Completion and Management

- There should be fixed timelines with regards to CRF completion after each subject's assessment/visit, ensuring data entry is completed on a regular basis. These timelines should be adhered to, to ensure consistent data collection, maximising completeness and accuracy throughout the life cycle of the trial.
- In the case of multi centre studies, copies of the CRFs should be sent to the lead site on a regular basis to ensure that a lack of data entry does not occur.
- In the case of multi-centre studies, please ensure that ALL ORIGINAL CRFS are to be sent to the lead centre to their data management personnel for review, whilst copies are to be kept at the local sites that are participating within the study, whether it be a photocopy or an NCR copy (non carbon copy paper).
- If the lead site becomes aware of a data discrepancy documented on the CRF the lead site can raise a query raising a data clarification form/email/query (data query). This form/email/process acts as a means to request amended data to rectify the incorrect data in the CRF whilst maintaining an auditable data trail for the clinical study.

SOP 38b Associated Document 1 - CRF Design Guidance

The following has been taken from SOP 38b AD 1, for more information please click here