PATIENT STUDY ID: _____ **SCREENING DATE:** ____/____/____

PATIENT SIGNATURE: _____

INFORMED CONSENT FORM

PROJECT TITLE*:* Development of a two-stage cervical cancer screening algorithm for Botswana

Principal Investigator
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What you should know about this research study:

- We give you this informed consent document so that you may read about the purpose, risks, and benefits of this research study.
- You have the right to refuse to take part or agree to take part now and change your mind later.
- Please review this consent form carefully. Ask any questions before you make a decision.
- Your participation is voluntary.

PURPOSE

The purpose of the study is to see if it is possible to test women in Botswana for a virus called Human Papillomavirus, or HPV, using a vaginal sample and to determine the appropriate follow-up for a positive HPV test. HPV is a common infection that is spread through sexual contact and you may have it without having any symptoms. Sometimes it goes away on its own. If it does not go away on its own, it can cause genital warts and cervical cancer. You are being asked to participate in this study because you are attending the gynaecology clinic or Infectious Disease Clinical Center (IDCC) at Princess Marina Hospital and you are 25 years of age or older. Before you sign this form, please ask any questions on any aspect of this study that is unclear to you. You may take as much time as necessary to think it over.

PROCEDURES AND DURATION

If you decide to participate you will be asked to provide a sample for HPV testing during your visit to the clinic today. A health care professional will collect a sample for HPV testing, which will involve an examination with a speculum. Then, a health care professional will instruct you on how to collect a sample from your own vagina for HPV testing. Your sample(s) will be tested for certain types of HPV, called high-risk HPV, by a machine. You will receive the results of the test by phone in about a week, and the results will be explained to you. We can make an appointment for you to come in to talk about them if you want to. If you test positive, we will ask you to come back for follow-up testing. This testing will take about 15 minutes and will include a pelvic exam with further cervical cancer screening procedures, which include application of acetic acid (vinegar) to the cervix followed by visual inspection of the cervix and inspection of the cervix under the microscope. If any abnormality is detected, we will take a biopsy of the cervix.

PATIENT STUDY ID: _____ SCREENING DATE: ____ / ____ / ____

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RISKS AND DISCOMFORTS

Undergoing cervical cancer screening can cause worry or concern, regardless of the test results. For this reason, both before and after you have these tests done, we will give you counseling about the meaning of the results. If you have HPV, we will provide you with appropriate follow-up testing and discuss ways to take care of yourself and avoid cervical cancer.

Cervical cancer screening and diagnosis might cause mild physical discomfort as the test involves a pelvic examination and possible biopsy. We will inform you of what to expect at each step of the examination.

Other rare side effects of cervical cancer screening include: 1) bleeding that is very heavy or lasts longer than two weeks; 2) fever or chills; and 3) infection, such as heavy, yellow-colored, or bad-smelling discharge from your vagina. You should contact study staff if you feel you have any of these symptoms.

Women who test positive for HPV or have a cervical cancer screening abnormality might feel uncomfortable, anxious or upset about their result. They might fear that someone they know might learn they have this infection. We will not give your name or results to other people. We will do everything possible to ensure that your results and your participation in the study remain confidential.

BENEFITS AND/OR COMPENSATION

You will know whether or not you have HPV, which can cause cervical cancer. You will undergo follow-up testing if you have a positive result. The benefit to you of cervical cancer screening and diagnosis is that we can diagnose pre-cancer in the cervix and prevent cervical cancer. You will be referred for further evaluation if you need it. This study also will determine the number of women who have HPV. We hope this information will help in the future to prevent, identify, and treat cervical cancer in Botswana.

There is no cost to you for participation in this study. There is no compensation for this study.

CONFIDENTIALITY

The information and samples we collect from you will remain confidential. Written documents for the study will be kept at locked offices in Gaborone. Any data stored on computers will have a security code. Only the research team and your provider will have access to your name and the study results.

The research team and your provider may have access to study data and records to monitor the study. Publications and/or presentations that result from this study will not identify you by name.

VOLUNTARY PARTICIPATION

Participation in this study is voluntary. If you decide not to participate in this study, your decision will not affect your care, and you can still seek cervical cancer screening at Princess Marina Hospital**.** If you decide to participate, you are free to withdraw your consent and to discontinue participation at any time without penalty. Withdrawal from the study will not affect your care. Any refusal to observe and meet appointments agreed upon with the central investigator will be considered as implicit withdrawal and therefore will terminate your participation in the investigation without your prior request.

If you believe you are injured as a direct result of your participation in this study or should you have questions about the study and your rights as a research participant, contact one of the Investigators at the top of this consent. You will be offered the necessary care to treat your injury at Princess Marina Hospital.

PATIENT STUDY ID: _____ **SCREENING DATE:** ____/____/____

PATIENT SIGNATURE: _____

AUTHORIZATION

You are making a decision whether or not to participate in this study. Your signature indicates that you have read and understood the information provided above, have had all your questions answered, and have decided to participate.

_____	_____
Name of Research Participant (please print)	Date
_____	_____
Signature of Research Participant	Date
_____	_____
Signature of Study Staff who consented the participant	Date

SAMPLE STORAGE

Do you agree to allow us to store your samples for future studies? If your samples are used for future studies, they may be transported to collaborating laboratories, but your identity will always remain confidential.

☐ Yes Signature_____
☐ No

FUTURE CONTACT

Do you agree to be contacted in the future regarding participation in future research related to cervical cancer screening and treatment?

☐ Yes Signature_____ Phone 1_____ Phone number 2 _____
☐ No

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 participant; 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 Office of Research and Development, University of Botswana, Phone: Ms Dimpho Njadingwe on 355-2900, E-mail: research@mopipi.ub.bw, Telefax: [0267] 395-7573.