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| **University of Cape Town**<br>**Clinical Research Centre** | **Standard Operating Procedures** |
| **Title** | **Data recording** |
| **Number** | 08 |
| **Version** | 1 |

| | Name | Title | Signature | Date |
|---|---|---|---|---|
| **Reviewer** | Brenda Wright | Project Manager | | 5 May 2015 |
| **Authoriser** | Delva Shamley | CRC Director | | 5/5/2015 |
| | | | Effective date | 5 May 2015 |
| | | | Review date | 5 May 2018 |

## 1. Purpose/scope

To describe the procedure for recording source and Case Record Form (CRF) data for trials (and associated activities, such as a volunteer database) conducted by the Clinical Research Centre (CRC).

## 2. Templates/forms

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| CRC 8.1 | eCRF Database completion log |
| CRC 8.2 | e-CRF data entry quality check log |

## 3. Glossary/definitions

### Case Record/Report Form (CRF)

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 trial and the quality of the data produced (See South African Good Clinical Practice Guideline, Second Edition. 2006. Appendix C).

### Investigator Site File (ISF)

Files of Essential Documents held by the Investigator. NB on occasion the CRC may also hold the Sponsor's Essential Documents in a Trial Master File, where the Principal Investigator (PI) assumes a Sponsor-investigator role.

**Source documents/data**

Source data is all information in 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 trial).

## 4. Responsibilities and procedure

### 4.1 General

**4.1.1** 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.

**4.1.2** 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 ddmmmyyyy. This prevents confusion with areas of the world using a different order of day, month, year. 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.

### 4.2 Source data

**4.2.1** 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 business, name of the document, protocol number, filename (including version control), reference to relevant Standard Operating Procedure 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.

4.2.1.1 Version control

Version control is always shown in the footer of the source document. First draft will be draft version 0.1 with date. After this draft has been reviewed, changes if necessary will be made on draft version 0.2 with date of changes. When all changes are final, documents are saved in final version 1.0 with the appropriate date. Should final version 1.0 need changes, it will be placed into draft version 1.1, sent for review until approved to be placed into final version 2.0. Changes are never made in final versions. Superseded versions of source documents will be stamped accordingly and kept in the Site file to show the audit trail. A master copy of the most current source document will also be kept in the Site file

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.

**4.2.2** Unless otherwise specified, initials have three fields e.g. 3 parts to name = RDW, 2 parts = R-W.

**4.2.3** Assessment results, 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 trial-specific (refer also to SOP 06 Safety assessments and reporting).

**4.2.4** 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.

**4.2.5** Errors detected should be discussed with an investigator as soon as possible, and corrective actions documented.

**4.2.6** If participants are contacted to clarify issues relating to data, the date and content of the conversation should be recorded in his/her file.

**4.2.7** Source data is stored between visits in a safe and confidential manner, and made available to team members or the external monitor as required.

**4.2.8** A log of protocol deviations relating to data recording should be maintained throughout the trial.

### 4.3 Paper CRF data

**4.3.1** CRFs will only be completed for enrolled subjects unless otherwise decided by the PI or Sponsor.

**4.3.2** Original and corrected entries into the CRF are maintained as above.

**4.3.3** Clinical data should not be entered into a CRF before it has been reviewed by an investigator.

**4.3.4** CRF entries will be logged on CRC 8.1 e-CRF back-up log

**4.3.5** 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 CRC 8.2 e-CRF data entry quality check log

**4.3.6** Corrections made to CRF data after the investigator has signed as above should be counter-signed and dated by an investigator.

### 4.4 e-CRF data

In the absence of any Sponsor-specific procedures the following procedure may be used or adapted as per trial-specific requirements:

**4.4.1** e-CRFs will only be completed for enrolled subjects unless otherwise decided by the PI or Sponsor.

**4.4.2** 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.

**4.4.3** Data entry should be documented in an eCRF Database completion log (CRC 8.1).

**4.4.4** Prior to the investigator (electronically or otherwise) signing declarations of completeness in an e-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 CRC 8.2 e-CRF data entry quality check log

**4.5** All documentation relating to data recording and quality control will be kept in the Investigator Site File (ISF).

## 5. Retention of Documents

Documents should be retained until at least 2 years after the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing applications or at least 2 years have elapsed since the formal discontinuation of clinical development of the Investigational Product

## 6. Document history:

| Version No. | Date | Reviewer | Details of changes |
|---|---|---|---|
| 1 | 03/2015 | B Wright | NA - first version of SOP |
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| | **University of Cape Town**<br>**Clinical Research Centre** | | **eCRF Database completion log** |
| **Trial number** | | **Participant number** | |

| Date | Document completed | Signature | Comment |
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| | **University of Cape Town**<br>**Clinical Research Centre** | | **CRC 8.2**<br>**eCRF Data entry quality check log** |
| **Trial number** | | **Participant number** | |

| Visit(s) | Date data checked | Pre-entry check and data entry findings | Qc'd by: | Resolution of findings: | Resolution date: |
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**Training Log for Data Recording**

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