COVER PAGE

Title: Innovative Tools to Expand HIV Self-Testing (I-TEST)

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SAINT LOUIS UNIVERSITY

Research Study Consent Form

STUDY TITLE:	Innovative Tools to Expand HIV Self-Testing (I-TEST)

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

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;
- How your personal health information will be treated during the study and after the study is over;
- Whether being in this study could involve any cost to you; and
- What to do if you have problems or questions about this study.

<u>Please read this consent form carefully.</u>

RESEARCH STUDY CONSENT FORM

Participant:		**IRB #:**	30347
	First Name / Last Name		
Principal Investigator (PI)	Juliet Iwelunmor	**Contact Phone #**	+234-803-306-5683
	First Name / Last Name Credentials		
Title of Project:	Innovative Tools to Expand HIV Self-Testing (I-TEST)		

"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 Dr. Juliet Iwelunmor and colleagues (Dr. Oliver Ezechi and Dr. Joe Tucker) because you are a young person between 14 and 24 years currently living in Lagos state.

This consent document may contain words that you do not understand. Please ask the research study doctor or research staff to explain anything that you do not understand.

Key Information for You to Consider

- **Purpose**. The purpose of this research is to assess how successful five youth participatory interventions on HIV testing and other key prevention services can increase uptake of HIV testing and other key prevention services. These interventions were developed by young people between 14-24 years in Nigeria.
- **Duration.** It is expected that your participation will last 6 months.
- **Study Procedures.** You will be assigned to an intervention. Following assignment to the intervention, you will be asked to complete a survey questionnaire prior to participating in the intervention. After this survey questionnaire, you will then be exposed to the intervention. Also, you will also complete two other survey questionnaires at 3-months and 6-months after completing the first survey questionnaire.
- **Risks.** Some of the foreseeable risks or discomforts of your participation include the potential obligation to enroll in this study, potential breach of confidentiality from survey data, and feeling uncomfortable with some of the questions in the survey questionnaire.
- **Benefits**. There is no direct benefit for your participation in this study. However, this study would help us understand strategies that can increase HIV testing and other key prevention services among young people in Nigeria.
- **Alternatives.** Participation is voluntary and the alternative is not participate in the

study.

1. WHY IS THIS RESEARCH STUDY BEING DONE?

The purpose of this study is to evaluate the effectiveness of five youth participatory interventions on HIV testing and other key prevention services among young people ages 14-24 in Nigeria. This research study will help us understand strategies to increase uptake of HIV testing and other sexually transmitted infections among young people ages 14-24 years in Nigeria.

We anticipate that a total of 1000 participants will be recruited for this study.

2. WHAT AM I BEING ASKED TO DO?

a) After recruitment to the study you will be assigned to any of the five youth participatory interventions based on which of them is closed to you. The interventions for this study include:

Intervention 1: This involves using “SMART Pack” a HIV self-testing kit to promote uptake of HIV self-testing among young people at community centers. The SMART pack is a re-branded and repackaged box for HIV self-testing kits. The intervention aims to promote distribution of HIVST kits through in institutions, vocational centers, and social media platforms. The intervention would also include a referral systems, where participants provided with the HIV self-testing kits are provided with information with youth-friendly health facilities for uptake of testing for sexually transmitted infections. For this pilot study, the intervention will be implemented in Yaba local government area in Lagos state.

Intervention 2: The intervention involves using “Luv Box” a box that include personal hygiene products and HIV self-testing kit as strategy to promote uptake of HIV testing among young people. The Luv box is packaged in two colors: blue and pink. The LUVBox would be made available in supermarkets, on-line stores, mini-marts, pharmacies, neighborhood stores and markets, for easy accessibility in hard to reach areas. For this pilot study, the intervention will be implemented in Yaba in Lagos state.

Intervention 3: The intervention involves using a program program called “Bili” that leverages community youth events such as football matches as a strategy to promote the uptake of HIV self-testing among young people. For this pilot study, the intervention will be implemented in Ngenevu/Bunker communities in Enugu state.

Intervention 4: This intervention involves using “BeterDoc Safety kits” that includes HIV self-testing kit, location and phone number to the health centers in the community as a strategy to promote update of HIV self-testing among young people. For this pilot study, the intervention will be implemented in Ibadan, Dugbe and Agbowo in Oyo state.

Intervention 5: This intervention involves using a program utilizes community vocational skills training centers to promote uptake of HIV self-testing among young people. For this pilot study, the intervention will be implemented in Akure South, Orita-Obele, Ipinsa, Ilara Mokin and Ijare in Ondo state.

Following, intervention assignment you be asked to provide informed consent to proceed with the research study. After providing informed consent for this study you will be asked to complete a baseline survey questionnaire. The survey questionnaire will ask for your basic demographic information, sexual behavior history, HIV testing history, questions related to testing for sexually transmitted infections, resilience, social support, self-efficacy, depression, sexual sensation seeking, and future orientation (positive outlook of life).
We will also be collecting your cellphone number to contact you for the follow-up assessments of the study. We will be covering all the cost for the phone service.

b) After completing the baseline questionnaire, you will be exposed to a youth participatory intervention for HIV testing and other key preventive services. The intervention involves providing you with HIV self-testing kits and referral to health centers to test for other sexually transmitted infections and confirmatory HIV testing if you believe that you need one. These services would be provided to you at no additional cost at the health facilities that you will be referred to. The intervention is just focused on providing you access to these services, we will only be asking if you were able to test or not test for these services.

c) Three months after completing the baseline survey questionnaire, you will be asked to complete a post-survey questionnaire. The survey questionnaire will collect information on basic demographic information, sexual behavior history, HIV testing history, questions related to testing for sexually transmitted infections, resilience, social support, self-efficacy, depression, sexual sensation seeking, and future orientation (positive outlook of life). will be contacting you through text messages or phone calls with the cell phone number you have provided to complete the follow-up survey.

d) Also, six months after completing the baseline survey questionnaire, you will be asked to complete a post-survey questionnaire. The survey questionnaire will collect information on basic demographic information, sexual behavior history, HIV testing history, questions related to testing for sexually transmitted infections, resilience, social support, self-efficacy, depression, sexual sensation seeking, and future orientation (positive outlook of life). We will be contacting you through text messages with the cell phone number you have provided to complete the follow-up survey.

Identifiers might be removed from your data collected in this research, and used for future research studies or distributed to other researchers for future research studies without your additional permission.

All components of this study will be completed at in a private room at the community center.

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

The time you may spend on this research study is 6 months. Specifically, we anticipate that each survey questionnaire (baseline survey questionnaire, 3-month follow-up survey questionnaire, 6-month follow-up survey questionnaire) will last about 30 minutes.
We anticipate that the testing for other sexually transmitted infections and confirmatory HIV test (if you need it) at the youth-friendly health facilities would take about 45 minutes to 1 hour to complete.

The research study should be completed by June 2021

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 obligations to enroll in the study
b) some questions in the survey questions may make you feel uncomfortable. You do not have to answer questions that make you uncomfortable or any question you do not want to answer
c) There may loss of confidentiality (your data being seen by someone who shouldn't have access to it. To try to prevent this risk, only the research team will have access to participants' data. We also we will be collecting data using a secure survey application to prevent this from occurring)

As this study involves the use of your personal information, there is a chance that a loss of confidentiality will occur. The researchers have procedures in place to lessen the possibility of this happening, as described in section 7 of this form.

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 from this research study.

Even though you may not receive any benefit, other young people in Nigeria may benefit in the future because of what the researchers learn from this research study. Your participation in this study would help us understand programs that may increase uptake of HIV testing and other key prevention services among young people in Nigeria.

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 participating 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 record will remain private. In order to protect your information, Dr. Juliet Iwelunmor will store your data securely in a locked cabinet and a locked office at Saint Louis University. The survey questionnaire data will be collected through a password protected tablet using a secure software (RedCap) provided by Saint Louis University. Information collected for this research study may be shared with other researchers. If this information about you is shared, it will not include names, addresses, or other identifying 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.

A description of this study and 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 are no additional costs to you taking part in this research study. You will receive a ₦1200 gift voucher for your participation in each of the survey questionnaire. In total you will receive ₦3600 gift voucher if you complete the three survey questionnaires.

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 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 Dr. Juliet Iwelunmor at +234-803-306-5683.

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 314-977-7744 or irb@slu.edu.

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

Your participation in this research is voluntary. You may choose not to be a part of this research. There will be no penalty to you if you choose not to take part. You may leave the research study at any time. The research study doctor or research study staff 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 research study doctor'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. I have been asked if I wish to speak directly to the researcher or research study doctor responsible for this research study. The research team 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

_____ _____
Signature of Research Participant Date

SAINT LOUIS UNIVERSITY – INSTITUTIONAL REVIEW BOARD – APPROVAL STAMP

This form is valid only if the IRB's approval stamp is shown below.

SLU IRB #: 30347
Approved: 05-21-19
Expires: 05-20-20
Board #: 3
Saint Louis University

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 subject/patient has received a copy of this signed consent document.

Signature of Consenting Research Team Member	**Date**
First Name / Last Name *Credentials*	
Printed Name of Consenting Research Team Member	