[Current Date Long]

[Investigator Full Name], [Investigator Degree]

[Account Name]
[PI Address]

Site #: [Site Number]

Re: Protocol #: [Protocol Number] – Site Initiation Visit Confirmation

Protocol Entitled: [Protocol Description]

Visit Date: [Planned Start to End Date]

Dear Dr. [Investigator Last Name],

This letter serves as confirmation that the Site Initiation Visit for the above named protocol is scheduled for [Planned Start to End Date2] at (time). I expect the visit to last approximately (# hours). As the Principal Investigator, you are required to attend the portion of the visit that covers: protocol review, investigator responsibilities and reporting of safety events, which I anticipate should take approximately (# hours). Your Study Coordinator, [SC Full Name], however, will be required to attend the entire visit.

During the visit, I plan to discuss the following items:

* Site Staff, Facilities and Study Supplies
* Adherence to Protocol/Amendment(s) and Study Compliance
* Subject Recruitment & Enrollment
* Informed Consent Procedures
* Case Report Form (CRF) / Electronic Case Report Form (eCRF) Requirements
* Monitoring Procedures
* Test Article / Intervention
* Laboratory Procedures and Biological Samples
* Essential Documents
* Outstanding Issues that Require Resolution

Thank you again for your interest in this important clinical research study. I look forward to meeting with you and your staff. In the interim, should you have any questions, please do not hesitate to contact me at [CRA Phone] or e-mail [CRA Email].

Sincerely,

[CRA Full Name]

Clinical Research Associate

Duke Clinical Research Institute

DCRIElectronicSignaturePlaceHolder-DONOTDELETE

cc: [SC Full Name2], Study Coordinator

 [Insert Lead CRA name], Lead CRA