

**STUDY SYNOPSIS:** [Name of Study]

**OBJECTIVE:**Enter overall aim of trial

**ORGANIZATION:**

PI: [Enter Name]

Study Leaders: [Names Steering Committee]

Data Center: [Enter Names of Mgr and Statisticians]

Medical Monitor: [Enter Name]

NINDS Staff: [Enter Names]

DSMB Members: [Enter Names]

**DESIGN:**

General design info, # weeks, single/double blind, Treatment arms

Inclusion:

List major inclusion criteria

Exclusion:

List major exclusion criteria

Sample Size: N=

Enrolling Sites: N=

Randomization:[Stratification variables]

Statistical Methods: [ITT or other approach]

Interim Analysis: When planned, how many

DATE:

**SCHEDULED EVALUATIONS**

Visit Frequency: Identify Clinic Visits (Wk X,Y, etc) and Telephone Visits

Primary Outcome:Measure - list when collected (Wk 6, 12, etc)

Secondary Outcomes: Measures- list when collected (Wk 6, 12, etc)

Safety Assessments: **Measures- list when collected (Wk 6, 12, etc)**

**STUDY TREATMENTS**

**For each treatment including control -list treatment name, dose/frequency,**

**OUTCOME MEASURES**

Primary Outcome: Measure, when

Secondary Outcomes: **list measures**

**SAFETY:**

SAEs- When reported to DSMB

DSMB Reporting: Report frequency

IND: **Y/N Exemption #**

**TIMETABLE:**

Enrollment Period: Expected Start-End Dates/ expected #/mo.

First Interim Analysis:Date expected

Study Completion: Expected Last visit date

Any additional key time points