STUDY NAME (OR PXXX NUMBER)

Principal Investigator:  
Research Team:  
Date (DD/MM/YYYY - Version):

# INTRODUCTION

Provide a summary of the study background, aims, and design

# HYPOTHESIS

A summary of the hypotheses to be examined by the study

* Hypothesis 1 – a brief description of the first hypothesis
* Outcome
* Predictors
* Confounders
* Hypothesis 2 – a brief description of the second hypothesis (if applicable)
  + Outcome
  + Predictors
  + Confounders
* Additional hypothesis (if applicable)
* Exploratory – a brief description of any exploratory aims

# STUDY DESIGN

A brief overall summary of the study

* Study Population
  + Sampling plan (with inclusion/exclusion criteria)
  + Recruitment procedures (as applicable)
  + Consent plan for participants (as applicable)
  + Any screening procedures (as applicable)
* Experimental Design
  + A description of the study intervention group
  + A description of the study control group
  + Randomization (as applicable)

# SAFETY MONITORING PLAN

As applicable, a brief description of any safety monitoring, including

* Adverse events
* Monitoring procedures
* Reporting body (safety officer, COMIRB, etc.)
* Safety and efficacy stopping rules

# POWER ANALYSIS

Text about power analysis, including

* Statistical Software Program (and version)
* Alpha value
* Power analysis methods (including multiple testing considerations)
* Primary outcome powered on, and assumed values
* Primary predictor powered on, and assumed values

Results of power analysis, including:

* Interpretation of selected power analyses
* Plots, tables, etc.

# LITERATURE CITED