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

1. **Purpose/scope**

To describe the procedure for conducting participant follow-up visits in clinical trials conducted by the [institution/group].

1. **Templates/forms**

None

1. **Glossary/definitions**

See also: South African Good Clinical Practice (SAGCP) Guideline; ICH Guideline for Good Clinical Practice E6; and the UCT Human Research Ethics Committee (HREC) website for extensive ethical and regulatory guidance on the informed consent process and the format and content of informed consent documents.

**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 MCRG 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. **Preparing for the visit**

A Project Manager, Study coordinator or other designee prepares for the visit by:

* + 1. Making available adequate Essential Documentation (e.g. adding visit-specific source notes or paper CRFs to participant folders).
		2. Checking availability of an appropriate room(s), and allocating stock and equipment (including laboratory kits and requisition forms where necessary) for the visit.
	1. **During the visit**
		1. The allocated team members will arrive in good time to verify facilities are adequate.
		2. The investigator reviews the participant's medical history since the last visit with him/her, and staff members conduct protocol-specific assessments according to their delegated role.
		3. Safety assessments are performed and reported as per SOP CL04.
		4. Consent to continued participation in the trial may be discussed with the participant.
		5. Laboratory samples are collected, processed and sent to the relevant laboratory with correctly completed requisition forms, if necessary, as specified in the protocol.
		6. Remuneration is paid to the participant according to trial-specific requirements, and the time of and/or instructions for the next visit communicated to the participant.
	2. **After the visit the designated trial team member(s):**
		1. Performs data recording (SOP AD07).
		2. Facilitates collection of laboratory (or other external assessment) results as required. Should there be administrative errorsthese will be rectified immediately with the laboratory/external department and fully documented.
		3. Files laboratory/external assessment resultsin the relevant folder and ensures investigator review as per the protocol or other requirements (SOPs AD07, CL04).
		4. Ensures any on-going adverse events are followed up as per the protocol by either telephone with the participant or with further visits.
		5. Files relevant Essential Documents in the Investigator Site File (SOP AD03).
1. **Document history:**

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