

Patient-Centered Outcomes in the Surgical Treatment of Uterovaginal Prolapse

NCT05063331

04/29/2025

Institutional Review Board  
Informed Consent Document for Research  
STUDY-WIDE CONSENT

Study Title: PREMIER Trial: Patient-Centered Outcomes of Sacrocolpopexy versus Uterosacral Ligament Suspension for the Treatment of Uterovaginal Prolapse

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**Part 1 of 2: STUDY-WIDE CONSENT**

***You are being invited to take part in a research study. This study is a multi-site study, meaning it will take place at several different locations. Because this is a multi-site study this consent form includes two parts. Part 1 of this consent form is the Study-wide Consent and includes information that applies to all study sites. Part 2 of the consent form is the Study Site Information and includes information specific to the study site where you are being asked to enroll. Both parts together are the legal consent form and must be provided to you.***

**Key Information:** The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

**Why am I being invited to take part in a research study?**

You are being invited to participate in this research study because you have been diagnosed with uterovaginal prolapse (UVP) and have indicated that you want to have surgery. A prolapse is when an organ in the body slips out of place. Uterovaginal prolapse happens when muscles and ligaments weaken and become unable to hold the uterus in position. This can result in problems with urination or defecation, feeling pressure or pain, and a bulge in the vagina or tissue bulging out from the vagina.

**Things I should know about a research study**

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

**Introduction/Purpose**

The purpose of this study is to compare the two most common corrective surgeries in the U.S. for uterovaginal prolapse (UVP). No high-quality data exists to help guide patients and surgeons on the best option for treatment of UVP. The goal of the study is to determine which surgery works best from a patient's perspective and has the lowest number of short-term and long-term medical problems. We will track the outcomes for each type of surgery and explore

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what is most important to women when deciding on a treatment option. One surgery being studied is done through a cut (incision) made in the vagina—this is called a vaginal approach. The other surgery is done through small cuts (incisions) in your lower belly (abdomen)—this is called an abdominal approach. More information about the two kinds of surgeries involved in this study is provided later in this form.

The study will enroll 320 participants at multiple medical centers. You will only be invited to participate in this study if your surgeon considers that both types of surgery in this study are suitable for your care. Both types of surgery are performed regularly and are considered standard options for patients with UVP. Neither surgery itself is considered experimental; however, in this study, you will be assigned (randomly, by chance) to receive one surgery or the other surgery, instead of making the decision yourself. If you prefer to choose which surgery you are going to have, you should not participate in this study. The participants in the study will be equally divided between the two surgeries. Some questionnaires in the study are being tested out to see if they can be used in the future.

You do not have to be in this research study. You can ask all the questions you want and take as much time as you need before you decide. You may choose not to be in this study and get treatment without any consequences to your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study.

**Key Study Procedures**

If you join this study, the study will decide which type of surgery you will have for UVP. We will collect the information from the medical visits (outpatient and inpatient) related to your care leading up to surgery and for 3 years following your surgery. You will be asked to complete questionnaires about your symptoms and how UVP affects your quality of life. The questionnaires are often used in usual patient care, but we are asking you to complete them specifically for research purposes. Completing the questionnaires will take about 40 minutes or less at each of your 6 outpatient care visits over 3 years and about one hour of time over the two weeks following your surgery.

If you are a patient at University Hospitals Cleveland Medical Center or the Cleveland Clinic, you also may be asked to participate in an optional Interview Sub-study. A total of up to 40 participants will be invited to complete this sub-study. It consists of 3 interviews that are about

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one hour each. If you are invited to participate, there is a separate consent form for the sub-study with more details.

More detailed information about the study procedures can be found under “Detailed Study Procedures”.

**Key Risks**

There are risks associated with each type of surgery. Since you will not be choosing which surgery you receive in this study, the key risk is that you may be exposed to risks with one surgery that are different than the risks of the other surgery. More detailed information about the risks of this study can be found under “Detailed Risks.”

