PROLIFE FIELDWORKER

TRAINING MANUAL YEAR 1

The production of this manual was supported by the South African Medical Research Council with funds received from the South African National Department of Health, and the UK Medical Research Council, with funds received from the UK Government's Newton Fund

TABLE OF **CONTENTS**

INTRODUCTION TO **THE PROLIFE PROJECT**

TB is caused by a bacterium that spreads from person-to-person. However, **compared to the general population, people who smoke tobacco and drink excess amounts of alcohol are more likely to catch TB and die from it.** Furthermore, they are less likely to take their TB and HIV (if co-infected) medicines, leading to treatment failure and death. Unfortunately, alcohol use and/or tobacco smoking are common among TB patients in South Africa. Therefore, addressing these major risk factors should be a key priority in TB treatment.

WE AIM TO DEVELOP AND TEST A NEW APPROACH **- THE PROLIFE MODEL – TO MODIFY THESE BEHAVIOURS IN TB PATIENTS.**

The PROLIFE model comprises of three brief one-to-one brief motivational interviewing counselling sessions between TB patients and lay health workers. These counseling sessions will be augmented with subsequent text messaging twice per week for 2 to 3 months.

This intervention will be offered in primary healthcare clinics located in three high TB burden provinces in South Africa, namely in Sedibeng district (Gauteng), Lejweleputswa district (Free State) and Bojanala district (North West province). In the second phase of the project, we will test the PROLIFE model by comparing the results of those clinics that receive it with those that don't. We will also study which factors enable and which act as barriers to offering the PROLIFE model. Our team consists of scientists from different disciplines and collaborators from a wide range of disciplines including policy makers, managers, and health professionals.

This manual covers the formative phase of this project, more specifically the training for fieldworkers. Participants who are enrolled into the study will receive three counselling sessions, each one month apart, from a trained counsellor at their TB clinic. These sessions will provide participants with helpful information regarding tobacco cessation, reducing harmful drinking, and TB and HIV-related treatment adherence. Participants will also receive SMS messages with helpful information twice a week for three months. Three clinics per district will be selected to participate in the study such that a total of nine clinics will take part in the Prolife study. The study will aim to enroll 3 participants per clinic.

The following staff and participants are expected to be involved in the project:

- **9 x Fieldworkers – Mobile interface**
- **3 x District coordinators – Mobile interface**
- **National coordinator / Admin – Web interface (read and write access to data collected)**

Each admin user as well as the national coordinator will be given access to the Outreach management console and will be able to see all data1.

1 ADMINISTRATION OF THE SCREENING QUESTIONNAIRE

PROCEDURES

1.1 Ask the Professional nurse to refer adult TB patients to you who are due to start TB treatment or who already started treatment. They must have a TB blue card, so that you can obtain the necessary information.

1.2 Find a private well ventilated space (preferably outside under the gazebo or another cover. If it is not possible to interview outside, interview in a well-ventilated space with open windows and UV lights and preferably use a HEPA mask).

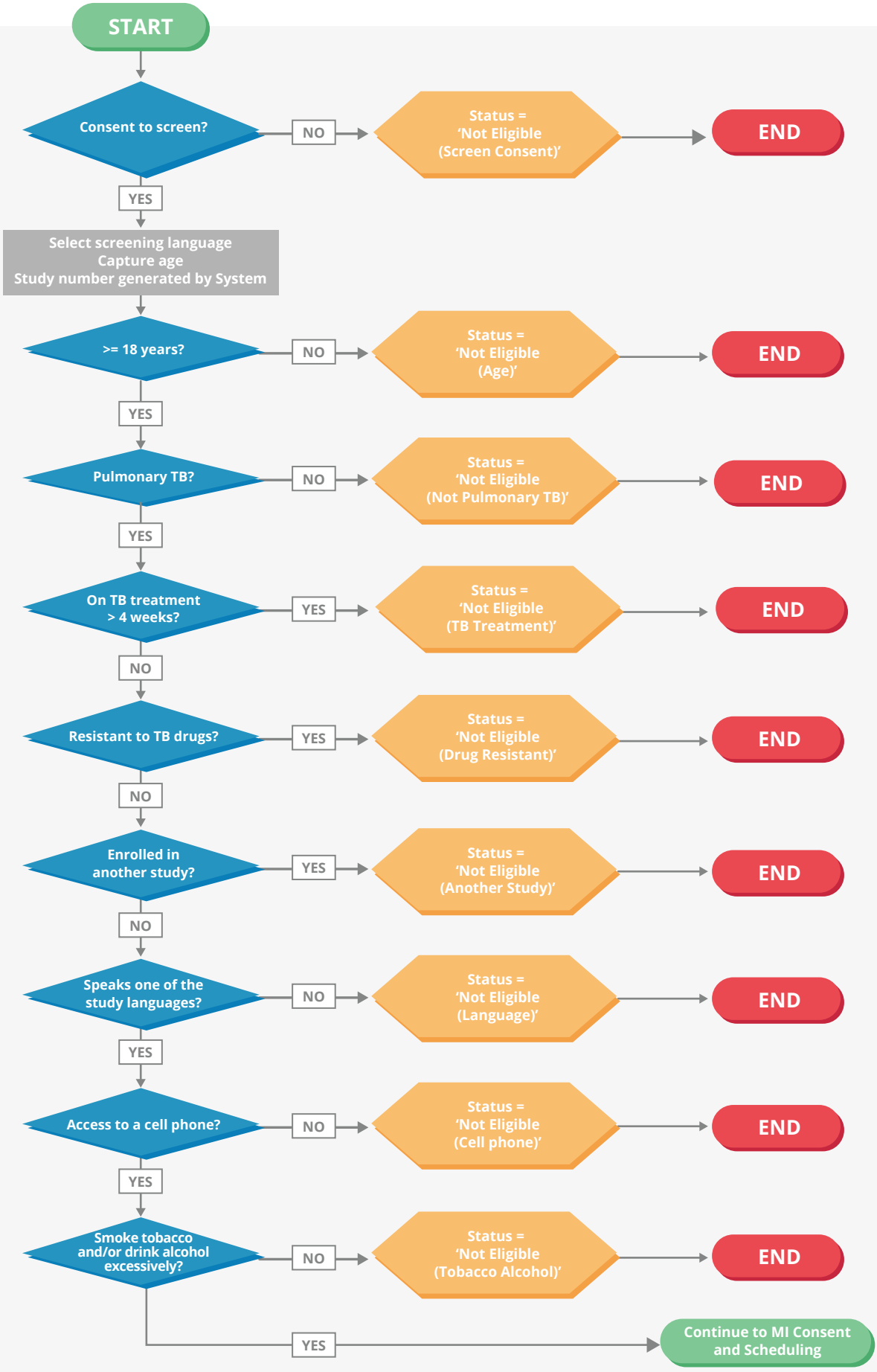
1.3 Explain the study in detail using the consent form and ask the patient whether he/she consents to participate in the screening leg of the study. Patient must sign consent form and receive a copy. The consent form must also be signed by a witness. The witness can be a family member or friend or fellow patient. Choose the consent form and questionnaire in the language preferred by the patient.

1.4 Guidelines re the completion of the screening questionnaire (appendix 2)

- Information of the screening questionnaire will be entered on the smartphone used for the study
- Choose the language for the interview. Do not come up with your own translation (unless there is a specific reason to clarify a term to the patient)
- **Study numbers will be generated automatically and consist of a number referring to the clinic number-fieldworker number-patient number. These study numbers are EXTREMELY important and will be used to identify the patient throughout the different follow-ups. This same study number will be tape recorded before the MI counselling session and will be recorded on your MI list.**
- Check the TB blue card for the TB related information, i.e. the patient should be on TB treatment for less than 1 month or not yet started on TB treatment and must have pulmonary tuberculosis (i.e. tuberculosis of the lung). He/she must not have drug-resistant tuberculosis.
- In addition the patient must be 18 year or older and must have a functional cell phone. He/she must not be enrolled for another study and must not be too ill to participate in the study.
- Furthermore the patient must be a current tobacco smoker and/or must be a harmful or hazardous drinker (AUDIT score ≥ 7 for women or ≥ 8 for men but < 20)
- Complete all questions on the device. The device will automatically end the interview if the patient is not eligible.

1.5 Screening questionnaire items: see flow diagram below and questionnaire in appendix 2.

Diagram 1: Screening (Fieldworkers)



Source: Mobenzi Prolife technical protocol-Version 4.0.

AUDIT SCORING INSTRUMENT	SCORING SYSTEM					YOUR SCORE
	0	1	2	3	4	
How often do you have a drink containing alcohol?	Never	Monthly or less	2 - 4 times per month	2 - 3 times per month	4+ times per month	
How many units of alcohol do you drink on a typical day when you are drinking?	1-2	3-4	5-6	7-9	10+	
How often have you had 6 or more units on a single occasion in the last year? (Please note that one drink is equivalent to one can or bottle of beer, cider or cooler, one glass of wine, or one tot of spirits).	Never	Less than monthly	Monthly	Weekly	Daily or almost daily	
How often during the last year have you found that you were not able to stop drinking once you had started?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily	
How often during the last year have you failed to do what was normally expected from you because of your drinking?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily	
How often during the last year have you needed an alcoholic drink in the morning to get yourself going after a heavy drinking session?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily	
How often during the last year have you had a feeling of guilt or remorse after drinking?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily	
How often during the last year have you been unable to remember what happened the night before because you had been drinking?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily	
Have you or somebody else been injured as a result of your drinking?	No		Yes, but not in the last year		Yes, during the last year	
Has a relative or friend, doctor or other health worker been concerned about your drinking or suggested that you cut down?	No		Yes, but not in the last year		Yes, during the last year	

EXPLANATION OF AUDIT SCORE

Hazardous drinking (AUDIT score between 8 and 15)

"Hazardous drinking is a pattern of alcohol consumption that increases the risk of harmful consequences for the user or others. Hazardous drinking patterns are of public health significance despite the absence of any current disorder in the individual user." (Babor et al., 1989)

"Scores between 8 and 15 are most appropriate for simple advice focused on the reduction of hazardous drinking." (Babor et al., 1989)

Harmful drinking (AUDIT score between 16 and 19)

"Harmful use refers to alcohol consumption that results in consequences to physical and mental health. Some would also consider social consequences among the harms caused by alcohol." (Babor et al., 1989)

Scores between 16 and 19 suggest brief counselling and continued monitoring.

