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Research Subject Informed Consent Form

Title of Study:	Integration of Hypertension Management into HIV Care in Nigeria: A Task Strengthening Strategy s20-00009
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1. About volunteering for this research study

You are being invited to take part in a research study. Your participation is voluntary which means you can choose whether or not you want to take part in this study.

People who agree to take part in research studies are called “subjects” or “research subjects” or “Participants” or “Patients”. These words are used throughout this consent form. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. You may also decide to discuss this study and this form with your family, friends, or doctor. If you have any questions about the study or about this form, please ask us. If you decide to take part in this study, you must sign this form. We will give you a copy of this form signed by you for you to keep.

2. What is the purpose of this study?

The purpose of this study is to understand the effect of practice facilitation (PF) on reducing systolic Blood Pressure (BP). And to assess its adoption and sustainability as an important practice in HIV clinics within Lagos Sate’s primary care delivery network practice in HIV clinics within Lagos Sate’s primary care delivery network. You are being asked to participate because you have uncontrolled blood pressure and you receive care at an HIV clinic.

3. How long will I be in the study? How many other people will be in the study?

This study will be completed over the course of 5 years. We are requesting your participation in the implementation phase which will take about 24 months to complete which will involve 5 visits. At each visit, in addition to your HIV clinic check up, the nurse will measure your blood pressure, weight, height and waist circumference. Also a sample of your urine will be collected and your blood glucose will be assessed using a finger stick test. We expect a total of 960 participants in this phase of the study

4. What will I be asked to do in the study?

This section will help you understand what is expected of you during your participation in the study. If you agree to participate in this study, then your first study visit will be today. We will ask you to sign this consent form before you complete any procedures with the study staff that are part of the study.

The HIV Clinic where you receive care will be assigned, by chance, to one of two study groups: Group A or Group B. Your clinic have a 50% chance of being in either group. The research assistant will inform you of your assigned group.

The only difference between the groups is that the **HIV Clinics** in Group A will not receive support from a practice outreach facilitator, while **HIV clinics** in Group B will be supported by a practice outreach facilitator.

Regardless of your clinic assignment, you will have the opportunity to participate in counseling sessions with a clinical staff member over 24 months, the sessions will occur during your clinic visits a baseline (this visit), at 6-month, 12-month, 18-month and 24-month visits. During the sessions, you will talk about how you take your high blood pressure medication, your concerns about taking your medications, and ways you can remember to take your medications every day. The sessions will last about 20 minutes each.

At each visit your blood pressure, weight, height and waist circumference will be measured, a sample of your urine will also be collected and your blood glucose will be assessed using a finger stick test.

Additionally, we will ask you questions about yourself (such as your sex, age, place of birth, health, education level, income, employment status, health insurance and other medical conditions you may have), and the medications you take.

With your permission, the study staff will also review your chart to assess the duration of your high blood pressure, blood pressure readings, changes in the type of medication or dosage you are prescribed to treat your high blood pressure, how often you visited the doctor and reasons for visits, use of other medications that are known to affect blood pressure, and medical comorbidities as well as your pharmacy refill information. The information collected from your chart will be labeled with a code number only. No names will be used.

5. What are the possible risks or discomforts?

Risk of Study

<u>Elevated blood pressure</u>
All participants will receive clinical care from the HIV clinics affiliated with the Lagos State Healthcare Board as part of this study; however, it is quite conceivable that you may have elevated BP readings during the course study (not as a result of the study intervention) that will require more aggressive management and you will be referred to the primary care physician in the HIV clinics. Similarly, any

medical problem that arises during study visits will be referred to the same channels. If at any study visit, BP is elevated >180 SBP or >110 DBP, you will receive medical attention immediately at the clinic. The research staff and Drs. Ezechi and Odusola will follow-up with your clinician to ensure proper medical follow-up.

Blood Pressure cuffs:

You may feel slight discomfort on your arms from the blood pressure cuffs during blood pressure readings. Study nurses will monitor this discomfort and adjust the cuffs as needed.

