

COVER PAGE

Title: Acceptability and Performance of HIV Self-Testing in a Youth Population in Nigeria

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SAINT LOUIS UNIVERSITY

Research Study Consent Form

STUDY TITLE:	Acceptability and Performance of HIV Self-Testing in a Youth Population in Nigeria
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This consent form contains important information to help you decide whether to participate in a research study.

The study staff will explain this study to you. Ask questions about anything that is not clear at any time. You may take home an unsigned copy of this consent form to think about and discuss with family or friends.

- **Being in a study is voluntary – your choice.**
- **If you join this study, you can still stop at any time.**
- **No one can promise that a study will help you.**
- **Do not join this study unless all of your questions are answered.**

After reading and discussing the information in this consent form you should know:

- Why this research study is being done;
- What will happen during the study;
- Any possible benefits to you;
- The possible risks to you;
- Other options you could choose instead of being in this study;
- Whether being in this study could involve any cost to you; and
- What to do if you have problems or questions about this study.

Please read this consent form carefully.

RESEARCH STUDY CONSENT FORM

Participant:		IRB #:	29882
	<i>First Name / Last Name</i>		
Principal Investigator (PI)	Juliet Iwelunmor	PhD	Contact Phone #
	<i>First Name / Last Name</i>		<i>Credentials</i>
	+234-803-306-5683		
Title of Project:	Acceptability and Performance of HIV Self-Testing in a Youth Population in Nigeria		

“You” refers to the person who takes part in the research study.

You are being asked to take part in a research study conducted by Juliet Iwelunmor, PhD, Oliver Ezechi, MD, Joseph Tucker, MD and other colleagues because the research study doctor needs to know whether young people in Nigeria will use oral HIV self-testing kits.

This consent document may contain words that you do not understand. Please ask the researcher to explain anything that you do not understand.

1. WHY IS THIS RESEARCH STUDY BEING DONE?

Many young people in Nigeria are at risk for getting HIV, but a lot of young people have never been tested for HIV. Testing for HIV is important for someone to know their HIV status and to help them start getting HIV care on time. This is important to help people who are living with HIV get care so that they can stay healthy. It is also important for people who are not living with HIV to know their HIV status so that they can make sure that they stay healthy and HIV negative. The purpose of this study is to understand what young people in Nigeria think about oral HIV self-testing (HIVST) and to understand how oral HIV self-testing would work among young people between 14-24 years in Nigeria. Oral HIVST is the type of test where a person collects their saliva, performs the HIV test, and interprets the result, in a private setting, either alone or with someone the person trusts.

2. WHAT AM I BEING ASKED TO DO?

- a) You will be asked to complete a pre-HIV testing questionnaire. This questionnaire will ask for your basic demographic information, HIV testing history, sexual behavior history, HIV self-testing knowledge, perceived importance of HIV self-testing, confidence in performing HIV self-test, and concerns with performing the test.
- b) After completing the pre-HIV testing questionnaire, you will be given instructions on how to perform the oral HIV self-test using OraQuick Rapid HIV 1/2 Antibody by OraSure Technologies. We would show you a short video to introduce you to HIV self-testing and how to use the HIV self-test kit. You will also be provided with a picture information on how to use the HIV self-test kit. The OraQuick Rapid HIV 1/2 Antibody by OraSure Technologies is a type of HIV testing where you can collect your saliva by yourself,

perform the HIV test, and get your result by yourself in privacy or with someone who you trust.

- c) After this instruction and video, you will be given the oral self-test kit to perform the test in private in a separate room. After completing the test, you will be asked to take a photograph of your test results using a photo verification software application (an app).
- d) When you are done with the HIV self-test, a trained research assistant with our partner organization, the Nigerian Institute of Medical Research (NIMR) will help you perform a confirmatory finger prick HIV test. The finger prick HIV test allows you to confirm your test result. According to the Nigerian guideline for HIV testing, people who perform the HIV self-test, are recommended to perform a finger prick HIV test. After completing the confirmatory finger prick HIV test, you will be asked to complete a post-HIV questionnaire which would ask similar questions like the pre-HIV questionnaire. The questions on the post-HIV questionnaire would also ask for basic demographic information, sexual behavior history, HIV self-testing knowledge, perceived importance of HIV self-testing, confidence in performing HIV self-test, and concerns with performing the test.