**Key Benefits**

Being in this study will not help you directly. The benefits to science and humankind that might result from this study are that we may better understand which surgery is best from a patient perspective and help health care providers create an individualized approach for surgical treatment of pelvic organ prolapse.

**Alternatives to Study Participation**

You do not have to be in this study to get health care at this medical center. Your condition can be treated without your participation in this study. Treatment alternatives will be discussed with your doctor. Ask your study doctor to talk about the options with you along with their risks and benefits.

**Detailed Information: The following is more detailed information about this study in addition to the information listed above.**

**Detailed Study Procedures**

The two kinds of surgery for UVP that we are studying are outlined below. These are only brief descriptions. Your surgeon will explain the surgical procedures and recovery in detail and answer any questions you have.

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<p><b>1. Total vaginal hysterectomy with uterosacral ligament suspension (vaginal approach)</b></p> <ul style="list-style-type: none"><li>• The surgical incision (cut) is made in your vaginal wall.</li><li>• Total hysterectomy is removal of the uterus and cervix</li><li>• Uterosacral ligament suspension is a procedure where the vaginal walls are stitched to a deep ligament of the pelvis to fix the prolapse.</li><li>• Surgery lasts approximately 2 – 2 ½ hours</li></ul>	<p><b>2. Minimally invasive supracervical hysterectomy with sacrocolpopexy using FDA-approved abdominal mesh (abdominal approach)</b></p> <ul style="list-style-type: none"><li>• Small surgical incisions (cuts) are made in your lower abdomen</li><li>• Supracervical hysterectomy is removal of the uterus while leaving the cervix in place</li><li>• Sacrocolpopexy is a procedure where a graft of mesh (like a patch) is sewn onto the cervix to fix the prolapse. The mesh is anchored with stitches to strong tissue in the pelvic area, usually a bony area at the base of the spinal column.</li><li>• FDA-approved abdominal mesh products are routinely used in this type of surgery. This is different from vaginal mesh that was previously FDA-approved and then banned and removed from the market.<ul style="list-style-type: none"><li>• This surgery may be done either laparoscopically (using a thin, lighted scope with a camera on the end) or with robot assistance (where the surgeon uses a computer to control the surgical instruments), depending on your surgeon's choice.</li></ul></li><li>• Surgery lasts approximately 3 - 4 hours</li></ul>
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The following things will be the same for both surgeries:

- Use of permanent or dissolvable stitches
- Management of pain and nausea
- Anticipated pain, nausea and recovery time
- Recommendations for resuming regular activities

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If you want to join the study, we will review your medical record and ask you some questions to determine if you are eligible to be in the study. If you are eligible and decide to join the study, we will collect information about your medical history and your UVP diagnosis and treatment plan. We will ask you to complete some questionnaires focused on your symptoms and how UVP affects your daily activities and your quality of life.

You will be randomized (selected by chance) to one of the two surgeries for UVP. Your surgery assignment will be chosen by a computer program-neither you nor your physician will control the choice. You will have a 50% (or 1 in 2) chance of being assigned to the surgery with the vaginal approach or the surgery with the abdominal approach. You will be informed of your assignment after your surgery.

You will complete brief questionnaires just prior to surgery and over the 8 weeks following surgery. There will be one phone call where we will ask you about how you have been feeling since surgery and any medication you took for pain or nausea within the two weeks after surgery.

You will have the usual schedule of clinical follow up visits over the next 3 years which will include any exams or testing that your doctor does for your ongoing care. At these outpatient clinic visits, we will also do the following things for this study: 1) you will be asked to complete the study a Questionnaire Packet, and 2) we will ask you about any new or worsening symptoms and about any changes in your health. Information (data) related to your care will be collected from your medical records throughout the length of the study—this will include detailed information from your pre-surgery doctor visits, your hospitalization for the surgery, and your clinical follow up visits with your doctor for 3 years.

