Study Title: Knowledge, Awareness, and Understanding of Stress Urinary Incontinence in Patients Attending a Urogynecology Clinic

Leading Investigator: Dr. Patricia Lee, Department of Obstetrics and Gynecology
Co-Investigators: Dr. Aysha Nedham, Department of Obstetrics and Gynecology

NCT number – unassigned yet
Document: Informed consent form FORMED CONSENT TO PARTICIPATE IN A RESEARCH STUDY

INFORMED CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Full Study Title: Knowledge, Awareness, and Understanding of Stress Urinary Incontinence in Patients Attending a Urogynecology Clinic

Principal Investigator: Dr Patricia Lee, SHSC, Department of Gynecology,416-480-6740

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Sponsor: No funds required

INFORMED CONSENT

You are being asked to consider participating in a research study. A research study is a way of gathering information on a health condition or to answer a question about something that is not well understood.

This form explains the purpose of this research study, provides information about the study procedures involved, possible risks and benefits, and the rights of participants. It also describes other options you have and your right to withdraw from (quit) the study at any time.

Please read this form carefully and ask any questions you may have. You may take as much time as you wish to decide whether or not to participate. Talk to others about the study if you wish. Please ask the study staff or one of the investigator(s) to clarify anything you do not understand or would like to know more about. Make sure all your questions are answered to your satisfaction before deciding whether to participate in this research study.

INTRODUCTION

You are being asked to be part of this study because you have symptoms of stress urinary incontinence (SUI) and are attending the urogynecology clinic.

Stress urinary incontinence is a common condition in which urine leaks with activities such as coughing, sneezing, laughing, or physical exertion. Although effective treatment options are available, patients' understanding of SUI, its causes, and available treatments may vary.

The Urogynecology Department is conducting a research study to better understand patients' knowledge and perceptions of stress urinary incontinence. Information collected from this study may help improve patient education and counseling in the future.

It is up to you to decide whether or not to take part in the study. We will describe the study and go through this consent form, which we will then give to you. We will ask you to sign the consent form to show you have agreed to take part. You are free to quit at any time, without giving a reason. This will not affect the standard of care you receive. Your agreement to be in this study does not take away any of your legal rights.

WHAT IS THE USUAL TREATMENT?

Stress urinary incontinence is commonly treated using conservative and surgical approaches depending on symptom severity and patient preference. Conservative options include pelvic floor muscle exercises (with or without pelvic floor physiotherapy), lifestyle modifications, and vaginal devices. Surgical options may include procedures such as midurethral sling surgery.
If you choose not to participate in this study, your doctor will discuss with you the treatment option(s) she or he feels are most appropriate for you.

WHAT WILL HAPPEN DURING THIS STUDY?

If you choose to take part in this study:

- You will be asked to complete a questionnaire related to your symptoms and your knowledge and perceptions of stress urinary incontinence before seeing your urogynecologist and repeat the same questionnaire after your appointment.
- You will be given a patient reading pamphlet about SUI to read.
- The questionnaire will take approximately 10–15 minutes to complete.
- No physical examination, tests, or treatments are required as part of this study.
- Your participation will take place during your clinic visit only.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Approximately 90 participants will take part in this study at Sunnybrook health Science Centre.

WHAT ARE THE RESPONSIBILITIES OF STUDY PARTICIPANTS?

If you choose to be a part of the study, it is important for you to understand that it is your responsibility to:

- Complete the study questionnaire to the best of your ability.
- Inform a member of the study staff if you wish to withdraw from the study.

WHAT ARE THE POSSIBLE RISKS OR HARMS OF PARTICIPATING IN THIS STUDY?

This study is considered low risk.
Some questions may be personal and could cause mild discomfort or embarrassment. You may skip any question you do not wish to answer. There are no physical risks associated with participating in this study.

WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?

You may or may not benefit directly from participating in this study. Your participation will provide information that may help improve education and care for future patients with stress urinary incontinence.

ARE STUDY PARTICIPANTS PAID TO PARTICIPATE IN THIS STUDY?

You will not be paid to participate in this study.

WHAT ARE THE COSTS OF PARTICIPATING IN THIS STUDY?

Participating in this study will not involve any additional costs to you or your private health care insurer.

CAN PARTICIPATION IN THIS STUDY END EARLY?

You may choose to withdraw from the study at any time. The investigators may also remove you from the study if it is determined to be in your best interest or if the study is stopped.

If you withdraw from the study, information collected before your withdrawal may still be used. No new information will be collected without your permission.

DO THE INVESTIGATORS HAVE ANY CONFLICTS OF INTEREST?

There are no conflicts of interest related to this study. The investigators do not receive personal financial benefit from conducting this research.

WHAT WILL HAPPEN TO THE RESULTS OF THE STUDY?

If the results of this study are published or presented, your identity will remain confidential. You may contact the study investigator for information about the results once the study is complete.

