[Date]

[Investigator]

[Address]

# **Re: [Protocol Number and Title]**

Dear Dr. [Investigator name],

It was a pleasure to meet with you and your Study team. I would like to take this opportunity to thank [Study staff name(s)] for [his/her/their] time during this visit.

1. During the visit I accomplished the following:
2. Reviewed the Investigator Site File

[Report any deficiencies or state that all was complete and up to date]

1. Reviewed the CRF and source data for the following participants:

[List participants and visits monitored]

[Comment on the state of CRFs and any corrections of CRFs]

1. Reviewed enrolment status

[Summarize screens, enrollments, active participants, discontinued participants, completed participants, etc]

1. Monitored for deviations

[Summarize deviations]

[Remind to submit to REB if applicable]

1. Reviewed participant documentation for Serious Adverse Events

[List any SAEs ongoing or unreported since the last visit]

[Remind to submit to REB if applicable]

1. Reviewed study drug dispensing and storage.

[Summarize what was reviewed and note any discrepancies]

1. As a result of the monitoring, the following issues were noted that require resolution:
2. [List discrepancies including subject number, etc. as applicable]

Once again, I would really like to thank [Study staff Name(s)] for [his/her/their] time during this monitoring visit. Please file this letter in the Investigator Site File. If you should have any questions regarding the study do not hesitate to call me or the study project manager at [Contact Numbers].

Sincerely,

[name]

[title]

Cc:

[Study Project Manager]

[Study Research Coordinator]

Acknowledgement of Receipt:

I hereby acknowledge the receipt of the Monitoring Visit Follow-up Letter and agree to resolve all the above mentioned items in a timely manner.

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Qualified Investigator Name Signature

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Date (dd-mmm-yyyy)