

## **Cover Page**

Results Submission on March 15, 2025

**Study Title:** Supporting Young Women's Reproductive Health by Harnessing Prosociality Among Drug Shopkeepers

**NIH Grant Number:** R03HD109561

**Clinical Trials Number:** NCT05525533

**Documents included:** Informed Consent Forms (2)

**Document Date:** 03/19/2024

# **CONSENT TO PARTICIPATE IN RESEARCH**

## **AmbassADDOs for Health**

### **Customer Feedback Sub-Study**

#### **Introduction**

My name is \_\_\_\_\_ and I am working for Dr. Amon Sabasaba of Health for a Prosperous Nation and Dr. Werner Moakola, a Research Coordinator for the AIDS Control Program at the Tanzania Ministry of Health, Community Development, Gender, Elderly, and Children. I am also working with Professor Jenny Liu at the University of California to conduct a research study, which I invite you to participate in. We are asking you to take part in the sub-study because you own an accredited drug-dispensing outlet (ADDO) or pharmacy located in one of the study areas in Shinyanga or Mwanza Region and are already participating in the parent study.

#### **Purpose**

The purpose of this sub-study is to provide you with information about young women's level of satisfaction when shopping at your store.

#### **Who pays for this study?**

This study is being funded by the National Institutes of Health of the United States of America.

#### **Procedures**

If you agree to participate in this research study, you will be asked to refer adolescent and young women who come to your shop to participate in a short, anonymous USSD feedback survey. We will provide you with a code to give to eligible young women that they can use on their mobile phones to complete the survey. If you are in the intervention arm of the parent study, this code may also be automatically made available on some of the study's products. The survey responses will be anonymously sent to the study team, who will then provide you with a written, paper report every two weeks.

#### **Study Groups:**

There are three study groups. If you decide to take part in the study, you will be placed in one of the three groups. Each group will receive different types of reports for showing you the survey responses from young women, which may include information from previous reports or from other participating shops in your region. You may be asked to publicly display performance scores if placed in the Public Feedback arm. You may also be invited to participate in activities that recognize shops with high customer satisfaction. The type of report and recognition activities may change over time.

Your initial group will be chosen by chance, for example, like flipping a coin to be in one of these groups. You will not be able to choose your group, and the study staff will not choose your group for you. You will have an equal chance of being placed in one of the three groups.

#### **Study time**

Participation in this study will involve receiving a report of customers' satisfaction from young women shoppers every two weeks. Please maintain the business records for your shop through the Maisha Meds system over the two-year study period; this will require you or your employees at most 10 minutes per business day. If you are selected to take part in the one-time in-depth interview as part of the parent study, we may ask questions about this sub-study and this will take no more than one hour to complete. Other activities will not require any

additional time from you.

### **Study location**

All study activities will take place at your drug shop or pharmacy. If you are selected for an in-depth interview as part of the parent study, we will arrange a time and place of your choosing, including at our private office.

### **Benefits**

If you agree to participate in this study, we will provide you with information on the shopping experiences of young women customers, which may inform how you provide services to your customers.

### **Risks/Discomforts**

There are some risks and/or discomforts associated with the study:

- Some of the forms in this study contain personal identifying information, and there is a small chance that this could result in a breach of confidentiality. However, we are doing everything we can to make sure that this does not happen.
- Some shops may be asked to publicly display performance scores (E.g. Visible “Gold Stars”) if by chance they end up in that group. There is the potential risk of loss of business if a shop receives poor scores and are asked to display these.

### **Confidentiality**

Your study data will be handled as confidentially as possible. To minimize the risks of loss of confidentiality, we will do the following:

- Any study information in the study database will not include your name and contact information. All of your information will instead be identified with a random code.
- Your research records will always be securely stored. Paper forms will be stored in a locked cabinet in our nearby locked office. Computer files or databases that contain your data will be stored in an encrypted format on password-protected computers and will require a password so that only authorized study personnel have access.
- Organizations that may look at and/or copy your research records for study purposes include NIMR and representatives from the University of California.
- Publications or presentations with results of this study will not use individual names or other personally identifiable information.

### **Future use of study data**

The research data will be maintained for possible use in future research by the research team or others. We will retain this data for up to 10 years after the study is over. The same measures described above will be taken to protect confidentiality of this study data.

## **Compensation/Payment**

You will not be compensated for your participation in this sub-study beyond the compensation already given in the parent study. If you are selected to participate in the in-depth interview as part of the parent study, you will be paid a total of 10,000 Tanzanian Shillings (~\$4) as outlined in the parent study consent form to thank you for your time.

## **Permission to Contact You for Future Studies**

The Ministry of Health, Community Development, Gender, Elderly, and Children, Health for a Prosperous Nation, and the University of California are passionate about research on how to improve access to sexual and reproductive health services and enhancing HIV testing and prevention for adolescent girls and young women. As such, we may be interested in contacting you about additional research studies with these organizations. Please tick (✓) the box to indicate your preference for being contacted again. If you agree to be contacted for future studies, we will save your contact information in a confidential file that only our study staff will have. You can also participate in this study and choose not to be contacted for future studies. Participation in future studies is completely voluntary and does not affect the services or benefits you may receive in the current study.

I agree to be contacted for future studies.  
 I do not agree to be contacted for future studies.

## **Costs**

You will not be charged for any of the study activities.

## **Treatment and Compensation for Injury**

It is important that you promptly tell Dr. Amon Sabasaba if you believe that you have been injured because of taking part in this study. You can tell him in person or call him at +255 71 5951085.

## **Rights**

### **Participation in research is completely voluntary.**

You have the right to decline to participate or to withdraw from the study at any time without penalty or loss of benefits to which you are otherwise entitled. You may refuse to answer any question or leave at any time for any reason including feeling distressed or uncomfortable.

## **Questions**

If you have any questions or concerns about this study, you can ask me or you can contact our office or Dr. Amon Sabasaba at +255 71 5951085 or [amons4u@gmail.com](mailto:amons4u@gmail.com) at any time. If you would like to direct your question to the international study team directly, you can contact Dr. Jenny Liu in the United States at +1 650 380 0762 or [Jenny.Liu2@ucsf.edu](mailto:Jenny.Liu2@ucsf.edu).

If you have any questions or concerns about your rights and treatment as a research subject, you may contact the National Institute for Medical Research at +255 22 2121400.

## Consent

You have been given a copy of this consent form to keep. If you wish to participate in this study, please sign and date below.

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Participant's Name (*please print*)

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Date

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Participant's Signature

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Date

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Participant's Thumbprint (if unable to sign)

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Date

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Person Obtaining Consent

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Date