Investigator-Initiated Study Protocol

Title:

Protocol Number:	*Mount Sinai Study Number*
Principal Investigator (PI):	*Name and contact information of the Principal Investigator*
Coordinating Center:	*List the name of the coordinating site*
Participating Sites:	*List the names of the participating sites*
Participating Site PIs:	*For multi-site trials, list participating site PIs and their contact information*
Additional Investigators:	*Name and contact information of any other investigators*
Funding Source(s):	*List the name(s) and contact information of the funding sponsor(s)*
National Clinical Trials (NCT)/ ClinicalTrials.gov Number:	*Include the National Clinical Trial (NCT) number assigned once the trial is registered on the ClinicalTrials.gov website*

Table of Contents

<<FOR SINGLE SITE STUDY>> This is an investigator-initiated study. The principal investigator (PI), <<INSERT PI Name>>, is conducting the study and acting as the sponsor. As the sponsor-investigator, both the legal/ethical obligations of a PI and those of a sponsor will be followed.

> *The trial will be carried out in accordance with Good Clinical Practice (GCP) as required by applicable United States (US) laws and applications, including but not limited to United States (US) Code of Federal Regulations (CFR) applicable to clinical studies (45 CFR Part 46).*

The PI will assure that no changes to the protocol will take place without documented approval from the Institutional Review Board (IRB). All personnel involved in the conduct of this study have completed Human Subjects Protection Training.

I agree to ensure that all staff members involved in the conduct of this study are informed about their obligations in meeting the above commitments.

Sponsor-Principal Investigator: _____
Print/Type Name

Signature: _____ ***Date:*** _____

<<FOR MULTI-SITE STUDY>>

Site Principal Investigator: _____
Print/Type Name

Signature: _____ ***Date:*** _____

1.0 List of Abbreviations

2.0 Participating Sites

<< list all participating sites here:>>

3.0 Hypothesis and Specific Aims

A brief statement of the purpose of the research project. This section should include the hypotheis and specific aims being tested in the research.

4.0 Background and Significance

Explain the background of this project so that IRB and other review committees will understand why it is important to perform this research project. Include:

- *Summary of study disease(s) and previously published data and pilot studies. Be sure to include a discussion of any data that does not support hypothesis. If a study similar to the one being proposed has already been completed, explain why the proposed study is necessary.*
- *For studies designed to compare or evaluate therapies, there should be a statement of the relative advantages or disadvantages of alternate modes of therapy.*
- *Please provide the scientific rationale/justification for conduct of the study*
- *If not obvious, explain why human subjects are necessary.*
- *Include references for all published data cited.*

5.0 Preliminary Studies/Progress Report

Please include relevant pre-clinical or clinical findings from other published research as needed

6.0 Research Methods

6.1 Outcome Measures

6.2 Description of Population to be Enrolled

6.3 Study Design and Research Methods

6.4 Description, Risks, and Justification of Procedures and Data Collection Tools

Please note that a loss of confidentiality is considered a risk.

6.5 Potential Scientific Problems

6.6 Data Analysis Plan

6.7 Summarize Knowledge to be Gained

7.0 References

Please include a list of relevant literature and citations for all publications referenced in the text of the protocol. Use a consistent, standard, modern format, which might be dependent upon the required format for the anticipated journal for publication (e.g., N Engl J Med, JAMA, etc.). The preferred format is International Committee of Medical Journal Editors (ICMJE). Include citations to product information such as manufacturer's IB, package insert, and device labeling.

Examples:

Journal citation
Veronesi U, Maisonneuve P, Decensi A. Tamoxifen: an enduring star. J Natl Cancer Inst. 2007 Feb 21;99(4):258-60.

Whole book citation
Belitz HD, Grosch W, Schieberle P. Food chemistry. 3rd rev. ed. Burghagen MM, translator. Berlin: Springer; 2004. 1070 p.

Chapter in a book citation
Riffenburgh RH. Statistics in medicine. 2nd ed. Amsterdam (Netherlands): Elsevier Academic Press; c2006. Chapter 24, Regression and correlation methods; p. 447-86.

Web Site citation
Complementary/Integrative Medicine [Internet]. Houston: University of Texas, M.D. Anderson Cancer Center; c2007 [cited 2007 Feb 21]. Available from: http://www.manderson.org/departments/CIMER/.

Electronic Mail citation

Backus, Joyce. Physician Internet search behavior: detailed study [Internet]. Message to: Karen Patrias. 2007 Mar 27 [cited 2007 Mar 28]. [2 paragraphs]

References to package insert, device labeling or investigational brochure

Cite date accessed, version number, and source of product information.