CUMC IRB# TO BE ASSIGNED

Protocol Title:

Principal Investigator(s):

Background Section

Study Purpose and Rationale *(Provide pertinent background information with references that are related to the need to conduct this study. If this is a clinical trial, the background should include both preclinical and clinical data. Be brief and to the point.*

Study Design (*Describe the methodology that will be used in this study, covering such factors as retrospective vs. prospective data collection, interventional vs. non-interventional, randomized vs. non-randomized, observational, experimental, ethnography, etc.):*

Statistical Procedures *(Provide sufficient details so that the adequacy of the statistical procedures can be evaluated including power calculations to justify the number of participants to be enrolled into the study. Definitions of subject terms such as enrolled and accrued as used for Rascal submissions can be found in the Subjects section.)*

Privacy and Data Security Section: *There is template language that we use for studies that do not share information outside of Columbia.*

Procedures Section

There is template language that we use for retrospective chart reviews that do not share information outside of Columbia. For retrospective/prospective chart reviews (that are combined together)- there are additional fields to complete.

Analysis of Existing Data and/or Prospective Record Review Section

Data Range of existing data, documents, or records (ie medical charts)

Beginning Date:_____

End Date:_____

Note that end dates beyond the initial IRB Protocol submission date or future requests for a date parameter extension beyond the provided end date may require informed consent and HIPAA Authorization to be obtained from subjects.

Recruitment and Consent Section

There is template language that we use for retrospective chart reviews that do not share information outside of Columbia. For retrospective/prospective chart reviews (that are combined together)- there are additional fields to complete.

Research Aims & Abstracts Section

Research Question(s)/Hypothesis:

Scientific Abstract:

Lay Abstract:

Subjects Section

Target Enrollment:

Number anticipated to be enrolled in the next approval period:

Does this study involve screening/assessment procedures to determine eligibility?

If YES:

Target Accrual:

Number anticipated to be accrued in the next approval period:

Target Enrollment Demographics:

Females

Males

Non-Specific:

Population Age *(if no minors, you still have to enter % for ages 18-65 and >65- it won't accept non-specific for adults only subject population)*

Population race: enter info or 100% non-specific

Population Ethnicity: enter info or 100% Non-specific

Vulnerable Population: *For databases, "None" should be selected*

Subject Population Justification: