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

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

DATE: