Protocol Title					
Protocol number:					
Lead Investigator:					
Lead Node:					
Protocol development Team					
Protocol coordinator:					
Protocol training director:					
c. Data Collection Phase					
	CTP1/Node	CTP2/Node	CTP3/Node	CTPN/Node	Total
Blue text = item is part of subset for OCC report to SC					
Start date (first participant randomized)					
Target stop date (last participant completes final follow-up					
Recruitment, treatment, and follow-up					
Number screened (past month)					
Number screened (cumulative)					
Total randomizations (targeted N per CTP)					
Total actual randomizations (past month)					
Total actual randomizations (cumulative)					
Actual mean # of subjects randomized per week (to date)					
Target mean # of subjects randomized per week					
Estimated time to ending--last pt randomized (weeks)					
Estimated time to ending (last patient randomization)					
Percent final follow ups complete (follow-ups completed/eligible) *Lis may add interim follow-up rates if desired					
Percent of randomized participants who are female					
Percent of randomized participants who are African American					
Percent of randomized participants who are Hispanic					
Percent of randomized participants who are Asian American					
Percent of randomized participants who are Native American					
Percent of randomized participants who are 17 or younger					
Quality assurance					
SAEs-Past month					
SAEs-Cumulative					
Number of QA visits-past month					
Number of QA visits-Cumulative					
Number of QA reports-Past month					
Number of QA reports-Cumulative					
Number of QA reports: completed/protocol specified					
Number of protocol violations-Past month (specify type below)					
Informed consent procedures					
Inclusion/exclusion criteria					
Concomitant medication/therapy					
Laboratory assessment or procedures					
Study procedures					
Serious adverse event					
Randomization procedure					
Study drug dosing					
Behavioral intervention compliance					
Visit schedule/interval					
Number of protocol violations-Cumulative (specify type below)					
Informed consent procedures					
Inclusion/exclusion criteria					
Concomitant medication/therapy					
Laboratory assessment or procedures					
Study procedures					
Serious adverse event					

Randomization procedure							
Study drug dosing					\		
Behavioral intervention compliance							
Visit schedule/interval							
Data:							
Completion rate: % of collected CRFs= Total # CRFs collected/# of CRFs expected							
Timeliness: % of collected CRFs entered within 7 days of collection= # CRFs entered within 7 day timeframe/Total # of CRFs collected							
Date accuracy: % of errors deterated=# of errors generated on CRFs/Total # of fields on CRFs							
Training							
# of staff trained/certified							
# of staff requiring training/certification							
IRB expiration date							
Any new staff-past month							
Number of fidelity checks-past month (behavioral trials)							
Number of fidelity checks-cumulative							
Regulatory							
IRB expiration date							
CTP withdrawal?							