SBS-rec PROTOCOL TEMPLATE FOR CLINICAL TRIALS

<<STUDY title>>

The title should include:

Please insert the title of the clinical trial describing the essential aspects of the study design

List of investigators and co-investigators:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Name | Role | Institution of Affiliation | Email address | Telephone |
|  |  |  |  |  |
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PROTOCOL SIGNATURE PAGE

*The PI must provide a declaration statement, his/ her signature, and date (next page)*

PROTOCOL SUMMARY

|  |  |
| --- | --- |
| Background  |  |
| Rationale |  |
| Objectives  |  |
| Endpoints |  |
| Study Design |  |
| Study setting |  |
| *Study population* |  |
| Analysis plan |  |

**LIST OF ABBREVIATIONS** << please insert this on a separate page>>

**LIST OF FIGURES AND TABLES** <<If applicable, please insert this on a separate page>>

**TABLE OF CONTENT** <<please insert this on a separate page>>

# OPERATIONAL Definitions of Terms <<please insert this on a separate page>>

1. INTRODUCTION

## Background

## Relevant literature

## Problem statement

## Rationale and significance

## Study Hypothesis*/ Research* question

# Objectives and Endpoints

**2.1 Objectives**

**2.2 Endpoints**

**3.0 METHODOLOGY**

# STUDY DESIGN

# Study SETTING

**3.3. STUDY POPULATION**

# Participant sampling technique

* 1. SAMPLE SIZE DETERMINATION

## ELIGIBILITY CRITERIA

### 3.6. Inclusion Criteria

* + 1. **Exclusion Criteria**
	1. **Study procedures**

## Drug/ Device Supplies

### 3.8.1 Administration

### Drug/ Device Storage and Drug/ Device Accountability

## Concomitant Medication(s)

## Study Period

*Describe the proposed study period including the duration of the study. It may be useful to separate this out by days and cycles. Describe if there is an allowable window for any assessments (e.g. “may be performed/collected +/- 3 days”). Note, in such cases the CSR and the data base must be designed to incorporate these windows so as not to result in a query, flag violation.*

*A schematic or a checklist may be considered. An example is given below. Additional columns and rows may be added.*

| **Protocol Activity** | Screen | Day x | Day x | Day x | Day x | Day x | Day x | Day x | Day x | End of Treatment |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Informed Consent |  |  |  |  |  |  |  |  |  |  |
| General Medical History and Physical Examination |  |  |  |  |  |  |  |  |  |  |
| Weight |  |  |  |  |  |  |  |  |  |  |
| Laboratory |  |  |  |  |  |  |  |  |  |  |
|  Hematology |  |  |  |  |  |  |  |  |  |  |
|  Blood Chemistry |  |  |  |  |  |  |  |  |  |  |
|  Urinalysis |  |  |  |  |  |  |  |  |  |  |
|  Coagulation |  |  |  |  |  |  |  |  |  |  |
|  Pregnancy test a |  |  |  |  |  |  |  |  |  |  |
| Registration/Randomization |  |  |  |  |  |  |  |  |  |  |
| Study Treatment |  |  |  |  |  |  |  |  |  |  |
| Assessments |  |  |  |  |  |  |  |  |  |  |
|  Efficacy  |  |  |  |  |  |  |  |  |  |  |
|  Safety |  |  |  |  |  |  |  |  |  |  |

## Follow-up Visit

## Participant Withdrawal

# ASSESSMENTS

## Safety

## Pregnancy Testing

## Pharmacokinetics Assessments (if applicable)

### Blood for PK analysis of <drug(s)>

**5. SAMPLE PROCESSING, TRANSPORTATION AND STORAGE**

###  Shipment of human biological specimen (if applicable)

*Whenever feasible, samples should remain in Uganda for analysis. However, if samples are to be shipped outside Uganda for analysis include a justification. Please mention here where the samples will be shipped to, include a justification and also mention that a MTA has been developed and will be approved by the REC & UNCST prior to shipment of samples. In addition, provide a monitoring/ tracking plan for the shipped samples.*

*Sample transfer and analysis will be governed by a material transfer agreement which will be signed between both parties. At the end of the analysis, unused samples will be discarded.*

# ADVERSE EVENT REPORTING

## Adverse Events

## Serious Adverse Events

## Severity Assessment

## Causality Assessment

## Reporting Requirements

## Post-Recruitment Illness

# DATA ANALYSIS/STATISTICAL METHODS

## Analysis of Endpoints

*A description of how the endpoints will be analyzed, summarized and presented should be provided.*

### Analysis of Primary Endpoint

## Safety Analysis

## Data Safety and Monitoring Committee

# QUALITY CONTROL AND QUALITY ASSURANCE

# DATA HANDLING/Record retention

## Case Report Forms (CRF)/Electronic Data Record

A CRF is required and should be completed for each included participant.

## Record Retention

## Confidentiality

# ETHICal considerations

## Research Ethics Committee (REC)

This trial will be reviewed and approved by the School of Biomedical Sciences Research Ethics Committee (SBS-REC). It is the responsibility of the investigator to have prospective approval of the study protocol, protocol amendments, informed consent documents, and other relevant documents from the SBS-REC. All correspondence with the SBS-REC should be retained in the regulatory or trial master file. Copies of REC approvals shall be filed with other study documents.

## Ethical Conduct of the Study

## Participant Information and Consent

# DISSEMINATION OF STUDY FINDINGS

# Capacity Building

# Funding

# REFERENCES

**LIST OF APPENDICES**

* Risk mitigation plan for current and future pandemics
* Community Engagement plan
* Clinical trial insurance for research participants
* Investigator Brochure
* Plan for destruction of study drug