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| **TGHN-256x151px**  **Standard Operating Procedure** | | | **SOP No:**  **Version: 1**  **Effective Date:** | |
| **Title: Data Recording** | | | | |
|  | NAME | **SIGNATURE** | | **DATE** |
| **PREPARED BY** |  |  | |  |
| **REVIEWED BY** |  |  | |  |
| **QA UNIT**  **AUTHORITY** |  |  | |  |
| **APPROVAL**  **AUTHORITY** |  |  | |  |

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 [group/institution].

1. **Templates/forms**

AD07.1 eCRF data entry tracking log

AD07.2 eCRF back-up log

1. **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 [group] 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).

1. **Responsibilities and procedure**
   1. **General**
      1. It should be clear as regards to who completes original information, who transcribes should data to a case record/report form (CRF) who performs quality control checks (if relevant) and who enters data into a database.
      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.
   2. **Source data**
      1. 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.
      2. Unless otherwise specified, initials have three fields e.g. 3 parts to name = RDW, 2 parts = R-W.
      3. Assessment results, including of 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 CL04 Safety assessments and reporting).
      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.
      5. Errors detected should be discussed with an investigator as soon as possible, and corrective actions documented.
      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**.**
      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.
      8. A log of protocol deviations relating to data recording should be maintained throughout the trial (SOP QA02).
   3. **Paper CRF data**
      1. CRFs will only be completed for enrolled subjects unless otherwise decided by the PI or Sponsor.
      2. Original and corrected entries into the CRF are maintained as above.
      3. Clinical data should not be entered into a CRF before it has been reviewed by an investigator.
      4. 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.
      5. Corrections made to CRF data after the investigator has signed as above should be counter-signed and dated by an investigator.
   4. **eCRF data**

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

* + 1. eCRFs will only be completed for enrolled subjects unless otherwise decided by the PI or Sponsor.
    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.
    3. Data entry should be documented in an eCRF data entry tracking log (AD07.1).
    4. 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.
  1. All documentation relating to data recording and quality control will be kept in the Investigator Site File (ISF).

1. **Document history:**

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| **Version No.** | **Date** | **Reviewer** | **Details of changes** |
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