Alcohol dependence (AUDIT score higher than 20)

"Alcohol dependence is a cluster of behavioural, cognitive, and physiological phenomena that may develop after repeated alcohol use. Typically, these phenomena include a strong desire to consume alcohol, impaired control over its use, persistent drinking despite harmful consequences, a higher priority given to drinking than to other activities and obligations, increased alcohol tolerance, and a physical withdrawal reaction when alcohol use is discontinued." (Babor et al., 1989)

AUDIT scores of 20 or above clearly warrant further diagnostic evaluation for alcohol dependence.

---

2 ORGANISATION OF MOTIVATIONAL INTERVIEWING SESSIONS

2.1 If the patient is eligible for Motivational Interviewing (a current smoker or problem/hazardous drinker), ask whether he/she is interested to continue with the study and be enrolled for 3 Motivational Interviewing sessions.

2.2 If interested, **administer the consent form for the MI and exit interview** (appendix 3).

2.3 Enter the demographic information on the mobile device.

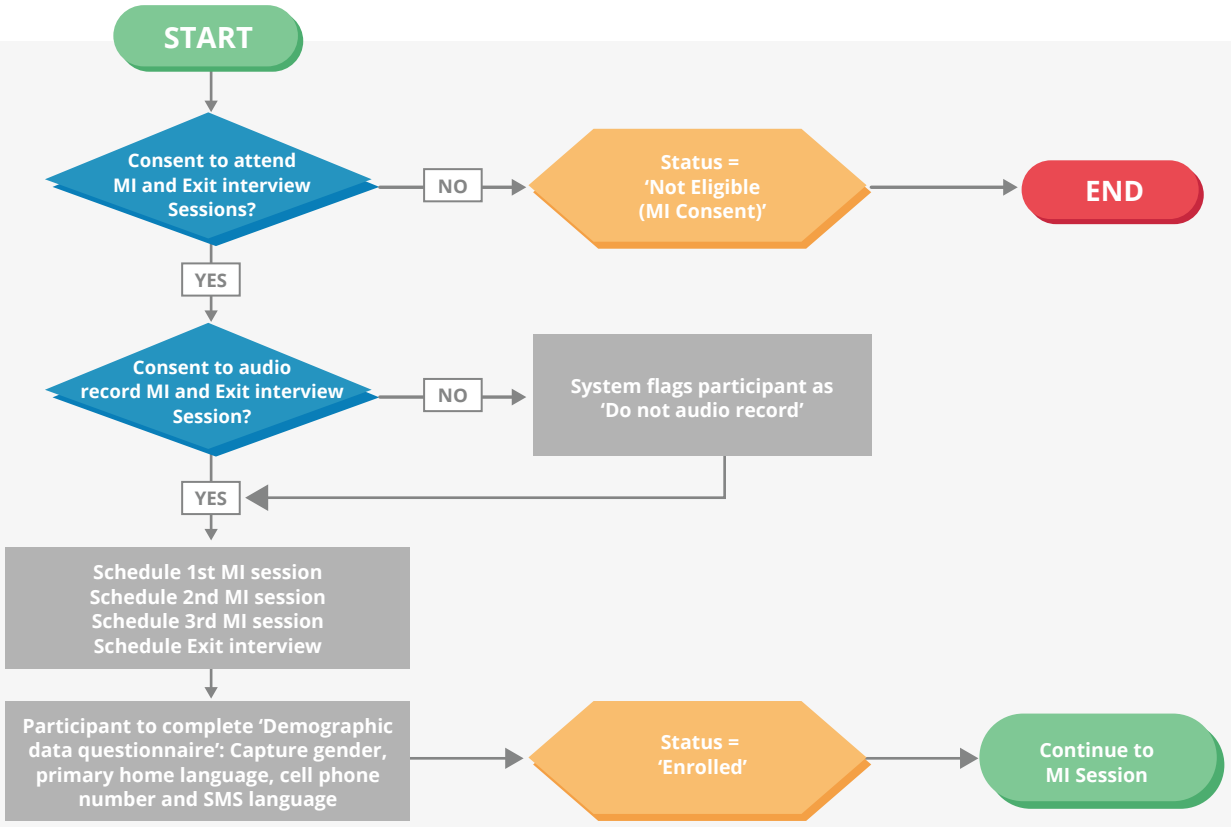
2.4 Now agree on a time and date for the first MI interview and for the follow-up interviews and schedule them on the device.

- The first MI session should preferably be on the same day of the completion of the screening questionnaire.
- The second MI session should ideally be 4 weeks from the first interview and MI session.

Where possible, the date should be the same as the return date for the TB treatment. However, if for some reason this date does not suit the participant you may give him/her another date within a 2 week window period. The device will automatically let you know if a date is outside that window period.

- The third MI session should approximately be 8 weeks from the first interview and MI session. Try to find a date that suits the participant. Explain to the patient that you expect him/her for the interview even if he/she is a few days earlier or later. However, the patient should not come more than 5 days before or after the planned date.

Diagram 2: MI Consent and Scheduling (Fieldworker)



Source: Mobenzi Prolife technical protocol-Version 4.0.

2.5 Accompany the participant to the first MI interview with the LHW.

2.6 The MI session must be recorded both with a recording device and with the LHWs cell phone (provided by the research team) as a backup. Activate the recorder and the cell phone for recording. Read in the **date, the patient study number** and the **LHW code in the recorder**. Then hand the recorder to the LHW for the actual MI session. Leave the room before the actual MI session starts.

2.7 At the end of each session, the participant will return to the fieldworker so that you can capture that the session occurred and give them a voucher for attending the counselling session. Capture the session date and the Lay Health Worker (LHW) who provided the counselling session onto your device.

The SMS stream of messages (TB adherence, smoking and/or alcohol) will automatically be initiated 1 day after the scheduled date of the first MI session. See Appendix 4 for the SMS message tables.

2.8 Collect the recorder and cell phone from the LHW after the MI session and complete the MI tracking form (see below). Enter the session on your mobile device. Remind the participant about the arrangements for the next MI session. **Copy the recorded MI session on the provided memory sticks** and lock recorders and memory stick in the provided secure cabinet at the clinic.

2.9 **Give the participant a shopping voucher to the value of R60 and ask them to sign the shopping voucher register**.

IMPROVING TB OUTCOMES BY MODIFYING LIFE-STYLE BEHAVIOURS THROUGH A BRIEF MOTIVATIONAL INTERVENTION

PROLIFE

PARTICIPANT CONTACT DETAILS FOR TELEPHONIC CONTACTS

This list must be kept under lock in the research cabinet and can only be accessed to obtain the name and surname of participants when and if they need to be called by the district coordinator, i.e. when the participant did not come for the MI session as planned.

Clinic Name: _____

Name of fieldworker: _____

Date: DD/MM/YY	Study number	Name and surname of participant

3 FOLLOW-UP AT 1 MONTH (4 WEEKS) AND 2 MONTHS (8 WEEKS)

Participants will be sent an automatic SMS reminder for their visits, 3 days before the planned date.

Every day the fieldworker must check on his/her hand held device who is due for return visits that day and verify whether the patient is present for the follow-up counselling.

If a participant fails to attend a scheduled MI session, the fieldworker will have the ability to send an SMS to the participant to encourage them to attend the missed MI session as soon as possible. When selecting the 'Send SMS' menu action, the device will automatically launch the SMS Inbox of the phone with the participant's phone number and the default message entered. The fieldworker will then push the 'Send' button in order to send the SMS.

SMS text: *Dear Study Participant – You did not attend your scheduled [Timepoint] Motivational Interview session on [Date] at [Clinic]. Please attend this session as soon as possible.*

If the participant is indeed at the clinic, the field worker accompanies the patient to the LHW. The patient should receive counselling from the same LHW for all 3 sessions. At the end of each MI session, remember to give the participant a shopping voucher and make him/her sign receipt. If – in exceptional circumstances the LHW is not available, please arrange an alternative visiting date with the participant.

Important note: If patients return more than 5 days before the planned MI session date or more than 5 days after the planned MI date, they can no longer be interviewed for that time point.

4 EXIT INTERVIEW WITH THE PATIENT

After the third MI session, the patient should be interviewed about his/her experiences with the MI sessions and the exit interview. The **district coordinator** must administer the exit interview to the patient.

The fieldworker must inform the district coordinator about the date and the time of the last MI session so that the district coordinator can hold the exit interview with the patient immediately after the MI session, if possible.

The district coordinator will enter responses to semi-structured questions on his/her mobile device and will record the open questions on the recorder and the cell-phone (as a back-up). Training and

supervision will be provided by Prof Morojele of the MRC.

