pertinent information after participation?

**** See [www.mountcarmelhealth.com/medical-professionals/research/](http://www.mountcarmelhealth.com/medical-professionals/research/) or call 614-546-4325 for a sample informed consent document. ****

10. **Patient Confidentiality** – The principal investigator must ensure that the research participant’s confidentiality is maintained. Participants should be identified by their initials and a study ID number only. Documents should be kept in strict confidence by the investigator. Any use of personally identifiable data or private health information (PHI) must be justified by the investigator and approved by the IRB.

11. **References** – Include selected references, which highlight methods, controversies, and study outcomes.

**References:**


[http://www.surveysystem.com/sscalc.htm](http://www.surveysystem.com/sscalc.htm)

[www.mountcarmelhealth.com/medical-professionals/research/](http://www.mountcarmelhealth.com/medical-professionals/research/)