

**The Cleveland Clinic Foundation  
Consent to Participate in a Research Study**

**Study title:** Urinary retention rates after immediate removal of Foley catheter versus backfill void trial following total laparoscopic hysterectomy: A randomized controlled trial.

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You are being invited to participate in a research study. A research study is designed to answer specific questions about new ways to prevent, detect, and treat disease. Being in a research study is different from being a patient. The purpose of this document is to provide a written summary of the discussion and exchange of research information you had with the research team. It is also for use as a reference during the study.

**Please note:**

- **You are being asked to participate in a research study**
- **Ask as many questions as needed so you can make an informed decision.**
- **Carefully consider the risks, benefits, and alternatives of the research**
- **Your decision to participate is completely voluntary and will have no effect on the quality of your medical care if you choose not to participate. You can also withdraw from the study at anytime.**

**1. INFORMATION ON THE RESEARCH**

**Why is the research study being done?**

Women who have a laparoscopic removal of the uterus (total laparoscopic hysterectomy) are at risk of having problems urinating after surgery, called urinary retention. At this time, the risk of urinary retention is anywhere from 4% to 34%. Urinary retention may lead to re-admission to the hospital, the need for draining of the bladder using a catheter, the need for self-catheterization at home, temporary or permanent bladder dysfunction, bladder rupture, or kidney failure. The risk factors for developing urinary retention after total laparoscopic hysterectomy are not well known. Additionally, prevention of urinary retention has not been made standard in the medical literature. This research study is being performed in order to determine the risk factors for developing urinary retention as well as the best method of checking bladder function after total laparoscopic hysterectomy.

**What is involved if you decide to take part in this research study?**

*Pre-Surgery*

The study team will review this consent with you and ask you to sign. If you decide to participate, the study team will use your electronic medical record to collect information about you including your age, race, body mass index, obstetric and gynecologic history, smoking status, surgical history, and the reason for your surgery. You will be asked to complete a questionnaire which should take less than 5 minutes of your time. Additionally, an ultrasound of your bladder will be performed by a member of the study team or by a nurse in the clinic after

you completely empty your bladder. This ultrasound will be used to measure the amount of urine you normally have left in your bladder after you urinate.

### *Day of Surgery*

#### *Surgical Procedure (total laparoscopic hysterectomy)*

If you decide to take part in this research study, your surgery will occur as it normally would. On the day of your surgery, you will meet your surgeons, anesthesiologist, and nursing teams before your surgery starts. You will then be taken to the operating room, laid down on the operating room bed, and receive anesthesia, like standard care. Next, your surgeon will place a Foley catheter into your bladder and proceed with your surgery as he normally would.

### *Research Procedure*

After your hysterectomy is complete, an envelope will be opened to indicate your study group. This process is called randomization and like the flip of a coin, there will be 2 possible groups. Neither the research team nor you can choose the group assignment; the assignment will be chosen by chance. One group of patients will be randomly assigned to keeping the Foley catheter in the bladder surgery and the other group of patients will be randomly assigned to not keeping the Foley catheter in the bladder after surgery. If you are a part of the group of patients with a Foley catheter after surgery, then you will have a “backfill” bladder challenge in the recovery room once you are awake and alert. If you are a part of the group of patients without a Foley catheter after surgery, then you will have an “autofill” bladder challenge in the recovery room. The details of each bladder challenge are outlined below.

#### *Group A: Backfill Bladder Challenge*

In the recovery room, you will have about 300 mL of sterile water instilled into your bladder through the Foley catheter. The Foley catheter will then be removed and you will be allowed to urinate in the restroom over a collection bin. The amount of urine that you make will be measured. A bladder ultrasound will be performed to measure the amount of urine left in your bladder. If the amount of urine is greater than 100 mL, you will have a new Foley catheter placed in your bladder and will be discharged home.

#### *Group B: Autofill Bladder Challenge*

In the recovery room, you will be asked to urinate over a collection bin when you are awake and able to walk to the restroom. The amount of urine that you make will be measured. A bladder ultrasound will be performed to measure the amount of urine left in your bladder. If the amount of urine is greater than 100 mL, you will have a Foley catheter placed in your bladder and will be discharged home.

### *Bladder Challenge Follow Up*

If you are discharged home without a Foley catheter, you will follow up in the office 10-14 days after your surgery as you normally would after this type of surgery. If you are discharged home with a Foley catheter, you will be asked to come to the gynecology office the day after your surgery to have a repeat bladder challenge using the “backfill” method. If you have greater than 100 mL of urine left in your bladder after the challenge is complete, a new Foley catheter will be placed in your bladder again, which is standard protocol. The bladder challenge will then be repeated 1 week later. If once again, greater than 100 mL of urine remain in your bladder, then

you will follow up with Urogynecology for follow up and you will be taught self-catheterization to be performed at home.

#### *Post-Surgery Follow up*

You will have a post-operative appointment in the gynecology office 10-14 days after your hysterectomy as is standard protocol. As a study participant, you will be asked to complete a questionnaire which should take you about 5 minutes to complete. During the appointment, you will also have an exam performed and will be able to ask any questions you may have about your surgery at that time. Please note, the study described is for research purposes only. It is not the purpose of this study to look for or provide you with any medical information or diagnoses relating to your present condition or any other disease or illness. Therefore, you will not receive results from these research studies.

## **2. ALTERNATIVES**

### **What are the alternatives to participation in the research study?**

If you do not wish to participate in this study, you will receive the standard surgical and post-surgical care. Currently, all patients undergoing hysterectomy also receive a bladder challenge; however, the type of bladder challenge performed will be under the discretion of your surgeon.

## **3. RISKS**

### **What are the risks of participating in the research study?**

When a Foley catheter is placed into the bladder, a risk of developing a urinary tract infection exists. However, in the context of this study, the risk of a urinary tract infection is not greater than if you were not a part of this study since a Foley catheter is a standard step in all of the total laparoscopic hysterectomies performed in Cleveland Clinic Florida. Aside from this risk, some of the questions asked as part of the study may make you feel uncomfortable. You may refuse to answer any of the questions. Additionally, there is a potential risk of loss of confidentiality of your data. Every effort will be made to keep your information confidential through the use of several safeguards. All of your completed forms and questionnaires will be stored in a locked filing cabinet at Cleveland Clinic Florida. The key will only be accessible to the research team. Additionally, any electronic information collected will be maintained on a secure database on a password-protected computer at Cleveland Clinic Florida.

## **4. BENEFITS**

### **What are possible benefits of participating in the research?**

The knowledge gained from this study may benefit future patients. However, you will not have direct benefit from participating in this research study.

## **5. COSTS**

### **Are there any costs to you if you participate in this study?**

The materials used in this study will not cost you any extra money since they are all standard materials used for your surgery. Additionally, any extra visits to the office for urinary testing will be billed as part of your post-operative care and should not incur extra costs to you as a result. Hence, participating in this study will not incur any extra charges to you. Additionally, participating in this research will not cause your surgery to be prolonged so the costs of the surgery should remain the same as if you were not participating in this study.

## **6. COMPENSATION**

### **Are there any payments to you if you participate in this study?**

No compensation will be provided for participating in this research study.

## **7. RESEARCH RELATED INJURY**

### **What will happen if you are injured as a result of taking part in the research?**

In the event you are injured as a result of participation in this research, medical care is available to you. The costs of such medical care will be billed to you or your insurance company. There are no plans to provide compensation for lost wages, direct or indirect losses. The Cleveland Clinic will not voluntarily provide compensation for research related injury. You are not waiving any legal rights by signing this form. Further information about research related injury is available by contacting the Institutional Review Board at (800) 223- 2273 Ext 42924.

## **8. PRIVACY AND CONFIDENTIALITY**

### **What will happen to your information that is collected for this research?**

Cleveland Clinic has rules and procedures to protect information about you. Federal and State laws also protect your privacy.

The research team working on the study will collect information about you. This includes your health information and data collected for this research study. Generally, only people on the research team will know that you are in the research study. However, sometimes other people at Cleveland Clinic may see or give out your information. These include people who review research studies including the Institutional Review Board and Research Compliance, their staff, lawyers, or other Cleveland Clinic staff.

People outside Cleveland Clinic may need to see your information for this study. Examples include government groups (such as the Food and Drug Administration), safety monitors, other hospitals in the study and the sponsor of the research and their agents. Cleveland Clinic will do our best to ensure your information is kept confidential and that only the health information which is minimally required to conduct the study is used or disclosed to people outside Cleveland Clinic; however, people outside Cleveland Clinic who receive your information may not be covered by this promise.

You do not have to give this permission to use and give out your information; however you will not be able to participate in this research study without providing this permission by signing this consent form. The use and disclosure of your information has no expiration date.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U. S. law. This Website will not include information that can identify you. At most, the Website will include a summary of the results. You can search the Website at any time.

You may cancel your permission to use and disclose your information at any time by notifying the Principal Investigator in writing, Dr. Michael Sprague, 2950 Cleveland Clinic Blvd, Weston, FL 33331. If you do cancel your permission to use and disclose your information, your participation in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in the study.

## **9. CONFLICT OF INTEREST**

**Do the researchers or institution have any conflicts of interest relating to this study?**

None of the researchers or the institution has any conflicts of interest relating to this study.

## **10. QUESTIONS**

**Who do you call if you have any questions or problems?**

If you have any questions or problems, please call 954-659-5559 to speak with Dr. Michael Sprague or Dr. Sara Farag, or you may call the Institutional Review Board at (800) 223-2273 Ext 42924. If you are calling after regular office hours, you may call 954-689-5000.

## **11. VOLUNTARY PARTICIPATION**

**What are your rights as a research participant?**

Taking part in this study is voluntary. You will be told of any new, relevant information from the research that may affect your health, welfare, or willingness to continue in this study. You may choose not to take part or may leave the study at any time. Withdrawing from the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to withdraw from the study you should discuss with your study doctor your decision to ensure a safe withdrawal.

## **12. SIGNATURES**

**Statement of Participant**

I have read and have had verbally explained to me the above information and have had all my questions answered to my satisfaction. I understand that my participation is voluntary and that I may stop my participation in the study at any time. Signing this form does not waive any of my legal rights. I understand that a copy of this consent will be provided to me. By signing below, I agree to take part in this research study.

\_\_\_\_\_  
Printed name of Participant

\_\_\_\_\_  
Participant Signature

\_\_\_\_\_  
Date

**Statement of Person Conducting Informed Consent Discussion**

I have discussed the information contained in this document with the participant and it is my opinion that the participant understands the risks, benefits, alternatives and procedures involved with this research study.

\_\_\_\_\_  
Printed name of person obtaining consent

\_\_\_\_\_  
Signature of person obtaining consent

\_\_\_\_\_  
Date