PARTICIPANT'S INFORMATION & INFORMED

CONSENT DOCUMENT

STUDY TITLE: Evaluation of performance, acceptability and usability of a novel Lateral Flow Assay (LFA) for point-of-care detection of *Neisseria gonorrhoeae* (NG) infection among pregnant and symptomatic women in South Africa.

Principal Investigators: Mandisa Mdingi

Institution: Foundation for Professional Development

DATE AND TIME OF FIRST INFORMED CONSENT DISCUSSION:

Date	**Month**	**Year**

:
Time

Dear Prospective Participant,

Dear Mr/Ms .....

INTRODUCTION

We are conducting a research study of a novel rapid test for point-of-care detection of *Neisseria gonorrhoeae* at five facilities in the Buffalo City Metropolitan Health District. This test provides an easy-to-use, cheap opportunity for diagnosis of gonorrhoea in individuals with and without STI-associated symptoms. In addition to the evaluation of test performance, we would also like to find out from district managers and healthcare providers about initial impressions, device characteristics, ease-of-use, experience, acceptability, and potential implementation strategies for this test. This will help inform future test implementation and roll-out.

NATURE AND PURPOSE OF THIS STUDY

This study is designed to gather your perspectives of the rapid Point of Care testing for *Neisseria gonorrhoeae* and how best to integrate this testing into your clinical operations. The information gathered will help us understand how we can better utilise such testing technologies in clinics and improve health outcomes for patients. For that purpose, we would like to invite you to a focus group

discussion with other district managers or healthcare providers to learn and ask the group about their expectations, experience and thoughts about the test, its use and implementation.

EXPLANATION OF PROCEDURES AND WHAT WILL BE EXPECTED FROM PARTICIPANTS

If you agree to participate, we will ask you to sign the informed consent form to document that you agree to participate. We would then like to include you in a focus group discussion today. These interviews will be conducted by an experienced interviewer, will begin after the health care providers have finished their duties and will take approximately 30-60 minutes to complete. You may also be asked to complete short surveys focused on new technology usability, readiness and implementation. These will not take longer than 10 minutes to complete. All interviews will be conducted in a private location, and with your permission will be audio-recorded for analysis. A trained note-taker will support the interview for accurate documentation of the discussion.

POSSIBLE RISKS AND DISCOMFORTS INVOLVED

There are no risks associated with participation in this study. You are free to refuse to answer any questions that may cause you psychological discomfort; counselling services are available if required. We will not disclose your participation except to those who are part of this focus group discussion. Your answers will remain confidential and will not be shared with your employer, colleagues or anyone else outside of the research team or focus group.

POSSIBLE BENEFITS OF THIS STUDY

This study aims to improve detection of *Neisseria gonorrhoeae* and management of sexually transmitted infections across the world. This test is the first in the world that allows for point-of-care detection of *Neisseria gonorrhoea* and is unique in its kind. Although there are no direct benefits for you, participation in this study will greatly enhance understanding of the novel test and contributes to addressing the burden of sexually transmitted infections worldwide.

COMPENSATION

To reimburse you for the time spent on the interview, we will offer you a paper R100 voucher for the local food store (e.g. Shoprite, Spar, Checkers). You can hand in this voucher at the store of your choice to buy groceries.

YOUR RIGHTS AS A RESEARCH PARTICIPANT

Your participation in this study is entirely voluntary and you can refuse to participate or stop at any time without providing a reason.

ETHICS APPROVAL

This Protocol was approved by the Faculty of Health Sciences Research Ethics Committee of the University of Pretoria. The study is conducted in accordance with the Declaration of Helsinki, for biomedical research involving human/subjects. A copy of the Declaration may be obtained from the investigator should you wish to review it.

CONFIDENTIALITY

All information obtained during this study is confidential. Each participant will be provided with a numeric participant identification number to ensure confidentiality of the information that is collected. We will keep your name confidential, but we will ask you to provide a cell phone number so that we can send you reminders about interview days and times. The principal investigator and his research team are the only people that have access to this information. Results will be published or presented in such a fashion that patients remain unidentifiable.

FURTHER INFORMATION

If I have any questions, concerns, or complaints about this study you may contact the principal investigator or the Human Research Ethics Committee:

Mandisa Mdingi	Professor TM Rossouw
	Chairperson
	Faculty of Health Sciences Research Ethics Committee
Principal Investigator	University of Pretoria
Foundation for Professional	
Development	
Tel: 087 150 9279	012 356 3084 / 012 356 3085

CONSENT TO PARTICIPATE IN THIS STUDY

- I confirm that the person requesting my consent to take part in this study has told me about the nature and process, any risks or discomforts, and the benefits of the study.
- I have received, read and understood the above-written information about the study.
- I am aware that the interview will be audio-recorded.
- I have had adequate time for questions and no objections to participate in this study.
- I am aware that the information obtained in the study, including personal details, will be anonymously processed, and presented in the reporting of results.
- I understand that I will not be penalised in any way should I wish to discontinue with the study participation and that withdrawal will not affect my employment. I am participating willingly.
- I have received a signed copy of this informed consent document.

Participant's name (Please print)	Date
Participant's signature	Date
Researcher's name (Please print)	Date
Researcher's signature	Date

Signature of the Witness	Date