# Standard Operating Procedures for Subject Tracing

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# Standard Operating Procedures for: Subject Tracing

## PURPOSE

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| This standard operating procedure (SOP) describes the procedures for tracing potential lost to follow up subjects in the endTB Clinical Trial.  |

## SCOPE

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| This SOP applies to the activities at sites monitored by the endTB clinical trial involved in tracing participants who have missed study visit(s) over the course of the trial. |

## RESPONSIBLE FUNCTIONS

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| **Function** | **Activities** |
| **Delegated site personnel** | * Follow SOP SM-003-CT for recruitment and retention of participants
* Identify potential lost to follow up subject
* Conduct tracing by phone, text, and/or email
* Conduct tracing by home visit
* Document tracing event and outcome
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## DEFINITIONS and ABBREVIATIONS

**Subject Tracing:** A combination of interventions carried out by a team of healthcare providers to reach subjects who have missed one or more study visits. The aim is to encourage subjects who have missed study visit(s) to return and continue participation.

## PROCEDURE:

### Identify Missed Appointments

**Delegated site personnel** responsible for overseeing and ensuring timely follow up of subjects must review both visit register and electronic visit tracking tool regularly to identify any missed visits. Site personnel should follow SOP SM-003-CT Recruitment and Retention of Participants to collect subjects’ contact information.

### Tracing by Telephone Calls, Texting, and/or Emailing

For participants who have missed one or more study visit(s), **delegated site personnel** are recommended to follow the procedures detailed below:

* + 1. Review subject’s file thoroughly to retrieve the subject’s primary and alternative contact information.
		2. Become familiar with the subject’s file, in particular the date of the last visit and the purpose of the missed visit, before making the call.
		3. On the day of missed visit, call and/or text all available numbers of the subject, subject’s study treatment supporter and other personal contacts (authorized by participant), email all known addresses to reach the subject. Call back all disconnected or unanswered phone numbers for a week to see if they are reconnected.
		4. Conduct a phone call directly with the subject. If the subject cannot be reached, check with the treatment supporter and other contacts to obtain updated subject contact information.
		5. When connected with the subject, check on overall well-being. If any AE is reported, follow SOP ***PV-001-CT Safety data collection and reporting at trial sites*** to report this information. Explore reason(s) for missing visits. Offer assistance needed to facilitate visit completion. Make sure contact information is updated in subject file as needed.
		6. Set up an appointment date for subject’s return to the clinic or home visit.
		7. Document follow-up attempt and/or outcome in subject’s file and on the Site Subject Tracing Log (Appendix 1).
		8. If someone else answers the phone, inquire about subject’s status and document updated contact details in the subject’s file. Be careful not to divulge subject’s information to unauthorized individual(s) (e.g. those not listed as family member(s) and/or personal supporter to the subject).
		9. If no connection can be made with the subject and/or alternative contact(s) despite two attempts, delegated site personnel should schedule a home visit to the subject’s home with the treatment supporter within three days, if possible.

After every attempted text/phone call/email, **delegated site personnel** should document the details of the attempt in the subject’s file:

* Date and time of the call/text/email
* Telephone number and/or email address used to reach subject
* Name of the person reached, if any
* Outcome/findings of the call

If the subject is dead, the Site Investigator must be informed immediately. Responsible clinical staff must document the death and primary cause of death in subject’s medical record, report the Serious Adverse Event, and complete applicable Case Report Form for early termination of study participation and treatment outcome. Delegated site personnel may need to schedule a home visit to meet participant’s family member(s).

### Tracing by Home Visit

**Delegated site personnel and/or treatment supporter** may conduct home visit(s) to subject’s home to locate subject. If the visit is set up without contact with the subject, designee should visit the last known address of the subject or other location provided by the subject or his/her family.

**Delegated site personnel and/or treatment supporter** is recommended to follow the procedural details below:

1. Review subject’s file and read the latest contact details to get an idea of what has been going on with the case.
2. Knock on door-
	1. If anyone answers:
		* Explain who you are and why you are there; be careful not to reveal subject’s information to unauthorized individual.
		* Ask if the subject is around.
		* If the subject is located, check on overall well-being. If any AE is reported, follow SOP… Explore reason(s) for missing visits. Offer assistance needed to facilitate visit completion. Make sure contact information is updated in subject file as needed.
	2. If no one answers the door and subject had provided prior permission to contact neighbors:
		* Go to neighbors and repeat step 2a.
		* Leave your business cards and contact information
		* Return to subject’s house and leave a note with business card.

After every home visit, **delegated site personnel** should document the visit details in the subject’s file:

* Date and time of the home visit
* Physical addresses visited to reach subject
* Name of the person interviewed, if any
* Outcome/findings of the visit

## REFERENCES

* The National ART Program Swaziland SOP for Patient Linkage, Retention and Follow-Up in HIV Care

## APPENDIX

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| **Appendices & Forms for completion** |
| **Number** | **Title** |
| 1 | Site Subject Tracing Log |