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

1. **Purpose/scope**

To describe the procedure in preparing for and conducting screening visits for clinical trials conducted by the [Group/institution].

1. **Templates/forms**

CL01.1 Pre-screening eligibility check-list

CL01.2 Volunteer contact list

CL01.3 Screening log

CL01.4 Remuneration log

CL01.5 Ward rules for participants

CL01.6 Screening procedures

CL01.7 Screening algorithm

CL01.8 Participant appointment cards

CL01.9 Participant General Practitioner or referral letter

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. **Preparing for screening:**

The Principal Investigator (PI) delegates activities related to screening to suitably competent member(s) of the trial team. Preparation for screening involves:

* + 1. Developing adequate Essential Documentation or other templates that may include, but is not limited to: pre-screening eligibility check-lists (CL01.1), an appointment book, volunteer contact lists (CL01.2), screening logs (CL01.3), remuneration logs (CL01.4) and participant folders. The latter will contain an original approved information leaflet and consent form, ward rules for participants (CL01.5) if required, and screening source data templates (and/or Case Record Forms [CRFs] if these are to be used as source). NB The screening log may be combined with the enrolment log when required (SOP CL04). In addition, screening procedures (CL01.6) and algorithms (CL01.7), participant appointment cards (CL01.8), and Participant General Practitioner or other referral letter (CL01.9) may be developed.
		2. Placing adverts (approved by the relevant research ethics committee/s) in locations approved by relevant intuitions (e.g. UCT, Groote Schuur and other provincial hospitals).
		3. Liaising with other institutions who have agreed to refer patients (for instance, making available inclusion/exclusion lists). If arrangements are agreed for potential participants' medical records to be reviewed at such institutions, copies of relevant data (relating at least to key protocol eligibility requirements) should be requested for those who attend screening visits. A record of the screening visit (with the protocol number) is also made in the original medical records and arrangements made as to how information arising from the trial will be communicated with the referral institution.
		4. Checking availability of the consultation rooms to be used, and allocating stock and equipment (including laboratory kits and requisition forms).
		5. Completing and collating pre-screening eligibility check-lists in response to calls and referrals, and documenting each potential participant on a volunteer contact list. All pre-screened participants will be informed of their recruitment status.
		6. Booking appointments for screening visits, according to availability of the trial team, and making available adequate directions to the ward and contact numbers of appropriate trial team member(s).
	1. **During screening**
		1. On the day of screening the allocated team will arrive in good time to verify facilities are adequate.
		2. Informed consent will be sought as per SOP CL02
		3. Participants who have given informed consent will normally be allocated a screening number at this point as per the protocol, to be used on participant-specific documentation. All screened subjects will be listed on the screening log (CL01.3).
		4. The investigator reviews the participant's medical history. If he/she is still eligible for inclusion at that point trial assessments are performed, or the participant is discharged from screening. If any abnormalities are detected, further investigation of the medical history is recommended as relevant.
		5. Biological samples, if necessary, are packaged into bags labelled for transport to the laboratory, with the correct completed requisition form.
		6. Remuneration, if part of the trial, is paid to the participant, and recorded according to any trial -specific requirements (CL01.4).
		7. A copy of ward rules, if required, may also be discussed (CL01.5) and given to the participant to take home, for repeated review in detail at the time of admission should he/she be enrolled.
		8. The information and consent documents should declare where the trial team require to contact the participant's own medical practitioner or referral institution to verify medical history or share trial medical information.
	2. **After screening**

As soon as possible after participants have been screened a designee:

* + 1. Performs a check of data recorded (SOP AD07).
		2. Addresses any errors noted with the information and consent forms, If the participant has already left the trial facility, this will usually involve requesting he/she bring his/her copy to the next visit (if relevant) when all copies will be corrected as above. The main aim in this process is to ensure valid consent is documented accurately.
		3. 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.
		4. Files laboratory/external assessment resultsin the relevant folder and ensures investigator review (SOPs AD07). If any clinically relevant abnormalities are detected on laboratory tests, further investigation of the medical history is recommended as relevant.
		5. Liaises with the investigator for selection of the required number of participants (and reserves, if necessary).
		6. Contacts (or arranges for the investigator to contact if necessary) each screened participant to inform him/her of the results of the assessments and either their selection, reserve status, or ineligibility. Should a repeat of assessments be indicated this is conducted at a further scheduled visit. Should it be required, the participant is referred back to their medical practitioner with details of any abnormal findings from the screening assessments.
		7. Specifies on the screening log which participants are eligible for enrolment or indicates the reason for screen failure.
		8. Facilitates completion of CRFs for all selected participants with data generated thus far.
		9. Files Essential Documents (including a record of correspondence) in the ISF (SOP AD03).
		10. Wherever possible, with the participant's permission, contacts his/her own medical practitioner to verify medical history and inform that he/she may be included in the trial.
		11. At subsequent visits willingness to continue participation, and any additional questions asked and answered, should be discussed and noted in the source. Should there be updates to trial information that require re-consent, the process above will be repeated where necessary with the appropriately approved documents.
1. **Document history:**

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