



PROTOCOL TITLE

The Site Initiation for the _____ will be conducted by teleconference with a review of slides. The material reviewed the protocol includes (examples listed below):

- Study background and rationale
- Explanation of study drug
- Inclusion/Exclusion criteria
- Review each study visit
- Double-Blind placebo....
- Contact with study subjects
- Discuss diary.....
- Pharmacy and study drug randomization and labeling
- Adverse Event Reporting
- DSMB & GCP
- eRAP data entry overview (for data coordinators only)

My signature attests that I have participated on the conference call or reviewed the slides independently:

I participated in the teleconference and review of slides

I reviewed the slides

Name: _____

Signature: _____

Site: _____

Date: _____