Data Collection: The type of data that we will collect for the study includes: your date of birth, your medical history including medications, the dates and medical notes from your clinical visits related to the diagnosis and treatment for UVP and any follow-up (this may include test results and information from exams and procedures). Some measurements (for example, cervical length) may be taken during surgery for research purposes. We will also collect standard information that is collected for many research studies like your race and ethnicity, your zip code, your education history, and your employment status and income level. We will collect most of this information from your medical record and some of it by asking you directly or having you fill out a form.

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Questionnaires: The questionnaires will be available to complete online or on paper. If there is a technical issue, we can also administer the questionnaire verbally and record your answers. To complete the questionnaires online, we may send them to your email address. We would like to provide them to you in whatever method is most convenient for you at each time point during the study. The questionnaires will cover a variety of topics including:

- How much pain and nausea you experience
- Bladder and bowel functioning (problems with urination/defecation)
- Sexual function and body image
- How UVP affects your activities and feelings in daily life
- Your satisfaction level with your medical care

Changes in your health: Throughout the study, we will ask you about any changes in your health and whether you have had any new or worsening symptoms.

Keeping in contact: Throughout the study, we will contact you to confirm research visits. We may also need to reach you regarding scheduling, to give you an update about the research, ask about changes in your health, or to check in with you on completing the questionnaires. Usually, we will contact you by phone. However, we will also give you a separate form to fill out with any alternate preferred methods of contact (for example, text message, email).

The table below shows a summary of each study visit. Whenever possible, the study visits will be done at the same time as your patient care visits. If we are unable to collect all the information we need for the study from you at your scheduled visit, we may call you to collect this by phone. If completed by phone, this would not exceed the lengths of time estimated below for these study activities.

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**Study Visit Summary**

Visit #	Timing	Study Procedures
1	Baseline -- Up to 12 months before surgery	<ul style="list-style-type: none"> <li>Review medical history, demographics and any changes in your health or symptoms (<i>about 15 minutes</i>)</li> <li>Questionnaire Packet (<i>about 40 minutes</i>)</li> </ul>
2	Day of surgery (or 1-3 days before surgery)	<ul style="list-style-type: none"> <li>Brief questionnaires before surgery (<i>about 1 minute</i>)</li> </ul>
	At home after surgery	<ul style="list-style-type: none"> <li>Brief questionnaires 1 day after surgery and then weekly for 8 weeks after surgery (<i>about 1-5 minutes each time</i>)</li> <li>One phone call (2 weeks after surgery) to review any changes in your health or symptoms <i>and to ask to about use of pain and nausea medication</i> (<i>about 10 minutes</i>)</li> </ul>
3	2 months after surgery	At each of these visits: <ul style="list-style-type: none"> <li>Review any changes in your health and symptoms (<i>about 10 minutes at each visit</i>)</li> <li>Questionnaire Packet (<i>about 30 minutes at each visit and 40 minutes at the 6 month visit</i>)</li> </ul>
4	6 months after surgery	
5	1 year after surgery	
6	2 years after surgery	
7	3 years after surgery	

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**Study Results**

Your scores on the questionnaires that you complete for the study will not be shared with you.

**Detailed Risks:**

Surgery: Your surgeon will be explaining the risks of both surgeries in detail with you. The risks are summarized below. Like many other surgeries, there is a risk of life-threatening or fatal complications, although that is not expected. Your risks may vary depending on your age, your overall health, and the severity and type of your prolapse. Before the surgery, talk with your healthcare provider about all your concerns.