The participant must receive a separate shopping voucher for this exit interview.

5 GENERAL INTERVIEWING TECHNIQUES AND INSTRUCTION FOR COMPLETION OF THE QUESTIONNAIRES
(FOR FIELDWORKERS AND DISTRICT COORDINATORS)

(Instruction Modified from GATS field interview manuals.
www.cdc.gov/tobacco/global/gats/manuals/pdfs.field_interviews.pdf)

5.1 INTRODUCTION

As a Field interviewer, you are responsible for ensuring that the questionnaires are administered properly. It is extremely important that you adhere closely to all procedures and that you administer the questionnaire exactly as it is written. In this section we will explain the correct procedures for administering the questionnaires.

5.2 GENERAL QUESTIONNAIRE CONVENTIONS

Rule 1: ALL questions must be read ALOUD word by word exactly as written in the questionnaire. For example: "Have you ever tried or experimented with tobacco smoking (cigarettes, cigars, cigarillos, hubbly bubbly/hooka, pipes?"

The only questions that must not be read are those that you were instructed to skip.

Rule 2: Answers to questions must also be read ALOUD word by word to the respondent if they are *"prompted"*

For example: question 2.5 of the patient exit questionnaire. However, no answer options should be read out for unprompted questions, for example question 2.4 of the patient exit questionnaire.

Rule 3: In general, if you make a mistake, do not use tippex. Draw a single line through the original information in a way that the information is not obscured and insert the correct data next to it.

Rule 4: correct answers must be CIRCLED, not crossed
(if you use paper based questionnaires)

5.3 STANDARDISATION OF QUESTIONNAIRE ADMINISTRATION

Every Field interviewer must administer *every* question in the questionnaire to *every* respondent in the same way. This consistency helps to eliminate variability and the collection of "biased" ("wrong") information. Follow the guidelines listed below to ensure that you are administering the questionnaire in a non-biased standardised manner:

ASKING THE QUESTIONS

- **Ask the questions using the exact words**. All questions must be read exactly as they appear in the questionnaire; to do otherwise risks invalidating the survey
- **Read the questions slowly**. As you become familiar with the questions, it is tempting to begin reading through the questions more quickly. Remember, however, that this is the first time the respondents has heard these questions. You must read slowly enough to allow the respondent time to understand everything you are asking.
- **Ask every question that is specified in the questionnaire (unless instructed to skip)**. Never presume that the answer to an upcoming question has already been provided by a previous answer.
- **Read the complete questions as displayed.** The respondent may interrupt you and answer before having heard the complete question. When this happens, read the question again, making sure the respondent hears the question through to the end. Do not assume a premature response applies to the question as written.
- **Repeat questions that are misinterpreted or misunderstood by the respondent**. The respondent might tell you that he or she did not understand the question, or he or she might look confused when trying to answer the question. The respondent might also give an answer that seems illogical or irrelevant to the question. In any of these circumstances, you should simply repeat the question exactly as written. If the respondent asks you a specific question (for example: "what do you mean by health care provider") and the definition for this item was given in the course or the manual, give this explanation. If no specific guidance was provided, do not give your own subjective guidance, but rather say "whatever 'health care provider' means to you".
  If several respondents seem to have difficulty with the same questions, inform the research coordinator and ask for guidance.
- **Do not suggest answers to the respondent**. As you proceed through the interview, you will come across questions that you might think you know the answers to based on prior information you have heard. You may feel the urge to suggest answers to the respondent. Resist this urge. Read the question as written.
- **Responses must represent the respondent's own opinions without bias introduced by the field interviewer**. Do not influence a respondent's answer with your behaviour (that is, your body language, you attitude, your tone of voice or any other way).

PROBING

Probing is a technique used to help ensure that the answers given by a respondents are as accurate and as complete as possible. Effective probes serve two purposes: (1) they encourage a respondent to express him or herself completely, and (2) they help the respondent focus on the specific requirements of the question.

To know when to use a probe, you must be thoroughly familiar with the questionnaire and what constitutes an acceptable response; that is, you must know what is being measured and what constitutes an acceptable response.

Only neutral or nondirective probes (those that do not influence the respondent) should be used in the interview. Some examples of proper probing techniques follow:

- **Neutral questions or statements**. These probes encourage a respondent to explain further or elaborate on a response without leading or directing the respondent to a particular answer. These must be stated in a neutral or non-challenging tone. Some examples of neutral probes include the following:
  - "What do you mean?"
  - "Please explain that."
  - "Which would you say is the closest?"
- **The silent probe**. A timely pause is the easiest and often the most useful type of probe. This pause lets your respondent know that you are expecting or waiting for additional information.
- **Clarification**. Use clarification probes when you judge the respondent's answer to be unclear, inconsistent, ambiguous or contradictory. You must take care, however, not to appear to challenge the respondent. Instead tactfully express concern over not completely understanding the nature of the response. Some examples include the following:
  - "I'm not quite sure I understand what you mean by that. Could you tell me a little more?"
  - "I'm sorry, but a few minutes ago I thought you said [CONTRADICTORY INFORMATION]. Could you clarify this for me?"
- **Encouragement**. This technique involves conveying to the respondent that you understand what he or she has said, and you would like to hear more. Nonverbal probes of this nature include a nod of the head or an expectant expression. Some examples include the following:
  - "I see..."
  - "That's interesting..."
- **Repetition**. Repetition could be either repeating the question or the response. Repeating the question is useful when it appears that the respondent may have misunderstood the question or has deviated from the topic. Repeating the response may produce additional comments or explanation form the respondent, especially if you say it in the form of a question.

For example, if you ask, “Do you “currently” smoke tobacco on a daily basis, less than daily, or not at all?” and the respondent says “a lot", you could look at him and say “a lot?”. You are likely to get additional details or information, such as “Well, I’d say at least once a day.”
It may also be helpful to simply repeat the response options so the respondent knows that you need one of the listed responses.

“DON’T KNOW” RESPONSES

When the respondent says, “I don’t know”, it can mean two things: (1) either he or she is not sure of an answer and needs more time to think, or (2) he or she actually does not know the answer to the question. You must distinguish between the two.

A respondent may say. “I don’t know”, when asked to offer an opinion or attitude. He or she may find it difficult to put feelings into words. If you suspect this is the case, you should put him or her at ease by saying, “There is no right or wrong answer. Just tell me how you feel about this.” Similarly, if a respondent is unsure about an answer choice, you should encourage him or her to provide a best estimate.

When a respondent is uncomfortable answering such questions, he or she may respond “I don’t know”, in an effort to avoid the question. If this appears to be the case, you again must make every effort to put your respondent at ease, reassuring him or her that the answers are confidential and are very important to the survey.

In the end, the respondent may insist that he or she does not know how to answer that particular question. Once you have properly probed for an answer, you should accept the response in the interest of not alienating the respondent even you believe he or she may be avoiding the question. Remember that there may be times when the respondent actually does not know the answer to a question.

Many of the same rules apply when a respondent says, “I don’t want to answer that question- I refuse.” When a respondent is uncomfortable answering such a questions, he or she may respond, “I don’t want to answer that question” of “I’m uncomfortable answering that”, in an effort to avoid the question. If this appears to be the case, you should make every effort to put the respondent at ease, reassuring him or her that the answers are confidential and are very important to the survey.

Despite your efforts to assure the respondent, he or she has the right to refuse to answer any question. You should not bully or harass the respondent to answer a question.

6 TUBERCULOSIS RECORD INFORMATION

The tuberculosis related information must be obtained from the blue TB cards (GW 20/12)

6.1 TB treatment start date: on second page under the heading: Regimen and dosage. If the patient started TB treatment more than 1 month ago, then the patient cannot be enrolled.

6.2 Pulmonary Tuberculosis versus extrapulmonary TB: this information is available on the first page of the TB card under the heading "classification of disease

7 STORAGE OF COMPLETED QUESTIONNAIRES, FORMS AND EQUIPMENT

All completed consent forms (and questionnaires if applicable) must be stored safely in the locked research cabinet at the clinic. Consent forms must be separated from the questionnaires and kept in a separate envelope. They will be checked on a weekly basis by the district coordinator.

The recording device and cell phone used as backup recorder and the memory sticks must also be locked away safely in the locked research cabinet.

8 STUDY PARTICIPANTS SHOPPING VOUCHER MONITORING FORM

The form below must be completed to monitor the issuing of lunch packets to the study participants:

FORM FOR MONITORING OF SHOPPING VOUCHER DISBURSEMENT

I confirm that I received a shopping voucher as reimbursement for my costs incurred for participating in the study.

DATE	STUDY NUMBER OF STUDY PARTICIPANT	PURPOSE (I.E. MI1, MI2, MI3, EXIT INTERVIEW)	SIGNATURE

9 ROLES AND RESPONSIBILITIES OF FIELDWORKERS, DISTRICT COORDINATORS, LAY HEALTH WORKERS, SITE LEADS AND THE SENIOR RESEARCH COORDINATOR

FIELDWORKERS

- Identify patients for screening
- Administer consent forms for screening questionnaires and administer actual screening questions on their hand held device
- Administer consent forms for "TB PATIENT CONSENT FORM FOR THE PILOTING OF THE MOTIVATIONAL INTERVIEWING AND SMS-MESSAGE: SEMI-STRUCTURED INTERVIEW"
- Schedule MI sessions
- Administer demographic questions on the patient MI piloting questionnaire ("TB PATIENT CONSENT FORM FOR THE PILOTING OF THE MOTIVATIONAL INTERVIEWING AND SMS-MESSAGE: SEMI-STRUCTURED INTERVIEW"), accompany participant to LHW and set up the recording devices. Record the date, study number and LHW number on the recording device and the back-up cell phone.
- Administer and control shopping voucher
- Safeguard patient phone numbers, consent forms, recording devices, and data.
- Send SMS reminders to patients who did not come for return visits
- Liaise with district coordinator.

