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| **TGHN-256x151px**  **Standard Operating Procedure** | | | **SOP No:**  **Version: 1**  **Effective Date:** | |
| **Title: Set up and maintenance of the Investigator Site File** | | | | |
|  | NAME | **SIGNATURE** | | **DATE** |
| **PREPARED BY** |  |  | |  |
| **REVIEWED BY** |  |  | |  |
| **QA UNIT**  **AUTHORITY** |  |  | |  |
| **APPROVAL**  **AUTHORITY** |  |  | |  |

1. **Purpose/scope**

To describe the procedure for ensuring that the Investigator Site File (ISF) is adequately prepared and maintained during a trial conducted by the [group/institution].

1. **Templates/forms**

AD03.1 Contents of the Investigator Site File

AD03.2 Checklist of Essential Documents

AD03.3 File note

1. **Glossary/definitions**

**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/institution] may also hold the Sponsor's Essential Documents in a Trial Master File, where the Principal Investigator (PI) assumes a Sponsor-investigator role.

1. **Responsibilities and procedure**
   1. **Generation of Essential Documents**
      1. The Principal Investigator (PI) delegates authorship of relevant Essential Documents to competent and suitably trained members of the trial team.
      2. The version of important documents (e.g. protocol, informed consent forms, case record forms, trial-specific guidelines) should be controlled and contain at least a trial reference number, version and/or date.
      3. Trial-specific forms are developed by reference to the SOPs where relevant.
      4. Pre-typed dates and stamps are not acceptable.
   2. **Setting up and access to the ISF**
      1. The ISF is set up during the planning stages of the trial according to AD03.1 (though actual content may vary depending of the nature and scope of the trial).
      2. A suitable place accessible to only those members of a trial team who require it will be chosen. Cabinets should be fire-resistant and protected from water damage (from leaks, plumbing and water-based fire systems). Both cabinets and the room they are stored in should be lockable.
      3. Sponsors, regulatory authorise and ethics committees will be given supervised access to the relevant ISF on request.
   3. **Maintenance of the ISF**
      1. The PI delegates a member of the trial team to verify contents of the ISF before, during and after completion of the trial (AD03.2). The trial should not start until section 1 has been checked as complete, or archived until section 3 has been checked as complete. Section 2 will not be dated as new documents are developed/received.
      2. Paper documents will be filed in ISF without undue delay, while electronic copies (scanned where necessary) will be placed in the allocated trial directory where possible (exceptions may include signed informed consent forms, source documents, completed CRFs, participant logs and IP accountability forms).
      3. Working copies of documents distributed to members of the trial team should be managed to ensure outdated versions are replaced when amended or updated. Outdated copies should be retrieved and destroyed, retaining at least one for archive.
      4. If an essential document is removed from the ISF, a file note (AD03.3) is placed in the ISF stating the purpose of removal and its location.
2. **Document history:**

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