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

1. **Purpose/scope**

To describe the procedure for [group/institution] staff involved with attending or managing monitoring visits.

1. **Templates/forms**

QA03.1 Monitoring visit log

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. The Project Manager (or designee) is generally responsible for liaising with monitors or others (e.g. others from the Sponsor) about visits, and informs the Principal Investigator (PI) and other relevant trial team members of the agreed dates/times. If a laboratory visit is requested by the monitor, the laboratory is approached to verify the best date/time.
   2. Records of all communications with monitors should be kept as per SOP AD03.
   3. The Project Manager (or designee) should facilitate relevant data entry and quality checks prior to the visit (SOP AD07).
   4. By the day of the visit the Project Manager (or designee) will ensure that:

* All appropriate data and documentation is available to the monitor.
* A suitable room has been booked (if necessary).
* Staff required to be present are available, in particular the PI, as possible.
  1. During or after the visit, corrections to data will be made as per SOP AD07.
  2. The Project Manager (or designee) will request the monitor (or other visitor) sign/date a monitoring visit log (QA03.1 or Sponsor-specific alternative).
  3. After the visit the Project Manager (or designee) will follow up any outstanding queries, reporting back to the monitor within the specified timeline.

1. **Document history:**

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