

***This is a guide only for an *investigator-initiated* protocol.
Not all components will be applicable to your study.**

Insert Title of Protocol

The title must be descriptive and concise.

- Principal Investigator:** Insert full name of investigator and degree(s) leads the study and makes a major contribution)
- Co-Investigators:** List in order of importance to the study
- Research Site(s):** Insert name of site(s) where research will be conducted
- Institution:** Insert name of institution the author(s) represent, if applicable
- Funding Sponsor:** Insert name, address and phone number of funding sponsor, if applicable

CONFIDENTIALITY STATEMENT

This document is confidential and to be distributed for review only to investigators, potential investigators, consultants, study staff, and the applicable independent ethics committees or institutional review boards. The contents of this document shall not be disclosed to others without written authorization from the **institution or individual** unless it is necessary to obtain informed consent from potential study participants.

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Introduction

The introduction should open with remarks that state this document is a clinical research protocol and the described study will be conducted in compliance with the protocol and Good Clinical Practice standards and associated federal regulations (FDA Title 21 part 312).

Remaining paragraphs in this section should contain an introductory explanation of the study.

Study Objectives

Describe the specific aims for the study.

This should include both primary and any secondary objectives, as illustrated:

Primary Objective

Example: To assess the efficacy of XXXX on decreasing size.

Secondary Objective

Example: To assess the safety and tolerability of two doses of XXXX.

Study Design

General Design

Describe the study design of the study (e.g. case series, case-control, retrospective, etc.)

Primary Outcome Variable

Describe the primary outcome variable to be analyzed in the study.

Secondary Outcome Variables

Describe any secondary outcome variables to be analyzed in the study.

Subject Selection and Withdrawal

Inclusion Criteria

Create a list of criteria subjects must meet to be eligible for study inclusion.

Exclusion Criteria

Create a list of criteria that would exclude a subject from the study.

Subject Recruitment and Screening

Describe how subjects will be recruited for the study (e.g. from investigator or sub-investigator clinical practice(s), referring physicians, advertisement(s), etc.) Specify any advertising for recruitment in the Attachments section of this protocol. Note: any advertisements, hand-outs, posters, etc. for this site must be approved by the University of South Alabama's IRB before implementing their use.

Also include in this section any screening requirements such as laboratory or diagnostic testing necessary to meet any noted inclusion or exclusion criteria. Greater detail can be included in the Study Procedures section of this protocol.

Early Withdrawal of Subjects

Describe scenarios under which a subject may withdraw or be withdrawn from the study prior to completion (e.g. safety reasons, failure of subject to adhere to protocol, subject's request to withdraw, etc.).

Statistical Plan

Sample Size Determination

Describe how the sample size was determined for this study. The sample size should be based upon the primary outcome variable. If the authors have determined that a sample size estimation was not necessary, please provide rationale.

Statistical Methods

Describe how the data will be summarized (ie, medians and ranges, percentages with 95% confidence intervals, etc). Identify the statistical test for the analysis of the primary outcome variable. Define the tests for the analysis of the secondary outcome variables. Set the level of significance, ie, significance will be assessed at $p < 0.05$. If no statistical tests are planned, denote that only summary/descriptive statistics will be used.

Study Procedures

Describe what data will be accessed and how it will be obtained. Identify all variables that will be extracted. All variables should be listed on your data sheet. Identify the time period for the charts to be reviewed.

Risks & Benefits

Discuss why the risks to subjects, if any, are reasonable in relation to the anticipated benefits and/or knowledge that might reasonably be expected from the results.

Data & Safety Monitoring Plan

Include a written plan of the measures that will be taken to ensure the safety of clinical research subjects and protect the validity and integrity of research data.

Adverse Events/Serious Adverse Events/Unanticipated Problems Include an explanation of how adverse events, serious adverse events and unanticipated problems will be recorded, maintained and reported. *REQUIRED*

Data Handling and Record Keeping

Confidentiality

Include a statement that advises information about study subjects will be kept confidential and managed according to the requirements of HIPAA (Health Insurance Portability and Accountability Act of 1996). Explain who will have access to the collected data and why, and who will use or disclose any information.

Records Storage and Retention

Describe how and where data (both hard copy and electronic) will be stored.

Regulatory Binder

A statement should be made that a regulatory binder will be kept containing all information pertinent to the study for a period of no less than 7 years. This will include items such as this protocol, the letter or approval from the IRB, the Waiver of Authorization form, and all other information pertinent to the study.

Study Monitoring, Auditing and Inspecting

A statement must be included that states the investigator will permit study-related monitoring, audits and inspections by University of South Alabama IRB, the sponsor and government regulatory bodies of all study related documents.

Participation as an investigator in this study implies acceptance of potential inspection by government regulatory authorities and applicable University of South Alabama compliance and quality assurance offices.

Budget

Include a brief summary of estimated expenses for this study. Include the projected funding source, if applicable.

Publication Plan

Describe your plan for publication.

Include the following text verbatim for all retrospective protocols:

Findings will be shared and discussed with all of the investigators for the study. An estimated timeline for creation of an abstract will be defined at that time. An abstract of the completed study, after input from all the authors, will be submitted to (meeting of choice, date of meeting). A manuscript of the study, having received input from all of the authors, is tentatively scheduled for submission on (*insert date*).

References

Identify any literature cited for any information referenced in the protocol. Organize this information like that found in a medical journal.

Attachments

Identify all pertinent documents associated with the management of this study (e.g. waiver of informed consent, data sheet, etc).