Risks related to both surgeries -- vaginal approach and abdominal approach	
Infection, excess bleeding, pain, cramping, vaginal bleeding, vaginal discharge, constipation, bowel obstruction, overactive bladder, urinary incontinence, bladder infection, blood clots in the legs, blood clots that can travel to the lungs and cause breathing problems, injury to nearby organs (such as the bowel or ureters), wound healing problems, pain during sexual intercourse, failure of the organs to stay in place, return of prolapse symptoms, need for more surgery	
General surgery risks: heart and lung complications, stroke, reaction to anesthesia, nausea	
Risks specific to surgery with the vaginal approach	Risks specific to surgery with the abdominal approach
<ul style="list-style-type: none"><li>• Breakdown of the vaginal incisions</li><li>• Ureteral obstruction or kinking</li></ul>	<ul style="list-style-type: none"><li>• Infection in the mesh</li><li>• Mesh becomes exposed in the vagina</li></ul>

Questionnaires: Some of the questions may cause you to feel uncomfortable because they ask about your experiences with UVP. You have the option to not answer any questions. As there are several questionnaires, it may be tiring or boring to complete them. Some questions ask about your mood; if any responses show distress that you and your study doctor are not already managing, your study doctor may check in with you and provide resources.

Breach of confidentiality: There is a risk that someone without our permission might view your data either by accident or by hacking the data. We are protecting against this by keeping all of the data separate from your name and in password protected documents/databases on secure computers/systems.

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Risks that are not known: There may be risks that we do not know about at this time.

**Reasons why the study doctor may take you out of this study**

The study doctor may end your participation in this study if you do not complete the study visits/study assessments or if there are concerns for your health and safety.

**What will happen if you decide to stop being in this study?**

If you decide to stop being part of the study, you should tell your study doctor. If you decide not to participate in the study, it will not change your regular medical care in any way.

**Clinical Trials Registry**

U.S. NATIONAL INSTITUTES OF HEALTH (NIH) CLINICAL TRIAL DATABASE: A description of this clinical trial will be available on <https://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 this website at any time to find out information about the trial and basic results. The ClinicalTrials.gov Identifier to look up this study is: NCT05063331

**Confidentiality**

Your data and study records will be labelled with a unique ID number to maintain confidentiality and no other identifiers will be stored. Your name will only appear on your consent form and on a Linking Log that connects your name to your unique Study ID—these documents will be stored in secure locations with access limited to the local study team.

Efforts will be made to keep the personal information in your research record confidential, but absolute confidentiality cannot be guaranteed. The University Hospitals Cleveland Medical Center Institutional Review Board may review your study records. If your records are reviewed your identity could become known.

Your data will be shared with our collaborators at Case Western Reserve University, Cleveland Clinic, MetroHealth Medical Center, Duke University Medical Center, the University of Pittsburgh, Mayo Clinic, and Northwestern University; however, the only personal identifiers that are being shared among this group are your zip code and dates associated with your care and your study visits (this is called a limited data set). We will remove all personal identifiers when we share the data with the U.S. National Institute of Child Health and Human Development (this is called a de-identified data set). We will be contributing to the NICHD Data

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and Specimen Hub (DASH), which is a database that allows researchers to share and access de-identified data from studies funded by the NICHD.

This study receives funding from NICHD, which is part of the U.S. National Institutes of Health (NIH), and so your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means. It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

**Future Use of De-identified Data**

If identifiers are removed from your identifiable private information that is collected during this research, that information could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

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**Part 2 of 2: STUDY SITE INFORMATION**

Site Name:	University Hospitals Cleveland Medical Center
Site Principal Investigator:	Adonis Hijaz, MD
Site Principal Investigator Contact:	(216) 844-3009

***This part of the consent form includes information about the site that is asking you to participate in this study and is specific to participation at your site only. Before making your decision, both the site-specific information and the general study information should be reviewed with you. Your medical record will contain a note saying you are in a research study and may contain some research information about you. Anyone you authorize to receive your medical record will also get this information.***

**Financial Information**

After each study visit listed below that you complete, you will receive a \$25.00 payment for your time spent taking part in this study. Payments will be made in the form of a Visa or Mastercard gift card or a retail gift card that is given to you in person or by mail. If you complete all of the study visits, this will add up to \$175.00 in total. If your visit is at a location with parking fees, you will be given a parking voucher for free parking for that day.

