**RESEARCH PROTOCOL TEMPLATE**

**[Sponsor Name]**

**CLINICAL RESEARCH PROTOCOL**

**[PROTOCOL NAME]**

|  |  |  |  |
| --- | --- | --- | --- |
| PROTOCOL NO. |  | VERSION NO. |  |
| IND NO. |  | DATE |  |
| INVESTIGATIONAL PRODUCT NAME |  |
| TRIAL PHASE |  |
| SPONSOR(S),NAME AND ADDRESS |  |
| FUNDING ORGANIZATION |  |
| PRINCIPAL INVESTIGATORname and contact information |   |
| MEDICAL MONITORname and contact information |  |
| COORDINATING CENTER(if applicable) |  |

**APPROVED BY:**

|  |  |
| --- | --- |
|  |  |
| *Principle Investigator or Sponsor Signature and Title*  | *Date* |

|  |
| --- |
|  |
| *SITE* |

# PROTOCOL AGREEMENT

I have read and understand the protocol below. In my capacity as Investigator, my duties include making sure of the safety of the study participants enrolled by supervising them and providing [PI OR SPONSOR NAME] with complete and timely information. This information will be provided as outlined in this study protocol. All the information relating to this study will be held in strict confidence and these confidentiality requirements apply to all staff at this study site or involved with this study. I agree to maintain the procedures required to perform this study in accordance with Good Clinical Practice principles and to abide by the terms of this protocol.

|  |  |  |  |
| --- | --- | --- | --- |
| PROTOCOL NO. |  | PROTOCOL DATE |  |
| PROTOCOL TITLE |  |

|  |  |
| --- | --- |
|  |  |
| *Investigator Signature*  | *Date* |

|  |
| --- |
|  |
| *Name and Title (Print)* |

####

|  |  |
| --- | --- |
| CONTACT INFORMATION |  |

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Table of Contents

[PROTOCOL AGREEMENT 2](#_Toc8636736)

[PROTOCOL SYNOPSIS 3](#_Toc8636737)

[1. STUDY TEAM AND SITE(S) 3](#_Toc8636738)

[2. STUDY OBJECTIVES 3](#_Toc8636739)

[PRIMARY OBJECTIVE 3](#_Toc8636740)

[SECONDARY OBJECTIVE(S) 3](#_Toc8636741)

[3. BACKGROUND 3](#_Toc8636742)

[4. STUDY DESIGN 3](#_Toc8636743)

[5. SUBJECT INCLUSION AND EXCLUSION CRITERIA 3](#_Toc8636744)

[6. STUDY ENROLLMENT PROCEDURES 3](#_Toc8636745)

[7. STUDY INTERVENTION, DURATION, AND ROUTE OF ADMINISTRATION 3](#_Toc8636746)

[8. STUDY PROCEDURES 3](#_Toc8636747)

[STUDY EVALUATION SCHEDULE 3](#_Toc8636748)

[SCHEDULE EXPLANATIONS 3](#_Toc8636749)

[9. SAFETY ASSESSMENT 3](#_Toc8636750)

[10. INTERVENTION DISCONTINUATION 3](#_Toc8636751)

[11. STATISTICAL AND ANALYTICAL CONSIDERATIONS 3](#_Toc8636752)

[12. DATA COLLECTION 3](#_Toc8636753)

[13. QUALITY ASSURANCE 3](#_Toc8636754)

[14. PARTICIPANTS RIGHTS 3](#_Toc8636755)

[15. COMMITTEES 3](#_Toc8636756)

[16. PUBLICATION 3](#_Toc8636757)

[17. REFERENCES 3](#_Toc8636758)

[18. SUPPLEMENTS / APPENDICES 3](#_Toc8636759)

# PROTOCOL SYNOPSIS

Fill in a brief summary in each category

|  |  |
| --- | --- |
| PROJECT TITLE |  |
| SPONSOR(S) |  |
| FUNDING ORGANIZATION |  |
| NUMBER OF SITE |  |
| RATIONALE |  |
| STUDY DESIGN |  |
| PRIMARY OBJECTIVE |  |
| SECONDARY OBJECTIVE(S) |  |
| NUMBER OF SUBJECTS |  |
| SUBJECT SELECTION CRITERIA |  |
| PRODUCT, DOSE, AND ROUTE OF ADMINISTRATION |  |
| (CONTROL) PRODUCT, DOSE, AND ROUTE OF ADMINISTRATION |  |
| DURATION OF SUBJECT PARTICIPATION AND STUDY DURATION |
| SCREENING |  |
| TREATMENT |  |
| FOLLOW-UP |  |

# Study Team and Site(s)

*List study team and participating sites for this study. Include contact information for the study duration.*

# Study Objectives

## Primary Objective

*List the primary study objective, including the hypothesis in measurable language.*

## Secondary Objective(s)

*Secondary objectives may include non-experimental objectives and be related to a hypothesis.*

# Background

Describe the study problem and priority. Include the medical and scientific rationale that justifies studying the problem. Include any data from other studies relevant to this intervention proposal. Include the name and description of the proposed intervention, including the dosage, route of administration, period, and frequency of intervention.

