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Research Subject Informed Consent Form

Title of Study: **Community Mobilization for Improved Clean Cookstove Uptake, Household Air Pollution Reduction, and Hypertension Prevention**

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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”. 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. 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 research study is to understand if a program of clean fuel-clean-stove use will work in your community, how it impacts Blood Pressure (BP), and if it will be continued in your community in Lagos State once the study is over. You are being asked to participate because you use Kerosene, charcoal, or firewood as your primary cooking fuel.

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. Your participation may take about 12 months. We expect a total of 640 households in this 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 participant in this study, we will ask you to sign this consent form before the following procedures will take place:

You will be asked to allow 3 visits from CHEWS (Community Health Extension Worker). The visits with CHEWs will consist of:

- measuring clean fuel clean stoves,
- the level of household air pollution,
- and blood pressure of two adults in each household including the primary cook.
- If you have elevated blood pressure, you will be referred to clinical care as part of this study.

5. What are the possible risks or discomforts?

Risk of Study

Though we expect the level of risk to be minimal, potential risks to the participant may include the following:

Elevated Blood Pressure: Subjects with elevated BP will be referred to any of the Lagos State community health centers in the participating communities. This referral system will be addressed by the Lagos State MoH. Study participants will be made aware of this at the consent visit. Similarly, any medical problem that arises during study visits will be referred via the same channels. If at any study visit, BP is elevated >180 SBP or >110 DBP, the participant will be directed to seek medical attention immediately at an affiliated community health center. All such participants will be required to bring to the next study visit a signed document attesting that they sought care. The research assistants and Dr. Ojengbede will follow-up with the participant's clinician to ensure proper medical follow-up.

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 University of Ibadan, NYU, University of Chicago, Saint Louis University.

Anxiety: Some personal and sensitive information may be requested from you during the course (in baseline visits, household visits with nurses, etc.) 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?

You may benefit personally from being in this study by improving your blood pressure control, reducing the cardiovascular risk profile, and increasing household's role as active participants in the management of their hypertension and exposure to household air pollution.

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

As a research subject in this study, 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.

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.

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. Oladosu Ojengbede. His information is 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 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.

12. How will you protect my confidentiality?

The records of this research will be kept private. In any sort of report, we might publish, we will not include any information that will make it possible to identify a participant. Research records, including audio recordings, will be kept in a locked file, and access will be limited to the researchers, the review board responsible for protecting human participants, and regulatory agencies. Personal information including your name will be removed and replaced by numerical codes in all transcripts. In addition, the researcher will create passwords for any electronic data generated; only members of research teams will know these passwords.

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. In compliance with NYU Langone Health policies and procedures and with HIPAA, only those individuals with a job purpose can access this information.

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.

13. 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 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.

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
- Other partners involved in the research (University of Ibadan, NYU, University of Chicago, Saint Louis University)

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 information at any time for this research study. 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 information for this study will never expire unless you withdraw it.

14. 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.

15. 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. Oladosu Ojengbede, his information is listed at the top of page 1 of this consent form.

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