CLINICAL STUDY PROTOCOL

Hackensack Meridian *Health*

Protocol Title

Protocol Version

Click here to enter a date.

version x

GUIDELINES FOR WRITING A PROTOCOL

Please use this template for the following study types:

1. Social Behavioral
2. Prospective Data and/or Sample Collection
3. Observational
4. All interventional studies EXCLUDING studies using a drug/ device/ or biologic.

Please, DO NOT use this template for:

1. Studies that are using a drug/device/biologic. **Use Drug/Device/Biologic Protocol Template.**
2. Retrospective Chart Reviews. **Use Retrospective Chart Review Protocol Template.**

Instructions

1. Delete all non-applicable sections. Reformat protocol as applicable.
2. Add any additional sections as needed.
3. DELETE ALL GUIDANCE, INSTRUCTIONS AND EXAMPLES PRIOR TO FINALIZING AND SUBMITTING YOUR PROTOCOL DOCUMENT.

Study Personnel

PI: Name, Title

Department,

Contact information

Sub-I(s): Name, Department

Statistical support (if applicable): Name, Title

Protocol Development support (if applicable): Name, Title

Name and information of sponsor:

(if not appliable, have Hackensack Meridian *Health* as the study sponsor)

Abbreviations

Abbreviation	Explanation

If you do not have abbreviations, please delete.

If you do, please make sure they are spelled out the first time you use them and they are also included in this table.

Glossary of Terms-move to end

Glossary	Explanation

Provide definitions here if you have any, or delete.

Summary

Provide a brief overview of the research, including

- Objectives
- Duration
- Research design
- Number and description of participants

1 – Introduction

The introduction should cover the following:

- Why is this topic important
- What do we know (what's been done before)
- What don't we know (gap)
- **What do we want to do**

Each of these points can be covered in a couple of sentences or can each can have a paragraph dedicated to it.

Make sure you conclude the introduction with a couple of sentences (or a paragraph) providing a high lever overview of your proposed study.

2 – Background

2.1. Background/literature review

The background should offer an overview of the available literature.

Please make sure that you discuss the literature that supports YOUR proposed study. You can discuss 1-2 more general reference papers in the beginning but make sure that you focus on similar studies or studies demonstrating a gap.

You might also want to:

- Describe and provide the results of animal studies, laboratory studies and pilot studies done in the USA or elsewhere, and clinical studies conducted abroad.
- Summarize the known and potential risks and benefits, if any, to human subjects.
- If applicable, describe and/or justify the route of administration, dosage, dosage regimen, and treatment period(s). Do not use this template for a study using a drug/device/biologic (see instructions on cover page).

Conclude your background by identifying the gap and explaining in one sentence how you are going to fill it.

Make sure your background is as long as needed. This is not a school project that requires a 10-15 page long literature review. A protocol only needs to include the background to allow the reader/reviewer to familiarize with the area.

Try to avoid a structure where each paragraph summarizes one single study. Summarize and present studies reporting similar findings or studies on similar populations together. Try to be critical and discuss their limitations especially if you are planning to base your study on doing something already done but better! That will give you a good justification of why you are proposing a study.

3 – Rationale, Objectives and Hypothesis

The rationale for the study, the investigator's goals, and/or the hypothesis to be tested should be stated here. Objectives should be broken down by primary and secondary which will then lead to your primary/secondary variables.

3.1. Study Rationale/Problem Statement/Research question or Study significance

Explain in one sentence what the need you intend to cover is.

3.2. Hypothesis (if applicable)

A statement that can be tested with an experiment (usually suggests a relationship). Scientists generally base scientific hypotheses on previous observations that cannot satisfactorily be explained with available scientific theory/ data.

3.3. Primary Objective

The main goal you are trying to achieve. It derives from the research question.

3.4. Primary Outcome Variable(s)

Quantitative measures deriving from the objective(s). Defines the outcomes that the study will measure

3.5. Secondary Objective(s) (if applicable)

3.6. Secondary Outcome Variable(s) (if applicable)

3.7. Exploratory Objective(s) and Exploratory Outcome Variable(s) (if appliable)

4 - Study Design

4.1 General Design

Describe in a sentence or two the general design of the study. Make sure you mention whether this is a retrospective/prospective study and the type of the protocol (e.g. prospective data / sample collection /clinical trial/survey-based).
Please ensure there is a clear distinction between what is taking place as standard of care (SOC) versus what is done for research purposes.

