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| Investigator-Sponsored Studies |
| Protocol Template |
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| Instructions:   * The purpose of this document is to provide a structure or general guideline to help you create a protocol for consideration. The following template is to be used as you see fit and is only a template to help guide protocol development. * If you choose to use portions or the entire template, please remove any guiding language highlighted in grey before submission. * It is not mandated to use any of this document. |
| Credit: NIH/FDA Protocol Template Version 1.0 – 04/07/17 |

Full Study Title:

Short Study Title:

|  |  |
| --- | --- |
|  | |
| Sponsor-Investigator: | Name:  Telephone:  Fax:  E-mail:  Address: |
| Institute: |  |
| Co-Investigators: | *[If applicable]* |
| Coordinating Center/s: | *[If applicable]* |
| Date and Version |  |

**Abstract:**

*[Provide a brief paragraph summary of the study background, aims and design.]*

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# Introduction

## Background

[*Provide a summary of relevant non-clinical or clinical data that have potential clinical significance]*

## Rationale

*[Provide a brief justification for the proposed study (e.g., describe the patient population and disease/condition, current standard of care if one exists, and limitations of knowledge or available therapy. NOTE: Please include details related to gender, race, and/or ethnicity when describing the patient population affected by the disease/condition of interest.)]*

## Risk-Benefit Rationale

### Potential Benefits

*[Provide any potential benefits that could come from the study]*

### Potential Risks

*[Provide any potential sources of potential risk from the study]*

# Study Purpose & Design

## Objectives

*[State any primary, secondary, safety, and/or exploratory objectives here]*

## Study Design

*[Describe the overall study design e.g., double-blind, placebo-controlled, parallel design, open labelled. Give the expected duration of participant participation, number of visits, and a description of the sequence and duration of all trial periods e.g. screening period, interventional period, post treatment follow-up periods. Recommend a visual representation, refer to examples within the appendices.]*

## Endpoints

*[Define all endpoints related to each objective you have outlined]*

### Primary Endpoints

### Secondary Endpoints

## Eligibility

*[Please include a brief description of how the eligibility criteria will facilitate (or will not hinder) recruitment of a study population that accurately reflects the patient population typically affected by the disease/condition being studied with regard to gender, race, and/or ethnicity.]*

### Inclusion

*[Provide all inclusion criteria]*

### Exclusion

*[Provide all exclusion criteria]*

## Participation Selection

### Study Sites and Number of Participants

*[State enrollment targets and anticipated number of active study sites. Detailed statistical method used to identify sample size should be stated in the “Statistical Methods” section]*

### Participant Recruitment

*[State any recruitment methods to be used throughout the study]*

### Participant Screening

*[State what method will be used to screen potential participants. Please define screen failures in the context of this study]*

### Participant Enrollment

*[Define when a participant is officially considered enrolled in the study.]*

## Informed Consent

*[Briefly define informed consent procedures that will be followed.]*

# Procedures

## Study Flowchart

*[Provide a flowchart of how the study will be conducted. This should include any randomization/assignment to arms and all innervational and data collection time points. Please refer to the Example#1 in the appendix]*

## Baseline Visit

*[Describe all Baseline Visit procedures.]*

### Allocation, Randomization, Blinding

*[Define procedures for arm allocation, randomization method, and blinding procedures, if applicable.]*

## Treatment Procedure

*[Describe the study treatment procedures and any investigational devices involved.]*

## Follow-up Visit

*[Describe all Follow-up Visit procedures. Time points with specific time windows for visit or data collection should be defined.]*

## End of Study

*[Define what criteria is needed for the study to be considered as “Ended”. An example of study end can be “when participants are no longer being examined or the last participant’s last study visit has occurred.]*

## Data Collection

### Baseline Data

*[Define all data that will be collected at the Baseline Visits.]*

### Treatment Procedure Data

*[Define all data that will be collected at during the Treatment Procedure.]*

### Follow-up Data

*[Define all data that will be collected at follow-up visits.]*

## Table of Data Collection and Procedures

*[A comprehensive table depicting the timeline of the study and data points collected at each timepoint should be provided. Refer to Example#2 in the appendix for reference]*

## Participant Withdrawal

*[Describe how participant withdrawal will be managed and documented. State if withdrawal from the study will result in exclusion of the data for that participant from analysis.]*

## Criteria for Discontinuation, Unblinding & Termination

*[Define criteria for discontinuation or unblinding of subjects. State if discontinuation from the study will result in exclusion of the data for that participant from analysis. Identify any outcomes that may lead to study termination.]*

# Data Management

## Data Management

### Data Platform & Entry

*[Include any data platforms that maybe used and if they are compliant for clinical trial use. Briefly describe how data will be documented on said platform.]*

### Maintenance of Study Documents

*[Provide any details on source documents retention and expected timelines for storage.]*

## Participant Confidentiality

*[Describe procedures used to protect the privacy of participants and maintain confidentiality of data collected.]*

## Availability and Retention of Biological Specimens

*[Provide any relevant procedures if establishing a repository for sharing specimens with other researchers or institutes. If applicable, identify who these may be and the timeline this would take place in. This includes contributing de-identified specimens to an existing repository]*

# Statistical Methods

## General Statistical Considerations

*[Describe the statistical methods to be employed for the analyses of all endpoints as they correlate to their respective objectives.]*