Blood Test:

The fingerstick is drawing a very small amount of blood (a few drops) from your finger tip that may result in some bruising of the skin, some bleeding or swelling at the site of stick. Pressure will be applied to the site of the fingerstick immediately to stop the bleeding.

Violation of participant privacy and confidentiality

Loss of confidentiality is the potential risk to study subjects.In order to prevent this Names of patients will be replaced with identification numbers. All health record data will be de-identified prior to transfer from the data warehouses to the central repository managed by NYU. Locked file cabinets will be used to store materials with identifying information (e.g., participant consent forms). Only members of the research team will have access to participant's personal information file. The data collected for this study will be used strictly for the purposes of the study and will only be available to relevant research staff at the Nigerian Institute of Medical Research, Saint Louis University and NYU.

Anxiety:

Some personal and sensitive information may be requested from you during the course of this research study. You do not have to answer any questions you choose not to and it will not affect the care you receive from your healthcare provider. You might feel inconvenienced by giving your time for the study visits.

6. What if new information becomes available?

During the course of this study, we may find more information that could be important to you.

This includes information that might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

7. What are the possible benefits of the study?

The study procedures may benefit you by improving your blood pressure control, reducing your cardiovascular risk, and increasing your role as an active participant in the management of your HTN.. The ultimate goal of the study is to develop a strategy on how to make it a part of a routine activities at HIV clinics. The study may also have relevance to other HIV clinics by testing new strategies for implementing interventions for improving hypertension control in high-risk populations.

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8. What other choices do I have if I do not participate?

Your participation is completely voluntary. This means that you do not have to participate in this study unless you want to. Your decision whether or not to participate in this study will not affect your relationship with your medical providers. If you do not agree to consent to participating in this study, you will continue to receive appropriate medical care.

9. Will I be paid for being in this study?

There is no monetary compensation for participation in the study. You will be receiving medical care as a part of this research study. You or your insurance company will not be charged or held responsible for the costs of that care.

10. Will I have to pay for anything?

There is no cost for participation in the study. All study-related costs associated with your being in this study will be paid by the National Institute of Health. You will be responsible for paying for services rendered that are not part of this study such as doctor visits and test not related to your blood pressure.

11. What happens if I am injured from being in the study?

For medical emergencies please visit the closest clinic to you. If you think you have been injured as a result of taking part in this research study, contact Dr. Oliver Ezechi, his number and email are listed at the top of page 1 of this consent form. There are no plans for the NYU School of Medicine or Medical Center to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

12. When is the study over? Can I leave the Study before it ends?

This study is expected to end after all participants have completed all semi-structured interview or individual interviews, BP measurements, anthropometric measurements and all information has been collected. This study may also be stopped or your participation ended at any time by your physician, nurse, or study sponsor without your consent because:

- You meet an exclusion criterion (either newly developed or not previously recognized) that precludes further study participation
- You have not followed study instructions.
- The study sponsor, the principal investigator or other body responsible for monitoring the safety of the study has decided to stop the study.

If you decide to participate, you are free to leave the study at anytime. Leaving the study will not interfere with your future care, payment for your health care or your eligibility for health care benefits.

13. How will you protect my confidentiality?

Your medical information is protected health information, or “PHI”, and is protected by federal and state laws, such as the Health Insurance Portability and Accountability Act, or HIPAA. This includes information in your research record as well as information in your medical record at NYU Langone Health. In compliance with NYU Langone Health policies and procedures and with HIPAA, only those individuals with a job purpose can access this information.

Medical information created by this research study may become part of your medical record. We may include your research information in your medical record for several reasons, including for the billing of services provided in connection with the study, to securely document any medical services you receive, and so that other members of the NYU Langone Health community who may treat you have access to important information about your health.

