PS 09A: PARTICIPANT INFORMATION SHEET FOR ACASI and LDS

Malawi-Liverpool-Wellcome Clinical Research Programme P O Box 30096, Chichiri, Blantyre 3, Malawi Tel: +265 1876444 • Fax: +265 1875774 • www.mlw.medcol.mw



Monitoring social harms following introduction of peer-led self-testing among female sex workers and men who have sex with men

Audio Computer-Assisted Self-Interviews and Longitudinal Diary Studies

1. Why are we doing this study?

This study is designed to make it easier for people in Malawi to test themselves for HIV ("self-testing") in a safe and accurate way. The primary aim of this study is to monitor any adverse outcomes that may occur during the period of HIV testing.

2. Why are we asking you to take part in this study?

We have been providing HIV self-testing in urban Blantyre and it is likely that you have participated as someone who has decided to self-test. You may also have participated in other aspects of the study. We want to know about the experience of self-testing for people who use it and why they choose to self-test. We are also interested in understanding how self-testing affects people's lives afterwards, especially in the community and at home. This can help us to provide sufficient support for people who decide to self-test.

3. What will happen if you decide to take part in this study?

If you decide to take part in the study, we will ask about where you live, your contact information, and your age and occupation. We will then will ask you to complete a short questionnaire when we enrol you and again after 3 months. The questionnaire will be on a computer that you will complete yourself. The computer will ask you questions on testing practices, sexual behaviours, and cases of social harms before and immediately after HIV self-testing.

We will then provide you with a diary that we will ask you to complete regularly for 3 months. We will visit you frequently during this time to give you as much support as you need to complete the diary.

You may also be asked to take part in another interview.

4. Who are we asking to participate?

We are asking people who have recently self-tested. You have been selected because you are between the ages of 16 and 49 and identified as female sex worker or men who have sex with men.

5. Where do we come from?

We work at the Malawi-Liverpool-Wellcome Trust Clinical Research Programme (MLW) and Population Services International (PSI). MLW and PSI conduct research and implement projects on diseases of local importance to Malawi and the region.

6. What are the risks and benefits of the study?

There are no direct benefits to participating in this study. Some people enjoy completing diaries because it allows them to monitor their lives. We will provide you with regular support during the 3-month diary period. The information that you provide anonymously will help us to make important decisions about how

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to provide greater access to HIV testing through self-testing and meet the needs of female sex workers or men who have sex with men.

We assure you that anything that will be discussed during the interview will remain confidential. Interviews will be conducted in a place of your choice and where you will be comfortable and feel safe to open up. We will take full responsibility of any issues that negatively affect you due to this research and you will be linked to care or support as soon as it happens.

It is possible you may find that some of the questions bring up challenging issues.

7. Do I have to participate in this study?

Your participation is voluntary. You may withdraw from the study at any time and without giving a reason. You can also decide to answer some questions, and not to answer other questions.

8. Confidentiality

All information obtained from the study will be stored securely on a voice-recorder and on paper and computer files and only researchers in this study will have access to them. Data entry will only be performed by the study team and confidentiality will be maintained at all data handling and storage processes.

9. Costs

Taking part in the study will not cost you anything. We will give you MWK 1000 for your time and to cover bus fares.

10. The Ethics Committees that have approved the study are:

Committee for Medical Research Ethical Considerations [COMREC] and London School of Hygiene and Tropical Medicine.

11. What if I have any questions?

If you have any questions about the disease or about this study please feel free to ask them. If you think of any questions after we have gone please feel free to contact us by calling the following number and asking for Wezzie Lora or Dr Nicola Desmond.

Tel: 01874628 / 01876444

Please contact the COMREC Secretariat should you wish further information about your rights, safety, and wellbeing in research:

COMREC Secretariat College of Medicine Research and Ethics Committee P/Bag 360, Chichiri, Blantyre 3, Malawi Telephone: 01877245/01877291