Amendments

If during the study life cycle, amendments are made to the protocol that are pertinent to the data collection endpoints, there should be changes made to the CRFs to reflect this and these documents should mirror each other. Any changes that are made should be documented and version controlled and filed in the Trial Master File (TMF) and the Investigator Site File (ISF) - if the study is multi-site.

SOP 38b Associated Document 1 - CRF Design Guidance

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