Dorset HealthCare University NHS Foundation Trust

Standard Operating Procedure for Case Report Form (CRF) Completion

Objectives	The objective of this SOP is to explain the local processes and requirements for completing Case Report Forms (CRF).
Scope	This procedure applies to all the Research & Development team completing CRFs.
Responsibility	Only the individuals named on the Delegation Log are responsible for completing the CRFs.
Related Document	None.

1 Purpose

The purpose of this Standard Operating Procedure (SOP) is to explain the local process, and general requirements, for completing Case Report Forms (CRF) capturing patient and study data at Dorset HealthCare University NHS Foundation Trust.

2 Introduction

ICH Good Clinical Practice Guidelines define a Case Report form (CRF) as:

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

CRFs hold all the necessary information about:

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

This list is not exhaustive and will be dictated by the study protocol.

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 in CRFs is therefore used directly as the basis for the study report and any publications, as well as supporting an application for marketing authority approval of a new or existing drug.

This SOP describes the procedure for completing, signing and correcting case report forms.

3 Training

New users must read and understand this SOP before carrying out this procedure. Existing users must read and understand the Revisions Section

4 Revisions

This is the second version of this SOP.

5 Procedure

5.1 For Printed Documents

Individual trials will normally provide training and/or Case Report Form (CRF) completion guidelines which must be followed.

The first record of any study related procedure must normally be made in the patient's medical record during the assessment/visit. Prints or copies of source data (such as investigation results, scans/bloods etc.) may be stored within the CRF while being worked on, and must be anonymised prior to the CRFs being sent to the sponsor or being archived, bearing only the patient's trial ID number. The information must then be transcribed into the CRF as soon as possible. CRFs must be up to date.

Medical notes (patient notes) may be held on secure electronic databases – these records will not be printed out since they are secure, retrievable and any changes will be documented (audit-trailed) i.e. they fulfil the criteria for source documents as required by ICH GCP.

For some studies it is a requirement that electronic laboratory assessments and investigational assessments that are held electronically are printed out. (This includes x-ray reports, CT & MRI reports, inpatient and surgical admission and discharge letters, and all outpatient letters). These documents all form part of the source data and therefore must be printed out for monitoring purposes. The Principal Investigator (PI) or appropriate staff named on the delegation log will be required to sign and date these reports and in some cases will assign clinical significance to any abnormal results. Signed results/reports should ultimately be stored in the patient's medical records.

Where CRF pages are being faxed to the Sponsor, a copy of the fax cover letter and the transmission report must be filed in the ISF or CRF according to local practice.

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 does not exist record, for example, unknown, missing, test not done, etc. Avoid using the ambiguous phrase 'not available'.
- Ensure accuracy and consistency with the source data and legibility of all data entries.
- Any discrepancies to source data must be explained.
- Never over-write an entry.

  Corrections must be made as follows:

  1 Cross out the incorrect entry with a single line so that the incorrect entry is still legible. Never use correction fluid or obliterate any entries made on the CRF.

  2 Enter correct data.

3 Initial and date the correction and give an explanation of the correction if it is not obvious why it changed.

For example:

~~2009~~ 2010

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- Never write the patient's full name on the CRF, only use initials. (N.B. some CRFs may have a space to enter the full patient name, in this case entering initials only is still acceptable).
- The CRF must be signed where indicated by the Principal Investigator or delegated staff member, to assert that he/she believes they are complete and correct.
- CRFs must be kept in a secure location during the course of the study.
- CRFs must be archived when the study has finished. They may be kept off site in a commercial archive, which is secure and environmentally controlled to maintain the data in readable condition in accordance with the trial protocol after the last study subject had completed the study.
- The procedure to be followed for the correction of entries on the CRF or to answer data queries must be agreed with the Study organising body and must be adhered to.

5.2 For Electronic Documents

Electronic documents may be web-based or a trial specific lap-top may be provided. There are several electronic CRF's in existence and training must be given for each individual study. This may be on a one-to-one basis, web-based or on CD-ROM. The same basis principles apply as for printed documents as well as the following:

- Electronic signatures are personal and must not be used by more than one person. They are legally binding as written signatures.
- Likewise, user names and passwords to log-in must never be shared.
- If a lap-top is provided, it is the site's responsibility to ensure that it is kept in a secure location.

5.3 Data Queries

Data queries are normally filed in the CRF. Multiple queries relating to different patients are sometimes held on one sheet – in this case the irrelevant data must be obscured. The accompanying letter should be filed in the Investigator Site File (ISF).

6 Appendices

There are no appendices to this SOP.

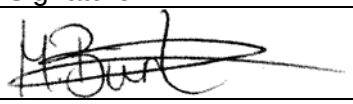
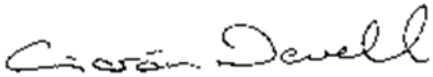
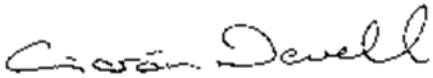
7 Responsibilities

Only individuals delegated and named on the Delegation of Authority and Signature Log may complete the CRFs.

8 Review

This SOP should be reviewed every two years unless new guidance or legislation dictates a review any sooner.

Date reviewed: 12/04/19 Date of next review: 12/04/21

Written By	Signature	Date
Hazel Burt		12/04/19
Reviewed By	Signature	Date
Dr Ciarán Newell		12/04/19
Authorised By	Signature	Date
Dr Ciarán Newell		12/04/19