

VUMC Institutional Review Board
Informed Consent Document for Research

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Study Title: Traditional healer-initiated HIV counseling and testing in rural South Africa
Version Date: January 5, 2021
PI: Carolyn M Audet

Name of participant: _____ Age: _____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

Key Information:

1. This consent form contains information about a new study to implement HIV testing and linkage to care with traditional healers in the community.
2. You are visiting a traditional healer who has been trained to provide HIV testing and counseling. He/she can provide that test to you today.
3. If you are eligible and consent to participate, you will receive a free HIV test, along with counseling and referral to the nearest health facility for treatment (if appropriate).
4. We will also invite you to attend an “open house” day at the health facility for re-testing in 6 months.
5. You can stop participating in the study at any time without penalty.
6. A risk of participating in this study is the trauma of receiving an HIV test result. However, the traditional healers will be well-trained to provide supportive referrals to the health system if someone is found to be HIV positive.

Key information about this study:

In South Africa, HIV testing has been undermined by HIV stigma, distrust in the allopathic health system, a preference for traditional medicine, and distance to the health facility. South Africa has made progress towards their 90-90-90 goals, yet a substantial number of people do not test regularly. We are proposing to have traditional healers provide HIV counseling and testing in the community to increase uptake of testing among people who are otherwise hesitant to test. If you agree to participate your traditional healer will provide you a free HIV test. Testing for HIV can trigger anxiety and stress. Your healer has been trained in HIV counseling, but they will also link you to a trained psychologist if you receive a positive test result. The study will include a baseline survey, an HIV test, and a follow up test (at the health facility) in six months.

Detailed Information:

The rest of this document includes detailed information about this study (in addition to the information listed above).

Good Day.

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My name is _____ and I work for the MRC/Wits Agincourt Research Unit. I am part of a new study that aims to provide HIV counseling and testing training to traditional healers in Bushbuckridge, South Africa. This study is being done by staff from Vanderbilt University Medical Center (VUMC) and the University of Witwatersrand (Wits). We are concerned that some people in the community are refusing an HIV test due to fears and mistrust associated with the health system. Many of these individuals see traditional healers for their treatment. We want to test a program that allows healers to conduct HIV testing in the community and link patients to the health facility for treatment (if they are positive) or for future testing.

You have been selected because you are seeking health services from a traditional healer in Bushbuckridge who provides HIV testing, treatment, or counseling support. In our study, we aim to increase the number of people who receive HIV counseling and testing among those who have not recently tested (in the past year). Because you have not had a test recently, we are inviting you to receive a test from your traditional healer today.

You do not have to be in this research study. You may choose not to be in this study. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study. If you agree to participate in this program, I will ask you to sign the form. Even if you agree to participate, you can stop participating at any time. I will give you a copy of this form. Please ask me to explain anything you do not understand. This form describes your rights as a participant. It is meant to answer your questions. We will read this form to you. Please feel free to ask any questions you may have about this.

Side effects and risks that you can expect if you take part in this study:

Your HIV test result may be positive, which could result in stress and concern. We will provide certified counseling services at the time of the test and provide a referral to a trained psychologist at the nearest health facility if you experience strong emotions. HIV treatment is provided confidentially and free of charge at all government run health facilities. By participating in this study you will lose time, including the 45 minutes to complete the baseline survey and HIV counseling and testing at study initiation, repeat testing (if applicable) and the end-line study survey (approximately 20 minutes). While we are taking steps to ensure privacy, including password protected databases and privacy training for study staff, there is always a chance of a breach in confidentiality.

Risks that are not known:

In any research study there are the possibility of unforeseeable risks. We try to minimize these by employing trained traditional healers to provide the best HIV counseling and testing services possible. It is possible that you have to compete a second test at the health facility if health care workers are less trusting of healer skills, but we hope that everyone will be open to receiving positive referrals.

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Good effects that might result from this study:

The benefits to science and humankind that might result from this study: While the test result may be stressful, the healer will be trained to effectively link you to the health facility for treatment, which could result in a healthier and longer life. If traditional healers can effectively provide HIV counseling and testing, it would allow for South Africa to open thousands of new testing facilities in communities which may allow us to reach people who would otherwise avoid HIV testing.

Procedures to be followed:

This study will begin today and last for the next seven months. If you agree to be part of this study, we will ask you questions about HIV stigma, trust in allopathic providers, belief in an HIV test, use of traditional medicine and perceived risk of HIV. After this survey we will provide an HIV test, using a fingerstick rapid test. If this test result is positive, you will be referred to the nearest health facility for treatment. If the test result is negative, you will be invited to an open house event at the health facility for a repeat test in 6 months. After that event, we will repeat the survey questions to see if anything has changed.

