Development

Please take into consideration the following points below when designing the CRF for your trial.

The principles laid out in this guidance apply to both Paper CRFs and e-CRFs.

Elements to be considered in CRF Design:

- **CRFs SHOULD NOT contain any patient identifiable material** – When Patients are entered/ randomised onto a study, they should be allocated a code number known as the patient identifier which can include their initials alongside an allocated number generally pertaining to their entry onto the study.
- **Patients Initials** (the first letter of the patient's forename, middle and surname constitute their initials e.g. John Edward Smith, the initials JES should be utilised. If the patient does not have a middle name, simply use a dash e.g. William Knight, the initials W-K should be utilised.)
- **CRFs should be appropriately versioned and dated** – if there are changes to be made to these documents, the version number and date should be updated accordingly, especially in the case of a protocol amendment that may lead to changes in the design of the CRFs.
- CRFs should be consistent with the protocol, as previously detailed.
- It is mandatory to record all visits and procedures that the protocol requests. This includes completion of questionnaires, participant diaries and telephone follow ups. This should include recording of dates.
- CRFs should enable to accurate capture of dose calculations and administration (what was taken / given to the participant, when and what dose).
- Avoid duplication of data collection – for example collecting the patient's age and their date of birth. (Only ask for DoB if you feel this is specifically needed often ages at consent is enough).
- Where ever possible avoid free text. Free text is very difficult to analyse.
- Where possible tick box or drop down options should be given. This particular option should be exhaustive – in that there should be a N/A or Other box option, when applicable. Where the 'Other' box is an appropriate option, there should allocated space for further information to be collected.

- For data points where actual values are to be captured, the number of boxes/spaces given should be adequate and if appropriate, reflect the number of decimal places desired. Please remember that there should be no blank spaces left on the CRF once completed.
- The measurement unit should be specified.
- Lab values should be detailed/referenced (with regards to units), if there are any conversions that are necessary (e.g. in multi-site studies - local lab unit of measurement variation), there should be space in which this can be completed and documented, with the original figure alongside the conversion factor.
- Each set of entries made on the CRF should be signed off and dated by the trained and authorised individual completing the CRF. The Chief Investigator or the Principal Investigator (if multi-site) should then review the data entered into the CRF, validating their review with a signature and date of review on each CRF page (or at the end of each visit, but page signature is suggested) for every trial subject in their care.

SOP 38b Associated Document 1 - CRF Design Guidance

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