Sheffield Teaching Hospitals NHS
NHS Foundation Trust
Research Department

STANDARD OPERATING PROCEDURE

STH Researcher

Maintaining the Case Report Form (CRF) for externally sponsored studies.

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	A101 Study set/start up
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Standard Operating Procedure: STH Researcher

Maintaining the Case Report Form (CRF) for externally sponsored studies

This SOP has been produced in accordance with Medicines for Human Use (Clinical Trials) Regulations 200, Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 and Research Governance Framework 2005. This SOP will outline the procedure for the completion and maintenance of the Case Report Form (CRF).

Background

The CRF is completed by the investigator, or delegated to another member of the research team (nurse/data manager), after each subject visit.

- Data entry must be verifiable in source documents (patient medical notes) as outlined in the study protocol.
- Entries must be written clearly in black ballpoint pen.
- Errors must be crossed through with one single line, dated and signed off. Correction fluid is not permitted.
- The CRF should be stored safely and securely on site. Adequate fire precautions must be operational in the building.
- The Monitor (CRA) from the Sponsor Company and the Auditors/Regulatory authorities must be given access to the CRF on request.
- For eCRF's, it is good practice that more than one person is trained in access and navigation of the application, to cover unexpected and planned absences.

Definition

The CRF is a paper or electronic (eCRF) document designed to record all the protocol-required information to be reported to the sponsor on each trial subject. A paper file using 'no carbon required' (NCR) paper is the most common format for the CRF. The contents of the CRF are confidential. The CRF and its contents are the property of the sponsor of the study.

Procedure for Commercial Study

1. The Sponsor decides on the most relevant method of data capture for the study and designs an appropriate tool (paper CRF, electronic CRF).
2. The Sponsor arranges and attends an initiation meeting with the STH Investigator and research team, providing a blank CRF and discusses what data is to be collected at each patient visit.
   2.1. The STH research team may develop a proforma to collect the required data at each visit or may record research data directly into to the patient notes, which can be used as source verifiable data.
3. The Sponsor and research team agrees on the method and feasible timeframe for data reporting.
4. The Sponsor and STH Investigator agree who is authorised to make data entries, make corrections and sign off pages.
5. The STH Investigator completes a Delegation of Duties Form to document who is responsible for CRF completion and files this in the Site File.
6. The authorised person completes the CRF as soon as data is available and ensures that all entries are source verifiable.
7. The authorised person discusses any unclear data with the relevant, qualified person.
8. The authorised person signs off the page (where appropriate).
9. The authorised person sends the data to the Sponsor by the method agreed.
   9.1. eCRF - data is generally submitted as soon as completed.
   9.2. Fax report - data is faxed to an allocated number. A 'fax send report' is filed with CRF.
   9.3. Post report - a copy is sent by post, marked as confidential with return address indicated and a copy of the cover letter is filed with original CRF.
   9.4. Collection - a study monitor attends the site, carries out Source Data Verification (SDV) and collects completed forms.

10. The STH Investigator ensures that, at the end of a study, a full copy of each completed CRF is stored as agreed prior to study set up.
11. The Sponsor and STH Investigator ensure that the eCRF is stored as agreed prior to study set up (disk or paper copy). The STH Investigator signs off the paper copy before storage if appropriate.

Procedure for Non-Commercial study

1. The Sponsor (or Chief Investigator) decides on the most relevant method of data capture for the study and designs an appropriate tool (paper CRF, electronic CRF).
2. The Sponsor, if appropriate, arranges and attends an initiation meeting with the STH Investigator and research team, providing a blank CRF and discusses what data is to be collected at each patient visit.
   2.1. The STH research team may develop a proforma to collect the required data at each visit or may record research data directly into to the patient notes, which can be used as source verifiable data.
3. The Sponsor (or CI) and research team agrees on the method and feasible timeframe for data reporting.
4. The Sponsor (or CI) and STH Investigator agree who is authorised to make data entries, make corrections and sign off page.
5. The STH Investigator completes a Delegation of Duties Form to document who is responsible for CRF completion and files this in the Site File.
6. The authorised person completes the CRF as soon as data is available and ensures that all entries are source verifiable.
7. The authorised person discuses any unclear data with the relevant, qualified person.
8. The authorised person signs off the page (where appropriate)
9. The authorised person sends the data to the Sponsor (or CI) by the method agreed.
   9.1. eCRF - data is generally submitted as soon as completed.
   9.2. Fax report - data is faxed to an allocated number. A ‘fax send report' is filed with CRF.
   9.3. Post report - a copy is sent by post, marked as confidential with a return address indicated and a copy of the cover letter is filed with original CRF.
   9.4. Collection - A study monitor attends the site, carries out Source Data Verification (SDV) and collects completed forms.
10. The STH Investigator ensures that, at the end of a study, a full copy of each completed CRF is stored as agreed prior to study set up.
11. The Sponsor (or CI) and STH Investigator ensure that the eCRF is stored as agreed prior to study set up (disk or paper copy). The STH Investigator signs off the paper copy before storage if appropriate.