Visit 1 Baseline, before surgery	Visit 2* Surgery and post- surgery	Visit 3 Two months after surgery	Visit 4 Six months after surgery	Visit 5 One year after surgery	Visit 6 Two years after surgery	Visit 7 Three years after surgery
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\*Your payment for Visit 2 will be processed after you complete the Post-surgery Phone Call two weeks after surgery. The payments for all other visits will be processed immediately after the day of your visit.

To receive payment you must agree to complete a W-9 form which requires you to provide an address and social security number to the accounting department. This payment to you may be considered taxable income by the IRS. You will be issued a 1099-Misc form only if payment exceeds \$600 from all studies in which you are participating, in a fiscal year.

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**Costs to you if you take part in this study**

This study is not paying for any of your medical bills. We recommend that you contact your insurance provider to determine your level of coverage. You are responsible for all of the costs of your clinical care including:

- All of your related pre-operative outpatient consultation/s
- Pre-operative testing
- Your hospitalization and surgical procedures
- Any medications prescribed for your medical care
- Any laboratory testing related to your medical care
- All of your related post-operative care and follow-up outpatient visits

Notice for Managed Care (Medicare Advantage Plan) Beneficiaries Certain services provided to you as a participant in a clinical trial are allowable to be billed to, and paid by, your medical insurance. These services are referred to as “covered” clinical trial services. If you have a Medicare Advantage Plan as part of your medical insurance, the Centers for Medicare & Medicaid Services (CMS) require that traditional Medicare will be billed for those covered clinical trial services. When this occurs, you will remain responsible for paying the coinsurance and deductibles according your Medicare Advantage Plan. Your Medicare Advantage Plan should cover any associated cost share related to Medicare. Please speak with a financial counselor to understand what the specific financial impact will be for you associated with participating in this clinical trial.

**Medical Records from Outside of University Hospitals (UH)**

If you are receiving medical care for your condition from a clinical facility outside of UH and your outside medical records are needed for this study, we will ask you to sign a “Release of Information” form so that we can obtain those medical records.

**Research-Related Injury**

In the event you suffer a research-related injury as a result of being in this study, University Hospitals is available to provide medical treatment for such injury. Provision of such medical treatment does not imply any negligence or other wrongdoing on the part of University Hospitals, the Sponsor or any of the physicians or other study personnel. If you believe that you have been injured as a result of participating in the study, please immediately contact the Principal Investigator or your study doctor at University Hospitals. If you cannot reach the Principal Investigator or your study doctor, do not delay treatment. You may seek treatment by another doctor. If you are seen or treated by a doctor other than the Principal Investigator or

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your study doctor, you should inform such doctor that you are in this study and, if possible, take this document with you to assist with your treatment. Always contact the Principal Investigator or your study doctor to alert them of any treatment you receive for an injury or illness you experience during this Study.

The costs for medical treatment as a result of a research-related injury may be billed to you or your medical insurance plan, if applicable. Medical insurance plans may or may not cover costs for medical treatment of research-related injuries. If you have insurance, you should check with your medical insurance plan before deciding to participate in this research study. In the event your medical insurance plan covers some or all of the treatment costs, you may still be responsible for co-pays or deductibles as required by your medical insurance plan.

Neither Sponsor nor University Hospitals has set aside any money to pay you or to pay for your treatment if you suffer a research-related injury as a result of being in the study. There are no plans for University Hospitals or Sponsor to provide other forms of compensation (such as lost wages or other indirect losses) to you for research-related injuries. You are not waiving any legal rights by signing this form, including the right to seek compensation for an injury. To help avoid injury, it is very important to follow all study directions.

**Who to call for any questions or in case you are injured**

In the event of any research-related injuries, call the Study Coordinator at (216) 844-8092 or the Principal Investigator at (216) 844-3009.

If you have any questions, concerns or complaints about the study in the future, you may also contact them later.

