CONSENT FORM

Patient ID: IPT ☐☐☐☐	Clinician initials: ☐☐☐	Date: ☐☐/☐☐/☐☐ *dd mm yy*

Instruction:

- *To be used at Diagnostic Inclusion Visit only. This form must be stored in the consent forms file and can only be handled by clinicians that care for patients.*
- *Available in English, Setswana and Kalanga.*

A Randomized, Placebo-Controlled Study of
Six Months vs. Continuous Isoniazid Tuberculosis Preventive Therapy
for Persons Living with HIV Infection in Botswana

General Consent

The government of Botswana has a program that gives people with HIV six months of isoniazid to prevent TB disease. However, it is not certain whether it is better for a person living with HIV to take the isoniazid for six months or for a longer period. The Botswana National Tuberculosis Programme of the Ministry of Health is working with research staff from the BOTUSA Project, to find out if a longer time of isoniazid treatment works better. In this research study we ask you to be either in a group of patients who will take isoniazid tablets continuously for three years or to be in another group of patients who will take isoniazid tablets for the usual six-month period followed by a placebo for 30 months. A placebo is a pill that looks like the medicine being tested, but does not contain any active ingredient. It is sometimes called a "sugar pill." The placebo is important to help find out if the isoniazid is really working. No one - even the research staff – will know which person is taking the isoniazid or the "sugar pill" until the end of the study.

When participating in the study there are certain things that we will ask you to do. We will ask you some questions, ask you to write a short exam to make sure you understand the study, listen to your chest, ask you to take a chest x-ray, do a TB skin test, and take a small amount of blood in a tube from a vein in your arm. The tube is about the size of a man's finger, or about one teaspoon. If everything looks fine for you to be part of the study, you will be given one month's supply of tablets to take at home. Then you will be asked to come back in two weeks, to talk with the study staff, and give another blood sample. If there are still no problems, you will be asked to continue with the tablets and come back for another supply at the end of the month. Every month after that, you will

come to this clinic to be checked and to get your medicines. "Being checked" means that you will answer simple questions about how you are feeling; you will have the tablets that are left from your last refill counted. However, you should come back sooner if you feel sick.

You will be a part of the study for three years, or until:

- you get sick with TB
- you decide on your own to leave the study.

Risks of the study

- Anytime someone has an HIV test done, it means there is also a very small chance that somebody may find out that you have been tested, or even find out your results. We will try very hard not to let this happen by locking up your records.

- The TB skin test can cause a little pain when the needle goes into the skin, and the skin may get red and swollen in a day or two. This usually goes away in a few more days. There is a small chance you can get an infection where the needle goes in, but we will try hard not to let that happen by using sterile needles and syringes.

- Taking the blood from your arm may cause mild pain from the needle and cause a slight change in color in the skin where the needle goes in. This takes a few days to go back to normal. Your body will replace the small amount of blood we take in a few days.

- Sometimes people feel dizzy when they give blood.

- Some people get side effects from the TB tablets (isoniazid). Most side effects are usually mild and don't last long, but rarely other side effects are serious. These more serious side effects can include: tingling sensations of your hands and feet or loss of feeling. You will be given another tablet called "vitamin B6" to try to lower the chance that will happen.

- Isoniazid can cause itching, rash, nausea, belly pain, joint pain, vomiting or diarrhea. Most people who take this tablet do not get these problems.

- Although not common, the most serious side effect from isoniazid is liver damage which can even cause death. This happens to less than 1 in a 100 people. People who are over 50 years, or who drink alcohol, have a higher risk of liver disease and death related to isoniazid. The symptoms include nausea, loss of appetite; pain the right side of your abdomen, and dark colored urine. If these symptoms

occur, you should immediately contact your study nurse, doctor or any other doctor nearest to you who will stop your tablets right away. Additionally, let us know so we can check you out in the clinic.