WHO IS ORGANIZING AND FUNDING THE RESEARCH?

This study is investigator-initiated and is not funded by any source.

WHO HAS REVIEWED THE STUDY?

This study has been reviewed by the Sunnybrook Health Science Centre Research Ethics Board, which oversees the ethical conduct of research studies.

FURTHER INFORMATION AND CONTACT DETAILS

If you have questions about this study or your rights as a research participant, please contact:

WHAT ARE THE RIGHTS OF PARTICIPANTS IN A RESEARCH STUDY?

All participants in a research study have the following rights:

- You have the right to have this form and all information concerning this study explained to you
- Participating in this study is your choice (voluntary). You have the right to choose not to participate, or to stop participating in this study at any time without having to provide a reason. If you choose to withdraw, your choice will not have any effect on your current or future medical treatment or health care OR your employment status. Should you choose to withdraw from the study you are encouraged to contact *Dr. Patricia Lee, Department of Gynecology, 416-480-6740.*

  You have the right to receive all significant information that could help you make a decision about participating in this study. You also have the right to ask questions about this study and your rights as a research participant, and to have them answered to your satisfaction, before you make any decision. You also have the right to ask questions and to receive answers throughout this study. If you have any questions about this study you may contact the person in charge of this study (Principal Investigator) **Dr. Patricia Lee**, Department of Gynecology, **416-480-6740**.
- If you have questions about your rights as a research participant or any ethical issues related to this study that you wish to discuss with someone not directly involved with the study, you may call the **Chair of the Sunnybrook Research Ethics Board at (416) 480-6100 ext. 688144.**

4. You have the right to have any information about you and your health that is collected, used or disclosed for this research study to be handled in a confidential manner. In this study we do not need to collect your name, telephone number, medical record number.

If you decide to participate in this study, the investigator(s) and study staff will look at your personal health information and collect only the information they need for this study. “Personal health information” is health information about you that could identify you because it includes information such as your;

- Date of birth,
- Ethnicity/race
- Menopausal status

The following people may come to the hospital to look at your personal health information to check that the information collected for the study is correct and to make sure the study followed the required laws and guidelines:

- Representatives of the Sunnybrook Research Ethics Board, a group of people who oversee the ethical conduct of research studies at Sunnybrook; and

Access to your personal health information will take place under the supervision of the Principal Investigator.

The investigator(s), study staff and the other people listed above will keep the information they see or receive about you confidential, to the extent permitted by applicable laws. Even though the risk of identifying you from the study data is very small, it can never be completely eliminated.

When the results of this study are published, your identity will not be disclosed.

The Principal Investigator will keep any personal health information about you in a secure and confidential location for 10 years and then destroyed as required by Sunnybrook policy.

- By signing this consent form, you do not give up any of your legal rights.
- You have the right to receive a copy of this signed and dated informed consent form before participating in this study.
- You have the right to be told about any new information that might reasonably affect your willingness to continue to participate in this study as soon as the information becomes available to the study staff.
- If you become sick or injured as a direct result of your participation in this study- which is very unlikely, your medical care will be provided. Financial compensation for such things as lost wages, disability or discomfort due to this type of injury is not routinely available
- If, as a result of your participation in this study, any new clinically important medical information about your health is obtained, you will be given the opportunity to decide whether you wish to be made aware of that information.
- You have the right to access, review and request changes to your personal health information.
- You have the right to be informed of the results of this study once the entire study is complete, if you opted to then you can voluntarily provide your name and contact information.

DOCUMENTATION OF INFORMED CONSENT

Full Study Title: Knowledge, Awareness, and Understanding of Stress Urinary Incontinence in Patients Attending a Urogynecology Clinic

Name of Participant: _____

By signing this form, I confirm that:

- This research study has been fully explained to me and all of my questions answered to my satisfaction
- I understand the requirements of participating in this research study
- I have been informed of the risks and benefits, if any, of participating in this research study
- I have been informed of any alternatives to participating in this research study
- I have been informed of the rights of research participants
- I do not give up any of my legal rights
- I have read each page of this form
- I authorize access to my personal health information, medical record and research study data as explained in this form
- I have agreed to participate in this study or agree to allow the person I am responsible for to participate in this study

_____ _____ _____

Name of participant/Substitute decision-maker (print) | Signature | Date

Person obtaining consent

By signing this form, I confirm that:

- This study and its purpose has been explained to the participant named above
- All questions asked by the participant have been answered
- I will give a copy of this signed and dated document to the participant

_____ _____ _____

Name of Person obtaining consent (print | Signature | Date

Statement of Investigator

I acknowledge my responsibility for the care and well-being of the above participant, to respect the rights and wishes of the participant as described in this informed consent document, and to conduct this study according to all applicable laws, regulations and guidelines relating to the ethical and legal conduct of research.

_____ _____ _____

Name of Investigator (print)	Signature	Date