If the researchers cannot be reached, or if you would like to talk to someone other than the researcher(s) about; concerns regarding the study; research participant's rights; research-related injury; or other human subject issues, please call the University Hospitals Cleveland Medical Center's Research Subject Rights phone line at (216) 983-4979 or write to: The Associate Chief Scientific Officer, The Center for Clinical Research, University Hospitals Cleveland Medical Center, 11100 Euclid Avenue, Lakeside 1400, Cleveland, Ohio, 44106-7061.

**Your Patient Care**

If your treating gynecologist is also a study doctor, they have an interest in your care and in the research. You do not need to be in the study to get care, and you can ask for a second opinion

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at any time.

**Student/Employee Rights**

If you are an employee or student at University Hospitals Cleveland Medical Center (UH) or Case Western Reserve University (CWRU), choosing not to participate or withdrawing from this study will not affect your employment or class standing, nor will the results be shared with your supervisor (unless your supervisor is also a member of the study team).

**Termination of Participation**

The Principal Investigator may end your participation in this study if you do not complete the study visits/study assessments or if there are concerns for your health and safety.

**Authorization to Use/Disclose Protected Health Information**

The Health Insurance Portability & Accountability Act (HIPAA) is a Federal law that helps to protect the privacy of your health information and to whom this information may be shared within and outside of University Hospitals. This Authorization form is specifically for a research study entitled "*Patient-centered Outcomes of Sacrocolpopexy versus Uterosacral Ligament Suspension for the Treatment of Uterovaginal Prolapse*" and will tell you what health information (called Protected Health Information or PHI) will be collected for this research study, who will see your PHI and in what ways they can use the information. In order for the Principal Investigator, Dr. Adonis Hijaz, and the research study staff to collect and use your PHI, you must sign this form. You will receive a copy of this signed form for your records. If you do not sign this form, you may not join this study. Your decision to allow the use and disclosure of your PHI is voluntary and will have no impact on your treatment at University Hospitals. By signing this form, you are allowing the researchers for this study to use and disclose your PHI in the manner described below.

Generally, the Principal Investigator and study staff at University Hospitals and Case Western Reserve University who are working on this research project will know that you are in a research study and will see and use your PHI. The researchers working on this study will collect the following PHI about you: your zip code and dates related to you and your medical care and your study visits, your name, medical record number, address, phone number, email and Social Security Number. This PHI will be used for the study to compare two surgeries for the management of uterovaginal prolapse. The only PHI that we will share with outside collaborators are dates related to your care and your zip code; the other PHI (your name, medical record number, address, phone number, email and Social Security Number) are only

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collected and used to contact you for the study and to process your payments and will not be shared outside of UH & CWRU. Your access to your PHI may be limited during the study to protect the study results.

Your PHI may also be shared with the following groups/persons associated with this research study or involved in the review of research: our collaborators at the Cleveland Clinic, MetroHealth Medical Center, Duke University Medical Center, University of Pittsburgh Medical Center, and Mayo Clinic; The U.S. National Institute of Child Health and Human Development (NICHD); other staff from the Principal Investigator's medical practice group; University Hospitals, including the Center for Clinical Research and the Law Department; any UH or CWRU employee required to process information for research, finance, compliance, or hospital operation, and Government representatives or Federal agencies, when required by law. It is possible, that in the future, additional research sites may be added. In this event, your PHI that was collected during this research project may be shared with research personnel at these additional sites.

Your permission to use and disclose your PHI does not expire. However, you have the right to change your mind at any time and revoke your authorization. If you revoke your authorization, the researchers will continue to use the information that they previously collected, but they will not collect any additional information. Also, if you revoke your authorization you may no longer be able to participate in the research study. To revoke your permission, you must do so in writing by sending a letter to Dr. Adonis Hijaz, Urology Institute, 11100 Euclid Avenue, Cleveland, OH 44106; If you have a complaint or concerns about the privacy of your health information, you may also write to the UH Privacy Officer, Management Service Center, 3605 Warrensville Center, MSC 9105, Shaker Heights, OH 44122 or to the Federal Department of Health and Human Services (DHHS) at DHHS Regional Manager, Office of Civil Rights, US Department of Health and Human Services Government Center, JF Kennedy Federal Building, Room 1875, Boston, MA 02203. Complaints should be sent within 180 days of finding out about the problem.

