MRCZ number: MRCZ/A/2038

The Centre for Sexual Health and HIV AIDS Research Zimbabwe (CeSHHAR Zimbabwe)
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TITLE OF THE STUDY: **A CLUSTER RANDOMISED TRIAL OF INTERVENTIONS TO IMPROVE LINKAGE TO CARE FOLLOWING COMMUNITY-BASED DISTRIBUTION OF HIV SELF-TEST KITS IN RURAL ZIMBABWEAN COMMUNITIES**

INFORMATION SHEET AND INFORMED CONSENT FORM-QUALITATIVE STUDY

PRINCIPAL INVESTIGATOR: Professor. Frances Cowan
PHONE NUMBER: +263-4-304583, 308042, 333393, 332074

WHAT YOU SHOULD KNOW ABOUT THIS RESEARCH STUDY:

- We give you this informed consent form so that you may read about the purpose, risks, and benefits of this research study.
- The main goal of research studies is to gain knowledge to inform how services may be provided. We cannot promise that this research will benefit you. This research can have risks that are minor.
- You have the right to refuse to take part, or agree to take part now and change your mind later.
- Whatever you decide, it will not affect your job.
- Please review this consent form carefully. Ask any questions before you make a decision.
- Your participation is voluntary.

This is an information sheet and an informed consent form. It will give you information about the study and will be used to document your willingness to take part should you choose to do so. You will be given a copy of this document to keep.

PURPOSE OF THE STUDY

You are being asked to take part in a study that seeks to understand barriers and facilitators to uptake of HIV-self-testing and the experiences of health care workers who have been providing HIV services after the introduction of self-testing. The study is being led by led by Professor Elizabeth Corbett of

London School of Hygiene and Tropical Medicine. Within Zimbabwe, the Principal Investigator is Professor Frances Cowan who works with the Centre for Sexual Health and HIV/AIDS Research (CeSHHAR) Zimbabwe in partnership with Ministry of Health and Child Care (MOHCC) and Population Services International Zimbabwe (PSI/Z).

IMPORTANCE OF THE STUDY

CeSHHAR Zimbabwe is conducting research on the acceptability and feasibility of HIV self-testing in Zimbabwe. As part of this research community health workers have been distributing HIV self-test kits in districts that you serve as part of your work in HIV services. Some of the aims of the study are to 1) make recommendations on the best methods for providing HIV self-test services in Zimbabwe, and 2) make recommendations on the best methods for ensuring that people who opt to self-test are well supported to access HIV treatment and care or prevention services after self-testing. In order to make these recommendations it is important that we have discussions with health care workers who have been providing HIV services in the context of HIV self-testing. Your experience in providing services to people who have tested themselves for HIV and your views on barriers and facilitators to HIV self-testing will provide useful insight into the best methods for providing HIV self-testing services. All this is important in order to increase the number of people who know their HIV status and who receive appropriate HIV prevention, treatment and care services.

STUDY PROCEDURES AND DURATION

We are inviting health care workers who work in communities where self-testing was introduced to participate in this research. Health workers who meet the following criteria will be asked to participate in this small study:

1) Working for either PSI Zimbabwe or Ministry of Health and Child Care in districts where HIV self-testing has been introduced
2) Willing and able to provide written informed consent

You have been invited to participate in this study because you meet the conditions mentioned above. If you are willing to participate, you will be asked to take part in a one-on-one in-depth interview with a member of the study team. During the interview you will be asked questions about your views on HIV self-testing; your experience of providing HIV services after the introduction of self-testing; barriers and facilitators to self-testing and your recommendations for a good self-testing program. The discussion will be conducted in private in a closed room at a convenient location. The discussion will take between 45 minutes to one hour. During the discussion, we will write down the information that you give us. However, it is very important that we record what you say accurately so that your views are not misrepresented. As it is often difficult to keep pace with writing down what is said in a discussion, we will also record the conversation using a tape recorder. The recording will not be labeled with your name but only with a study identity number that will be assigned to you. Your participation in the study will end on the same day that you do the interview.

RISKS AND DISCOMFORTS

The risks of participating in this study are minimal. It is possible that you may feel uncomfortable with some of the questions we will ask you. You can choose to skip questions or to stop participating in the interview if you feel uncomfortable.

BENEFITS AND/OR COMPENSATION

There are no direct benefits to you for participating in this study. We are hoping that findings from this study will be used to design the best methods for the provision of HIV self-testing services and for improving linkage to post-test services in Zimbabwe. However, since participating in this study will take you away from your home and work, we will offer you $5 as a token of our appreciation for your having taken the time to take part in this study.

COSTS TO YOU

There will be no additional costs to you except those related to the time taken while having a discussion with study staff.

CONFIDENTIALITY

Your personal details will not appear on the recording of the discussion or on any study-related documents. You will be assigned a study participant identity number which will be used to identify the tape that has your voice. All study records and audio recordings will be kept in a secure room in locked filing cabinets, and separate from any information that identifies you personally (such as this consent form), with access limited to study personnel. Interview audio recordings will be downloaded onto password protected computers at CeSHHAR offices and the original file will be deleted from the audio recorder. Your name will not be used in any reports or publications that may arise from this study.

Your details may be released to authorized individuals if required by the law. Information may also be given to regulatory authorities should they wish to see it for their regulatory duties. The bodies regulating this study are the Medical Research Council of Zimbabwe, London School of Hygiene and Tropical Medicine, and the University College London Ethics Committee.

VOLUNTARY PARTICIPATION

We hope that you will agree to take part in this study. However, you do not have to take part in this study if you do not want to. If you decide that you do not want to participate in this study, that decision will not affect your job or daily life in any way. If you decide that you want to take part now but then change your mind later, you may withdraw from the study at any time without having to give a reason.

OFFER TO ANSWER QUESTIONS

Before you sign this form, please ask any questions on any aspect of this study that may be unclear to you. You may take as much time as necessary to think it over. For any other questions that you may have about this study now or in the future, please contact the Study Coordinator,
Dr. Euphemia Sibanda on the following numbers: Cell: 0782743948, Landline: +263-4-304583, 308042, 333393, 332074.

AUTHORIZATION

YOU ARE MAKING A DECISION WHETHER OR NOT TO PARTICIPATE IN THIS STUDY. YOUR SIGNATURE SHOWS THAT YOU HAVE READ AND UNDERSTOOD THE INFORMATION PROVIDED ABOVE, HAVE HAD ALL YOUR QUESTIONS ANSWERED, AND HAVE DECIDED TO PARTICIPATE.

STATEMENT OF CONSENT TO BE AUDIO-TAPED

I understand that audio recordings will be taken during the study. (Mark either "Yes" or "No")

I agree to being audio-recorded Yes ☐

If yes, initial and date here: _____

No ☐

_____ _____

Name of Research Participant (please print) Date

_____ _____

Signature of Participant Time

_____ _____

Name of Witness Signature of Witness

(If participant is illiterate)

_____ _____

Name of study staff Signature of study staff obtaining consent

YOU WILL BE GIVEN A COPY OF THIS CONSENT FORM TO KEEP

If you have any questions concerning this study or consent form beyond those answered by the investigator, including questions about the research, your rights as a research subject or research-related injuries; or if you feel that you have been treated unfairly and would like to talk to someone other than a member of the research team, please feel free to contact the Medical Research Council of Zimbabwe and/or the Research Council of Zimbabwe using the contact information below.

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