Sheffield Teaching Hospitals NHS
NHS Foundation Trust

Research Department

STANDARD OPERATING PROCEDURE

STH Researcher

Using STH Generic Case Report Form

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	A116 Investigator Site File
	A123 Recording, management & reporting of AE s for STH sponsored studies
	A127 Archiving
Approved by	*Research Manager*

Standard Operating Procedure: STH Researcher

Using the STH generic case report form (CRF)

This SOP has been produced in accordance with Medicines for Human Use (Clinical Trials) Regulations 2004, Medicines for Human Use (Clinical Trials) Amendment Regulations 2006, ICH GCP and Research Governance Framework 2005. This SOP will outline the procedure for using the generic case report form provided by STH Research Department for studies where STH is the Sponsor.

Background

It is the sponsor's responsibility that accurate data is collected for each subject enrolled onto a study, which must reflect the source documentation (raw data). Source documents are defined as original records, or certified copies that contain clinical findings, observations or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial.

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 documentation 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 during the trial. Adequate fire precautions must be operational in the building.
- Sponsor auditors or regulatory authorities must be given access to the CRF on request.

Definition

The CRF is a paper document designed to record all the protocol required information to be reported for each trial subject. The contents of the CRF are confidential and must not use any patient identifiable data.

The Chief Investigator of the study must consider what data is required and include this in the study protocol. The generic CRF template can be adapted and added to with the assistance of the Research Department CRF contact, in order to best suit the needs of individual research study.

The generic CRF and its contents are ultimately the property of Sheffield Teaching Hospitals NHS Foundation Trust.

Procedure

1. The Chief Investigator (CI) identifies what data must be collected at each study visit for subjects enrolled in the study and documents this in the study protocol.
2. The CI works with the Research Coordinator at the Research Department to tailor the generic CRF to the needs of the study.
   - 2.1 If the templates need no editing from the standard generic form, the Research Coordinator provides the CI with .pdf versions of the CRF and the CI can re-print as necessary.
   - 2.2 If the template needs editing, the CRF lead makes the necessary changes to the Generic CRF using the template documents already set up.
   - 2.3 The CRF lead saves the new versions of the Generic CRF as .pdf documents and makes these available to the CI.

3. The CI prints the template CRF pages required for each patient and makes arrangements for these to be stored in the appropriate files (individual or whole study folders).
4. The CI completes a delegation of duties form to document who is responsible for CRF completion and files this in the site file.
5. The authorised person completes the CRF as soon as data is available and ensures that all entries are source verifiable.
6. The authorised person discusses any unclear data with the relevant, qualified person.
7. The authorised person stores the CRF pages in the agreed paper files.
8. The CI ensures that, at the end of the study, a full copy of each completed CRF is stored as agreed prior to study set up.

Appendix 1
STH Related Documents

	Document	Research Department Network Location	Website	Database	Created by
1	STH Generic CRFS	Directory\Research Governance\Data Management\Data Collection Tool	No	n/a	AL