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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 – HOUSEHOLD SURVEY AND DISCRETE CHOICE EXPERIMENT

PRINCIPAL INVESTIGATOR: Professor Frances Cowan
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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 usual access to health services.
- 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 research study that seeks to find out about issues related to testing oneself for HIV without the assistance of a health care worker. As part of the research, a few weeks ago community health workers gave out HIV self-test kits that people can use to test

themselves without the help of a health care worker. In this research we want to find out if using community health workers to give out self-test kits to people at home works well in terms of 1) making sure that all households get access to the self-test kits, 2) whether people who get the kits go on to test themselves for HIV, 3) whether people who test then go on to use prevention or treatment services according to the results of the test. In addition, we want to [BLANK PAGE ON REVERSE] find out how people would prefer to have self-test kits distributed within communities. This study is 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 PSI Zimbabwe and Ministry of Health and Child Care.

IMPORTANCE OF THE STUDY

HIV testing is an important step in ensuring access to HIV treatment and prevention services. Ministry of Health and Child Care want to find ways of increasing the number of people who test for HIV and know their status. HIV self-testing may make it easier for people to test. We already know from research that was conducted in Zimbabwe that people are able to accurately test themselves for HIV, and most find it acceptable. However before self-testing is extended to everyone who wants it, we need to know what the best methods are for distributing the self-test kits and supporting people to use them and seek onward services according to results of the test. This study will provide this required information and therefore enable us to design a good self-testing program.

STUDY PROCEDURES AND DURATION

We will ask eligible individuals to answer a questionnaire by indicating their answers on a screen of a tablet. The tablet will read out the questions to you. The following sorts of people are able to take part:

1) Age 16 years or older
2) Have lived in the study area for the past three months
3) Willing and able to give written informed consent to take part

You have been asked to take part in the study because you meet the conditions mentioned above. If you are willing to participate, you will be asked to complete a questionnaire where you will be asked various questions about yourself, including whether you have HIV tested before, access to self-test kits, testing yourself for HIV and your use of health services. About 7,500 people will be asked to complete this questionnaire. In addition, the first 500 people who are enrolled will also be asked to complete a short, second questionnaire where they will be asked about methods of ensuring that people get the necessary help after they have tested themselves for HIV. You will self-complete the second questionnaire/s on paper. This should take about one to one and a half hours. Lastly, we will ask you to give a few drops of your blood that will be collected as small spots on a white paper that will be air-dried. To collect the few drops of blood, we will prick your finger with a clean needle. We will then take the papers to a laboratory in Harare where we will run an HIV test on the blood. If a person tests positive, we will run additional tests to determine how recent the infection is and how much HIV virus there is in the blood. We will also test whether the person is taking medicines for treating HIV. The white paper on which we collect the blood will not have your name; it will only be identified by a study number. The white paper that has your samples will be destroyed after all the tests have been run. All samples will be destroyed by September 2018.

~~If you do not know your current HIV status, we encourage you to get tested for HIV. Alternatively, I~~ If you are willing, we can send your HIV results and, if you are HIV positive, the results showing the quantity of HIV virus that is in your blood to your local clinic. If you would like to collect your results from the clinic, you would have to give us additional identification information, such as your national identity number, that will enable you to collect your results. The results will be sent to the clinic in a sealed envelope. To give enough time for testing, allow two months from the date you have given your sample before going to the clinic. The clinic will only keep your results for three months. Your participation in the study will end on the same day that you complete the questionnaire/s and give your blood sample.

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 completing the questionnaire if you feel uncomfortable. A trained counselor will be available to help you with any uncomfortable feelings you may have. You will complete the questionnaire in private in a closed room or tent.

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 programs for distributing self-test kits and encouraging linkage to onward services after self-testing. However, since participating in this study will take you away from your work, we will offer you US$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 participating in this study.

IN THE EVENT OF INJURY

In the event of injury resulting from your participation in this study, treatment shall be offered by the study. Should you be injured as a result of your participation in the study, please contact Study Coordinator, Euphemia Sibanda on the following numbers: Cell 0782743948; Landline: +263-4-304583, 308042, 333393, 332074.

CONFIDENTIALITY

Your personal details will not appear on the questionnaire or on any study-related documents. You will be assigned a study participant identity number which will be used to identify the questionnaire. All study records 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. The questionnaires will be saved in password protected computers at CeSHHAR offices. 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, 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, daily life or regular health care 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.

Do you agree to participate in the questionnaire survey? Yes_____ No _____

Do you agree to provide a blood sample? Yes_____ No _____ NA_____

Do you want to receive the results of your HIV test? Yes_____ No _____ NA_____

_____ _____

Name of Research Participant (please print) Date

_____ _____

Signature of Participant Time

_____ _____

Name of Witness Signature of Witness

(*Required only 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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