**MANUSCRIPT ANALYSIS PLAN**

**Manuscript title:**  [Manuscript Title]

**Lead manuscript author:**  [Author/PI]

**Statistician(s):** [Lead and faculty statisticians]

**Senior ma**nus**cript author:**  [Author/PI]

**Last updated on:** January 11, 2017

# Study design **overview**

## Study design:

[Summarize both main study design and any additional design elements related to this manuscript.]

## Research objectives and hypotheses:

[Provide numbered list of research objectives and related hypotheses: e.g.,
 Objective 1:
 Objective 2:
 …]

## Population definition:

[Describe the population specific to this manuscript. In many cases, it may also be helpful to summarize the main study population.]

# Variables and definitions

## Outcomes:

### Primary outcome(s):

[Primary outcome(s) with definitions]

### Secondary outcome(s):

[Secondary outcome(s) with definitions]

### Descriptive outcome(s):

[Additional outcomes to include for descriptive purposes with definitions]

## Other variables:

[Define all other variables that will be utilized in analyses for this manuscript. Definitions are based on original data sources, using terms familiar to the investigators. Provide enough detail for the investigators to be able to understand and critically evaluate. Definitions should include the time point or timeframe, especially when the data element is available from multiple sources (e.g., hospital discharge, earliest prior to randomization, max value during hospital admission). Question wording and form names may be used to identify the source of a variable. Include definitions for study time points referenced in the MAP (e.g., Baseline, Day 1, Visit 0). This section should be organized with labels such as demographics, baseline characteristics, etc. This section may reference mock tables directly if variable details are included there.]

# Data summary and analysis plan

[Detail planned analyses for each objective/hypothesis with specifics as to statistical tests/methods, assumptions to be examined, and alternative approaches, if needed. Describe the planned analyses in enough detail that another statistician could perform the analysis without making ad hoc determinations. Statistical references and example code should be included for any non-standard analyses.]

# References

[Provide numbered lists of any references utilized in this document (e.g., for variable definitions or in analysis plan.]

# Summary of revisions

[After inferential results are shared with investigators, summarize changes to the study design, objectives/hypotheses, population, variable definitions, and analysis plan. Include the date the decision was made to make the change, and the discussion or justification leading to the change. Minor updates and clarifications to the analysis plan need not be detailed here.]

# Appendix: Planned tables and figures

[Mock-up or describe the patient flow diagram, tables and figures to include in the manuscript. Mock layout and content should be developed for tables and figures prior to start of analyses.]