SOP: Data Recording

PURPOSE

To describe the procedure for recording source and Case Record Form (CRF) data for research studies (and associated activities).

SCOPE

This procedure applies to any research studies cconducted by collaborators in the Sickle Africa Data Coordinating Centre (SADaCC) project.

GLOSSARY/DEFINITIONS

CRF	Case Record/Report Form: A printed, optical, or electronic document designed to record data on each trial participant during the course of the trial as defined by the protocol. The data should be collected by procedures, which guarantee preservation, retention and retrieval of information and allow easy access for verification, audit and inspection.
Essential documents	Documents which individually and collectively permit evaluation of the conduct of a clinical research study and the quality of the data produced.
ISF	Investigator Site File: Files of Essential Documents held by the Investigator.
SADaCC	Sickle Africa Data Coordinating Centre at the University of Cape Town
SOP	Standard Operating Procedure: Detailed written instructions to achieve uniformity of the performance of a specific function.
Source data	Source documents/data are original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents which are original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories and at medico-technical departments involved in the clinical research study).

RESPONSIBILITIES & PROCEDURES

GENERAL

- It should be clear as regards to who completes original information, who transcribes data to a case record/report form (CRF) who performs quality control checks (if relevant) and who enters data into a database.
- Signatures and dates should be in wet ink or through a validated electronic method. Pre-typed dates or stamps are not acceptable. Dates should have a consistent format, preferably dd-mm-yyyy. For time, use a 24 hour clock e.g. 09:31 for 31 minutes past 9 in the morning, 15:05 for 5 minutes past 3 in the afternoon. NB: Midnight is 00:00.
- All documentation relating to data recording and quality control will be kept in the Investigator Site File (ISF).

SOURCE DATA

Study Specific Source documents

- Study specific source documents are designed to reflect data that is protocol specific. These documents must be clearly identified, i.e., Header and Footers of documents should contain the name of the project, name of the document, protocol number, filename (including version control), references to relevant Standard Operating Procedures and page numbers. It should also contain the study visit number, space to add participant initials, participant number and the visit date. An Investigator will sign and date the source document once all the information needed is recorded.
- Source data should preferably be in black ink. Entries should be signed/dated at least on a visit basis and incorrect entries deleted with a single line. The correction should have an initial/date (and reason if not obvious). Alternatively each correction can be numbered with the initial and date entered in a footnote.

Furthermore:

- Unless otherwise specified, participant initials should be recorded with three letters e.g. 3 parts to name = RDW, 2 parts = R-W.
- Results of assessments, including clinical observations, laboratory assays, ECG traces etc., are reviewed by an investigator who documents clinical relevance with his/her signature and date. The process and review, however, may be study-specific.

- As soon as possible after source data are recorded a designee will review them to identify obvious errors and omissions, internal consistency and relation to exclusions/withdrawal criteria.
- Errors detected should be discussed with an investigator as soon as possible, and corrective actions documented.
- If participants are contacted to clarify issues relating to data, the date and content of the conversation should be recorded in his/her file.
- Source documents stored between visits in a safe and confidential manner, and made available to team members or the external monitor as required.
- A log of protocol deviations relating to data recording should be maintained throughout the study.

PAPER CRF DATA

- Paper CRFs will only be completed for enrolled subjects unless otherwise decided by the PI or Sponsor. Original and corrected entries into the CRF are maintained as above. Clinical data should not be entered into a CRF before it has been reviewed by an investigator. CRF entries will be logged on a log.
- Prior to the investigator signing declarations of completeness in a CRF, a designated team member may oversee a review of all, or a pre-specified selection of, CRF data for accurate transcription. This check will be recorded on a data entry quality check log. Corrections made to CRF data after the investigator has signed as above should be counter-signed and dated by an investigator.

ELECTRONIC CRF (ECRF) DATA

- In the absence of any Sponsor-specific procedures the following procedure may be used or adapted as per trial-specific requirements:
- eCRFs will only be completed for enrolled subjects unless otherwise decided by the PI or Sponsor.
- A member of the team designated to perform data entry direct from source documents will ensure that the relevant data have been declared complete by the investigator.
- Data entry should be documented in a log.
- Prior to the investigator (electronically or otherwise) signing declarations of completeness in an eCRF, a designated team member may oversee a review of all, or a pre-specified selection of, CRF data for accurate transcription. This check will be recorded on a data entry quality check log.