SOP 351 Completing a Case Report Form

For Use in:	Research
By:	All staff
For:	All staff involved in the conduct of research
Division responsible for document:	Research & Development
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Name of document author:	Francesca Dockerty
Job title of document author:	Clinical Trial Monitor
Name of document author's Line Manager:	Katie Walls
Job title of author's Line Manager:	Research Governance Coordinator
Supported by:	Julie Dawson NNUH Sarah Ruthven UEA
Assessed and approved by:	Julie Dawson: Research Services Manager NNUH Sarah Ruthven: Research Manager UEA
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SOP 351 v2

This Standard Operating Procedure (SOP) is available on the Research & Development pages on the NNUH website

Copies printed from the website are only valid on the day of printing

1. Contents

2. Definitions of Terms Used / Glossary

CRF's	Case Report Forms
ICH GCP	International Conference on the Harmonisation of Good Clinical Practice
PI	Principal Investigator
R&D	Research and Development
SOP	Standard Operating Procedure
SI	Statutory Instrument

3. Scope

This SOP describes the procedure for completion of Case Report Forms (CRF's) used in clinical trials to collect data generated for a trial subject, in accordance with the protocol, during their participation in a trial.

For CRF production and design please follow the procedure in SOP 350 - Designing and Developing a Case Report Form.

4. Rules

The patient's identity should remain confidential at all times. It is imperative that the patient is identified by a study number and/or initials only on the CRF

In some cases the CRF may be a source document, for example in a study where a participant is asked to perform a test and the score of the test is recorded directly into the CRF

CRF's should collect appropriate trial data only, in an appropriate format

A CRF can be either paper-based or an electronic data capture system

5. Responsibilities

The CI / PI is responsible for ensuring data is complete as well as being attributable, legible, contemporaneous, original and accurate.

The Study Team must ensure accurate documentation by ensuring it is attributable, legible, contemporaneous and complete till that point in time in accordance with the protocol including timescales, ICH GCP and all other local and regulatory guidelines.

6. Procedures

Paper CRFs (pCRFs) and electronic CRFs (eCRFs) completion:

- Be completed using the CRF guidance document
- Be legible
- Be complete, without omissions -If data is unavailable do not leave the field blank, provide an explanation i.e. test not done, missing
- Avoid using the ambiguous phrase, 'not available'
- Use indelible black pen, never use pencil
- Precisely reflect source documentation
- Clearly indicate if changes have been made.
  - If a pCRF is used these changes should be initialled, dated and explained where necessary
  - If an eCRF is used, a robust, validated and auditable change system should be used
- Any discrepancies with source data should be explained and the significance noted in the CRF and patients medical records
- For laboratory values outside the laboratory's reference range or range agreed with the study Sponsor, or if a value shows significant variation from one assessment to the next, this should be commented on by the Principal Investigator and the significance noted in the CRF and the patient's medical records
- Include an anonymised ID and visit reference on each page to allow the reconstruction of CRF should a page become detached
- Unless otherwise agreed, have laboratory values entered without conversion from printed reports even if in multi-center study units of measurement differ from site to site
- Be completed with reference to the timelines defined by the trial protocol
- If the CRFs are printed on carbonless duplication paper, always make sure that a suitable separator is inserted under the form being completed

CRF Approval

- Must be approved by the Principal Investigator (PI) or delegated member of staff upon completion
- This may be per page or per CRF dependent on the template used
- As an eCRF cannot accommodate an investigator's wet-ink signature; the investigator must instead be given their own user account and password to facilitate an audit trail
- The eCRF should have the functionality to allow role-based access to particular areas

Corrections in CRFs:

- Cross out the incorrect entry with a single line so that the incorrect entry is still readable
- Never over-write an entry
- Never use correction fluid
- Never obliterate entries made
- Enter the correct data
- Initial and date the correction
- Some corrections may require an explanation as to why the change has been made, especially for eCRF's where the system may ask for the reason
- Some corrections may also need to be initialled and dated by the study PI
- The procedure to be followed for the resolution of data queries should be agreed with the Sponsor and completed by site staff in a timely fashion
- Corrections should be undertaken in a timely manner and must be supported

7. End of the study

The Sponsor should not have exclusive control of the data, for instance when the data is held on the sponsor's servers and no contemporaneous copy of the data is maintained by the investigator. Often the sponsor's solution is to provide a copy of the entered data to the investigator at the end of the trial, for example on a disk.

Refer to **SOP 900 Archiving, retrieval and destruction of Research Documents** for more information and processes relating to the management of study documentation at the end of a study.

8. Referenced and associated SOP's

SOP 350	Designing and Developing a Case Report Form
SOP 900	Archiving, retrieval and destruction of Research Documents

9. Approval

Author:	Francesca Dockerty
Role:	**Clinical Trial Monitor**
Signature:	Francesca Dockerty
Date:	29/04/2020
Approved & Authorised NNUH:	**Julie Dawson**
Role:	**Research Services Manager**
Signature:	Julie Dawson
Date:	05/05/2020
Approved & Authorised UEA:	**Sarah Ruthven**
Role:	**Research Manager**
Signature:	Sarah Ruthven
Date:	07/05/2020

9. Reason for Update and Training Implication

This replaces SOP 351 v 1.1

Update	Reason	Training Implication	Action
Updated throughout Updated to new template	To reflect current practice and legislation	Yes	Review SOP and update training matrix