

YA TSIE

**Written Informed Consent/Assent/Parent-Guardian Permission Form
for Baseline Household Survey/HIV Incidence Cohort Enrollment**

About this form

This form gives key information about being in a research study. 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.
- 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?

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 are leading the project. The Botswana-Harvard Partnership is doing a study to test how well the project works. Thirty villages were picked to be in the study. Half of the villages will be picked at random (much like flipping a coin) for combination prevention. The other half will have enhanced routine care and HIV prevention programs.

Your household has been picked at random to be part of a survey. We are doing this survey to learn how many new HIV infections happen during the study, and to get information about HIV transmission and the use of HIV prevention and care services. 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 research study?

About 12,000 people.

How long will I take part in this research study?

The survey and tests take about one hour, but may take longer. We will take the time needed to counsel you and answer your questions. We will then return to your home once per year until the study ends (up to 3 times, depending on when you join). Those visits will each take about 45 minutes. Some people will be asked for blood samples. This will take about 10 minutes.

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

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. We may ask you about the people who live here. We will ask questions about yourself, HIV testing and your status, your health, medicines, and if you get HIV services in your village. We will also ask you questions about sex and your partners. You can skip any questions you don't want to answer.

We will ask you how we can reach you.

We may need to see and copy some of your medical records for this study.

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 today and each year. If you are HIV-positive and have proof, you do not need to test again.

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 HIV test result is not clear, we will take another small blood sample from a vein in your arm to re-test in the lab.

Study Groups

Annual HIV Testing Group: if your HIV test is negative and you usually stay here at least 14 nights per month, you will be part of a group studied to see how well the project works. You must be willing to have an HIV test each year to be in this group.

We may use blood left from the finger prick to confirm your HIV test. If there is not enough blood left, we will ask to take blood (3-6 ml, less than half a tablespoon) from a vein in your arm. You can have the blood drawn at a clinic if you prefer.

If you have become HIV-infected when we visit you again, you will have the below tests done (see "If you are HIV-infected").

Other Residents: If you are not in the Annual HIV Testing Group, but you usually stay here at least 3 nights per month, we will ask you to answer the survey questions at each visit. We may offer you an HIV test. You can also answer the survey questions even if you don't want or need an HIV test.

If you are HIV infected now or if you become HIV-infected during the study and you have not started taking anti-HIV drugs at the time of the study visit, you will get a CD4 count and a viral load test at that visit and at visits afterward. The CD4 test will not be done at the last study visit. We will give you the CD4 result right away. A CD4 count tells how well your body may be able to fight disease. The viral load test tells how much HIV virus is in your blood. We will give this result to your clinic. We may test a new way of measuring viral load in your home. 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).

We will take blood with a needle from a vein in your arm. We will take up to 20 mL or less than one and a half tablespoons. We will do this the first time we learn of your HIV infection, and the last time we visit you before the study ends. This will take about 10 minutes. The blood samples will be used for these tests:

1. To measure your viral load (noted above).
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 work in different places and with different groups of people. 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.
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.

We will not tell you the results of tests that do not affect your medical care.

You may be invited to be in another part of the research. If so, you will be asked to sign another form like this.

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 HIV, or are at risk for HIV, they may treat you unfairly.

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

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

There may be no direct benefit to you if you join this study.

If you have HIV: the CD4 count and viral load test result may help with your HIV care. If your village has combination prevention, you may be able to get anti-HIV drugs sooner by joining the study. This may have health benefits to you. Your taking part may help other people in your village or in other places.

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.

Will I get paid for being in this research study?

You will get 20-Pula worth of cell phone airtime for your time spent on the study at this visit and at each yearly study visit.

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 the Botswana Harvard Partnership or the sponsors to pay you for your injury. By signing this form, you will not be giving up any of your legal rights.

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

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. Study data shared with other researchers or publications will not have your name on it.

If there are any tests that cannot be done in the lab in Botswana, some samples (without your name on them) may be sent elsewhere for testing.

Can my taking part in the research end early?

You may be removed from the study without your consent for the following reasons:

- The study is stopped or cancelled.

- You are not able to attend study visits or complete the study procedures.

If I have any questions or concerns about this research, 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, please call Mr. P. Khulumani (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.

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 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.

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 this form)*

My signature and date indicates that the information in this form 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)

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 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 this 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)