The researchers and staff agree to protect your health information by using and disclosing it only as permitted by you in this Authorization and as directed by state and Federal law. University Hospitals is committed to protecting your confidentiality. Please understand that once your PHI has been disclosed to anyone outside of University Hospitals, there is a risk that your PHI may no longer be protected; however other Federal and State laws may provide continued protection of your information.

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Informed Consent Document for Research  
STUDY SITE INFORMATION

Study Title: PREMIER Trial: Patient-Centered Outcomes of Sacrocolpopexy versus Uterosacral Ligament Suspension for the Treatment of Uterovaginal Prolapse

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**If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.**

**Future Use of Identifiable Data**

It is possible that some of the identifiable data collected during this research project may be helpful for other project(s) as well. If this is the case, we would like to ask your permission to use your identifiable data in these project(s). Please check the box that correctly indicates your choice. The identifiable pieces of information would include your zip code and dates related to you and your medical care and your study visits.

- ☐ My identifiable data may be used for this project only.
- ☐ My identifiable data may be used for future research.

**Summary of Your Rights as a Participant in a Research Study**

Your participation in this research study is voluntary. Refusing to participate will not alter your usual health care or involve any penalty or loss of benefits to which you are otherwise entitled. If you decide to join the study, you may withdraw at any time and for any reason without penalty or loss of benefits. De-identified data from this study may be published, presented, or otherwise made publically available. If this happens, your identity will not be revealed. In the event new information becomes available that may affect the risks or benefits associated with this study or your willingness to participate in it, you will be notified so that you can decide whether or not to continue participating. If you experience physical injury or illness as a result of participating in this research study, medical care is available at University Hospitals Cleveland Medical Center (UHCMC) or elsewhere; however, UHCMC has no plans to provide free care or compensation for lost wages.

**Disclosure of Your Study Records**

Efforts will be made to keep the personal information in your research record private and confidential, but absolute confidentiality cannot be guaranteed. The University Hospitals Cleveland Medical Center Institutional Review Board may review your study records. If this study is regulated by the Food and Drug Administration (FDA), there is a possibility that the FDA might inspect your records. In addition, for treatment studies, the study sponsor and possibly foreign regulatory agencies may also review your records. If your records are reviewed your identity could become known.

Institutional Review Board  
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**Contact Information**

\_\_\_\_\_ has described to you what is going to be done, the risks, hazards, and benefits involved. The Principal Investigator [Dr. Adonis Hijaz] can also be contacted at (216)-844-3009. If you have any questions, concerns or complaints about the study in the future, you may also contact them later.

If the researchers cannot be reached, or if you would like to talk to someone other than the researcher(s) about; concerns regarding the study; research participant's rights; research-related injury; or other human subject issues, please call the University Hospitals Cleveland Medical Center's Research Subject Rights phone line at (216) 983-4979 or write to: The Associate Chief Scientific Officer, The Center for Clinical Research, University Hospitals Cleveland Medical Center, 11100 Euclid Avenue, Lakeside 1400, Cleveland, Ohio, 44106-7061.

**Signature**

Signing below indicates that you have been informed about the research study in which you voluntarily agree to participate; that you have asked any questions about the study that you may have; and that the information given to you has permitted you to make a fully informed and free decision about your participation in the study. By signing this consent form, you do not waive any legal rights, and the investigator(s) or sponsor(s) are not relieved of any liability they may have. A copy of this consent form will be provided to you.

x		
Signature of Participant	Date	Time
x		
Printed Name of Participant		

x		
Signature of person obtaining informed consent	Date	Time
x		
Printed name of person obtaining informed consent		