

**CRF DEVELOPMENT**

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| Reference Number | MMU-RKE SOP 005 |
| Version | Version 1.0, 1st February 2016 |
| Effective Date | 1st February 2016 |
| Review Date | 1st February 2018 |
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| **Version** | **Date** | **Reason for Change** |
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1. **Background**

A case report form (CRF) is a form on which individual participant data required by the study protocol are recorded. It may be a printed or electronic document. The CRF data is used to perform statistical analysis for the study. Design of individual CRFs will vary from study to study, but it is essential that the design ensures that:

* adequate collection of data has been performed
* proper paper trails can be kept to demonstrate the validity of the study (both during and after the study)
* only the data required by the protocol are captured in the CRF

1. **Purpose**

This Standard Operating Procedure (SOP) describes the process for creating, completing, amending and storing CRFs for all studies conducted in the NHS that record data from human subjects.

1. **Procedure** 
   1. **General Principles**

CRFs should be dated and versioned according to [SOP2 Document Control](http://www2.mmu.ac.uk/media/mmuacuk/content/documents/research/sop/SOP2-Document-Control.docx). As CRFs are not participant facing materials they do not require review by ethics committees, however any changes to the final CRFs used during a study should be documented in the Study Master File.

CRFs should be reviewed and signed off by the Chief Investigator (and Statistician where applicable) before they are used in the study. It is good practice for those who will record data on CRFs and those who will use this data to view them prior to sign off.

The CRF layout should have a logical ordering that follows the schedule of participant visits, should ask unambiguous questions and should be consistent with the protocol. The layout should act as a prompt for researchers to perform specific evaluations and allow monitors to verify that the protocol is being followed correctly. More guidance on layout choices can be found in [CRF Design Guide](http://www2.mmu.ac.uk/media/mmuacuk/content/documents/research/sop/linked-documents/CRF-Design-Guide.docx).

If the protocol allows data to be entered directly onto the case report forms (CRF), the CRF would then be considered a source document. If these CRFs are sent to the sponsor, the study site must retain a copy to ensure that the principal investigator can provide access to the source documents to a monitor, auditor, or regulatory agency.

* 1. **Completing CRFs**
* CRFs should be completed only by those authorised to do so in the study delegation log as soon as possible after each participant assessment.
* They should be completed using a black ink ballpoint pen.
* If the CRFs are printed on carbonless duplication paper, make sure that a suitable separator is inserted under the form being completed.
* Ensure data entry is as complete as possible without omissions. Do not leave blank spaces. If data are unavailable write, for example, ‘*unknown’, ‘missing’, ‘test not done’.* Do not use the ambiguous phrase, *‘not available’*.
* Ensure all entries are accurate, legible and verifiable with the source data in the medical record (where applicable).
* CRFs should be signed by all site personnel completing the CRF. The Principal Investigator at the local site is responsible for the accuracy of the CRF.
* Any discrepancies with source data should be explained and the significance noted in the CRF and patient’s medical records (where applicable). For laboratory values outside the laboratory’s reference range or some other range pre-identified in the study protocol, or if a value shows significant variation from one assessment to the next, this should be commented on and the significance noted in the CRF and patient’s medical records.
  1. **Amendments**

Corrections should be made by drawing a single line through the incorrect item and dating and initialling all correction. Tippex must not be used.

* 1. **Storing and Accessing Completed CRFs**

Completed CRFs must be stored when not in use in locked secure storage cabinets and accommodation. Access to case report forms should be restricted to the Investigators, study monitors, relevant Trust R&D staff, and Regulatory Authorities.

1. **Related Documents**

[SOP2 Document Control](http://www2.mmu.ac.uk/media/mmuacuk/content/documents/research/sop/SOP2-Document-Control.docx)

[CRF Design Guide](http://www2.mmu.ac.uk/media/mmuacuk/content/documents/research/sop/linked-documents/CRF-Design-Guide.docx)