SBS-rec PROTOCOL TEMPLATE FOR Non-CLINICAL TRIALS

<<STUDY title>>

List of investigators and co-investigators:

*<<please provide the following details>>*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Name | Role | Institution of Affiliation | Email address | Telephone |
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*<<Insert the name of the funding organization/ company>>*

PROTOCOL SIGNATURE PAGE

PROTOCOL SUMMARY << please insert this on a separate page>>

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

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

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# INTRODUCTION

## Background

## Relevant literature

## Problem statement.

## Rationale and significance

## Study Hypothesis*/ Research* question

***For academic proposals, researchers shall include chapter two as literature review.***

# STUDY OBJECTIVES AND OUTCOMES

## Objectives

## Outcomes

**METHODOLOGY**

# STUDY DESIGN

# SETTING

# STUDY POPULATION

# PARTICIPANT SAMPLING TECHNIQUE

# Sample Size Determination

# Eligibility criteria

## Inclusion Criteria

**3.6.2 Exclusion Criteria**

## 3.7 Study tools/ instruments

## 3.8 Study procedures

# 3.9 Data analysis/statistical methods

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**3.10 Data handling/Record retention**

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

## Record Retention

# 3.11 Ethical considerations

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# 3.13 Capacity building

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# REFERENCES

**LIST OF APPENDICES**

* Risk mitigation plan for current and future pandemics
* Community Engagement plan