Official Title: Designing an Ethnodrama Addressing PrEP Stigma Toward Young Cisgender Women in Kenya

NCT: NCT06501885

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Electronic Verbal Consent to Participate in a Research Study—Pre-Test

Title of Study: Development, Pre-Testing, and Pilot Testing of an Ethnodrama Intervention to Reduce Community-Based, PrEP-Related Stigma Toward Young Women in Siaya County, Kenya

Maseno University Scientific and Ethics Review Committee IRB Study # MUSERC/01366/24
Duke University Health System IRB Study # Pro00115054
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Impact RDO Investigator (Co-I): Jacob Onyango, **Phone number:** 0720 318 908
Study Contact telephone number: 0796143568

INTRODUCTION
This research study is being done by Impact Research and Development Organization in collaboration with Duke University in the US. It is funded by National Institutes of Health, USA. Before you decide if you want to participate in this study, we want you to know more about it. This is a consent form that gives information about this study. The study staff is available to talk more about the study.

WHAT IS THE PURPOSE OF THIS STUDY?
We are conducting a pre-test study. It is to collect views from different community members about short plays to reduce community-based, pre-exposure prophylaxis (PrEP)-related stigma toward young women in Siaya County. Researchers are interested in learning about people's thoughts on the play's storylines and on the audience interaction component of the plays.

WHO SHOULD BE IN THIS STUDY?
Men and women who live or work in Siaya County.

WHAT IS INVOLVED IN THE STUDY?
If you agree to take part, you will watch the short plays in person in a group with other men and women from Siaya County. After the plays, you will be asked to complete a survey with an interviewer. The survey will ask you questions about who you are, such as your age and gender. The survey will also ask you questions on how interesting you found the plays and how connected you felt toward the characters in the plays.

You will also be asked to take part in a small group discussion. During the discussion, you will be asked if you feel the storylines are realistic and whether the characters in the plays are like people in your community. You will be asked what you thought about the audience interaction components of the plays. You will also be asked how we can make the plays better. We will audio-record these discussions. You may be also asked to participate in another pre-test at another time.

WHAT ARE THE POSSIBLE BENEFITS FROM PARTICIPATING?
There are no personal benefits from taking part in the pre-test. However, we will use the information you tell us to improve the plays, which may reduce stigma experienced by young women in the future.

WHAT ARE THE RISKS OF PARTICIPATING?
As with all studies, there is a very small chance that other people could see the information you tell us. We will take many steps to prevent this from happening (see next section).

WILL MY INFORMATION BE KEPT CONFIDENTIAL?
We will protect information about you to the best of our ability. The information you share during the survey will be seen by researchers and staff who are part of this project. The information will not be linked to your name. All staff have signed a confidentiality agreement to keep the information you share confidential and not tell it to others

outside of the study. We will give you a number which will be used in place of your name on the data documents. All other information will be kept securely at Impact-RDO and Duke University for at least six years.

If you take part in the group discussion, we will ask members of the group to not tell others about the information shared during the discussion. But, there is a chance they may share what was said with others. Please keep this in mind when deciding what to share during the discussion.

WILL I RECEIVE ANY PAYMENT?
There are no costs to you to take part in this survey. You will receive 500 Ksh for your time spent participating in the study. Your transportation costs will also be covered.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?
Taking part in this study is completely voluntary. You do not have to take part in this or any research study. If you decide to take part, you may choose not to answer any question you are not comfortable answering. You may stop taking part at any time. Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researchers, your place of work or any services you have been receiving previously.

WHO DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
If you have any questions about the study, please contact study coordinator, through this phone number: 0796143568. You can also contact any of the study leaders listed on page 1. For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact Maseno University Scientific and Ethics Review Committee, P. O. Box, Private Bag, Kisumu; Telephone numbers+254 057 351622 EXT. 3050; Email address muerc-secretariate@maseno.
ac.ke or the Duke University Health System Institutional Review Board (IRB) Office at +1-919-668-5111 or https://irb.duhs.duke.edu/contact-us.

NOTE: A description of this clinical trial will be available on www.ClinicalTrials.gov. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

STATEMENT OF CONSENT
"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have had this consent form read to me and agree to be in this study, with the understanding that I may withdraw at any time. I was offered a copy of this consent form. If I do not want to take a copy today, I will be provided with a sheet containing important numbers to contact in case of questions or concerns, if I want it."

☐ I agree to participate

_____ _____
(Optional) Signature of Witness Date

_____
(Optional) Printed Name of Witness

_____ _____
Signature of Person Obtaining Consent (Staff) Date

_____
Printed Name of Person Obtaining Consent (Staff)