## Hypothesis

*[Outline your hypothesis for all objectives stated. If proposing a feasibility/safety study, state what hypothesis could be generated from this study, if any.]*

## Sample Size and Randomization

*[Describe the statistical methods used to determine population target size. Provide justification of sample size, including powering method and any relevant clinical justifications.]*

## Interim Analysis

*[Describe the statistical methods and justification for the interim analyses of any endpoints, as well as timing of planned or unplanned interim analyses.]*

## Methods to Account for Non-Adherence/Missing Data

*[Describe the statistical methods to be employed in the scenario of participant non-adherence or missing datapoints.]*

# Adverse Event & Device Deficiencies

## Adverse Events (AEs)

*[Provide the definition of an AE and how AEs will be documented and duration of follow-up.]*

## Serious Adverse Events (SAEs)

*[Provide the definition of an SAE and how SAEs will be documented, reported, reporting timeframes and duration of follow-up.]*

## Unanticipated Serious Adverse Device Effects (USADEs)

*[Provide the definition of a USADE and how USADEs will be documented, reported, reporting timeframes and duration of follow-up.]*

## Device or Procedure Relatedness

### Device-Relatedness

*[Provide the definition of Device-Relatedness.]*

### Procedure-Relatedness

*[Provide the definition of Procedure-Relatedness.]*

### Relatedness Assessment Criteria

*[Provide Relatedness definitions (e.g. definite, probable, possible, remote (unlikely), not related, or unknown).]*

### Adverse Event Severity

*[Provide Severity definitions (e.g. mild, moderate, or severe).]*

## Device Failures, Malfunctions, & Misuse

*[Provide the definition of any failures, malfunction or misuse related to the device being deployed during this study.]*

# Protocol Compliance

## Institutional Review Boards and Independent Ethics Committees

*[Briefly detail all applicable regulatory oversight entities needed for the approval of the conduct of this study. (e.g. IRB, FDA, Ethics committee)]*

## Protocol Deviations

*[Provide plans for detecting, reviewing, and reporting deviations from the protocol.]*

# Monitoring

## Monitoring

*[Detail monitoring activities for the study to verify the quality of the data, conduct of the trial and compliance with all applicable regulations. Consider any modifications required for COVID-19.]*

# Outsourcing of Duties & Functions

## Contract Research Organizations (CROs)

*[If applicable, mention any CROs that will be used and the role and responsibilities they will have in the study.]*

# Study Committees

*[Detail any study committees. Outline roles and responsibilities. Common committees are listed below. Note, not all of these committees are required, and committee type will depend on the type of study. Consult with your regulatory board if there are questions about which oversight is appropriate.]*

## Steering Committee

## Independent Medical Monitor (IMM)

## Clinical Events Committee (CEC)

## Data Safety Monitoring Board (DSMB)

# Publication Policy

*[Plans to make dataset partially or fully available to any entity. Indicate anticipated Journals/Conferences/Forums etc. of interest for publication.]*

# References

# Appendices

## Protocol Revision History

*[Track major updates to the protocol if the protocol is amended.]*

## Study-Specific Adverse Event Definitions

*[List and define all study-specific Adverse Events.]*

***Example #1 Flow diagram*** *(e.g., randomized controlled trial) (Credit: NIH/FDA Clinical Protocol Template)*

Prior to

Total N: Obtain informed consent. Screen potential participants by inclusion and exclusion criteria; obtain history, document.

Enrollment

Randomize

Perform baseline assessments.

list specimens to be collected, examinations or imaging or laboratory assays to be performed, questionnaires to be completed

Administer initial study intervention.

Visit 1

Time Point

Repeat study intervention (*if applicable*).

Visit 2

Time Point

Follow-up assessments of study endpoints and safety

list specimens to be collected, examinations or imaging or laboratory assays to be performed, questionnaires to be completed

Visit 3

Time Point

Follow-up assessments of study endpoints and safety

list specimens to be collected, examinations or imaging or laboratory assays to be performed, questionnaires to be completed

Visit 4

Time Point

**Final Assessments**

List analyses to be performed

Visit X

Time Point

***Example #2 Table of Procedures and Data Capture***

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Assessment** | **Screening & Enrollment** | **Baseline** | **Pre-op** | **Intra-op** | **Post-Op** | | | **Follow-Up** |
|  |  |  |  | ***Day 0*** | ***Day 1*** | ***Day 2*** | ***Day 3*** | ***Day 30***  ***(+/- 5 Days)*** |
| Informed Consent | **X** |  |  |  |  |  |  |  |
| Inclusion/Exclusion Criteria | **X** |  |  |  |  |  |  |  |
| Demographics | **X** |  |  |  |  |  |  | **X** |
| Medical History | **X** |  |  |  |  |  |  |  |
| Physical Examination | **X** | **X** | **X** |  |  |  | **X** | **X** |
| Current Medications | **X** | **X** |  |  |  |  |  |  |
| Laboratory | **X** | **X** | **X** |  |  | **X** |  | **X** |
| Urine Analysis | **X** | **X** | **X** |  |  | **X** |  | **X** |
| Randomization |  | **X** |  |  |  |  |  |  |
| Adverse Event Assessment |  |  | **X** | **X** | **X** | **X** | **X** | **X** |

**Summary of Changes from Previous Version:**

|  |  |  |
| --- | --- | --- |
| **Affected Section(s)** | **Summary of Revisions Made** | **Rationale** |
|  |  |  |
|  |  |  |