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 Ms .....

INTRODUCTION

We are conducting a study that evaluates a novel test for the detection of gonorrhoea, one of the sexually transmitted infections. This document provides information about this research study and will inform you to decide if you would like to participate.

Before you agree to take part in this study, you should fully understand what the study entails. If you have any questions, please feel free to ask us. You should not agree to take part unless you are completely happy about all the information provided and the procedures involved.

THE NATURE AND PURPOSE OF THIS STUDY

Sexually transmitted infections (STIs) may present as genital discharge but can also occur without symptoms. The only way to detect asymptomatic infections is to perform a diagnostic test. However, these tests are generally not available in healthcare facilities in South Africa as they are expensive and take considerable time to process before results are available. Recently, a novel test has been developed that may be used within the facilities at point-of-care. This test can provide a diagnosis of gonorrhoea, an important STI.

The aim of this study is to perform an evaluation of a lateral flow assay, a novel test for detection of gonorrhoea. This test will be compared to another STI test called GeneXpert; this test is generally not available in the public sector in South Africa but is widely used for STI testing throughout the world. In this project, we would like to test you for gonorrhoea both with the GeneXpert test and the novel lateral flow assay. We will also ask you to collect a sample yourself, and we will compare this to a sample collected by a healthcare worker to see if it could be a better way of collecting a sample in the future. We also want to know how you felt about collecting your own sample. After you have finished collecting your sample, we will ask you to complete a short survey about your experience.

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 then have a short questionnaire that we would like to complete with you. This includes questions about your relationship status, clinical history, and symptoms. It will not take more than 10 minutes to complete this questionnaire. We recognise that some of these questions may be sensitive and difficult to answer. You must feel free to refuse to answer any of these questions at any given time if you do not feel comfortable answering. We prefer that you refuse to answer than to make up an answer.

If you do not know your HIV status, you will be offered a free HIV test as part of standard practice; also, free rapid syphilis testing will be provided as part of the comprehensive STI screen. Then a research nurse will collect three vaginal swabs and one vaginal swab that you will collect yourself. The specimen) is tested with the GeneXpert machine, the novel lateral flow assay, and kept for further analysis of discordant results including, detection of other STIs and similar bacteria (other *Neisseria* species) that may influence the test results. If you are uncomfortable collecting a swab yourself, the nurse will collect the three swabs only.

The GeneXpert test will take up to 90 minutes to complete and will provide you with a test result for *Neisseria gonorrhoeae* and *Chlamydia trachomatis,* two important STIs. Based on the outcome of this test, if an STI is diagnosed, we will provide you with the appropriate treatment. Also, as part of routine clinical care, if an STI is diagnosed, you will be provided with the standard notification slip of the Department of Health to give to your sexual partner(s) because your partner(s) may also be infected without knowing it and require treatment.

We would like to ask your permission to store samples for a maximum duration of 5 years. Your biological specimens might be used to support the development of other new diagnostics tests for STI infections in low- and middle-income countries. This will only be done following approval of such a research study protocol by the University of Pretoria Human Research Ethics Committee.

POSSIBLE RISKS AND DISCOMFORTS INVOLVED

There are no medical risks associated with the study. You are free to refuse to answer any questions that may cause you psychological discomfort; counselling services are available if required. Collection vaginal swab specimens is well accepted for diagnostic and research purposes throughout the world. Collection of these swabs might cause a 'tingling' sensation and may be considered of none to mild discomfort. These specimens are routine practice in STI testing throughout the world.

POSSIBLE BENEFITS OF THIS STUDY

This study contributes to improving detection and treatment of gonorrhoea in the world, and especially in poor countries where diagnostic tests are currently not available. Through participation in this study, we will be able to provide you with a free comprehensive STI screening that you would normally not receive, and that makes it easier to provide you with counselling and information and to treat your symptoms and asymptomatic infections if present, with the correct antibiotics.

COMPENSATION

There are no costs involved for you to be part of the study. To reimburse you for the time spent with our research nurse, we will offer all participants a paper R100 voucher for the local food store (e.g. Shoprite, Spar, Checkers) once off. 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 stating any reason. The decision to withdraw or not to participate in the study will by no means affect the clinical care that you receive for your symptoms – you will receive the same treatment as anyone else.

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. 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:

Mrs Mandisa Mdingi	Professor TM Rossouw
	Faculty of Health Sciences Research Ethics Committee
Principal Investigator	University of Pretoria
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 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 and that withdrawal will not affect my further treatments.
- I am participating willingly.
- I have received a signed copy of this informed consent agreement.

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

AFFIRMATION OF INFORMED CONSENT BY AN ILLITERATE PARTICIPANT (if applicable)

I, the undersigned, ……....., have read and have explained fully to the participant, named …… , the informed consent document, which describes the nature and purpose of the study in which I have asked the him/her to participate. The explanation I have given mentioned both the possible risks and benefits of the study. The participant indicated that he/she understands that he/she will be free to withdraw from the study at any time for any reason and without jeopardising his/hers standard care.

I hereby certify that the patient has agreed to participate in this study.

Participant's name (Please print)	Date
Participant's signature	Date
Investigator's Name (Please print)	Date
Investigator's Signature	Date
Name of the person who witnessed the informed consent (Please print)	Date
Signature of the Witness	Date