LAY HEALTH WORKERS

- Provide 3 MI counselling sessions to each participant
- Complete the MI record form

DISTRICT COORDINATORS

- Transfer the MI sessions recorded on the recorder to a computer and from there on memory sticks.
- Overall monitoring of data collection and adherence to protocol procedures
- Regular supervisory visits to each clinic (at least once a week)
- Conduct exit interviews with study participants
- Call participants who are late for their return visit
- Call the LHWs to inform them about the MI sessions due, as needed.
- Manage HR-related issues
  (i.e. unplanned absence of LHW of fieldworkers, remuneration issues)
- Liaise with the senior research coordinator and the site leads
- Organize shopping vouchers
- Any other operational task as required by the site leads or the senior research coordinator

SITE LEADS

- Overall academic and operational supervisory role.

SENIOR RESEARCH COORDINATOR (AT SMU)

- Research project coordination and operationalization at national level.
- Liaise with site leads, district coordinators, principal investigators, co-investigators, national and international stake holders.

APPENDICES

1 PROLIFE PRESENTATION

Printed version of presentation accompanied by manual.

2 SCREENING QUESTIONNAIRE

SCREENING INSTRUMENT TO DETERMINE WHETHER TB PATIENTS ARE ELIGIBLE FOR THE MOTIVATIONAL INTERVIEWING AND SMS PILOTING

STUDY TITLE: Improving TB outcomes by modifying life-style behaviours through a brief motivational intervention (PROLIFE)

PHASE 1: DEVELOPMENT AND FEASIBILITY STUDY
Funder MRC-Newton Foundation
PRINCIPAL INVESTIGATORS

Prof Olalekan Ayo-Yusuf (Principal Investigator)	Sefako Makgatho University/ University of Pretoria
Dr Kamran Siddiqi (Co-principal investigator)	University of York

DAYTIME AND AFTER HOURS TELEPHONE NUMBER(S):
Daytime numbers: 012 521 4611
After hours: 083 442 1970 (Principal Investigator Prof OA Ayo-Yusuf)

DATE AND TIME OF FIRST INFORMED CONSENT DISCUSSION:

_____ _____
DD/MM/YY TIME

Dear Mr/Mrs _____

INTRODUCTION

Good day,

You are invited to participate in a screening survey for a research study. Before you decide whether or not to take part, here is why we are doing the study and what it involves. As you may know, tuberculosis (TB) is a serious concern in our country. There are many factors that influence successful TB outcomes, including HIV, treatment adherence, smoking and alcohol use. A team of local and international stakeholders and experts will develop an intervention that will target tobacco smoking, problem alcohol drinking and TB and antiretroviral treatment adherence. This study is funded by the Newton Fund and Medical Research Council.

WHAT IS THE PROLIFE TRIAL ABOUT? WHY ARE YOU ASKED TO PARTICIPATE IN THIS STUDY?

The Prolife study is a research study on tobacco smoking, alcohol and treatment adherence in TB patients and we are inviting you to take part in this study. The study is funded by the Medical Research Council-Newton Foundation and is approved by the ethics committees of Sefako Makgatho University, the University of York, the University of Pretoria, the University of Witwatersrand and South African Medical Research Council in South Africa. Here, we explain why we are doing the Prolife Study and what it will involve. This will help you to decide whether to participate in this study. You are free to choose whether or not to participate in this study.

The purpose of this screening procedure is to collect information about you to determine whether or not you qualify to take part in the study. This screening will involve you answering some questions on your current health, smoking and alcohol drinking behaviour. A research assistant will also examine your medical records during this screening procedure. In order to qualify, you must be an adult with pulmonary tuberculosis who smokes tobacco or who drinks alcohol.

WHAT WILL I HAVE TO DO?

You will have to give consent for the screening including the examining of your medical records. If you agree to the screening procedure (or to participate) you will be asked a series of questions to determine your eligibility. These questions include information about your current health, treatment and smoking and drinking behaviour. This screening procedure will take approximately 10 minutes.

ARE THERE ANY RISKS OR DISCOMFORT INVOLVED?

There are no direct risks to your health but you might feel uncomfortable in answering certain questions. If you do, you may withdraw from the screening at any time.

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART IN THE STUDY?

You may qualify to participate in the research study and it is hoped that the information collected from the study will help the researches to develop an intervention which may benefit your health.

REIMBURSEMENT

You will not receive reimbursement for the screening. You will also not be charged for the screening.

HAS THE STUDY RECEIVED ETHICAL APPROVAL?

This Protocol was submitted to the Research Ethics Committees of the relevant Universities: Sefako Makgatho University; University of York; University of Witwatersrand; the University of Pretoria, the Medical Research Council; and the University of the Free State. The study has been structured in accordance with the Declaration of Helsinki (last update: October 2013), which deals with the recommendations guiding doctors in biomedical research involving human/subjects. A copy of the Declaration may be obtained from the investigator should you wish to review it. If you have any queries related to ethics, you may contact:

WHERE CAN I OBTAIN ADDITIONAL INFORMATION?

IF I HAVE ANY QUESTIONS CONCERNING THIS STUDY, I SHOULD CONTACT:

- Dr Mohlatlego H Sebola, tel: 012 521 4611 or cell: 071 200 3117
- Dr Olu Omole, tel: 016 950 6192 cell: 076 472 1289 (Sedibeng district)
- Prof John Tumbo, tel: 012 521 4314 or cell: 082 885 8332 (Bojanala district)
- Dr Michelle Engelbrecht, tel: 051 401 3256 or cell: 083 304 8182 (Lejweleputswa district)

IF I HAVE ANY QUERIES RELATED TO ETHICS, I SHOULD CONTACT:

1. Dr C.Baker at Sefako Makgatho Health Sciences University
   (telephone number: 012 521 5617);
2. Dr S Holland at the University of York (telephone number: 019 0432 4031);
3. University of the Witwatersrand
   Prof P Cleaton Jones, Chair, Tel 011 717 2301, Email: peter.cleaton-jones1@wits.ac.za
   Ms Z Ndlovu, Administrative Officer, Email: zanele.ndlovu@wits.ac.za
   Mr Rhulani Mkansi, Administrative Officer, Email: rhulani.mkansi@wits.ac.za

Mr Lebo Moeng, Administrative Officer, Email: lebo.moeng@wits.ac.za
Tel: 011 717 2700/2656/1234/1252

4. Professor W Van Staden at the University of Pretoria
(telephone numbers: 012 354 1677/ 012 354 1330);
5. Professor D du Toit at the South African Medical Research Council
(telephone number: 021 938 0687).
6. The Chairperson: University of the Free State Ethics Committee: Health Sciences
Block D, Deans Division, Room D104
PO Box 2339 (Internal Box G40)
Bloemfontein
Tel: 051 – 401 7795
e-mail: EthicsFHS@ufs.ac.za

VOLUNTARY PARTICIPATION/WITHDRAWAL

Your participation in this screening is voluntary. At any time, you may change your mind and choose not to participate at any time, without penalty or loss of benefit unrelated to the screening. We may also stop the screening if you are not eligible.

CONFIDENTIALITY

Your answers will be confidential. No one will have access to your personal information and answers except for the research team. All the information we collect from you will be kept confidential on secure computers and in locked filing cabinets in locked offices and transferred safely to the country's coordinating centre to be secured. The study materials will be kept for 15 years; after which time they will be destroyed. We will need you to provide your name and sign this consent form, but the form will be kept safely in a locked cabinet in the office of the researcher. Your identity and location in this study will remain strictly confidential.

CONSENT TO PARTICIPATE IN THIS STUDY

I have read or had read to me in a language that I understand the above information before signing this consent form. The content and meaning of this information have been explained to me. I have been given opportunity to ask questions and am satisfied that they have been answered satisfactorily. I understand that if I do not participate it will not alter my management in any way. I hereby volunteer to take part in this screening stage of the study.

I have received a signed copy of this informed consent agreement.

Study participant's Name	_____ (Please print)		
Study participant's Signature	_____	Date	_____
Investigator's Name	_____ (Please print)		
Investigator's Signature	_____	Date	_____
Witness's Name	_____ (Please print)		
Witness's Signature	_____	Date	_____

VERBAL PATIENT INFORMED CONSENT

(This section is only applicable to participants who are unable to read and write)

I, the undersigned, _____, have read and have explained fully to the study participant's, named _____and/or his/her relative, the patient information leaflet, which has indicated the nature and purpose of the study in which I have asked the patient to participate. The explanation I have given has mentioned both the possible risks and benefits of the study and the alternative treatments available for his/her illness. The patient indicated that he/she understands that he/she will be free to withdraw from the study at any time for any reason and without jeopardizing his/her treatment.

The patient consents to the obtaining of information from his/her TB file to determine the type of TB she/he has and to determine for how long she/he has been on treatment.

I hereby certify that the patient has agreed to participate in this study.