You have a right to access information in your medical record. In some cases, when necessary to protect the integrity of the research, you will not be allowed to see or copy certain information relating to the study while the study is in progress, but you will have the right to see and copy the information once the study is over in accordance with NYU Langone Health policies and applicable law.

Certificate of Confidentiality

To help us further protect your confidentiality, this research is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH). The NIH has issued a Certificate of Confidentiality for this research. This adds special protection for the research information (data, documents) that may identify you. Research information protected by this Certificate of Confidentiality cannot be disclosed to anyone else who is not connected with the research, without your consent. With this Certificate of Confidentiality, the researchers may not disclose or use research information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, without your consent. However, disclosure, without your consent, is still necessary if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases). The Certificate of Confidentiality cannot be used to refuse a request for information from appropriate government agencies responsible for project oversight. The Certificate of Confidentiality does not prevent you from releasing information about yourself and your involvement in this research, including for your medical treatment. Federal regulations may also allow for the use or sharing of information for other scientific research. By agreeing to be in this research and signing below, you are giving your consent to share research information with others at NIMR and NYU Langone Health.

14. HIPAA Authorization

As noted in the Confidentiality section above, federal law requires us, and our affiliated researchers, health care providers, and physician network to protect the privacy of information that identifies you and relates to your past, present, and future physical and mental health conditions. We are asking for your permission (authorization) to use and share your health information with others in connection with this study- in other words, for purposes of this research, including conducting and overseeing the study.

Your treatment outside of this study, payment for your health care, and your health care benefits will not be affected even if you do not authorize the use and disclosure of your information for this study.

What information may be used or shared with others in connection with this study?
All information in your research record for this study may be used and shared with those individuals listed in this section. Additionally, information in your medical record that the research team believes may be important to the study may be accessed by those listed here. This includes, for example, results from your physical examinations, laboratory tests, procedures, questionnaires, and diaries.

Who may use and share information in connection with this study?
The following individuals may use, share, or receive your information for this research study:

- The research team, including the Principal Investigator, study coordinators, and personnel responsible for the support or oversight of the study
- The study sponsor: National Institute of Health
- Governmental agencies responsible for research oversight (e.g., the Food and Drug Administration or FDA).
- Health care providers, including your doctors and others who provide services to you in connection with this study, and laboratories or other individuals who analyze your health information in connection with this study.
- Other study sites involved in the research

Your information may be re-disclosed or used for other purposes if the person who receives your information is not required by law to protect the privacy of the information.

What if I do not want to give permission to use and share my information for this study?
Signing this form is voluntary. You do not have to give us permission to use and share your information, but if you do not, you will not be able to participate in this study.

Can I change my mind and withdraw permission to use or share my information?
Yes, you may withdraw or take back your permission to use and share your health information at any time for this research study. If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. To withdraw your permission, send a written notice to the principal investigator for the study noted at the top of page 1 of this form. If you withdraw your permission, you will not be able to stay in this study.

How long may my information be used or shared?
Your permission to use or share your personal health information for this study will never expire unless you withdraw it.

15. The Institutional Review Board (IRB) and how it protects you

The IRB reviews all human research studies – including this study. The IRB follows Federal Government rules and guidelines designed to protect the rights and welfare of the people taking part in the research studies. The IRB also reviews research to make sure the risks for all studies are as small as possible. The NYU IRB Office number is (212) 263-4110. The Nigerian Institute of Medical Research (NIMR) IRB

office number is +234-0909-016-6992 / +234-0909-213-3886. The NIMR and NYU School of Medicine's IRB is made up of:

- Doctors, nurses, non-scientists, and people from the Community

16. Who can I call with questions, or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with Dr. Oliver Ezechi listed on top of the page 1 of this consent form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Institutional Review Board (IRB) at +234-0909-016-6992 / +234-0909-213-3886..

When you sign this form, you are agreeing to take part in this research study as described to you. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer.

Name of Subject (Print)	Signature of Subject	Date

Name of Person Obtaining Consent (Print)	Signature of Person Obtaining Consent	Date