The SAFE Study:
Satisfaction and Adherence to Follow-up with Colposcopy Exams

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1. Invitation

You are being invited to take part in this research study because you are attending your first colposcopy visit at the VGH Women's Clinic.

2. Your participation is voluntary

Your participation is voluntary. You have the right to refuse to participate in this study. If you decide to participate, you may still choose to withdraw from the study at any time without any negative consequences to the medical care to which you are entitled or are presently receiving.

You should be aware that there is a difference for both you and your doctor between being a patient and being a research participant. As a patient, all medical procedures and treatments are carried out for your benefit only according to standard accepted practice. As a research participant, you and your doctor also must take into account the requirements for this research study, which may include participating in a novel method of receiving your colposcopy results which is not currently the standard practice, and completing a questionnaire which does not impact your medical care. This consent form describes the procedures that are being carried out for research purposes. Please review the consent document carefully when deciding whether or not you wish to be part of the research and sign this consent only if you accept being a research participant.

If you wish to participate in this study, you will be asked to sign this form. Please take time to read the following information carefully and to discuss it with your family, friends, and doctor before you decide.

3. Who is conducting this study?

This study is being conducted by a group of women's health researchers including the Program Director for the BC Colposcopy Program who are affiliated with the University of British Columbia, BC Cancer Agency and the Women's Health Research Institute. It is being sponsored by the UBC Division of Gynaecologic Oncology. The Principal Investigator (Dr. Marette Lee) has received financial compensation from the Division of Gynaecologic Oncology through a research award for the work required in doing this clinical research, but investigators will not receive payments from this award and there is no conflict of interest to declare.

4. Background

Cervical cancer is the second most common cancer and third leading cause of cancer death in women worldwide. Pap tests can find changes in cells of the cervix before they have time

to turn into cancer. If there are abnormal changes, they can be examined with a microscope (colposcopy) and have a biopsy (tissue sample) taken for further testing. If the testing reveals very abnormal changes (high-grade dysplasia), they can be removed with a Loop Electrosurgical Excision Procedure (LEEP). This system for preventing cervical cancer depends on patients understanding and following through with their colposcopy follow-up and treatment appointments.

Currently at Vancouver General Hospital (VGH), the largest colposcopy clinic in the province, colposcopy results are sent to the referring or family physician who then contacts the patient. This two-step process without direct communication between the colposcopy clinic and patient may lead to confusion and anxiety, errors, missed appointments, increased costs to the healthcare system, and may even lead to worse patient health outcomes.

5. What is the purpose of the study?

The goal of this study is to test if receiving colposcopy results directly from a trained colposcopy nurse in our clinic who is able to offer education and support improves patient satisfaction with the colposcopy process and decreases the stress or anxiety patients experience. We are also looking at whether this gives patients a better understanding of their diagnosis, increases the likelihood that patients attend their colposcopy appointments, or improves their health outcomes.

6. Who can participate in this study?

Women 19 years of age or older who are presenting for their first visit at the VGH Colposcopy Clinic.

7. Who should not participate in this study?

You will not be eligible to participate in this study if:

- You are unable to speak conversational English
- You are unable or refuse to provide consent
- You are currently pregnant
- You do not have a family physician or referring physician who will be able to provide you with your colposcopy results

8. What does the study involve?

We aim to recruit 200 participants in total to participate in this study, with 100 participants in each of the intervention and control groups. After being recruited, you will be randomized to either the intervention or control group. Randomization is like flipping a coin to assign which group you will be in, and you have an equal chance of being assigned to either group.

The control group will receive their results the standard way that it is done at the clinic. After the colposcopy visit, control patients will be given a slip of paper reminding them to call their referring physician for their colposcopy results in three weeks. Once the biopsy pathology result comes back, the colposcopists prepare and send the result reports to referring physicians within two weeks of the visit. The referring physician then contacts the patient to let them know the next steps in follow-up or treatment.

The intervention group will instead directly receive their results from a colposcopy clinic nurse (the Patient Liaison) at the VGH clinic, via telephone. The colposcopy nurse will explain the colposcopy results and recommended follow-up or treatment. She will also be available to answer patient questions within her scope, offer educational or support resources to patients, or pass on questions to one of the colposcopy physicians who can give more specific information to the patient if needed. This telephone visit is expected to take about 10 minutes.

All participants (both control and intervention group) will then be contacted by our study coordinator to fill out a questionnaire once they have received their colposcopy results. The questionnaire can be filled out online or may be done over the phone with the research coordinator if you prefer. It will take approximately 10-20 minutes to complete and you are not required to answer questions that you are not comfortable answering. In approximately 6 months after your first clinic visit, your colposcopy clinic chart will be reviewed. We will be looking at the rate of attendance at recommended follow-up or treatment visits and the results of these visits.

9. What are the possible harms and discomforts?

You may encounter questions that you do not feel comfortable answering when completing the questionnaire. Should this occur, you may leave these unanswered, or at any time withdraw from the study.

10. What are the potential benefits of participating?

No one knows whether or not you will benefit from this study. Those who receive their results from the Patient Liaison may receive their results earlier and receive additional education and support to help them understand their diagnosis and treatment and plan follow-up visits. This direct contact with the colposcopy nurse who can offer support and counseling may also decrease the anxiety or other negative emotions associated with the colposcopy process and improve access to educational and support resources.

We hope that the information learned from this study can be used in the future to improve the experience of all colposcopy patients and teach us ways to improve attendance at colposcopy appointments to improve health outcomes for our patients.

11. What are the alternatives to study participation?

If you choose not to participate in this study or to withdraw at a later date, you will still receive the same care at the colposcopy clinic and your referring/family physician will receive your colposcopy results when the report is available.

12. What if new information becomes available that may affect my decision to participate?

You will be advised of any new information that becomes available that may affect your willingness to remain in this study.

13. What happens if I decide to withdraw my consent to participate?

You may withdraw from this study at any time without giving reasons with no impact on the care you receive. If you choose to enter the study and then decide to withdraw at a later time, you have the right to request the withdrawal of your information collected during the study. This request will be respected to the extent possible. Please note however that there may be exceptions where the data will not be able to be withdrawn for example where the data is no longer identifiable (meaning it cannot be linked in any way back to your identity) or where the data has been merged with other data. If you would like to request the withdrawal of your data, please let your study doctor know.

14. Can I be asked to leave the study?

If you are not able to follow the requirements of the study or for any other reason, the study doctor may withdraw you from the study and will arrange for your care to continue per the current standard. If you are asked to leave the study, the reasons for this will be explained to you and you will have the opportunity to ask questions about this decision.

15. How will my taking part in this study be kept confidential?

Your confidentiality will be respected. However, research records and health or other source records identifying you may be inspected in the presence of the Investigator/her designates and the UBC Clinical Research Ethics Board for the purposes of monitoring the research. No information or records that disclose your identity will be published without your consent, nor will any information or records that disclose your identity be removed or released without your consent unless required by law.

You will be assigned a unique study number as a participant in this study. This number will not include any personal information that could identify you (e.g., it will not include your Personal Health Number, SIN, or your initials, etc.). Only this number will be used on any

research-related information collected about you during the course of this study, so that your identity will be kept confidential. Information that contains your identity will remain only with the Principal Investigator and/or designates. The list that matches your name to the unique study number that is used on your research-related information will not be removed or released without your consent unless required by law.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected. You also have the legal right of access to the information about you and, if need be, an opportunity to correct any errors in this information. Further details about these laws are available on request to your study doctor.

16. Reimbursement

All research-related medical care and treatment and any related tests that you will receive during your participation in this study will be provided at no cost to you. You will not receive reimbursement or payment for any expenses as a result of participation.

17. Who do I contact if I have questions about the study during my participation?

If you have any questions or desire further information about this study before or during participation, or if you experience any adverse effects, you can contact the Principal Investigator Dr. Marette Lee or any of the other study members at the contact information provided on page one of this document.

18. Who do I contact if I have any questions or concerns about my rights as a participant?

If you have any concerns or complaints about your rights as a research participant and/or your experiences while participating in this study, contact the Research Participant Complaint Line in the University of British Columbia Office of Research Ethics by e-mail at RSIL@ors.ubc.ca or by phone at 604-822-8598 (Toll Free: 1-877-822-8598).

19. After the study is finished

We will provide participants with a summary of the study results once the study and analysis has been completed, which we anticipate to be in July of 2018. We will also attempt to share these results with the medical community in the form of scientific conferences or journals.

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Participant Consent

My signature on this consent form means:

- I have read and understood the information in this consent form.
- I have had enough time to think about the information provided.
- I have been able to ask for advice if needed.
- I have been able to ask questions and have had satisfactory responses to my questions.
- I understand that all of the information collected will be kept confidential and that the results will only be used for scientific purposes.
- I understand that my participation in this study is voluntary.
- I understand that I am completely free at any time to refuse to participate or to withdraw from this study at any time, and that this will not change the quality of care that I receive.
- I authorize access to my health records as described in this consent form.
- I understand that I am not waiving any of my legal rights as a result of signing this consent form.
- I understand that there is no guarantee that this study will provide any benefits to me.

I will receive a signed copy of this consent form for my own records.

I consent to participate in this study.

Participant's Signature	Printed name		Date
Signature of Witness	Printed name	Study Role	Date
Signature of Person Obtaining Consent	Printed name	Study Role	Date