<PI name>

<PI address>

<Date Letter Sent>

Dear Dr <PI name>,

**Site Initiation Visit 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 site initiation visit conducted on <date of visit>.

Please find attached the Site Initiation Visit report which details the training delivered as part of the SIV process and the topics discussed during the visit. Please read the report and sign the PI declaration if you are happy with the content, filing the original signed SIV report in the Investigator Site File (ISF) and providing a copy for the Trial Master File (TMF). Alternatively, if you would like to discuss any changes to the report please let me know as soon as possible.

Please see below for a list of findings and actions resulting from the visit. Actions required prior to the site opening for recruitment are clearly marked:

**Essential Documentation**

*Action:*

**Delegation & Training**

*Action:*

**IMP Accountability and Storage**

*Action:*

**Lab Sample Accountability and Storage**

*Action:*

Please refer to the attached Action Log for a full list of the open action items. Please ensure that these are resolved in a timely manner.

As discussed with the team during the SIV the study cannot begin recruitment at site until Sponsor Authorisation to Open (SATO) is granted. The completed SATO form will be sent to site once all actions from the SIV which require completion prior to SATO are resolved.

For members of the site team who were unable to attend the SIV or who are delegated study tasks after the visit has taken place please ensure appropriate protocol and SOP training is undertaken and this is documented on the study specific training log prior to undertaking any study specific tasks.

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: