HKU Med LKS Faculty of Medicine
Department of Obstetrics & Gynaecology
香港大學婦產科學系

PARTICIPANT INFORMATION SHEET
(VERSION 1 DATED 2019/04/30)

STUDY TITLE: The Feasibility of Self-Sampling Based HPV Testing in Women in Hong Kong as a Primary Screening Tool for Cervical Cancer

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives and your family doctor if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

WHAT IS THE PURPOSE OF THE STUDY?

This study aims to assess acceptability of self-sampled material as a primary screening tool for cervical cancer. We also seek to explore other factors such as diagnostic accuracy and patient acceptance of different service delivery models.

WHY HAVE I BEEN CHOSEN?

You have been invited because you are a woman between the ages of 30-65, who has not undergone conventional cervical cancer screening (i.e. a clinician taken Pap smear) in the last 3 years.

DO I HAVE TO TAKE PART?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time without the need to provide a reason. This will not affect the standard of care you receive.

WHAT WILL HAPPEN TO ME IF I TAKE PART?

If you decide to take part, you will be required to submit a self-sampled specimen for HPV testing. You will also be asked to undergo an additional clinician-sampled cervical specimen taking, which you may decline, in order to obtain a comparative result. You will also be required to fill in a set of questionnaires after self-sampling aimed at determining participant demographics and attitudes towards self-sampling. If any abnormal results were found, you would be referred to speciality for management. The specimen would be kept unlimitedly for future exploration of biomarkers that may be useful.

WHAT ARE THE SIDE EFFECTS OF TAKING PART?

There are no adverse effects.

WHAT ARE THE DISADVANTAGES AND RISKS OF TAKING PART?

Other than the possible discomfort caused by self or clinician conducted cervical sampling, and the time taken to collect, deliver, and attend a clinician sampling appointment, there are no discernable disadvantages or risks to taking part of this study.

WHAT ARE THE BENEFITS OF TAKING PART?

You will receive free cervical cancer screening (HPV test + pap smear) .

WILL MY TAKING PART IN THIS STUDY BE KEPT CONFIDENTIAL?

The data collected in this study will only be used for research purposes and will remain strictly confidential. Your name will not be used in any publications that may result from this research without your prior permission.

WHAT WILL HAPPEN TO THE RESULTS OF THE RESEARCH STUDY?

The results will be analyzed and presented in international journals and/or research conferences.

WHO IS ORGANISING AND FUNDING THE RESEARCH?

Researchers in Department of Obstetrics and Gynaecology, the University of Hong Kong, will organize the research. The research is funded by Roche Diagnostics (Hong Kong) Limited and Karen Leung Foundation.

WHO HAS REVIEWED THE STUDY?

The Institutional Review Board of the University of Hong Kong/Hospital Authority Hong Kong West Cluster has reviewed the study.

CONTACT FOR FURTHER INFORMATION

Any questions you may have about this study, now or at any time in the future, will be fully answered. If you have any questions, you may contact Dr. Karen KL Chan, Department of Obstetrics and Gynaecology, the University of Hong Kong Tel: 2255-4518.

Thank you very much for taking part in this study. You will be given a copy of the information sheet and a signed consent form to keep.

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PARTICIPANT CONSENT FORM
(VERSION 1 DATED 2019/04/30)

Title of Project: The Feasibility of Self-Sampling Based HPV Testing in Women in Hong Kong as a Primary Screening Tool for Cervical Cancer

Name of Researcher: Dr. CHAN Karen Kar Loen

		Please tick
1.	I confirm that I have read and understood the information sheet for the above study and have had the opportunity to ask questions.	☐
2.	I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	☐
3.	I understand that sections of any of my medical notes may be looked at by responsible individuals from the research team or from regulatory authorities where it is relevant to my taking part in the research. I give permission to these individuals to have access to my records.	☐
4.	I agree to take part in the above study.	☐

Confidentiality

You have the rights of access to personal data and publicly available study results, if and when needed.

Under the laws of Hong Kong (in particular the Personal Data (Privacy) Ordinance, Cap 486), you enjoy or may enjoy rights for the protection of the confidentiality of your personal data, such as those regarding the collection, custody, retention, management, control, use (including analysis or comparison), transfer in or out of Hong Kong, non-disclosure, erasure and/or in any way dealing with or disposing of any of your personal data in or for this study. For any query, you should consult the Privacy Commissioner for Personal Data or his office (Tel No. 2827 2827) as to the proper monitoring or supervision of your personal data protection so that your full awareness and understanding of the significance of compliance with the law governing privacy data is assured.

By consenting to participate in this study, you expressly authorize:

- The principal investigator and his research team and the Institutional Review Board of the University of Hong Kong / Hospital Authority Hong Kong West Cluster responsible for overseeing this study to get access to, to use, and to retain your personal data for the purposes and in the manner described in this informed consent process; and
- The relevant government agencies (e.g. the Hong Kong Department of Health) to get access to your personal data for the purposes of checking and verifying the integrity of study data and assessing compliance with the study protocol and relevant requirements.

_____	_____	_____
Name of participant	*Date*	*Signature*
_____	_____	_____
Name of Witness (if applicable)	*Date*	*Signature*
_____	_____	_____
Name of person taking consent different from researcher)	*Date*	*Signature*
_____	_____	_____
Researcher	*Date*	*Signature*

Copies to: Participant, Researcher's File