You might also want to:

Include a schematic diagram of the study design, procedures and stages as applicable.
Describe of the measures taken to minimize/avoid bias (randomization, blinding).

4.1.1 Study Duration (if applicable)

Describe how long the study is going to last. Take into consideration the time you will need for the data collection and the time needed for data analysis.

If this is a clinical trial in which patients will be actively involved, make sure you specify the duration for which they will be involved and the time needed to analyze the data collected.

4.1.2 Number of Study Sites

Mention the site(s) that will be involved in this study. Include their name and location.

4.2 Study Population

Describe the patient pool you will choose your participants from and their general characteristics.

4.2.1. Number of Participants

Specify the number of participants that will be recruited for your proposed study.

To avoid repetitions, delete this section if you have already covered this above.

4.2.2. Eligibility Criteria

Inclusion Criteria: All eligibility criteria should be listed. (Medical criteria, age, demonstration of disease, ailment, etc., proof of failure using standard therapy, laboratory assessments for eligibility, etc.).

Exclusion Criteria: Age limits, if applicable; minors, pregnant women, mental incompetents, if applicable; use of other medications concomitantly, if applicable; subjects with other diseases, severity of illness, etc.

4.2.3. Vulnerable populations (if applicable)

4.2.4. Withdrawal criteria (as applicable)

(a) When and how to withdraw subjects from the study

(b) The type and timing of the data to be collected for withdrawn subjects

(c) Whether and how subjects are to be replaced

(d) The follow-up for subjects withdrawn (if applicable)

4.3. Study procedures

All procedures that are STUDY-RELATED have to be described here. Please avoid long explanations of procedures that are standard of care unless it is to explain your research activities. Please make sure there is a clear distinction between what is the standard of care and what is done for research purposes.

If you will conduct genetic or genomic testing as part of your study, please make sure you specify if you will be using targeted analysis or whole exome/genome sequencing and ensure consistency between the protocol and the consent form.

Recruitment, consent and any interventions must be described here. Interventions might include but are not limited to clinical procedures, surveys, interviews, focus groups and educational interventions. Also include plans to return results to participants and/or their

treating physician and explain where lab tests will take place (CLIA vs. non-CLIA certified lab).

4.3.1. Study discontinuation (if applicable)

4.3.2. Concomitant medication (if applicable)

4.4. Risks and Benefits

The PI should explain what benefits might be derived from participation in the study, noting in particular, the benefit over standard treatment (e.g. access to additional follow-up or consultation that would not take place as per SOC).

If there are no direct benefits to participants, the potential benefits to society should be mentioned.

The PI should detail the possible risks to the subject and whether side effects are reversible. Any discomfort should also be carefully noted.

The measures takes to minimize the risks should also be mentioned.

Risks related to breach of confidentiality or data must be described

5 – Methods **(if the study is using a drug/device/biologic, please note that this is NOT the right protocol template)**

All methods that will be used in the study procedures described above have to be explained here. The statistical analysis plan has to be included here, including the timing of any planned interim analysis and the criteria for termination of the trial. In the statistical section you might also need to include procedures for accounting for missing, unused, or spurious data and for reporting deviations from original statistical plan.

If this is a treatment/diagnostic/prevention (non drug/device/biologic) study, the investigator should explain the treatment /diagnosis/prevention plan. Baseline diagnostic tests, initial laboratory assessments for eligibility, any EKGs, physical exams, etc., should be noted. The use of patient diaries should be noted, the number of visits, dose modification or adjustments, and the route of administration of drugs should be included. The PI should indicate if subjects are to be hospitalized for any part of the study.

If this is not a treatment study, the PI should list measures to be used, tests, interviews, videotaping, and the amount of time the patient will be involved in each component of the study. All tools, surveys etc. that are going to be used should be explained here. Also include how they have been created and validated.