- Taking isoniazid can cause other medicines not to work right. Please tell your study nurse before you start any other tablets if you are taking any other medicine before you are started on isoniazid. If you are sick and cannot be seen by our study doctors please inform whoever is assessing you for your illness that you are on the IPT Study and may be receiving isoniazid.

We will see you in the clinic from time to time to check you and try to keep these things from happening. If you have side effects, you must tell your study nurse right away so you can be evaluated and told what to do. For serious side effects, you might have some blood tests, or be asked to stop the tablets.

Benefits

Everyone in the study takes at least six months of the TB tablets which reduce the chance that you will get TB disease. You will also be seen by a nurse or doctor once a month. If you get sick with TB disease, you may be diagnosed and treated sooner. If you feel sick, you can come back to the clinic anytime. This research may also improve the care doctors give to other persons living with HIV/AIDS.

Compensation: If you agree to be in the study, you will not be paid for your participation. However, you will receive P10.00 for each clinic visit. This money will cover transportation fare to and from the clinic as well as the cost of refreshments.

Study Related Injury: If you are hurt as a result of being in this study, your care will be paid for by BOTUSA. If you believe you have been hurt, you can contact Barudi Mosimaneotsile at BOTUSA (390-1696).

Confidentiality: We will keep your medical records in a locked cabinet in (Francistown or Gaborone), and only people who will take care of you in the study will be able to see them. We will keep them as private as the law in Botswana allows. When the study is over, we will destroy the study records. Your name will never be used in any speech or writing about this study. We will not give any of your results to anyone or tell your HIV status to other people such as your friends, family, or boss.

Patient ID: **IPT**☐☐☐☐	**Date:** ☐☐/☐☐/☐☐ *dd mm yy*	**AF11** *22-Nov-04* **Page 4 of 5**

Cost: If you choose to be in this study, it will take about 30 minutes to answer some background questions, give the blood sample, and have the chest x-ray done. Then you will be asked to come back to be checked each month and get the tablets refilled, which will also take about 30 minutes. There is no additional cost to you for any test done as part of this study or any referrals to the government HIV care services such as the ARV or the PMTCT programs.

Refusal to participate: If you do not want to take part in this research study you will still get normal care and treatment here at the clinic. If you agree to be in the research study you can change your mind at any time and stop being in the study. If you change your mind, you can still get normal care and treatment through the government referral system. "Normal care and treatment" may mean you decide to take IPT through the government program which is not a research study. If other scientists make discoveries about IPT while this study is going on, we will tell you so that you can decide if you want to stay in the study or not.

If you have any questions about your rights in this study you can talk to Mrs. Sejo Mabutho, Senior Social Worker, phone 241 1374 and direct line 241 6685 or Dr. Christine Mwangi, Pathologist, phone 2411 000 pager 308, whose offices are at Nyangabgwe Hospital, or Ms. Shenaaz El Halabi at the Department of Policy Planning Monitoring & Evaluation, Ministry of Health Headquarters, P/Bag 0038, Gaborone, phone 317-0585 ext. 2018.

When you sign below, it shows that you agree to let us enroll you in the study. If there is any part of the study that is not clear to you, ask the nurse or doctor about it now. Do not sign until you get answers for all your questions. If you think of questions about the study later, you can call Dr. Taraz Samandari at the BOTUSA Project, Gaborone (390-1696). You may have a copy of this consent, and you will be given a card with contact information so you can contact us in the future.

Patient ID: **IPT**☐☐☐☐	**Date:** ☐☐/☐☐/☐☐ *dd mm yy*	**AF11** *22-Nov-04* **Page5 of 5**

If you agree to be in this study, please sign below.

Patient Name in Block Letters:

_____ _____

First Name Last Name

_____

Patient's signature (1) Date

If you furthermore agree to give permission so that we may access your medical records at the hospital, please sign below.

_____

Patient's signature (2) Date

_____

Witness for written or oral consent Date

☐☐☐

Initials of clinician

DO NOT SEPARATE PAGES
KEEP TOGETHER & PLACE IN PATIENT FOLDER