The Ohio State University Combined Consent to Participate in Research and HIPAA Research Authorization

Study Title: **Spontaneous Void Requirements for Patients Undergoing Ambulatory Anorectal Surgery**

Principal Investigator: **Syed Husain, MD**

Sponsor: **The Ohio State University Wexner Medical Center**

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.
- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.
- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

1. Why is this study being done?

You are being asked to participate in this research study because you are scheduled for anorectal surgery at the Ohio State University Wexner Medical Center.

Urinary retention, or inability to empty the bladder, is a common complication after anorectal surgery that can lead to increased bladder infections, hospital readmission, damage to bladder muscles, and increased confusion in the elderly. The rate of urinary retention after anorectal surgery is between 16-20%. Urinary retention may occur as a consequence of painkillers used during surgery, or irritation to nerves in the area below the waist. As a result, spontaneous urination is a common discharge requirement for many post-anesthesia care units.

However, a recent review found that patients can be safely discharged without urinating after anorectal procedures without increasing the risk of emergency department visits or readmissions. Furthermore, a requirement to urinate before discharge may significantly prolong a patient's hospital stay without much added benefit. However, this research is limited.

As a result, this study is being done to compare hospital readmissions, complications, and emergency room visit rates between patients at The Ohio State University Wexner Medical Center who are required to urinate in the post-anesthesia care unit (PACU) after surgery, to those who are sent home without the requirement to urinate after surgery. We hope to find that not requiring patients to urinate prior to discharge will result in shorter lengths of stay in the post-anesthesia care unit without increasing hospital readmissions or emergency room visits.

2. How many people will take part in this study?

100 patients will take part in this study.

3. What will happen if I take part in this study?

If you agree to take part in this study, you will be randomly assigned to one of two groups. This means that you will have a 1 out of 2 chance to be assigned to one of the following groups:

- Group 1 will be required to urinate spontaneously after surgery before being sent home. This is the current standard procedure at the OSUWMC PACU.
- Group 2 will be sent home after surgery without specific requirement to urinate after surgery.

All other discharge criteria will remain the same per standard hospital guidelines. There will be about 50 participants assigned to each group. Patients in each group will complete a follow-up questionnaire over the phone about 30 days after surgery to assess hospital readmissions and emergency room visits over the 30 day period. In addition, the study team will access your medical records to obtain information from before and after surgery, including information on demographics, medical and surgical history, anorectoral surgery and outcomes, length of hospital stay, and any hospital readmissions after surgery.

4. How long will I be in the study?

Your participation in this study will last ~1 month. You will be asked to participate in a brief phone call 30 days after your surgery. This phone call will take approximately 10-15 minutes to complete. The study team will collect information about any hospital readmissions that occur up to 30 days after you leave the hospital post-surgery.

5. Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

6. What risks, side effects or discomforts can I expect from being in the study?

Risks Associated with No Spontaneous Urination:
If you are randomized to the study group that is not required to spontaneously urinate after surgery, there is a risk that you may experience more complications or hospital readmissions than if you had been required to urinate.

Loss of confidentiality:
One potential risk of participating in this study is that confidential information about the subject may be accidentally disclosed. We will use our best efforts to keep the information about you secure, and we think the risk of accidental disclosure is very small.

7. What benefits can I expect from being in the study?

You may or may not benefit from participating in this study.

If you are randomized to the study group that is required to spontaneously urinate after surgery, there is a chance that you may experience fewer complications or hospital readmissions than if you had not been required to urinate.

There is also a chance that if you are not required to urinate after surgery you will be able to leave the hospital sooner without additional complications.

Your participation in this research may benefit other anorectal surgery patients in the future.

8. What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

9. What are the costs of taking part in this study?

There will be no cost to you for your participation other than the potential cost of telephone charges. The costs for your standard of care procedures will be billed to you or your insurance.

10. Will I be paid for taking part in this study?

You will not be paid for taking part in this study.

11. What happens if I am injured because I took part in this study?

If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Wexner Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

12. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

13. Will my study-related information be kept confidential?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;

- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

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.

14. HIPAA AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

I. What information may be used and given to others?

- Past and present medical records;
- Research records;
- Records about phone calls made as part of this research;
- Records about your study visits;
- Information that includes personal identifiers, such as your name, or a number associated with you as an individual;
- Information gathered for this research about:
  Laboratory, x-ray, and other test results
  Diaries and questionnaires

II. Who may use and give out information about you?

Researchers and study staff.

III. Who might get this information?

- The sponsor of this research. "Sponsor" means any persons or companies that are:
  - working for or with the sponsor; or
  - owned by the sponsor.
- Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information;
- If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic or physician's office record.

IV. Your information <u>may</u> be given to:

- The U.S. Food and Drug Administration (FDA), Department of Health and Human Services (DHHS) agencies, and other federal and state entities;
- Governmental agencies in other countries;

- Governmental agencies to whom certain diseases (reportable diseases) must be reported; and
- The Ohio State University units involved in managing and approving the research study including the Office of Research and the Office of Responsible Research Practices.

V. Why will this information be used and/or given to others?

- To do the research;
- To study the results; and
- To make sure that the research was done right.

VI. When will my permission end?

There is no date at which your permission ends. Your information will be used indefinitely. This is because the information used and created during the study may be analyzed for many years, and it is not possible to know when this will be complete.

VII. May I withdraw or revoke (cancel) my permission?

Yes. Your authorization will be good for the time period indicated above unless you change your mind and revoke it in writing. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the researchers. If you withdraw your permission, you will not be able to stay in this study. When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

VIII. What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study and receive research-related treatment. However, if you are being treated as a patient here, you will still be able to receive care.

IX. Is my health information protected after it has been given to others?

There is a risk that your information will be given to others without your permission. Any information that is shared may no longer be protected by federal privacy rules.

X. May I review or copy my information?

Signing this authorization also means that you may not be able to see or copy your study-related information until the study is completed.

15. Who can answer my questions about the study?

For questions, concerns, or complaints about the study, or if you feel you have been harmed as a result of study participation, you may contact **Syed Husain, MD at 614-293-3230**.

For questions related to your privacy rights under HIPAA or related to this research authorization, please contact:

HIPAA Privacy Officer
600 Ackerman Road, Suite E2140
Columbus, OH 43202

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact Ms. Sandra Meadows in the Office of Responsible Research Practices at 1-800-678-6251.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact **Syed Husain, MD at 614-293-3230**.

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this combined consent and HIPAA research authorization form**.**

Printed name of subject	**Signature of subject**
	AM/PM
	Date and time
Printed name of person authorized to consent for subject (when applicable)	**Signature of person authorized to consent for subject (when applicable)**
Relationship to the subject	**AM/PM** **Date and time**

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent	**Signature of person obtaining consent**
	AM/PM
	Date and time

Witness(es) - *May be left blank if not required by the IRB*

Printed name of witness	**Signature of witness**
	AM/PM
	Date and time
Printed name of witness	**Signature of witness**
	AM/PM
	Date and time