# Study Design

Describe the study design and how it will answer the study question. This should include the type of study, primary and secondary outcome(s), population, sample size, study location, period of enrollment and follow-up, intervention and route of administration, randomization (as necessary), and any other relevant protocol information.

# Subject Inclusion and Exclusion Criteria

Provide statements describing how the participants must meet all the inclusion and exclusion criteria to participate in this study and list the criteria. The study population should be clearly defined. For example, list the demographic criteria, required laboratory data, any prior therapies allowed or disallowed, ability to understand and meet all study requirements, if contraception is necessary, exclusion criteria, such as specific health status, use of excluded drugs, cancer status, and chemical dependency status.

# Study Enrollment Procedures

Describe the methods and procedures for identifying and enrolling subjects, how they are documented, how consent is obtained, and any randomization procedures.

# Study Intervention, Duration, and Route of Administration

This section should describe each intervention, duration, and how each is administered. Any adverse effects expected are listed here, and dose escalation, if applicable. How the intervention is acquired, stored, and disposed of should be discussed. Documentation for intervention accountability should also be discussed. Other medications restricted, allowed, and required are discussed. The extent to which these medications are complied with are all discussed in this section.

# Study Procedures

## Study Evaluation Schedule

*A chart is recommended for the management of assessments required and the periods of evaluation. Adjust and fill the chart in as needed. Examples of required evaluations and suggested periods are started for you.*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| ASSESSMENT | SCREENING APPT | VISIT 1 | VISIT 2 | VISIT 3 | VISIT 4 | FINAL VISIT |
| Informed Consent | **X** |  |  |  |  |  |
| Demographics | **X** |  |  |  |  |  |
| Medical History | **X** |  |  |  |  |  |
| General Physical Exam | **X** |  |  |  |  |  |
| Treatment Administration Form |  | **X** |  |  |  |  |
| Adverse Events Form |  | **X** | **X** | **X** | **X** | **X** |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

## Schedule Explanations

This section may be used to explain the required assessments, what each period is, and any special considerations or instructions necessary. These should match what is available in the column headers of the chart above. These should include information on the screening or baseline assessments, randomization, blinding, follow-up visits, and final assessments.

# Safety Assessment

This section should list any expected adverse events, and how these could be managed. Any toxicities seen in earlier IND studies should be mentioned here. Also, in this section should be listed safety measures, as identified in laboratory findings, methods and timing for safety parameters based on the risk profile, definitions for adverse events (AE) and serious adverse events (SAE) and laboratory values used to identify their possibility, time frames for reporting and collecting information on AEs and SAEs, the reporting system, how AEs will be followed up on, and what the specific guidelines for independent monitoring are.

# Intervention Discontinuation

This section will list criteria for intervention discontinuation and how these criteria could be met. Also listed should be possible reasons for discontinuation, any modifications to the schedule should it be discontinued, duration of follow-up, any temporary discontinuation criteria, any evaluations should participants be temporarily or permanently discontinued from the study.

# Statistical and Analytical Considerations

This section should include primary and secondary statistical hypotheses, why the study design was chosen, the primary and secondary outcome measures, and the validity and reliability of these measures. Also discussed should be sample size and randomization, treatment assignment procedures, how the population is defined, any interim analyses, primary and secondary outcome analyses, the statistical methods used to consider any necessary intervention effect between groups, and if necessary, the expected positive within group correlations among different study arms.

# Data Collection

This section details the data collection: how the data will be collected, the required forms, how these forms will be kept confidential, and what source data is expected. Site responsibility for data collection and management will be detailed, as well as (if necessary) the responsibilities of the coordinating center.

# Quality Assurance

Training for study staff will be detailed in this section, whether there is a control committee and their required practices, any quality control metrics, how protocol deviations will be identified and documented, how protocol compliance will be assured, and the schedule for reviews. If there is a manual of procedures (MOP), it may be referenced here.

# Participants Rights

Included in this section should be references to the Institutional Review Board (IRB) requirements, informed consent documents, procedures for participant confidentiality, and study discontinuation requirements.

# Committees

Any committees associated with the study should be listed here along with their role in the study.

# Publication

The requirements and procedures for publication should be outlined here.

# References

Any citations referenced in this protocol should be listed here.

# Supplements / Appendices

Any additional documentation or appendices should be included here.

|  |
| --- |
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