(The study participant's name and date must be completed by the investigator)		
Study participant's Name	_____ (Please print)	
Study participant's Mark/Thumb print		Date _____
Investigator's Name	_____ (Please print)	
Investigator's Signature	_____	Date _____
Witness's Name	_____ (Please print)	
Witness's Signature	_____	Date _____

(Witness signs that he/she has witnessed the process of informed consent)

CONSENT TO EXAMINE PATIENT'S MEDICAL RECORD

I have read or had read to me in a language that I understand the information about this study before signing this consent form. The content and meaning of this information have been explained to me. I have been given opportunity to ask questions and I am satisfied that they have been answered satisfactorily. I understand that if I do not give consent for my medical records to be examined by the researchers, it will not alter my management in any way. I hereby consent to my medical records being examined at this stage of the study.

	YES	NO
I consent to the obtaining of information from my TB file to determine the type of TB I have and to determine for how long I have been on treatment.	1	2

I have received a signed copy of this informed consent agreement.

Study participant's Name _____
(Please print)

Study participant's Signature _____ Date _____

Investigator's Name _____
(Please print)

Investigator's Signature _____ Date _____

Witness's Name _____
(Please print)

Witness's Signature _____ Date _____

VERBAL CONSENT TO EXAMINE MEDICAL RECORDS

(This section is only applicable to participants who are unable to read and write)

I, the undersigned, _____, have read and have explained fully to the study participant's, named _____and/or his/her relative, the patient information leaflet, which has indicated the nature and purpose of the study in which I have asked the patient to consent that his/her medical record be examined. The patient indicated that he/she understands that he/she will be free to withdraw her/his consent at any time, for any reason and without jeopardizing his/her treatment.

The patient consents to the obtaining of information from his/her TB file to determine the type of TB she/he has and to determine for how long she/he has been on treatment.

I hereby certify that the patient has agreed to participate in this study.

(The study participant's name and date must be completed by the investigator)		
Study participant's Name	_____ (Please print)	
Study participant's Mark/Thumb print		Date _____
Investigator's Name	_____ (Please print)	
Investigator's Signature	_____	Date _____
Witness's Name	_____ (Please print)	
Witness's Signature	_____	Date _____

(Witness signs that he/she has witnessed the process of informed consent)

ELIGIBILITY CRITERIA OVERVIEW

Unique study number for the participant

Please indicate Yes (Y) or No (N) to the following questions

		NO	YES
1.	Is the patient 18 years or older? **(If "No" please end the interview)**.	0	1
2.	Does patient have pulmonary TB? (To be extracted from the TB blue card or from information from the TB nurse on admission to the clinic). **(If "No" please end the interview).**	0	1
3.	Has the patient been on treatment for more than four weeks? (To be extracted from the TB blue card or the green card or the pink hospital referral form or from information from the TB nurse on admission to the clinic). **(If "Yes" please end the interview)**.	0	1
4.	Are you currently taking part in another study? **(If "Yes" please end the interview)**.	0	1
5.	Do you have easy access to a functional cell phone? This will allow us to SMS you supportive messages and send you reminders regarding appointments. If yes, what is your cell phone number: _____ Alternative cell phone number: _____ **(If No easily accessible cell phone, please end the interview)**.	0	1
6.	Name of the clinic or health centre:		
7.	What is your age?(Age in completed years)		
		Male	**Female**
8.	Sex	0	1
		NO	**YES**
9.	Have you ever tried or experimented with tobacco smoking (cigarettes, cigars, cigarillos, hubbly bubbly/hooka, pipes), even one or two puffs?	0	1
10.	During the past 30 days, on how many days did you smoke tobacco (cigarettes, cigars, cigarillos, hubbly bubbly/hooka, pipes)?		
		NO	**YES**
11.	Have you had a drink containing alcohol in the past 12 months?	0	1

If ZERO for question 10 and NO for questions 11 end the interview.

Below is a list of questions about your drinking behaviour.
Please circle the score (1-4) that best reflects your behaviour.

	Never	Monthly or less	2 to 4 times a month	2 to 3 times a week	4 or more times a week	Sub totals
12. How often do you have a drink containing alcohol?	0	1	2	3	4	
	1 or 2	3 or 4	5 or 6	7 to 9	7 to 9	
13. How many drinks containing alcohol do you have on a typical day when you are drinking? (Please note that one drink is equivalent to one can or bottle of beer, cider or cooler, one glass of wine, or one tot of spirits).	0	1	2	3	4	
	Never	Monthly or less	2 to 4 times a month	2 to 3 times a week	4 or more times a week	Sub totals
14. How often do you have six or more drinks on one occasion?	0	1	2	3	4	
15. How often during the last year have you found that you were not able to stop drinking once you have started?	0	1	2	3	4	
16. How often during the last year have you failed to do what was normally expected from you because of drinking?	0	1	2	3	4	
17. How often during the last year have you needed a first drink in the morning to get yourself going after a heavy drinking session?	0	1	2	3	4	
18. How often during the last year have you had a feeling of guilt or remorse after drinking?	0	1	2	3	4	
19. How often during the last year have you been unable to remember what happened the night before because you had been drinking?	0	1	2	3	4	

	No	Yes, but not in the last year	Yes, during the last year	
20. Have you or someone else been injured as a result of your drinking?	0	2	4	
21. Has a relative, friend, or a doctor or another health worker been concerned about your drinking or suggested you cut down?	0	2	4	

Please calculate the **total AUDIT score:**

Respondent is a CURRENT smoker (smoked tobacco in the past month)	**Eligible:** proceed with MI and SMS pilot PIC
AUDIT score is ≥8 for men or ≥7 for women AND the AUDIT score is <20	**Eligible:** proceed with MI and SMS pilot PIC
AUDIT score is <8 for men or <7 for women AND the respondent is NOT a current smoker (smoked zero cigarettes/cigars/cigarillos/pipes in the past month)	**Not eligible:** do not proceed with MI and SMS pilot PIC
AUDIT score is ≥20 and the respondent is NOT a current smoker (smoked zero cigarettes/cigars/cigarillos/pipes in the past month)	**Not eligible:** do not proceed with MI and SMS pilot PIC

Thank you very much.

3 EXIT QUESTIONNAIRE FOR PATIENTS + CONSENT FORMS FOR MOTIVATIONAL INTERVIEWING AND FOR EXIT QUESTIONNAIRE

TB PATIENT CONSENT FORM FOR THE PILOTING OF THE MOTIVATIONAL INTERVIEWING AND SMS-MESSAGE: SEMI-STRUCTURED INTERVIEW

STUDY TITLE: Improving TB outcomes by modifying life-style behaviours through a brief motivational intervention (PROLIFE)

PHASE 1: DEVELOPMENT AND FEASIBILITY STUDY
Funder MRC-Newton Foundation
PRINCIPAL INVESTIGATORS

Prof Olalekan Ayo-Yusuf (Principal Investigator)	Sefako Makgatho University/ University of Pretoria
Dr Kamran Siddiqi (Co-principal investigator)	University of York

DAYTIME AND AFTER HOURS TELEPHONE NUMBER(S):
Daytime numbers: 012 521 4611
After hours: 083 442 1970 (Principal Investigator Prof OA Ayo-Yusuf)

DATE AND TIME OF FIRST INFORMED CONSENT DISCUSSION:

_____ _____
DD/MM/YY TIME

Dear Mr/Mrs _____

INTRODUCTION

You are invited to volunteer for a research study. This information leaflet is to help you to decide if you would like to participate. Before you agree to take part in this study you should fully understand what is involved. If you have any questions, which are not fully explained in this leaflet, do not hesitate to ask the investigator. You should not agree to take part unless you are completely happy about all the procedures involved. In the best interests of your health, it is strongly recommended that you discuss with or inform your personal doctor of your possible participation in this study, wherever possible.

WHAT IS THE PROLIFE TRIAL ABOUT? WHY ARE YOU ASKED TO PARTICIPATE IN THIS STUDY?

The Prolife study is a research study on tobacco smoking, alcohol and treatment adherence in TB patients and we are inviting you to take part in this study. The study is funded by the Medical Research Council-Newton Foundation and is approved by the ethics committees of Sefako Makgatho University, the University of York, the University of Pretoria, the University of Witwatersrand and South African Medical Research Council in South Africa.

Here, we explain why we are doing the Prolife Study and what it will involve. This will help you to decide whether to participate in this study. You are free to choose whether or not to participate in this study.

Tobacco smoking and excessive alcohol use is bad for health, particularly for those with TB. If TB patients continue to smoke during their treatment, drink too much alcohol or forget to take their treatment; they may not recover from TB. The Prolife study aims to test how best to get TB patients to stop smoking, reduce harmful drinking and be adherent to their treatment (TB and/or HIV-treatment as applicable).

WHAT WILL I HAVE TO DO?

As you are a smoker or you drink alcohol quite heavily, you will receive three counselling sessions of about 20 minutes' duration - each one month apart- from a trained counsellor at the TB clinic. The counsellor will help you to quit smoking or reduce alcohol consumption and will help you to take your treatment regularly and correctly. These counselling sessions will provide you with helpful information regarding tobacco cessation if you are a smoker, guidance on how to reduce harmful drinking, TB and HIV-related treatment and how to adhere to the treatment. You will also receive Short Messages (SMS) via your cell phone with helpful information. These messages will be sent to you twice a week for 3 months.

The counsellor will tape record the counselling session, but your name will not be reflected anywhere on the records. This tape-recorded conversation will help us to determine the quality of the counselling and to train the counsellors further if needed.

After the final counselling session, you will also be asked a few short questions about what you liked and disliked about the counselling sessions and the SMS messages.

ARE THERE ANY RISKS OR DISCOMFORT INVOLVED?

You may feel a bit uncomfortable disclosing personal issues relating to tobacco smoking or alcohol use or problems with taking your medication. However, we are here to help you to address any problem you may have with regards to those issues. We stress that all information will be kept confidential.

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART IN THE STUDY?

The counselling sessions and SMS messages may help you to quit smoking or reduce alcohol consumption and help you to take your medication better. This will help you to heal from your TB.

REIMBURSEMENT

To cover your travel expenses for the extra visits, you will be reimbursed to the value of 60 Rand per counselling session.

I UNDERSTAND THAT IF I DO NOT WANT TO PARTICIPATE IN THIS STUDY, I WILL STILL RECEIVE STANDARD TREATMENT FOR MY ILLNESS. I MAY AT ANY TIME WITHDRAW FROM THIS STUDY.

HAS THE STUDY RECEIVED ETHICAL APPROVAL?

This Protocol was submitted to the Research Ethics Committees of the relevant Universities: Sefako Makgatho University; University of York; University of Witwatersrand; the University of Pretoria, the Medical Research Council; and the University of the Free State.

Written approval has been granted by the above mentioned committees. The study has been structured in accordance with the Declaration of Helsinki (last update: October 2013), which deals with the recommendations guiding doctors in biomedical research involving human/subjects. A copy of the Declaration may be obtained from the investigator should you wish to review it.

WHERE CAN I OBTAIN ADDITIONAL INFORMATION?

If I have any questions concerning this study, I should contact:

- Dr Mohlatlego H Sebola, tel: 012 521 4611 or cell: 071 200 3117
- Dr Olu Omole, tel: 016 950 6192 cell: 076 472 1289 (Sedibeng district)
- Prof John Tumbo, tel: 012 521 4314 or cell: 082 885 8332 (Bojanala district)
- Dr Michelle Engelbrecht, tel: 051 401 3256 or cell: 083 304 8182 (Lejweleputswa district)

If I have any queries related to ethics, I should contact one of the following:

1. Dr C.Baker at Sefako Makgatho Health Sciences University
   (Telephone number: 012 521 5617);
2. Dr S Holland at the University of York (Telephone number: 019 0432 4031);
3. Prof P Cleaton-Jones: University of the Witwatersrand
   (Telephone numbers: 011 274 9278/ 011 274 9279/ 011 274 9255);
4. Professor W Van Staden at the University of Pretoria
   (Telephone numbers: 012 354 1677/ 012 354 1330);
5. Professor D du Toit at the South African Medical Research Council
   (Telephone number: 021 938 0687).
6. The Chairperson: University of the Free State Ethics Committee: Health Sciences
   Block D, Deans Division, Room D104
   PO Box 2339 (Internal Box G40)
   Bloemfontein
   Tel: 051 – 401 7795
   e-mail: EthicsFHS@ufs.ac.za

IF I TAKE PART WILL MY INFORMATION BE KEPT CONFIDENTIAL?

All the information we collect from you will be kept confidential on secure computers and in locked filing cabinets in locked offices and transferred safely to the country's coordinating centre at Sefako Makgatho University to be secured. The study materials will be kept for 15 years; after which time they will be destroyed. Your identity and location in this study will remain strictly confidential. The results of the study, including data, may be published for scientific purposes but will not give your name or include any identifiable references to you.

CONSENT TO PARTICIPATE IN THIS STUDY

I have read or had read to me in a language that I understand the above information before signing this consent form. The content and meaning of this information have been explained to me. I have been given opportunity to ask questions and am satisfied that they have been answered satisfactorily. I understand that if I do not participate it will not alter my management in any way. I hereby volunteer to take part in this study.

I have received a signed copy of this informed consent agreement.

Study participant's Name	_____ (Please print)		
Study participant's Signature	_____	Date	_____
Investigator's Name	_____ (Please print)		
Investigator's Signature	_____	Date	_____
Witness's Name	_____ (Please print)		
Witness's Signature	_____	Date	_____

VERBAL PATIENT INFORMED CONSENT

(This section is only applicable to participants who are unable to read and write)

I, the undersigned, _____, have read and have explained fully to the study participant's, named _____ and/or his/her relative, the patient information leaflet, which has indicated the nature and purpose of the study in which I have asked the patient to participate. The explanation I have given has mentioned both the possible risks and benefits of the study and the alternative treatments available for his/her illness.

The patient indicated that he/she understands that he/she will be free to withdraw from the study at any time for any reason and without jeopardizing his/her treatment.

I hereby certify that the patient has agreed to participate in this study.

(The study participant's name and date must be completed by the investigator)		
Study participant's Name	_____ (Please print)	
Study participant's Mark/Thumb print		Date _____
Investigator's Name	_____ (Please print)	
Investigator's Signature	_____	Date _____
Witness's Name	_____ (Please print)	
Witness's Signature	_____	Date _____

(Witness signs that he/she has witnessed the process of informed consent)

CONSENT TO ALLOW AUDIO RECORDING

I have read or had read to me in a language that I understand, the above information regarding this study and the need for an audio recording of the interview before signing this consent form. The content and meaning of this information have been explained to me. I have been given opportunity to ask questions and I am satisfied that they have been answered satisfactorily. I understand that if I do not consent to this audio recording, it will not alter my management in any way. I further understand that I can request that the tape recorder or video recorder be turned off at any time and may request that the tape or any portion thereof be erased. I may terminate this permission to tape at any time. The contents of these taped sessions are confidential and the information will not be shared outside the context of this research. The tapes will be stored in a secure location and will not be used for any other purpose without my explicit written permission. The tapes will be erased after they have served their purpose.

I have received a signed copy of this informed consent agreement.

Study participant's Name	_____ (Please print)		
Study participant's Signature	_____	Date	_____
Investigator's Name	_____ (Please print)		
Investigator's Signature	_____	Date	_____
Witness's Name	_____ (Please print)		
Witness's Signature	_____	Date	_____

VERBAL PATIENT CONSENT FOR AUDIO RECORDING

(This section is only applicable to participants who are unable to read and write)

I, the undersigned, _____, have read and have explained fully to the study participant's, named _____ and/or his/her relative, in a language that he/she/they understand, the above information regarding this study and the need for an audio recording of the interview before asking him/her/them to sign this consent form as evidence that the content and meaning of this information have been understood by her/him/them. I have given him/her/ them opportunity to ask questions and they are satisfied that they have been answered satisfactorily. The he/she understands: that if she/he does not consent to this audio recording, it will not alter her/his management in any way, that he/she can request that the tape recorder be turned off at any time and may request that the tape or any portion thereof be erased, that he/she may terminate this permission to tape at any time, that the contents of these taped sessions are confidential and the information will not be shared outside the context of this research, that the tapes will be stored in a secure location and will not be used for any other purpose without his/her explicit written permission and that the tapes will be erased after they have served their purpose.

I hereby certify that the patient has consented to the audio recording.

(The study participant's name and date must be completed by the investigator)

Study participant's Name _____
(Please print)

Study participant's Mark/Thumb print

Date _____

Investigator's Name _____
(Please print)

Investigator's Signature _____ Date _____

Witness's Name

_____
(Please print)

Witness's Signature _____ Date _____

(Witness signs that he/she has witnessed the process of informed consent)

STUDY TITLE: Improving TB outcomes by modifying life-style behaviours through a brief motivational intervention (PROLIFE)

Funder MRC-Newton Foundation
SEMI-STRUCTURED INTERVIEW WITH RESPONDENTS (TB patients)

Semi Structured Interview Number:	
Date of Interview:	_____/_____/_____
Clinic:	
Time started:	_____:_____
Time ended:	_____:_____
	Notes Typed
Date:	_____/_____/_____
Signature:	_____
	Transcribed
Date begun:	_____/_____/_____
Date ended:	_____/_____/_____
Signature:	_____

GENERAL INFORMATION

Thank you for agreeing to take part in this-interview (IDI). We want to hear from people such as yourself who have been involved in the counselling programme of the Prolife study that has been implemented in various clinics around the country. We would like to ask you various questions about how you feel about the programme.

Please note that there are no right or wrong answers to these questions. Your opinion is very important. It will help us to improve the project by knowing what may work and what may not work to help people quit smoking, reduce their alcohol use and become more adherent to their medication. Please remember that your responses will remain confidential and will only be shared with members of the research team.

THANK YOU VERY MUCH FOR YOUR ASSISTANCE WITH THIS ACTIVITY.

SECTION 1: DEMOGRAPHIC DATA

1.1. What is your age? (Completed age in years)												
						Male				Female		
1.2. Sex of the respondent						0				1		
1.3. What is your primary home language? (list maximum 2 primary home languages)												
Sesotho	1	Setswana	2	Northern Sotho	3	Isizulu	4	Isixhosa	5			
English	6	Afrikaans	7	Siswati	8	Thsivenda	9	Xitsonga	10	Isindebele	11	
1.4. In which language do you want to receive SMS messages?												
Sesotho	1	Setswana	2	Isizulu	3	English	4					

SECTION 2: THE COUNSELLING PROGRAMME

2.1. How many sessions of the programme did you complete?	Session				
	Very unhelpful	**Somewhat Unhelpful**	**Helpful**	**Somewhat Helpful**	**Very Helpful**
2.2. How would you rate the intervention sessions you attended?	0	1	2	3	4
	Not at all	**A little**	**Quite a lot**	**Very much**	**A great deal**
2.3. How much did you enjoy the intervention sessions?	0	1	2	3	4

2.4. What were some of the benefits of the sessions to you? (unprompted, circle the correct answers the respondent gives spontaneously)

2.4.1. I drink less alcohol no	1	2.4.2. I smoke less cigarettes now	1
2.4.3. I use drugs less now	1	2.4.4. I quit smoking cigarettes	1
2.4.5. I know more about tobacco's negative effects	1	2.4.6. I know more about alcohol's negative effects	1
2.4.7. I learned a skill I can use	1	2.4.8. I am more adherent to my TB medication	1
2.4.9. I am more adherent to my ARVs	1	2.4.10. I feel in better emotional health	1
2.4.11. I feel in better physical health	1	2.4.12. I started ART treatment as a result of the intervention	1
2.4.13. Other (Please specify):	1	2.4.14. These sessions did not benefit me in any way	1

2.5. Please indicated which one of the following statements is correct:

	NO	**YES**		**NO**	**YES**
2.5.1. I drink less alcohol now	0	1	2.5.2. I smoke less cigarettes now	0	1
2.5.3. I use drugs less now	0	1	2.5.4. I quit smoking cigarettes	0	1
2.5.5. I know more about tobacco's negative effects	0	1	2.5.6. I know more about alcohol's negative effects	0	1
2.5.7. I learned a skill I can use	0	1	2.5.8. I am more adherent to my TB medication	0	1
2.5.9. I am more adherent to my ARVs	0	1	2.5.10. I feel in better emotional health	0	1
2.5.11. I feel in better physical health	0	1	2.5.12. I started ART treatment as a result of the intervention	0	1
2.5.13. These sessions did not benefit me in any way	0	1			

2.6. Were there ever barriers that prevented you from attending the sessions?		0	1
2.7. If there were barriers that prevented you from attending the sessions, what were they?		Not applicable, I did not have any barriers.	99
2.8. Were there any factors that made it easier for you to attend the sessions?		0	1
2.9. If there were factors that made it easier for you to attend the sessions, what were they?		Not applicable, I did not have any facilitators.	99
2.10. In your opinion, would other people benefit from attending these sessions?		0	1
2.11. What aspects about the sessions do you think need to be changed, in order to make them more effective?		Not applicable, nothing needs to be changed	99

SECTION 3: YOUR COUNSELLOR

Now can you tell me about your experience of your counsellor?

	Not at all	A little	Quite a lot	Very much	A great deal
3.1. How much did you like her/his style of interacting with you?	0	1	2	3	4
3.2. How would you describe your counsellor?					

3.3. Which of the following words describes your counsellor?

	NO	YES		NO	YES
3.3.1. Knowledgeable	0	1	3.3.2. Kind	0	1
3.3.3. Directive	0	1	3.3.4. Judgemental	0	1
3.3.5. Helpful	0	1	3.3.6. Non-judgemental	0	1
3.3.7. Easy-going	0	1	3.3.8. Gentle	0	1
3.3.9. Trustworthy	0	1	3.3.10. Good listener	0	1
3.3.11. Warm	0	1	3.3.12. Cold	0	1
3.3.13. Scolding	0	1	3.3.14. Other (Please specify)	0	1

3.4. In what ways might your counsellor improve, if any?		Not applicable, my counsellor does not need to improve in any way.	99

SECTION 4: SMS

Finally I would like to ask you about the SMSes that you received as part of the intervention programme.

4.1. How often did you receive SMS messages?

	Very helpful	Somewhat helpful	Helpful	Somewhat unhelpful	Very unhelpful
4.2. How would you rate this aspect of the intervention?	4	3	2	1	0

4.3. What did you enjoy about receiving an SMS on a regular basis?	

4.4. What did you not enjoy about receiving an SMS on a regular basis?					
	Far too long	**A bit too long**	**The right length**	**A bit too short**	**Far too short**
4.5. Did you think the messages were too long, too short or about the right length?	0	1	2	3	4
	Far too frequently	**A bit too frequently**	**Frequently enough**	**A bit too infrequently**	**Far too infrequently**
4.6. Did you think that the messages were sent out too frequently, too infrequently or did you receive them frequently enough?	0	1	2	3	4
				NO	**YES**
4.7. Was it easy to understand the messages?				0	1
	They should have lasted for much longer	**They should have lasted for a bit longer**	**They were just right**	**They should have been stopped a bit earlier**	**They should have been stopped much earlier**
4.8. Would you have liked the messages to last for longer, or to have been stopped earlier or were they just right?	0	1	2	3	4
4.9. Tell me about your experiences of receiving the messages when other people were around?					
	Extremely comfortable	**Very un-comfortable**	**Comfortable**	**Bit un-comfortable**	**Very un-comfortable**
4.10. How would you have felt if other people had seen the messages?	0	1	2	3	4
	Very easy to understand	**Somewhat easy to understand**	**Easy to understand**	**Somewhat difficult to understand**	**Very difficult to understand**
4.11. What did you think about the languages used in the SMS messages?	4	3	2	2	1
			NO	**YES**	**Don't know**
4.12. Was the effect of the counselling sessions improved by having the SMS messages?			0	1	9
4.13. Can you describe ways in which the SMS messages helped you?					
				NO	**YES**
4.14. Did you experience any technical problems with your cell phone during the period of the period of the study which prevented you from receiving the messages, such as having a flat battery, the phone being out of order, unavailable or stolen?				0	1
If yes to 4.14, please explain.					9
4.15. Do you have any other comments about the messages?					

4.16. Can you tell me what you liked about being part of this programme overall?	
4.17. Can you tell me what you did not like about being part of this programme overall?	
4.18. Can we talk about what you think can be done to improve the programme overall?	
4.19. Is there anything else you'd like to discuss about having been involved in this intervention programme?	

THANK YOU VERY MUCH FOR YOUR ASSISTANCE WITH THIS PROJECT.

Time Ended: _____:_____

4 SMS MESSAGE CONTENTS AND SEQUENCE

1. TB+HIV MEDICATION AND FOLLOW-UP ADHERENCE

MI SESSION	WEEK	DAY	TB+HIV MEDICATION AND FOLLOW-UP ADHERENCE
1	1	1	Remember to cover your mouth when you cough; this prevents TB germs from spreading in the air.
		4	For a complete cure, you will need to take TB medicines daily for at least 6 months.
	2	1	Take your TB medicines always at the same time, like when you brush your teeth. This will help you remember.
		4	It is normal for TB medicines to cause side effects. Common ones include nausea, stomach pains, vomiting, orange urine, joint aches, and skin rash.
	3	1	If you have any problems or concerns about your medication, do not stop. Consult your TB nurse or doctor. They have tips to help you take your pills.
		4	Keep windows open around you, if possible. Fresh air helps reduce TB germs.
	4	1	If you stop taking your medicines or don't take them correctly, you can pass TB germs on to others.
		4	Ask a family member or friend to help you remember taking TB medicines.
2	5	1	Do take your TB medicines in full dose, even when you feel good. It is the only way to kill TB germs.
		4	Adopt a healthy lifestyle. Reduce your chances of ever developing TB again.

2. TOBACCO USE

MI SESSION	WEEK	DAY	TB+HIV MEDICATION AND FOLLOW-UP ADHERENCE
2	6	1	Replace smoke with a smile. Replace illness with happiness. Quit today.
		4	Craving to smoke is temporary but damage to your lungs may be permanent.
	7	1	Within 1 month of quitting, you will cough less and breathe easily.
		4	Alcohol use and smoking will make it harder for your TB to be cured.
	8	1	The best way to quit tobacco is to stop immediately.
		4	It helps to tell your friends and family "I am ready to quit smoking completely".
3	9	1	After quitting, your body craves for nicotine; this is expected. You may feel constipated, irritable, restless, or lightheaded. This will pass.

3. ALCOHOL USE

MI SESSION	WEEK	DAY	TB+HIV MEDICATION AND FOLLOW-UP ADHERENCE
3	9	4	Alcohol damages your liver and your body's protection against infection such as TB and HIV.
	10	1	Cutting down on alcohol will help you recover faster from your TB.
		4	Heavy alcohol drinking can make people forget to take their TB medication and they stay sick longer.
	11	1	Drinking less saves you money. Think about what extra money could buy you and your family.
		4	Stopping drinking alcohol while you are on TB medication is best. But if you do drink, drink less.
	12	1	It is normal to be nervous when reducing your drinking. It helps to talk to your family, friends, or other people to support you.
		4	If you struggle to reduce your drinking, help is at hand. Talk to your nurse or another health professional. You are not alone.

5 TB RECORD REVIEW

Continued on next page.

SOUTH AFRICA
NATIONAL TUBERCULOSIS CONTROL PROGRAMME

GW 20/12
Nov-06

PATIENT CLINIC/ HOSPITAL CARD

Registration Number: ☐☐☐☐/yy

Registration Date: dd mm yyyy

N Newly Registered
M Moved in from facility in this sub-district
T Transferred in from outside the sub-district

Sub-District _____ Facility _____

PATIENT DETAILS

Surname _____ Full Name(s) _____ Nickname _____

ID Number/Date of birth: yy mm dd ☐☐☐☐☐☐☐

Age: ☐ Gender: M F

Residential Address *(Where you live)*

_____
_____
_____
Tel/Cellphone: _____

Work address (Name of company/employer)

_____
_____
_____
Tel: _____

NEXT OF KIN' or FRIEND DETAILS *(Contact person - not staying with the patient)*

Surname _____ Full Name(s) _____ Nickname _____

Residential Address *(Where he/she lives)*

_____
_____
_____
Tel/Cellphone: _____

Work address

_____
_____
_____
Tel: _____

PATIENT CATEGORY

N New Patient

RC Relapse AFB positive PTB *(Retreatment after Cure)*

RF Re-treatment after Failure (AFB positive PTB)

RD Re-treatment after default (AFB positive PTB)

OR All Other Re-treatment cases, *not included in the above mentioned categories*

CLASSIFICATION OF DISEASE

ICD10 Code *(According to list in the back of the TB Register)*: ☐

Pulmonary TB: ☐ Extra PTB: ☐ Site for Extra PTB: _____ Both: ☐

NOTIFICATION INFORMATION

Has patient been notified? Y N

Notification date: dd mm yyyy

Notified by *(Print name)*: _____

"The printing of these materials was supported by funding from USAID through the TASC II TB project"

Registration Number: ____/____
(Nickname) _____
First Name: _____
Surname: _____

SPUTUM RESULTS

Pretreatment		End of intensive phase (*take sputum 7-11 weeks of the intensive phase)*				End of treatment		Tuberculosis Culture** *Please tick appropriate box(s)*							
		2 months		3 months		5/7 months					Resistance				
Smear Date	Smear Result	Smear Date	Smear Result	Smear Date	Smear Result	Smear Date	Smear Result	Specimen Date	Culture Result	DST Done	R	H	Z	E	S
Appointment for sputum follow-ups															

** 'Non converters', 'Retreatment cases' and 'HIV Positive - smear negative PTB cases'

REGIMEN AND DOSAGES

Treatment Start Date d d m m y y y y

☐ Regimen 1 - New Adult Cases ☐ Regimen 2 - Re-treatment Adult Cases ☐ Regimen 3 - Children ☐ Other _____

a. INTENSIVE PHASE

Drug:	RHZE	RHZ	S
Dosage			

R = Rifampicin H = Isoniazid Z = Pyrazinamide

OTHER *(Specify)*			

E = Ethambutol S = Streptomycin

Weight when treatment started
kg.

Use one of the following symbols in the block to register the drugs that have been administered

√ = medication taken under supervision at clinic

x = patient did not take medication

- = medication collected for self administration or supervision elsewhere (-) to indicate the number of days supply was given

*Extra row is to record **Streptomycin "S"***

Month	Date																													No.of Dose
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	
For third month of Rx (Non-converters and Re-treatments)																																
For third month of Rx (Non-converters and Re-treatments)																																

Self administration: ☐

TREATMENT SUPERVISOR DOT throughout Intensive Phase Y N

Facility ☐

Community ☐ *Relative* ☐ *Employer* ☐ *NGO Caregiver* ☐ *Caregiver* ☐ *Volunteer* ☐ *Other (Specify):* _____

Name: _____ Tel/Cellphone: _____

Address: _____

b. CONTINUATION PHASE

Drug	RH (150/75)	RH (300/150)	RH (60/30)	E
Number tabs				

OTHER *(Specify)*			

Month	Date																													No.of Dosages
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	

Self administration: ☐

TREATMENT SUPERVISOR DOT throughout Continuation Phase: Y N

Facility ☐

Community ☐ *Relative* ☐ *Employer* ☐ *NGO Caregiver* ☐ *Caregiver* ☐ *Volunteer* ☐ *Other (Specify):* _____

Name: _____ Tel/Cellphone: _____

Address: _____

CLINICAL PROGRESS NOTES

HIV-Status:

Counselled: | Y | N | *KP | Tested: | Y | N | *KP | *KP = Known Positive*

Test Date 1: | d | d | m | m | y | y | y | y | Result: [ ] P = Positive N = Negative KP = Known Positive

Test Date 2: | d | d | m | m | y | y | y | y | Result: [ ] P = Positive N = Negative KP = Known Positive

Cotrimoxazole: | Y | N | Prior | Start Date: | d | d | m | m | y | y | y | y | Referred for CCMT/HIV care | Y | N |

Referred to *(Please specify facility name)* ____________

ART: | Y | N | Prior | Start Date: | d | d | m | m | y | y | y | y | CD4-Count: ____________

Other Medical Conditions:

Pregnant | Y | N | Epilepsy | Y | N | Diabetes | Y | N | Mental Health | Y | N |

Hypertension | Y | N | Chemotherapy | Y | N | Corticosteroids | Y | N |

Other: | Y | N | *Please specify:* ____________

Family Planning | Y | N | *Adjusted* | Y | N |

Other Chronic Treatment *(Specify)*

____

____

____

If not diagnosed according to Smear Microscopy - Basis of Diagnosis:

Date: | d | d | m | m | y | y | y | y | Aspiration/Biopsy [ ] CSF [ ]

Mantoux [ ] ______ mm X-Rays [ ]

Other *(Specify)* ____________

Patient registered by *(Please print)*: ____________

Date	Weight	Progress Notes	Return Date	Signature

Date	Weight	Progress Notes	Return Date	Signature

PATIENT CONTACTS *(Close contacts)*

Name	Age	Relationship	Sputum	X-Ray	Mantoux	Test result	Chemoprophylaxis		Treatment/ Prophylaxis Start Date
							H	RH	

Referred Patients:

☐ Moved *(Patient moved to another facility in the same sub-district - not counted as a final outcome)*

☐ Transferred Out *(Patient transferred to another Sub-district, district, province or country and for whom treatment outcome*

Transferred or Moved to: Facility: _____ (Sub)-district: _____

Province: _____ Country: _____

Patient continuing treatment: Yes: ☐ Unknown: ☐ *(Please attach acknowledgement slip here)*

TREATMENT OUTCOMES

☐ Cured *(Patient, initially smear-positive, who converted to smear-negative at, or 1 month prior to completion of treatment and on at least one previous occasion)*

☐ Treatment Completed *(Patient who has completed treatment but does not have bacteriologic proof of cure.)*

☐ Treatment Defaulted *(Patient whose treatment is interrupted for 2 consecutive months or more.)*

☐ Treatment Failure *(Patient who remains smear-positive at 5 months or later during treatment.)*

☐ Died *(Patient who dies for any reason during TB treatment.)*

Treatment outcome Date: d d m m y y y y Discharged by *(Print name)* : _____

Signature: _____

6 IMPORTANT CONTACT DETAILS (FIELDWORKERS, DISTRICT COORDINATORS, SENIOR PROJECT MANAGER, SITE LEADS)

DISTRICT	DISTRICT COORDINATOR AND SITE LEAD	LAY HEALTH WORKERS	FIELD WORKERS
Bojanala	Prof John Tumbo, Tel: 012 521 4314 or cell: 082 885 8332	• Alinah Nqulu • Neo Mogale • Irene Mokoka • Gladies Letjana • Erik Segoe	• Bongani Mashaba • TBA • TBA
Letjweleputswa	Dr Michelle Engelbrecht Tel: 051 401 3256 or cell: 083 304 8182	• Puseletso Mokhothu • Merriam Mokebe • Refilwe Molelekwa • Mmamanini Molelekwa	• Moeti Marumo • Tshepo Thabane • Nondlela Gladys
Sedibeng	Thembisile Mabaso Site lead: Dr Olu Omole, Tel: 016 950 6192 Cell: 076 472 1289	• Lydia Mone • Narries Swartz • Nonkosinathi Mosenga • Melita Mojabeng • Khubeka Moshodi	• Thabitha Mokoena • Gaogiwe Lerato • Phunzile Mkwanazi
DAYTIME AND AFTER HOURS TELEPHONE NUMBER(S):			
Ms Matshidiso Malefo	Senior Project Manager	Cell: 084 585 6419 Matshidiso.malefo@smu.ac.za	Sefako Makgatho University
Dr Mohlatlego H Sebola	Research Manager	Tel: 012 521 4611 Cell: 071 200 3117	Sefako Makgatho University
Prof OA Ayo-Yusuf	Principal Investigator	Daytime numbers: Tel: 012 521 4611 After hours: 083 4421 970	Sefako Makgatho University/ University of Pretoria

RESEARCH INVESTIGATORS

NAME AND SURNAME	INSTITUTION	ROLE IN PROJECT
Prof Olalekan Ayo-Yusuf	Sefako Makgatho University	Principal Investigator for South Africa (PI 1)
Dr Kamran Siddiqi	University of York	Co-Principal investigator UK (PI 2)
Prof Goedele M. Louwagie	University of Pretoria	Central coordination
Prof Neo Morojele	South African Medical Research Council	MI training
Dr Noreen Medge	University of York	Liaise between UK and South Africa partners
Mr Mohlatlego Sebola	Sefako Makgatho University	Project manager
Ms T Malefo	Sefako Makgatho University	Project study coordinator
Ms Debbie Bell	LAG Consultancy and Training	Motivational Interviewing Trainer
Regan Wentzel	LAG Consultancy and Training	Motivational Interviewing Co-trainer
Dr Tolullah Oni	University of Cape Town	Advisory role on TB/NCD interaction
Dr Michelle Engelbrecht (ME)	University of the Free State	Lejweleputswa sub-district site lead
Dr Olufemi Omole (OO)	University of Witwatersrand	Sedibeng sub-district site lead
Prof John Tumbo (JT)	Sefako Makgatho University	Bojanelo sub-district site lead

As lay health workers you will report to the Study Coordinator who will manage your work and answer any project-related queries you may have.

REFERENCES

Babor TF, De La Fuente JR, Saunders J, Grant M: The Alcohol Use Disorders Identification Test: Guidelines for Use in Primary Health Care. WHO Publication No. 89.4. Geneva, World Health Organization, 1989