

# Completing the Case Report Form

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**Clinical S.O.P. No.: 14**  
Version 2.0

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# Completing the Case Report Form

## DOCUMENT HISTORY

Version number	Detail of purpose / change	Author / edited by	Date edited
1.0	New SOP	Shona Brearley	
2.0	Information added regarding electronic CRFs	Louise Greig / Moira Dryburgh	June 2012

## 1. Introduction

The CRF, whether paper or electronic, contains the source data for much of the information regarding a clinical trial and should be treated as an essential document for conducting a clinical trial to ICH GCP guidelines.

## 2. Objectives

To describe the procedure used within the Scottish Diabetes Research Network for completing Case Report Forms (CRF)

Data recorded on a CRF can be generated from source data or documents, or can be directly collected in the CRF in accordance with the protocol.

## 3. Responsibility

Only nurses who have been trained in this procedure and deemed competent should complete this procedure.

The sponsor/investigator should make sure that all clinical data recorded on a paper or electronic CRF, are accurate, complete and legible.

## 4. Equipment

- Black ballpoint pen.
- Computer for e-CRFs

## 5. General Points

CRFs are the official documentation of the trial for both Sponsor and regulatory authorities.

The data collected on the CRF is used directly as the basis for the trial report and any publications as well as making up part of the data for regulatory approval of a new drug.

The CRF should be completed as fully as possible whilst the patient is present. The case report form is used in a study to collect necessary information about:

- The participant
- Study procedures
- Study interventions
- Administration of the Investigational Product (if applicable)
- Outcome of assessments and tests
- Adverse events

The CRF should be completed promptly and accurately and completed in accordance with the study protocol. The study design will provide the visit schedule and when visits are due.

Data recorded in the CRF, which are drawn from source data or documents, should correspond to the data appearing in these documents.

CRFs should be kept in a secure location during the course of the study and archived in accordance with GCP regulations.

## 6. Procedure for paper CRFs

- Always use black ink.
- If the CRF is printed on carbonless duplication paper always make sure that a suitable separator is inserted under the form being completed.
- Complete all items/comments in the space provided. If the information is unavailable or a test is not performed, record 'NA' (not applicable), 'NK' (not known) or 'ND' (not done) in the appropriate place.
- Keep comments concise.
- Errors should be crossed out with a single line so as to remain legible and the new data written next to the incorrect data. All alterations must be initialled and dated. Do not use correction fluid.
- Where appropriate, indicate choices by marking the relevant box with a cross '☒', or a tick '☑' according to the sponsoring company requirements.
- When the answer is a choice of scores, record a discrete number, not a combination e.g. record 2 not 1/2. If indicated more than one discrete number may be recorded.
- Avoid abbreviations.
- Record dates as day/month/year e.g. 1<sup>st</sup> May 2006 will be documented as 01/05/2006.
- Record times in 24hour clock e.g. 2:00pm as 14:00, midnight as 00:00.
- Please ensure all forms are completed and signed.
- Please do not complete any shaded areas in the CRF.
- If the subject does not complete the study, please document the reason for discontinuation on the study conclusion summary page.

## 7. Procedure for electronic CRFs

- Electronic CRFs will be completed using a study specific laptop computer, or a Web based application may be used to access the e-CRF. Electronic CRFs enable data to be typed directly into computer fields and transmitted electronically to Data Management.

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- In order to access the electronic database you will be provided with individual login information that you will need to store safely.
- Ensure you have the necessary patient data / source documents etc., if not entering data at point of seeing the patient.
- Process for electronic data capture
  - Data capture
  - Data entry
  - Data querying
- Only the site staff with appropriate access may modify electronic data entries.