Payments for your time spent taking part in this study or expenses:

None

Costs to you if you take part in this study:

There is no cost to you for taking part in this study.

If you agree to take part in this research study, you and/or your insurance will not have to pay for the tests and treatments that are being done only for research. However, you are still responsible for paying for the usual care you would normally receive for the treatment of your illness. This includes treatments and tests you would need even if you were not in this study. These costs will be billed to you and/or your insurance.

You have the right to ask what it may cost you to take part in this study. If you would like assistance, financial counseling is available through the Vanderbilt Financial Assistance Program. The study staff can help you contact this program. You have the right to contact your insurance company to discuss the costs of your routine care (non-research) further before choosing to be in the study. You may choose not to be in this study if your insurance does not pay for your routine care (non-research) costs and your doctor will discuss other treatment plans with you.

Payment in case you are injured because of this research study:

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If it is determined by Vanderbilt and the Investigator [with NIMH input] that an injury occurred as a direct result of the tests or treatments that are done for research, then you and/or your insurance will not have to pay for the cost of immediate medical care provided by **any local government run health facility in Bushbuckridge** to treat the injury.

There are no plans for Vanderbilt [or NIMH] to pay for any injury caused by the usual care you would normally receive for treating your illness or the costs of any additional care. There are no plans for Vanderbilt [or NIMH] to give you money for the injury.

Who to call for any questions or in case you are injured:

If you should have any questions about study or wish to have additional counseling related to your care, please feel free to contact the study manager, TBC, at the MRC/Wits Agincourt Research Unit at TBC. This study has been approved by the Human Research Ethics Committee (Medical) of the University of the Witwatersrand, Johannesburg ("Committee"). A principal function of this Committee is to safeguard the rights and dignity of all human subjects who agree to participate in a research project and the integrity of the research.

If you have any concern over the way the study is being conducted, please contact the Chairperson of this Committee who is Professor Clement Penny, who may be contacted on telephone number 011 717 2301, or by e-mail on Clement.Penny@wits.ac.za. The telephone numbers for the Committee secretariat are 011 717 2700/1234 and the e-mail addresses are Zanele.Ndlovu@wits.ac.za and Rhulani.Mukansi@wits.ac.za. You may also contact the Vanderbilt University Medical Center Institutional Review Board (IRB) office in the U.S. at +001-615-322-2918 or toll free at +001-866-224-8273.

Reasons why the study doctor may take you out of this study:

None

What will happen if you decide to stop being in this study?

If you decide to stop being part of the study, you should tell your study doctor. Deciding to not be part of the study will not change your regular medical care in any way.

Clinical Trials Registry:

A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this Web site at any time.

Confidentiality:

We will make every effort to keep your personal information confidential. However, it is not possible to guarantee total confidentiality. The information obtained during this study will be stored securely at the

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MRC/Wits Agincourt Research Unit's field offices and on a protected database. Only trained study staff will have to access this clinical information.

This study may have some support from the National Institutes of Health (NIH). If so, your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

Privacy:

Any samples and information about you may be made available to others to use for research. To protect your privacy, we will not release your name. You will not receive any benefit as a result of the tests done on your samples. These tests may help us or other researchers learn more about the causes, risks, treatments, or how to prevent this and other health problems.

Study Results:

We will gather former participants and community members once the study ends to tell you the results. You are welcome to attend this meeting to learn if our training program was effective.

Authorization to Use/Disclose Protected Health Information

What information is being collected, used, or shared?

To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Vanderbilt University Medical Center and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?

The people who may request, receive or use your private health information include the researchers and their staff. Additionally, we may share your information with other people at Vanderbilt, for example if

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needed for your clinical care or study oversight. By signing this form, you give permission to the research team to share your information with others outside of Vanderbilt University Medical Center. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers and other agents and contractors used by the study team. We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?

You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your information be used or shared?

Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?

You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization. You have the right to see and copy the PHI we gather on you for as long as the study doctor or research site holds this data. To ensure the scientific quality of the research study, you will not be able to review some of your research data until after the research study is finished.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

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Printed Name of Participant

Date

	Thumbprint of Participant

Signature of Participant

Date

Signature of Witness (if thumbprint used)

Date

Signature of Person Who Explained This Form

Date

I have explained to the participant the study purpose and procedures and we have discussed all the risks that are involved. I have answered questions to the best of my ability.