There are some warning and precautions, you need to be aware off with using OraQuick for HIV test:

- A positive result with this test does not mean that you are definitely infected with HIV, but rather that additional testing should be done in a medical setting. Please note that the confirmatory test you will be doing with the Nigerian Institute of Medical Research (NIMR) qualifies as a medical setting.
- A negative result with this test does not mean that you are definitely not infected with HIV, especially when you think you have been exposed to the virus 3 months prior. If you test is negative and you engage in activities that put you at risk for HIV on a regular basis, you should test regularly.
- This product should not be used to make decisions on behavior that may put you at increased risk for HIV.
- For additional information please refer to the product Package Insert which can be found inside the HIV test kit.

Also, feel free to ask Dr. Iwelunmor any questions or concerns you may have in regards to using OraQuick HIV test kit or at any stage of the research process.

3. HOW LONG WILL I BE IN THE RESEARCH STUDY?

The time you may spend on this research study is 2 hours. Specifically, we anticipate the HIV self-testing and confirmatory rapid HIV blood-prick test will last about 1 hour 30 minutes, and the pre-and-post test HIV questionnaire will last about 30 minutes.

The research study should be completed by December 2019.

4. WHAT ARE THE RISKS?

There are certain risks and discomforts that may occur if you take part in this research study. They include:

- a) potential feelings of obligation to enroll in the study

- b) potential loss of confidentiality related to data from questionnaires and HIV test results.
- c) some questions on the pre and post HIV questionnaires may make participants feels comfortable.
- d) participants may experience stress regarding self-testing
- e) participants may also receive in-accurate results with self-testing, which may cause stress for participants
- g) screening positive for HIV may be a source of psychological distress to study participants. Also, having confirmatory test after testing positive for HIV can also trigger more distress.
- h) participants who have a positive HIV test result may be distraught about disclosing to their partner, family members, and friends. Stigma and discrimination have been associated with HIV/AIDS positive populations.

As part of the process involved in obtaining written informed consent, participants will be reminded that their responses to questionnaires will be confidential and that they may refuse to participate in the project or withdraw at any time without explanation. They will be informed that their decision to participate or not will in no way affect their ability to obtain health care from medical facilities

Also, study participants will be counselled before and after performing self-test. The research assistant on this project are trained to provide HIV counseling before and after testing. This is to minimize some of the distress that comes with testing for HIV.

In addition, we will develop a list of referral services for participants. To support youth who test positive for HIV, we have developed an agreement with the Nigerian Institute for Medical Research, to provide care for participants we identify who test positive for HIV.

Also, to minimize some of these risks a trained clinical monitor will work to ensure that the safety and rights of participants in the research are protected. The trained clinical monitor will work to ensure that we collect quality data in an ethical manner. Also, we will not refer to participants individually in any presentations or publication of results from this study. However, please note that we have to report some incidence as required by law. This includes suspicion of child abuse, elder abuse, and threat of imminent action on suicidal or homicidal ideation based on personal reports or reports from other participants. If side effects or discomfort occur, Dr. Juliet Iwelunmor and Dr. Oliver Ezechi will try to help these by linking you to appropriate local health services for HIV care in Nigeria (such as Nigerian Institute of Medical Research).

The research team is willing to discuss any questions you might have about these risks and discomforts.

5. ARE THERE BENEFITS TO BEING IN THIS RESEARCH STUDY?

You may not benefit directly from this research study. However, the research study of your use of HIV self-testing kits may help to prevent HIV among young people in Nigeria. In addition, you will gain the benefit of knowing your HIV status.

6. WHAT OTHER OPTIONS ARE THERE?

You may choose not to be in this research study. Being in this study is voluntary. You can also stop being in the study at any time. Your decision not to participate or your decision to withdraw later will not result in any penalty.

