Signing Off and Training

- The CRF design should be reviewed and signed off by CI, and the statistician.

  The CI and Statistician should check if:

  - Sufficient data is being collected to answer all trial research questions.
  - All data points outlined in the protocol are being collected.
  - No data points are being collected that are not outlined in the protocol.
  - CRF design meets with DPA and GCP.
- There should be a clear, consistent procedure for the completion of the CRF pages, this should include procedures for any amendments that need to be made to the CRFs as well as instruction for corrections. This can be provided within a training session or/and instruction to be included on the CRF pages.
- Each study is individual with its own specifications, with the responsibilities that are to be allocated to trained study members documented in the site delegation log.

SOP 38b Associated Document 1 - CRF Design Guidance

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