The PI should make clear which methodologies are standard clinical care and which are experimental: e.g. if lumbar punctures are to be performed, it should be clear which, if any, would have been performed off study.

Any monitoring should be described. The PI should also discuss reasons for dropping any participant from the study. (Relapse, lack of patient compliance, etc.).

If applicable also include:

- Assessment of efficacy (specification of the efficacy parameters; methods and timing for assessing, recording, and analyzing efficacy parameters).
- Assessment of safety (Specification of safety parameters; the methods and timing for assessing, recording, and analyzing safety parameters; procedures for eliciting reports of and for recording and reporting adverse event and intercurrent illnesses; the type and duration of the follow-up of subjects after adverse events).

5.1. Screening

5.2. Recruitment, enrollment and retention (including screen failures as applicable)

5.3. Study intervention (including schedule of events and study visits)

5.4. Assignment / randomization (if applicable)

5.5. Section of instruments (to include for all studies with a social behavioral intervention)

5.6. Data collection (data points, source and storage)

5.7. Follow-up and end-of study (if applicable)

5.8. Statistical Method

5.8.1. Sample size calculation and justification

5.8.2. Statistical Analysis Plan

Primary Analysis

Secondary Analysis (if applicable)

Exploratory Analysis (if applicable)

Interim Analysis (if applicable)

6 - Trial Administration

The sections below (or some of the sections) might not be necessary depending on the study type and/or study design. Please delete if not applicable.

6.1. Ethical Considerations - Institutional Review Board (IRB) Review

Sample language: The study will be conducted according to the International Conference on Harmonization (ICH), Good Clinical Practice (GCP), the Declaration of Helsinki, Institutional Review Boards (IRB) and in accordance with the U.S. Code of Federal Regulations on Protection of Human Rights (21 CFR 50).

6.2. Institutional Review Board (IRB) Review (list the IRB of record)

Sample language: The final study (ICF, HIPAA form as applicable) and data collection tools will be approved by the Institutional Review Board (IRB) at HMH. Approval will be received in writing before study initiation.

Any changes to the study design will be formally documented in amendments and be approved by the IRB prior to implementation.

6.3. Data management (collection, storage etc.)

6.4. Confidentiality

The investigator should explain how patient confidentiality will be preserved, how data will be kept confidential and used for professional purposes, whether charts will be coded, kept in locked files, etc.

All protocols require one of the following:

1. A HIPAA Authorization (as part of the informed consent form)
2. A Request to Waive Authorization
3. A Data Use agreement (for use with limited data sets)

Sample language (for coded data): Patient charts, collected data, and analyses of the data will adhere to HIPAA & institutional patient confidentiality requirements. A unique identifier (study ID number) will be assigned to each patient. The study ID number will be included in the data collection tools and analysis software while the list with direct identifiers and ID numbers will be stored separately in a HMH password protected computer and/or locked office.

If results of the study are published, individual names or other identifying information will not be used.

6.5. Informed consent

6.6. Data Quality Assurance (if applicable)

Describe the quality control and assurance for the conduct of the study to ensure that Good Clinical Practice is followed. Any steps that will be implemented as part of the study to ensure standardization of the collection of accurate, consistent, complete and reliable data, such as training sessions, monitoring of investigator sites, instruction manuals, use of central laboratory or reading center should be included.

6.7. Study Records (retention etc.)

Sample language: Records will be retained in accordance with regulatory and organizational requirements, but for no less than six (6) years following the completion of the study. Disposal of records will be performed according to regulations.

6.8. Credentials, Training

Any training (observation of a new surgical technique, etc.) should be addressed. Any additional investigators should be mentioned specifically.

6.9. Financing and Insurance (if applicable)

6.10. Publication Plan (if applicable)

Appendices

Appendix #	Name	Title	Section	Topic

If data collection takes place as part of the study, a complete list with all datapoints to be collected needs to be included here or be uploaded as a separate attachment during IRB submission.

If applicable, the data collection sheet can also be included here.

If identifiers are collected, all those datapoints need to be marked as PHI and either included in a separate list or marked differently in the overall list.

Delete if not applicable.

List of Tables

Delete if not applicable.