

# GUIDELINES FOR WRITING A MINIMAL RISK RESEARCH PROTOCOL

Office for Human Research Studies

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## **GENERAL INSTRUCTIONS**

This document is intended to guide investigators in preparing a minimal risk research trial for submission and review. These guidelines may be used for specimen/data collection and banking studies.

Any questions about the instructions or the protocol submission and review process should be addressed to the **Office for Human Research Studies (OHRS)** at Dana-Farber Cancer Institute (DFCI), tel. (617) 632-3029.

The OHRS mailing address is: Dana-Farber Cancer Institute, 20 Overland Street, 2<sup>nd</sup> Floor, MA 02215.

## **MATERIALS FOR NEW PROTOCOLS**

The following materials will be needed when preparing a new protocol document for submission to the OHRS. Materials may be obtained from the OHRS website <http://www.dfhcc.harvard.edu/clinical-research-support/office-for-human-research-studies-ohrs/submitting-a-new-protocol/>

1. NEW RESEARCH APPLICATION FORMS – One of the following forms must be completed and submitted with the protocol document:
  - New Project Application - Medical Record Review:  
[http://www.dfhcc.harvard.edu/fileadmin/DFHCC\\_Admin/Clinical\\_Trials/OPRS/Forms\\_Instructions/New\\_Submission/New\\_Project\\_-\\_Medical\\_Record\\_Review.doc](http://www.dfhcc.harvard.edu/fileadmin/DFHCC_Admin/Clinical_Trials/OPRS/Forms_Instructions/New_Submission/New_Project_-_Medical_Record_Review.doc)
  - New Project Application - Research Use of Human Material/Tissue:  
[http://www.dfhcc.harvard.edu/fileadmin/DFHCC\\_Admin/Clinical\\_Trials/OPRS/Forms\\_Instructions/New\\_Submission/New\\_Project\\_-\\_Use\\_of\\_Human\\_Material\\_Tissue.doc](http://www.dfhcc.harvard.edu/fileadmin/DFHCC_Admin/Clinical_Trials/OPRS/Forms_Instructions/New_Submission/New_Project_-_Use_of_Human_Material_Tissue.doc)
2. CONSENT FORM TEMPLATE – All new submissions require the use of the DF/HCC Informed Consent Template. Consent forms must be submitted on a disk.

## **PROTOCOL PAGE SETUP**

1. Font: Times New Roman, 12 pt.
2. Margins: Left/Right – Minimum 0.5 inches;  
Top/Bottom- Minimum 0.4 inches for the header and footer
3. Header: The short title and the date that the protocol was written or last updated should be included on each page.
4. Pagination: Bottom of page, centered.
5. Section Headings: Format the protocol using the major section numbers (1.0, 2.0, etc.). Subheadings (1.1, 2.12, etc.) may be used where appropriate.

**NOTE**  
Protocols written and submitted in a grant format will not be accepted for review.

**TABLE OF CONTENTS**

A Table of Contents must be included with the protocol. However, the list of headings below is meant to serve as a guide and some may not be applicable. Revise and replace as needed.

Example:  
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## 1.0 ABSTRACT

A brief summary of the study background, aims and design.

## 2.0 BACKGROUND/RATIONALE

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. Include the potential benefits to subjects and/or society

## 3.0 OBJECTIVES/STUDY AIMS

☐ Specify objectives and hypotheses to be tested in the research project.

## 4.0 ELIGIBILITY

☐ Identify the patient/donor population being evaluated by the protocol. List the inclusion and exclusion criteria and the source of subjects/donors.

☐

## 5.0 SUBJECT ENROLLMENT

☐ Describe the methods of enrollment, including procedures for patient/donor registration, when applicable. Outline the procedures for obtaining informed consent. Consider the following:

- Where will recruitment occur?
- Where and when will consent be obtained?
- Who will obtain consent?
- What is the advertising plan, if applicable?
- What recruitment materials will be provided to the potential participant, if applicable?
- What procedures will be used for screening?
- What happens with screen failures (including any data gathered during screening)?

## 6.0 STUDY DESIGN/PROCEDURES

The study design should describe an adequate plan for answering the hypotheses listed above. Provide a thorough description of all study procedures, assessments and subject activities in a logical and sequential format. Include the expected duration of subject participation.

## 7.0 SPECIMEN/DATA COLLECTION/PROCEDURES

Outline the process for specimen/data procurement. Consider the following:

### ***For specimen/data banking studies:***

- What types of specimen/data will be collected.
- Where will the specimens/data be housed and who will be responsible for oversight of the bank?
- How long will the specimens/data be kept?
- How will the specimens/data be destroyed upon study completion?
- If specimens/data will be banked for future use, what will be the process for providing investigators with access to the bank and how will this be tracked?

### ***For record review studies:***

- What is the source of the medical information?
- Does the chart information to be used in the study already exist?
- Will some or all of the chart information to be used be from data sources created in the future (e.g., after the date of IRB approval)?
- What is the time period of the medical information under review?
- Who will have access to this collected information?
- How long will the information be kept and what are the plans for destroying it once the study is completed?

- Is there a list of variables that will be used from the medical record chart?
- What are the plans for maintaining the privacy and confidentiality of the information?
- Are there any plans for coding, or de-identifying the information that is collected?

## **8.0 LABORATORY/DATA ANALYSIS**

Outline how samples will be analyzed and the procedures/tests involved.

## **9.0 STATISTICAL CONSIDERATIONS**

The statistical section should clearly outline how the data will be evaluated in relation to each of the objectives. Describe the statistical methods for determining the sample size for the study. Summarize the statistical approach to the analysis of the study data. Include how the study endpoints will be achieved and a description of the power analysis.

## **10.0 REGULATORY REQUIREMENTS**

10.1 Informed Consent – In accordance with US FDA Regulations, it is the investigator’s responsibility to obtain written informed consent from the patient or patient’s legally authorized guardian/representative after adequate explanation of the aims, methods, anticipated benefits, and potential hazards of the study and before any study medications are administered. The research subject must be given a copy of the signed informed consent document. The original signed copy of the informed consent must be retained in the Institution’s medical records. Do not include it as part of the “Table of Contents”; it is treated as a separate document by the OHRS. See Part C for information of Consent Form content.

If a waiver of informed consent or a waiver of the requirement for documentation of informed consent will be requested, address the following here. Consider the following:

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

10.2 Patient Confidentiality –The investigator must ensure that the research subject’s confidentiality is maintained. Subjects 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.

## **11.0 REFERENCES**

This is a bibliography section for any information cited in the protocol. It should be organized in a standard bibliographical manner.