DSMB Report for Project Name

# 1 DSMB Plan

Preparation Date: 2020-11-09

# 2 Design Summary

## 2.1 Study Abstract

## 2.2 Primary Hypothesis

## 2.3 Primary and Secondary Aims

## 2.4 Inclusion and Exclusion Criteria

## 2.5 Intervention Group

## 2.6 Primary and Secondary Outcomes

## 2.7 Target Sample Size and Allocation

## 2.8 Data Collection Schedule

## 2.9 Timeline

# 3 Overall Study Status - Narrative

## 3.1 DSMB Meeting Minutes

## 3.2 Action Items and Response

## 3.3 Study Status and Chronolog since Previous Meeting

## 3.4 Challenges since Last Report and Steps to Handle Them

# 4 Recruitment and Participant Status

*Insert figure with participant flow chart*

# 5 Enrollment and Randomization

## 5.1 Current Enrollment and Randomization Numbers

*Insert figure with randomization actual vs expected*

*Insert table with screening, enrollment, randomization and withdrawal numbers*

*Insert table with counts of reasons for ineligibility among the consented*

## 5.2 Barriers to Meeting Recruitment Goals

## 5.3 Strategies in Place or Planned to Address Recruitment Shortfalls

# 6 Baseline Characteristics

*Insert table with demographic summary statistics of randomized participants*

# 7 Study Withdrawal

*Table with counts of reasons for study withdrawal*

*Table with date, time point and details for individal withdrawals*

# 8 Study Visit Completion and Data Recorded

*insert graph showing missing visits*

*insert table of visit completion status by site*

# 9 Protocol Deviations

*insert table of protocol deviations*

# 10 Safety Data

## 10.1 Serious Adverse Events

*insert table of serious adverse events by body system*

*insert table of serious adverse event descriptions*

## 10.2 Non-Serious Adverse Events

*insert table of non-serious adverse events by body system*

## 10.3 Unanticipated Problems

*insert table of unanticipated problems*

# 11 Any Other Pertinent Issues