7. WILL MY INFORMATION BE KEPT PRIVATE?

The results of the research study may be published, but your name or identity will not be revealed, and your information will remain private. In order to protect your information, the researcher Dr. Juliet Iwelunmor will store your data securely in a locked cabinet and locked office at Saint Louis University. The HIV pre and post-test questionnaires and pictures will be collected through a password protected tablet. The questionnaire data and images will be encrypted to ensure privacy and data security. Encryption means that the questionnaire data and images are converted in such a way that only authorized and trained researchers on this project will access to the information.

The Saint Louis University Institutional Review Board (the Board that is responsible for protecting the welfare of persons who take part in research), and other University officials may review your research study records. State laws or court orders may also require that information from your research records be released.

Please note that a description of this study and the study results will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This website will not include information that can identify you. You can search this website at any time.

8. WHAT ARE THE COSTS AND PAYMENTS?

There will be no additional costs to you for taking part in this research study. You will receive a N2000 voucher for your participation in this study.

9. WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS RESEARCH STUDY?

If you believe that you are injured as a result of your participation in the research study, please contact the research study doctor and/or the Chairperson of the Institutional Review Board as stated in section 10.

You will receive necessary medical treatment in the event that an injury results because of your participation in this research. The University will have the right to determine whether an injury is related to your participation in this study or happened because of your medical condition or other reasons which are not related to this study. If the injury is due to participation in the research, you will not have to pay for the cost of this treatment unless your injury is due to your own failure to follow the study doctor's instructions. There are no plans for Saint Louis University to pay for the costs of any additional care. You have not waived your legal rights by signing this form. If you have any questions, please call the Saint Louis University General Counsel's office at 314-977-5767.

10. WHO CAN I CALL IF I HAVE QUESTIONS?

If you have any questions or concerns about this research study, or if you have any problems that occur from taking part in this research study, you may call the researcher Dr. Juliet Iwelunmor at (+234-706-376-7599).

If you have questions, concerns or complaints about your rights as a research participant and would like to talk to someone not on the research team, please contact the Saint Louis University Institutional Review Board (IRB) at +1 314-977-7744 or irb@slu.edu. You can also contact the Nigerian Institute of Medical Research IRB at +234 909 213 3886 or nimr_irb@nimr.gov.ng

11. WHAT ARE MY RIGHTS AND WHAT ELSE SHOULD I KNOW AS A RESEARCH STUDY VOLUNTEER?

Your participation in this research study is voluntary. You may choose not to be a part of this research study. There will be no penalty to you if you choose not to take part. You may leave the research study at any time. The researcher will let you know of any new information that may affect whether you want to continue to take part in the research study.

Saint Louis University is receiving financial support from the National Institute of Child Health and Human Development (NICHD) to assist in the conduct of this research study. The amount of payment is enough to cover the Principal Investigator's and/or institution's expenses to perform the research study.

12. AM I SURE THAT I UNDERSTAND?

I have read this consent document and have been able to ask questions and state any concerns. The researcher has responded to my questions and concerns. I believe I understand the research study and the potential benefits and risks that are involved.

Statement of Consent

I give my informed and voluntary consent to take part in this research study. I will be given a copy of this consent document for my records.

Print Name of Participant

Consent Signature of Research Participant (14 and over) Date

<p align="center">SAINT LOUIS UNIVERSITY – INSTITUTIONAL REVIEW BOARD – APPROVAL STAMP</p> <p align="center">This form is valid only if the IRB’s approval stamp is shown below.</p> <p align="center">IRB #: 29882 Approved: 11-05-19 Expires: 11-19-20 Board #: 1 Saint Louis University</p> <p align="center"></p>
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I certify that I have explained to the above individual(s) the nature and purpose of the research study and the possible benefit and risks associated with participation. I have answered any questions that have been raised and the participant has received a copy of this signed consent document.

Signature of Consenting Research Team Member	Date
<i>First Name / Last Name</i>	<i>Credentials</i>
Printed Name of Consenting Research Team Member	