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Study Title: PEERNaija, A Mobile Health Platform Incentivizing Medication Adherence Among Youth Living in Nigeria

The purpose of this study is to test if our mobile app, PEER Naija, will help you do a better job in taking your HIV treatment medication. If you agree to take part, your participation will last for 18 months and will involve 6 study visits that will require you to download and use the app (as much or little as you like), answer survey questions, agree to a chart review, and have HIV labs drawn up to 3 times during the study. You may also be invited to attend a focus group. This study may have minor risks including breach of confidentiality or feeling embarrassed, uncomfortable or upset.

You may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of this research study, and the risks and possible benefits of participating.

If there is anything in this form you do not understand, please ask questions. Please take your time. You do not have to take part in this study if you do not want to. If you take part, you can leave the study at any time. You can read through the consent form yourself or request a study team member to read it to you.

In the sections that follow, the word "we" means the study doctor and other research staff. If you are a parent or legal guardian who is giving permission for a child, please note that the word "you" refers to your child.

What is the purpose of the study?
We want to test if our mobile app will help you do a better job in taking your HIV treatment medication.

What is involved in the study?
You will be asked to attend an in-person session where you will download and use a smartphone app created for the study on your personal Android phone, and respond to surveys. Study team members will review your app usage, which includes your use of the chatroom. Study team members will also look at your medical and pharmacy records. If you do not have HIV viral load labs in your medical records during the time of the study, you will be asked to have labs drawn. This could happen up to 3 times within the study period. At the end of the study period, you will be invited to attend a focus group session.

How long will you be in this study?
If you agree to take part, your participation will last for 18 months and will involve 6 study visits.

What are the study procedures?
The study involved the following tests and procedures:

Initial Session:	You will participate in a personal session, which will help you install and learn about the study app. During the session, you will be asked to complete a survey about your health and experiences with HIV. Surveys will be completed in a private space.
App Use:	You can use it as much or as little as you want to for the rest of the time you are in the study. You must also let a study team member know if your phone is ever lost, stolen, taken away, broken, or if the phone plan is disconnected while you are in this study. Anything you use or do in the app will be recorded and will be used for the study. The app is investigational and we do not know if it will help you take your medication.

Surveys:	At some of your study visits, you will fill out surveys on your demographics, your health care experiences, your smartphone and internet use, your HIV medication and how well you follow your schedule in taking medication, what you like/dislike about the study app, your experience with HIV, and mental health. You can choose to fill out surveys alone or with a study team member in a private room.
Chart Review:	A study team member will look at your medical and pharmacy records. These medical records will be those at NIMR. You do not need to be present for this part of the study.
Lab Draw:	If we do not have HIV viral load labs for you in your medical record, you will be asked to come in for labs up to 3 times during the study. These visits would occur at your initial visit, and again 6 and 12 months later.
Focus Group:	You will be invited to attend a focus group which will ask you questions about your experience using the app.

Some of the procedures (medical chart review, surveys, labs) in this study will be repeated several times.

What are the risks of this study?
While in this study, the following are risks associated with study app usage, session, surveys, and medical/pharmacy chart review:

- Breach of confidentiality
- Feeling embarrassed, uncomfortable, or upset

The study team will not use any study information for any purpose other than conducting the study. The study team are taking precautions to make sure any information collected from you in this study are protected to the best of their ability through password-protected files, conducting study visits in private spaces, and storing files on NIMR and VUMC secured network drives. We also recommend utilizing the password protection to unlock your phone and/or the study app to further protect your confidentiality.

If you become very upset or any issues come up that you want to discuss during or after your study visits, you will be able to speak with the study team and request to speak with the study doctor or your regular doctor. You may take breaks at any time while answering questions during the study visits. You do not have to answer any questions that make you too uncomfortable.

Why are you being asked to take part in this study?
You are 14-29 years old, HIV-positive, and/or have an unsuppressed viral load and/or have been out of care for at least 6 months within the last year, own an Android smartphone you are willing to use, are being treated at NIMR, and are having trouble remembering to take your HIV treatment medication.

How many people will take part?
About 50 participants will take part in this study.

Are there any benefits to taking part in this study?
The knowledge gained from this study may provide valuable information to the scientific community about how to use mobile technology to help youth living with HIV remember to take their HIV treatment medication.

Participants who take part in the study might benefit from using the app. The app might be useful to help you remember to take your medication. If it does, this might improve your HIV-related health outcomes. However, we cannot guarantee or promise that you will receive any direct benefit by participating in this study.

Do you need to give your consent in order to participate?
If you decide to participate in this study, you must sign this form. A copy will be given to you to keep as a record. Please consider the study time commitments and responsibilities as a research subject when making your decision about participating in this study. You will need to follow the study team's instructions.

What happens if you decide not to take part in this study?
Participation in this study is voluntary. You do not have to take part in order to receive care at NIMR. If you decide not to take part or if you change your mind later there will be no penalties or loss of any benefits to which you are otherwise entitled.

Can you stop your participation in the study early?
You can stop being in the study at any time. You do not have to give a reason.

Can the study doctor take you out of the study early?
The study doctor may take you off of the study if:

- The study is stopped.
- You cannot meet all the requirements of the study.
- New information suggests taking part in the study may not be in your best interests.

What choices do you have other than this study?
There are options for you other than this study including:

- Not participating in this study and continuing your usual medical care.
- You may discuss other options available to you with your doctor.

What about privacy, authorization for use of Personal Health Information (PHI) and confidentiality?
As part of this research, health information about you will be collected. This will include information from the screening, study visit and questionnaire. There are no research laboratory tests for this study. We will do our best to keep your personal information private and confidential. However, we cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. The results of this study may be shown at meetings and published in journals to inform other doctors and health professionals. We will keep your identity private in any publication or presentation.

Your information may be shared with Vanderbilt or the government, such as the Vanderbilt University Institutional Review Board, Federal Government Office for Human Research Protections, National Institutes of Health, or Members of the research team and other authorized staff at NIMR, APIN and VUMC. If you or someone else is in danger or if we are required to do so by law. Vanderbilt may give or sell your data without identifiers for other research projects not listed in this form. There are no plans to pay you for the use or transfer of this de-identified information.

By law, the study is required to protect your health information. The research staff will only allow access to your health information to the groups listed above. By signing this document, you are authorizing VUMC to use your health information for this research.

There is no set time for destroying the information that will be collected for this study. Your permission to use and share the information and data from this study will continue until the research study ends and will not expire. Researchers continue to analyze data for many years and it is not possible to know when they will be completely done.

Can you change your mind about the use of personal information?
You may change your mind and withdraw your permission to use and disclose your health information at any time. To take back your permission, it is preferred that you inform the study coordinator, Ifeoma Idigbe, via telephone at 08067095776.

Additionally, in a letter, state that you changed your mind and do not want any more of your health information collected. The personal information that has been collected already will be used if necessary for the research.

No new information will be collected. If you withdraw your permission to use your personal health information, you will be withdrawn from the study.

Additional Information
You will be informed if changes to the study are needed to protect your health. You will be told about any new information that could affect your willingness to stay in the study, such as new risks, benefits or alternative treatments.

Financial Information
While you are in this study, the cost of your usual medical care – procedures, medications and doctor visits – will continue as per the terms of agreement with NIMR.

Will there be any additional costs?
There are no costs to you for participating in the research procedures for this study.

Will you be paid for taking part in this study?
There will be payments for your time and effort in cash as well as reimbursement for travel. You will receive the payment at the end of your study visit.

- Participants will be given two transportation vouchers to help get to and from the study site.
- Participants will receive 2000 Nigerian Naira [NGN] per study visit for their time and effort.
- Some study participants will be entered into a lottery to receive a data bundle worth 1000 NGN.
- Participants who attend the focus group session will receive 3000 NGN for their time and effort.

Who is funding this research study?
The Vanderbilt University Medical Center (VUMC) and the National Institutes of Health (NIH) are funding this study. Ask the study coordinator if you have any questions about how this study is funded.

What if you have questions about the study?
If you have questions about the study, call the study coordinator, TBN.

Consent to Take Part in this Research Study and Authorization to Use and Disclose Health Information for the Research
The research study and consent form have been explained to you by:

_____ _____
Person Obtaining Consent Signature of Person Obtaining Consent

_____
Date

In this study, 16 to 29-year-old participants are capable of consenting for themselves and do not need parental permission to participate in the study.

By signing this form, you are indicating that you have had your questions answered, you agree to take part in this research study, and you are legally authorized to consent to your participation. You are also agreeing to let VUMC use and share your health information as explained above. If you do not agree to the collection, use and sharing of your health information, you cannot participate in this study.

_____ _____
Name of Subject Signature of Subject

_____
Date