

Standard Operating Procedure

Title: CASE REPORT FORM (CRF) COMPLETION		
REF: SOP 009	Version: 04	Issue No: 1
Template Source: Merseyside & Cheshire Cancer Research Network		Date: 18/02/05
Reviewed by: Professor Rod Owen		Date: 05/11/2009
Approved by: Dr M J Maxwell		Date: 21/05/07
Due for Revision		Date: 05/11/2012
This SOP is effective from:		Replaces: Version 03 (21/05/07)

1. BACKGROUND

This SOP is applicable to clinical trials only. ICH Good Clinical Practice Guidelines define a Case Report Form (CRF) as:

“A printed, optical or electronic document designed to record all of the protocol required information to be reported to the sponsor on each trial subject”

The reasons for having CRFs in a study is to collect the necessary information about:

- The patient
- Administration of the study drug
- Study procedures
- Outcome of the assessments
- Adverse events

CRFs are the official documentation of the study for the authorities, and together with the source documents will be closely examined during audits and inspections.

The data collected on the CRFs is therefore used directly as the basis for the study report and any publications, as well as supporting an application for marketing approval of a new or for new indication and/or dose for an existing drug.

2. PURPOSE

To describe the procedure for completing, signing and correcting case report forms.

3. OTHER RELATED PROCEDURES

- SOP 002 Study Team: Definition of Responsibilities
- SOP 005 Data Protection
- SOP 006 Study Files and Filing

CASE REPORT FORM (CRF) COMPLETION	
REF: SOP 009	VERSION: 03

4. WHEN

The first record of any study related procedure should be made in the patient's case sheet (the 'Original Document') during each clinic visit. The information should *then* be transcribed into the CRF as soon as possible. CRFs should *always* be maintained and be up to date.

5. WHO

Only individuals delegated by the Principal Investigator and named on the Delegation of Authority and Signature Log (FORM1SOP002) may complete the CRFs.

6. HOW

When completing a CRF:

- Always use a **black** ballpoint pen
- If the CRFs are printed on carbonless duplication paper, always make sure that a suitable separator is inserted under the form being completed.
- Never leave blank spaces. If data is unavailable write, for example, *unknown*, *missing*, *test not done* etc as appropriate. Avoid using the ambiguous phrase, 'not available'
- Ensure accuracy, consistency with the source data in the case sheet and legibility of all data entries.
- Any discrepancies to source data should be explained.
- Never over-write an entry. Corrections should be made as follows:
 - Cross out the incorrect entry with a single line so that the incorrect entry should still be readable
 - Enter the correct data
 - Initial and date the correction, and give an explanation of the correction if it is not obvious why it changed.

For example:

~~2003~~ 2004
RO 20/04/2007

- Enter laboratory values without conversion from printed reports
- Never write the patient's full name on the CRF, only use their initials.
- Never use correction fluid or obliterate any entries made on the CRF.

CASE REPORT FORM (CRF) COMPLETION	
REF: SOP 009	VERSION: 03

- The CRF must be signed where indicated by the Principal Investigator to assert that he/she believes they are complete and correct.
- CRFs should be kept in a secure location during the course of the study. CRFs should then be archived when the study has finished.
- For laboratory values outside the laboratory's reference range or some other range agreed with the study Sponsor, 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.
- The procedure to be followed for the correction of entries on the CRF, or to answer data queries should be agreed with the study Sponsor, and should be adhered to.
- Serious Adverse Events (SAEs) and Suspected Unexpected Serious Adverse Events (SUSARs) should be recorded on the documents provided by the Sponsor and the reporting procedure for SAEs and SUSARs clearly established.

Note: in certain instances the expedited reporting process need not be used to report death, but only **if** a Research Ethics Committee grants approval. Such circumstances might be death from progressive malignant disease in cancer trials; the deaths could be reported annually or in the Study Report. Unless exempt, **ALL deaths and life threatening** SAEs or SUSARS must reported within **24 hours to the Sponsor** and within **7 days to the Regulatory Authority**.