SAMPLE MONITORING VISIT FOLLOW-UP LETTER

<insert PI name>, MD
<insert site name>
<address>
<city, state, zip>
<country>

Site # <insert number>

Protocol Name / Number:

Monitoring Visit Date:

Dear <insert name of PI>:

This letter is to document and summarize observations made during the <insert type of monitoring> visit to your site on <insert date(s)>. During the visit, the following personnel were available to me: (insert names of CRC, regulatory, etc.).

Summary of observations / findings*:* *(Note the monitor should at a minimum comment on each of these items. This can be done in paragraph form. Insert tables or lists as appropriate.)*

1. Action items from the previous visit <were/were not> completed.

2. Screening / Enrollment / Recruitment Methods

3. Informed Consent

4. Protocol Compliance (is the approved written protocol being followed by all personnel). (*is there evidence that the PI is personally conducting / supervising the study).* List all Protocol Violations / Deviations (list) or other non-compliance

5. Adverse Event(s) / Unanticipated Device Effects (list)

6. Accurate, complete and current record keeping:
    a. Review of Regulatory Files
    b. Review of Essential Documents / Selected CRF and source documents: *(list every subject / CRF reviewed and any significant findings/missing documents; if this list is long, it can be made an attachment).*
    c. Data Clarification Forms (queries)

7. Staff / Training Needs (*any turn over of staff, training needs, new investigators, etc.?)*

8. Facilities (*do they remain adequate to support study activities?):*

9. Accurate, complete and timely reports to the IRB (and/or other regulatory)? Approval(s) *(current)?:*

10. Test Article Accountability

11. Sample Storage (if applicable)

12. Any regulatory (FDA/OHRP) audit of site or IRB since last monitoring visit: Also note if the IRB has audited the site since the last monitoring visit.

At the end of the monitoring visit, the following was discussed with you and your staff to correct deficiencies noted. (describe in detail discussions). Action items that need to be completed by (insert time frame) are: *(note, if this list is long, it can be made an attachment).*

1. list action items
2.

The next monitoring visit has been scheduled for <insert time> on <insert date>.

I look forward to visiting your site on . If you have any questions, please call me at . Please address all follow-up to action items to me at the following address:

<name of CRA>
address
City, State, Zip
Phone:

Sincerely,

Clinical Research Associate

Cc: Monitor Files
Sponsor