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| **TGHN-256x151px****Standard Operating Procedure** | **SOP No:** **Version: 1****Effective Date:**  |
| **Title: Pre and Post admission trial team meetings** |
|  | NAME | **SIGNATURE** | **DATE** |
| **PREPARED BY** |  |  |  |
| **REVIEWED BY** |  |  |  |
| **QA UNIT****AUTHORITY** |  |  |  |
| **APPROVAL****AUTHORITY** |  |  |  |

1. **Purpose/scope**

To describe the procedure for arranging pre- and/or post-admission trial team meetings for trials conducted by the [group/institution].

1. **Templates/forms**

None

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 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. Pre- and/or post-admission trial team meetings will be held at the discretion of the Principal Investigator (PI). Responsibility for their arrangement will be delegated to a competent and suitably trained member of the trial team.
	2. If the PI deems it necessary, shortly before the first admission period, all staff scheduled to be working during that time will report to the ward at a pre-arranged time.
	3. The staff member leading the meeting will review any changes to the trial planning and/or documentation (such as a protocol amendment, changes to, or new Essential Documentation, a new SOP or trial-specific guideline etc.) since the site initiation. Should a topic have not been covered in sufficient detail at the site initiation or training sessions it will be reviewed here. The staff schedule will be reviewed and reminders may also be given concerning the doses of any drugs and expected adverse drug reactions. Emergency procedures may be highlighted and the arrangements for meals for both participants and staff explained.
	4. The team may walk around the ward to confirm where all stock, equipment, emergency supplies/exits, documentation, drugs, food, amenities etc. will be located in relation to the beds.
	5. After the meeting minutes should be prepared, distributed and filed in the Investigator Site File (ISF). Any team member who did not attend should be briefed fully by suitable member(s) of the team and, should it be necessary, individual staff may also meet with the PI or delegated staff to review specific items in more detail before the admission.
	6. Attendance records will be completed as training sessions, and retained in the ISF as per SOP AD08.
	7. Post the first admission the PI, sub-investigators and as many other members of the team involved in this or subsequent admissions may meet again to review the admission and make any necessary changes to procedures or documentation etc. to optimise trial conduct.
	8. For subsequent admission periods, if all or most staff attended the previous meeting(s) and there are no major revisions identified, further pre-admission meetings may not be necessary.
2. **Document history:**

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