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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
Key words:	Completing a Case Report Form, CRF
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To be reviewed before: This document remains current after this date but will be under review	27th July 2026
Reference and / or Trust Docs ID No:	14935
Version No:	3
Description of changes:	Updated to new template Any discrepancies with source data should be explained and the significance noted in the CRF and patient's medical records. This should be signed and dated as appropriate. For lab values outside reference range delegated member of staff may comment Corrections in CRF should be supported with relevant evidence

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.

SOP 351 Completing a Case Report Form

1. Contents

2. Definitions of Terms Used / Glossary

CI	Chief Investigator
CRFs	Case Report Forms
ICH GCP	International Conference on the Harmonisation of Good clinical Practice
ID	Identity
PI	Principal Investigator
R&D	Research and Development
SI	Statutory Instrument
SOP	Standard Operating Procedure

3. Objectives

To describe the process for completing a Case Report Form

4. Scope

This SOP describes the procedure for completion of Case Report Forms (CRFs) 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.

5. 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
- CRFs should collect appropriate trial data only, in an appropriate format
- A CRF can either be paper-based or an electronic data capture system

6. 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 until that point in time in accordance with the protocol including timescales, ICH GCP and all other local and regulatory guidelines.

7. Procedure

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

- 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
- Ensure any discrepancies with source data are explained and the significance noted in the CRF and patient's medical records. This should be signed and dated as appropriate
- Ensure where laboratory values are 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 a delegated member of staff 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, a suitable separator should be 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 with relevant evidence

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. References and Related Documents

References	
ICH GCP E6 / SI 2004/1041	
SOP No.	**SOP Title**
SOP 350	Designing and Developing a Case Report Form
SOP 900	Archiving, retrieval and destruction of Research Documents

9. Approval

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Date	28 July 2023 | 2:23 BST

10. Reason for new version and Training Implication

This SOP replaces the previous version number V2

Changes made	What changes have been made to the contents of the document
Reason	• New template • Any discrepancies with source data should be explained and the significance noted in the CRF and patient's medical records. This should be signed and dated as appropriate. • For lab values outside reference range delegated member of staff may comment • Corrections in CRF should be supported with relevant evidence
Training Implication	**No**
Actions required	• NA