General information

It is of the utmost importance that the information captured in the CRF matches that listed in the final version of the protocol. All the data elements/points within the CRF must support the identifiable objectives of the protocol, in the form of the primary and secondary endpoints. It should serve to ensure the eligibility as well as the safety of the patient. It should also demonstrate compliance with study procedures and where possible adherence to GCP.

It is important that the CRFs **SHOULD NOT** collect any additional data that is not to be analysed or outside the requirements of the study aims.

The intention of the CRF is to collect complete and pertinent data and to ensure consistency and standardisation with regards to data collection. Therefore, it is necessary that these forms are clear, easy to use and collect the relevant information.

The Chief Investigator (CI) or delegate is responsible for the design and development of CRFs. Instructions should be given to all participating sites on how to complete the CRF (paper or electronic CRF) to ensure data is collected in a standardised fashion and meets the data protection act.

A CRF completion guide may be useful in a multi-centre study. As per JRMO SOP on Site activation and SOP 38 Trial data management systems a training log should exist to document training has been completed.

It is vital that it is documented within the site delegation log in which members of the study team have been appropriately trained with regards to their study role, including the protocol and their role requirements, including the correct completion of the CRFs.

SOP 38b Associated Document 1 - CRF Design Guidance

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