<PI name>

<PI address>

<Date Letter Sent>

Dear Dr <PI name>,

**Close Out Visits Follow Up Letter: <STUDY NAME> - <SITE NAME> - <DATE OF VISIT>**

Thank you to you and the study team for your time and assistance during the close out visit conducted on <date of visit>. During the visit I reviewed <brief description of visit>.

<The close out visit also included a visit to the Pharmacy Department.>

Please see below for a list of findings and actions resulting from the visit.

**Site Close Out Checklist**

*Action:*

**Essential Documentation**

*Action:*

**Trial Data**

*Action:*

**Delegation & Training**

*Action:*

**IMP Accountability**

*Action:*

**Lab Sample Accountability**

*Action:*

Please note that any changes made to trial or source documentation as a result of this close out visit should be made leaving a clear audit trail and dated consistently with the time the change is made.  For further guidance please see ACCORD SOP CR004.

Please refer to the attached Close Out Action Log for a full list of the open action items. Please ensure that these are resolved in a timely manner and, when all actions are complete, the close out statement on the action log is signed by the PI and returned to the monitor.

As discussed with the team during the close out visit the Investigator Site File (ISF) can now be prepared for archive. Any documents which may fade over time must be copied to preserve them for the duration of the archiving period and any item which may degrade the documentation over time e.g. poly-pockets, paper clips etc. should be removed. Identifiable data should be prepared for archiving according to local site policy. Please do not archive the ISF until receipt of the final Close Out letter which is sent by the monitor after all close out actions are resolved.

If you or the team wish to discuss any of the points in this follow up letter, or any other issues, please do not hesitate to get in touch.

Yours sincerely,

<NAME>

<ROLE>

<ADDRESS>

<EMAIL>

<PHONE>

CC: