PROvide MIner-friendly SErvices for Integrated TB/HIV Care in Lesotho Study (PROMISE)

Unique Protocol ID: **AAAR3789**
NCT03537872

Informed Consent Form, English
Version 6.0, 30August2018

IRB Approval Date: 10/03/2018

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

PROvide MIner-friendly SErvices for Integrated TB/HIV Care in Lesotho Study
(PROMISE Study)
Version 6.0, August 30, 2018
CUMC IRB-AAAR3789
Patients—MF SITES

Principal Investigator:
Andrea Howard, MD, MS
Individual Participant Duration in Study: 9 months
Anticipated Number of Participants (MF sites): 196
Flesch-Kincaid Grade Level: 7.5

What is the purpose?

The purpose of this study is to learn more about how health care providers can help patients start HIV medicines (ART) and medicine to prevent TB (IPT), and remember to take their medicines. Some clinics in this study will provide the same care that they have been giving. In other study clinics, health care providers and lay counselors will give more support to patients. At the end of the study, the clinics will be compared and the importance of giving more support to patients will be better understood.

What do I have to do if I agree to take part?

You are invited to take part in a research study. The United States Centers for Disease Control and Prevention (CDC) has paid for the study. You and other HIV patients in this clinic are being asked to be in the study. In total, about 524 patients at 5 health facilities will take part. If you are eligible and agree to take part, you will be in the study for 9 months.

If you agree to take part in the study and are eligible due to the care you receive, an interviewer will ask you questions. Some questions will be about your background, your health, and what you know about HIV and TB.

After this interview, there will be 3 more interviews every 3 months. This will help us know if you are taking your medicines and how you feel. You may also be asked to give a urine sample at one of the interviews, to check for IPT levels. Results of the test will not be shared with you or your health care provider. We will ask you for some contact information so we can remind you about your interviews.

At the end of the study, we will also record some information from your clinic records about your health, your clinic visits, and the medicines that you have received.

Interviews will be done in a private area of your choice. The first interview will take about 40-50 minutes. The other interviews will take about 15-30 minutes. We will try to do all interviews on the same days as your clinic visits. If the interviews cannot be on the same day as your clinic visit, we will call you to do the interview by phone.

If you do not qualify for this study or decide not to take part, you will still receive the same HIV and TB care as other patients at your clinic.

It is important to understand that this is not a study to test ART or IPT. We are studying a way to help clinics provide ART and IPT to more HIV patients. Everyone with HIV at your clinic will be assessed for ART and IPT by the clinic's health care providers.

Other study components

In-Depth Interview
You and other patients in this clinic may be asked to take part in one In-Depth Interview. Overall, about 40 patients at 2 clinics will take part.

If you choose to take part, an interviewer will ask you questions related to services you were given in this clinic and how they might be improved. The interview will be done in a private area of your choice. It will take about 1 hour. You will complete the in-depth interview on the same day.

The interviewer will take notes. The interview will also be audio-recorded so that we can make sure notes are complete and correct. Audio-recording of the interview is required to take part. Your name and other personal information will not be on the recording or the notes. If you do not want the interview to be recorded, you are not eligible to be in this part of the study.

If you do not qualify for this part of the study or decide not to take part, you will still receive the same HIV and TB care as other patients at your clinic.

Observed Clinic Visit
You and other patients and health care providers in this clinic may be asked to take part in an Observed Clinic Visit. Overall, about 60 patients and 32 health care providers at 4 clinics will take part.

The purpose of this part of the study is to measure how long it takes for nurses and lay counselors to provide care to HIV patients. If you agree to take part in this part of the study and are eligible due to the care you receive, a study staff member will observe your visit with the nurse or lay counselor. He or she will write down what time the visit started, and the time spent on each part of the visit. The times are the only thing that will be recorded during your visit.

What are the risks?
The study has the following risks:

There is a risk that people who do not work on the study may see information you gave during interviews, your lab test results, or medical record information. It is also possible that someone might be able to know your HIV status because you are taking part in the study. To protect you from these risks, all information collected will be confidential. You will be given a unique number and all information we collect will be labeled with this number, and not your name. Your answers to questions will only be labeled with your unique number. The list that connects your

name to this number will be kept in a locked file cabinet at the clinic. Only study staff will have access to the cabinet. Once all information has been recorded and data have been analyzed, the list that connects your name to the unique number will be destroyed. Your name will not be used in any report or published materials.

As part of this study, you will be asked to take part in interviews, and there is a risk that some questions may make you uncomfortable. You do not have to share anything you do not want to. You can refuse to answer any question and end the interview at any time.

For the Observed Clinic Visit, the risk of taking part is that you may feel uncomfortable having a person observe your visit with the nurse or lay counselor. You can ask for the observation to stop at any time.

Are there any benefits to taking part?
There is no direct benefit to you for taking part. What we learn from this study will help us develop programs to help people with HIV take ART and IPT.

Are there additional costs?
There are no costs to you for taking part in this study.

Will I be paid for taking part?
You will not be paid for taking part in the study. Each day that you have an interview, you will be given a snack and fizzy drink.

How will things I say be kept private?
Any study information that has your name will be kept private. While there is always a small chance that information could be stolen or lost, we will do everything we can to keep your information secure. It will not be shared with anyone at the clinic. All study staff will sign an agreement to confirm that this information will not be shared with anyone who is not study staff.

Any identifying information (such as name and phone number) that you give will not be stored with data collection forms (like the interviews you complete). A small number of study staff will have access to these forms. None of the data collection forms will have your name on them. Instead, you will be given a unique number that will be used on all data collection forms.

During the In-Depth Interview, you do not need to give your name. If you prefer, you can use a different name during the interview. The interview recording will not include your name but will be given a unique number, in order to protect your identity. The recording will be securely stored in the study office. The study team may check the recording to see if study staff have interpreted what you said correctly, but no one will know your name or have access to your identity. Personal information may be disclosed only if required by law. All recordings will be erased after study activities are complete.

The following people and/or agencies will be able to see and copy your research records:
- the investigators, study staff and other medical staff who may evaluate the study.

- members of the Institutional Review Board ('IRB') at Columbia University, the Lesotho National Health Institutional Review Board and Ethics Research Committee, and the United States Office of Human Research Protections ('OHRP'). The purpose of these groups is to protect the rights of research participants.
- approved persons working with the CDC, the study sponsor.

The Ethics Research Committee may check study procedures but will not have access to your name or personal identity. If study findings are published in a paper or speech, they will be combined together with all those taking part in the study. Study findings will not include your name or identity. If we quote what you say during an interview, it will not include your name or identity.

What happens if I decide not to take part?
Taking part in this study is your choice. You can decide not to take part or to stop at any time. Your choice will not affect the care you receive at the clinic.

What is the alternative?
The alternative is to not take part in the study.

What if there are new findings?
We will tell you about new information from PROMISE or other studies that may affect your health, welfare, or willingness to stay in the study. At the end of the study, you will be told when study results are available and how to learn about them.

Who do I contact if I have any questions or feel that I have been harmed by taking part in the study?
You may contact Dr. Koen Frederix, ICAP Technical Director, at 2232 6599.

If you have any questions about your rights as a person taking part in the study, you may contact the Lesotho National Health Institutional Review Board. The contact person is Dr. Thin, who can be reached at 59095356.

Statement of Consent

I have read or have had read to me the contents of this consent form. I have been encouraged to ask questions. I have received answers to my questions. I agree to take part in this study and its additional components as checked off below. I know that I can stop being in the study at any time. I am not giving up any of my legal rights by signing this form. I will be offered a copy of this form to keep for my records.

For PROMISE study enrolment

_____ I agree to take part in the interview today and in 3, 6 and 9 months, and to have information recorded from my clinic records.

For Urine Test

Please select your choice by initialling one of the following:

_____ I **DO** agree to take part in the urine test.

_____ I **DO NOT** agree to take part in the urine test.

For In-Depth Interview

Please select your choice by initialling one of the following:

_____ I **DO** agree to take part in the In-Depth Interview part of the study and to be audio-recorded.

_____ I **DO NOT** agree to take part in the In-Depth Interview part of the study and to be audio-recorded.

For Observed Clinic Visit

Please select your choice by initialling one of the following:

_____ I **DO** agree to take part in the Observed Clinic Visit part of the study.

_____ I **DO NOT** agree to take part in the Observed Clinic Visit part of the study.

Signatures

Study Subject

Print Name_____

Signature/Thumbprint_____

Date_____

Witness (if participant cannot read, witness should sign below)

Print Name_____

Signature _____

Date_____

Person obtaining Consent

Print Name_____

Signature_____

Date_____