[Current Date Long]  
  
[Investigator Full Name], [Investigator Degree]

[Account Name]  
[PI Address]

Site #: [Site Number]  
  
Re: Protocol #: [Protocol Number] – Periodic Monitoring Visit (enter visit number XX) Follow-up

Protocol Entitled: [Protocol Description]

Visit Date: [Actual Start to End Date]

Attendees: [Attendees]

Dear Dr. [Investigator Last Name],

I had the opportunity to meet with you and [SC Full Name] on [Actual Start to End Date2] during this Periodic Monitoring Visit for the above mentioned protocol. Please extend my thanks to everyone for their time and assistance.

During this visit the following were reviewed:

* Outstanding Issues that Required Resolution
* Subject Recruitment, Enrollment & Retention
* Adherence to Protocol/Amendment(s) and Study Compliance
* Test Article Accountability
* Laboratory Procedures and Biological Samples
* Essential Documents
* Site Staff, Facilities, & Study Supplies
* (Insert other items not already listed and provide necessary detail)
* Informed Consent

[Visit ICFs]

* CRFs and Source Documents

[Visit CRFs]

The protocol deviations that were noted during this visit include:

[Protocol Deviations]

The following is a summary of the findings and/or action items that arose during this visit, as well as any action items that have been resolved since the last visit and the associated resolutions. Outstanding items should be completed prior to the next scheduled visit.

[Visit Issues]

The next monitoring visit is scheduled for [Next visit date]. In the interim, should you have any questions, please do not hesitate to contact me at [CRA Phone] or e-mail [CRA Email]. Thank you again for your staff’s time and assistance during this visit.

Sincerely,

[CRA Full Name], (degrees/any certifications)

Clinical Research Associate

Duke Clinical Research Institute

DCRIElectronicSignaturePlaceHolder-DONOTDELETE

cc: [SC Full Name2], (degrees/certifications), Study Coordinator

(Insert Lead CRA name), Lead CRA