

YA TSIE
THE BOTSWANA COMBINATION PREVENTION PROJECT
Written Informed Consent/Assent Form for Participants in the End-of-Study Survey

About this form

Please read this form with care. It gives key information about being in a research study. You have the right to take your time to decide about joining. You may discuss it with your family if you wish. If you choose to take part, you will be asked to sign this form. You will get a copy to keep.

What you should know about a research study

- Someone will explain this research study to you.
- A research study is something you volunteer for.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part now and later change your mind.
- Whatever you choose it will not be held against you.
- Feel free to ask all the questions you want before you choose.

What is the purpose of this research?

To try to stop the spread of HIV in communities.

HIV is the virus that causes AIDS. There are many ways to stop HIV from spreading. These include knowing your HIV status, taking anti-HIV drugs, male circumcision, and drugs to prevent mother-to-child HIV transmission. The goal of the project is to expand and combine prevention tools to reduce the number of new HIV infections in a village. This is called “combination prevention.” The U.S. Centers for Disease Control and the Botswana Ministry of Health have led the project over the past few years. The Botswana-Harvard Partnership is doing a study to test how well the project works. Thirty villages, including yours, were picked to be in the study.

We invite you to take part because you are 16-64 years old and you usually stay here at least 3 nights per month.

How many people will take part in this part of the research study?

About 11,800 people

How long will I take part in this research study?

Today’s visit will take about 45 minutes. The time depends on whether you are just answering questions or also giving blood samples.

What can I expect if I take part in this research study?

We will ask you questions about yourself, HIV testing and your status, your health, medicines, and if you get any HIV services in your village, for example. We will also ask you questions about sex and your partners. We will find a private place to talk to you. If there isn’t a good place, we may invite you to a study clinic. You can skip any questions you don’t want to answer.

You can answer these questions even if you don’t want to be tested for HIV. We will ask you how we can reach you. We may need to see and copy some of your medical records for this study. This may include your medical card, or clinic or hospital medical records.

If you are under age 18 you will need permission from a parent or guardian to take part in the research.

HIV Tests

If your last HIV test was negative or if we don't know your HIV status, we will offer you an HIV test. If you are HIV-positive, and have proof, you do not need to test.

The HIV test is done by pricking your finger with a small blade to get a few drops of blood. It takes about 20 minutes for the result. We will talk to you about your result, and any care or services you may need. If your test result is not clear we may need to take another small blood sample (4-5mL or about 1 teaspoon) from a vein in your arm to re-test in the lab. Your result will be returned to you.

We would like to take blood from a vein in your arm if you are HIV-positive. We will use a needle and take up to 20 mL or less than one and a half tablespoons. This will take about 10 minutes. The blood samples would be used for these tests:

1. To measure how much HIV virus is in your blood (viral load). We may test a new way of measuring viral load in your home. We would use the samples already being drawn for this test. We would not share results of this new viral load test with you until we know it works as well as the standard test (which we will share with the clinic).
2. To study the type of virus you have. The purpose of this is to learn if the HIV spreading in the study villages can resist some anti-HIV drugs. It also tests if your virus is like other viruses spreading in the study villages. This will help us learn how well the programs are working in different places and with different groups of people.
3. To learn if you got HIV recently or some time ago.
4. For some samples, tests to determine the presence of HIV medication in the blood will be run.
5. If you are HIV infected and are not taking anti-HIV drugs at the time of the study visit, you will get a CD4 count. A CD4 count tells how well your body may be able to fight disease. We will give you the CD4 result right away.

We may find that you have a drug resistant type of HIV. If so, we will send this result to you or your doctor. But, these tests won't be done right away so this result may not be useful to you. We will not tell you the results of other tests that do not affect decisions about your care.

Some people who are not HIV positive may give a sample.

What are the risks and possible discomforts?

You may feel worried or embarrassed when answering questions about yourself, HIV, and sex.

If others think you are in this study because you have, or are at risk for, HIV they may treat you unfairly.

Drawing blood may cause pain, bruising and rarely a local infection. You may feel dizzy or faint.

Are there any benefits from being in this research study? What if I don't take part?

If you don't take part:

- You can still have an HIV test.
- We will tell you about programs in your village to prevent HIV.
- We will tell you about getting HIV care or drugs through local programs, if you need it.

There are no benefits to you if you join this study. This study will learn about ways to stop the spread of HIV, so your taking part may help other people in your village or in other places.

Will I get paid for taking part in this research study?

You will get 20 Pula worth of cell phone air time for your time spent on the study.

What will I have to pay for if I am in this research study?

There are no costs to you.

What happens if I am hurt by being in this research study?

You will be referred to local government services if needed. There will be no costs for this treatment. In making a referral, or giving treatment, the persons doing the research do not admit that your injury was their fault. There is no program through BHP or the sponsors to pay you for your injury, but that does not affect the legal rights you may have as a result of such an injury. By signing this form, you will not be giving up any of your legal rights.

If I join in this research study how will you protect my privacy? What happens to the information and samples you take?

We will find a private place to talk to you during the survey. We will not talk to others in your home about your HIV status or the survey answers you give us.

If study staff suspect, or there is a report of sexual abuse of a person under age 18, the study staff must tell a social worker with or without your consent.

Your records will be confidential. Data collected, including identifiable health information, may be seen by the study team and the groups overseeing the study (such as the Institutional Review Boards—committees that protect the safety and rights of research volunteers; the Botswana Ministry of Health; the study sponsors; or monitors checking the study). Your information will be given a study code number. Files that link your name to the code will be stored with high-level security. Paper files with your name on them will be stored safely, separate from your survey answers or other health details. Study computers are protected. Study data shared with other researchers will not have your name on it. You will not be named in any publication or presentation from this study.

There may be tests that cannot be done in the lab in Botswana. Some samples may be sent elsewhere for testing. Your samples will not have your name on them. Your identity will be protected.

If I have any questions or concerns about this research study, who can I talk to?

You can call us with any concerns, questions, or complaints, or if you are injured as a result of being in this study. Our phone numbers are listed below:

- *Dr. Joseph Makhema Tel: 3902671 ext 2201 Cell: 72100846*

The Health Research & Development Committee of the Botswana Ministry of Health approved this study. If you wish to speak with someone there about your rights as a research subject, please contact Mr. L. Moremi (phone: 363-2775).

STAFF:

☐ Check here if parent/guardian permission is needed and obtain signature on the following page before obtaining assent from the minor participant.

STATEMENT OF CONSENT (OR ASSENT, if participant is under age 18 and parent/guardian has granted written permission): I have read this form, or it has been read to me, and my questions have been answered. By signing below I agree to take part in the study.

PARTICIPANT SIGNATURE:

_____	_____
Name of participant (print)	Omang Number
_____	_____
Signature of participant	Date (dd/mm/yyyy)

Printed name of person obtaining consent/assent	
_____	_____
Signature of person obtaining consent/assent	Date (dd/mm/yyyy)

PARENT/GUARDIAN PERMISSION AND SIGNATURE:

I am either the parent or designated guardian of the participant named below. By signing below I grant permission for this participant under age 18 to take part in this research:

Name of participant under age 18	
_____	_____
Printed name of Parent/Guardian	Relationship to participant
_____	_____
Signature of Parent/Guardian	Date (dd/mm/yyyy)

Printed name of staff person obtaining permission	
_____	_____
Signature of staff person obtaining permission	Date (dd/mm/yyyy)

WITNESS STATEMENT AND SIGNATURE: *(only required when the participant or participant's parent/guardian cannot read the consent/assent form)*

My signature and date indicates that the information in this form was accurately explained to, and apparently understood by, the participant and/or the participant's parent/guardian, and that informed consent/assent/parental or guardian permission was freely given.

Name of Witness (print)

Signature of Witness

Date (dd/mm/yyyy)

Use of Samples in Future Research

If any of your samples are left after the study ends and all the study tests are done, we wish to store them at BHP, if you agree, for use in future HIV-related studies. Future research using your samples will have to be reviewed first by the Botswana Health Research Development Committee. If you agree, these samples may be stored for up to 10 years after the study ends. If there is any reason to store the samples for longer, approval will be granted from the HRDC first. **You can be in the study even if you don't want your samples stored for future studies.** Also, you can change your mind any time and ask us to destroy samples that might be in storage. If all your questions have been answered please check a box below whether you agree or not that your samples may be stored for other approved HIV-related research in the future, and sign your name.

STAFF:

☐ Check here if parent/guardian permission is needed and obtain signature on the following page before obtaining assent from the minor participant.

STATEMENT OF CONSENT (OR ASSENT, if participant is under age 18 and parent/guardian has granted written permission) for use of samples in future research:

I have read (or had read to me) the information above about the use of samples in future research. By checking a box below and signing I make my choice.

☐ YES, I agree for my blood samples to be stored after the study has ended for use in future HIV-related studies.

☐ NO, I do not agree for my samples to be stored after the study has ended

PARTICIPANT NAME AND SIGNATURE:

Name of participant (print)

Omang Number

Signature of participant

Date (dd/mm/yyyy)

Printed name of person obtaining consent/assent

Signature of person obtaining consent/assent

Date (dd/mm/yyyy)

PARENT/GUARDIAN PERMISSION AND SIGNATURE:

I am either the parent or designated guardian of the participant named below. By signing below I grant permission for this participant under age 18 to take part in this research by making his/her own decision about the long-term storage of his/her blood:

Name of participant under age 18

Printed name of Parent/Guardian

Relationship to participant

Signature of Parent/Guardian

Date (dd/mm/yyyy)

Printed name of staff person obtaining permission

Signature of staff person obtaining permission

Date (dd/mm/yyyy)**WITNESS STATEMENT AND SIGNATURE:** *(only required when the participant or participant's parent/guardian cannot read the consent/assent form)*

My signature and date indicates that the information about the use of samples in future research was explained to, and apparently understood by, the participant and/or the participant's parent/guardian, and that informed consent/assent/parental or guardian permission was freely given.

Name of Witness (print)

Signature of Witness

Date (dd/mm/yyyy)