OHIOHEALTH

CONSENT FORM

TITLE OF STUDY: RANDOMIZED STUDY OF ULTRALOW VERSUS STANDARD PNEUMOPERITONEUM PRESSURE DURING ROBOTIC PROSTATECTOMY USING THE AIRSEAL® INSUFFLATION SYSTEM

PRINCIPAL INVESTIGATOR: RONNEY ABAZA, MD, FACS

We are conducting a clinical trial (a type of research study). Clinical trials include only patients who choose to take part in the study. This consent form serves two purposes. First, it provides information on the procedures and risks involved in the clinical trial, so that you can decide if you want to take part in the study.

Second, this form will ask for your permission to use and release the medical information that we will get from you during this study. Please take your time to make your decision about taking part. You may discuss your decision with your friends and family. If you have any questions, you can ask your study doctor for more explanation.

This study is being funded by CONMED Corporation (the device manufacturer of the AirSeal® Insufflation System).

You are being asked to take part in this study because you are choosing to undergo robotic prostatectomy (prostate removal) surgery with Dr. Ronney Abaza at OhioHealth Dublin Methodist Hospital.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to compare different air pressures used during surgery to create a "pneumoperitoneum," which is an air bubble in the peritoneal cavity (abdomen, or belly area) to allow for the surgeon to have space and see to perform your prostate removal surgery. We will be comparing two different pressures, 6 mmHg and 15 mmHg, to see if the procedure can be performed using less air pressure.

WHAT IS INVESTIGATIONAL ABOUT THIS STUDY?

We are comparing 2 different pressures commonly used in surgery procedures at OhioHealth. We are looking to compare these pressures to look at outcomes following surgery, specifically pain and pain medication use.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

About 192 people will take part in this study locally through OhioHealth Dublin Methodist Hospital.

WHAT WILL HAPPEN IN THE STUDY?

You will be "randomized" into one of the study groups described below. Randomization means that you are put into a group by chance. It is like flipping a coin. A computer will decide which group you are in. Neither you nor the study doctor will choose what group you will be in. You will have an equal chance of being placed in either group. Randomization will occur at the time of surgery when the randomization envelope is opened by the Clinical Research Coordinator.

Control Group: 15 mmHg air pressure
Study Group: 6 mmHg air pressure

All patients will follow routine care with the surgeon, Dr. Abaza. The only other study activities include questionnaires, as described below.

Study Calendar.

	First Office Visit	**Surgery/ Hospital Stay**	**Days 1-2** *(at home)*	**1-Week Visit**	**1-Month Visit**	**3-Month Visit**
Consent	x					
Randomization		X*				
Office Visit	x			x	x	x
Post-Operative Questionnaire		x				
Post-Discharge Questionnaire			x			
Follow-Up Questionnaire				x	x	x
Quality of Recovery Questionnaire				x		
Phone Calls			x			

*Randomization will occur at time of surgery

- Post-Operative Questionnaire:
  - We will ask you to rate your pain every 2 hours while you are in the hospital, and right before you are discharged (sent home). We will ask about pain in 5 different body locations, and ask you to rate your pain on a scale of 0 (no pain) to 10 (worst possible pain).
  - We will ask you to rate your pain a maximum of 13 times while you are in the hospital, depending on when you are sent home and if you are awake or not.
  - We will also ask whether you were able to pass gas in the hospital prior to being sent home. We will ask you this a maximum of 4 times until you are able to pass gas.
- Post-Discharge Questionnaire:
  - If you are discharged the same day as your surgery, we will call to get your last pain scores the next day.

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  - If you are unable to pass gas while in the hospital, we will ask you about this as well when we call to ask about your pain.
  - If you are still unable to pass gas the day after you are sent home, we will call and ask again the next day as well, and the next day, until you are able to pass gas.
- Follow-Up Questionnaire:
  - At your regular follow-up visits with your doctor, we will ask questions related to your medications, pain, and weakness, which should take only a few minutes to complete.
  - This questionnaire will be completed a total of 3 times at each follow-up visit: 1 week, 1 month, and 3 months.
- Quality of Recovery (QoR)-15 Questionnaire:
  - At your regular follow-up visit with your doctor at 1 week, we will ask questions related to your quality of life after surgery, which should take only a few minutes to complete.

How Long Will I Be In The Study?

You will be in the study for 3 months.

You can stop being a part of this study at any time. However, if you decide to stop being in the study, please talk to the study doctor first.

What Are The Risks Of The Study?

There are no physical risks expected to be associated with the use of less air pressure (6mmHg versus 15mmHg) during surgery.

There may be side effects that we cannot predict. Many of these side effects are often manageable and reversible. You will be observed for side effects and all medically appropriate efforts will be made to prevent and/or control them. If there are side effects that cannot be controlled or reversed, they may result in serious injury or death.

YOU SHOULD REPORT ANY OF THESE PROBLEMS TO THE STUDY DOCTOR IMMEDIATELY SO THAT APPROPRIATE CARE CAN BE GIVEN. SIDE EFFECTS OTHER THAN THOSE LISTED HERE MAY ALSO OCCUR. TALK TO THE STUDY DOCTOR ABOUT ANY SIDE EFFECT THAT SEEMS UNUSUAL OR THAT IS ESPECIALLY BOTHERSOME TO YOU.

Are There Benefits To Taking Part In The Study?

If you agree to take part in this study, there may or may not be direct medical benefit to you. While doctors hope that treatment with a lower air pressure of 6 mmHg will be more beneficial, as compared to the usual air pressure of 15 mmHg, there is no proof of this. We do know that the information from this study will help doctors learn more about using lower air pressures during robotic prostate removal surgery. This information could help future patients with your condition.

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WHAT OTHER OPTIONS ARE THERE?

Instead of being in this study, you have these options:

- Regular treatment with your doctor, which could include either of the air pressures during surgery (6 mmHg or 15 mmHg)

Please talk to your doctor about these and other options.

WHAT ARE THE COSTS?

Taking part in this study will not lead to added costs to you or your insurance company.

While you are in this study, you may receive tests, procedures, and exams that are standard medical care. This standard medical care may or may not be covered by your medical insurance.

If your medical insurance does not pay for this standard medical care, you will be responsible for the cost of medical care related to your condition, including but not limited to tests, deductibles, co-payments, study doctor and clinic fees, hospitalization and procedures.

WHAT IF AN INJURY OCCURS BECAUSE OF THE STUDY TREATMENT?

OHIOHEALTH RESPONSIBILITY:

In the case of injury or illness resulting from this study, emergency medical treatment will be provided. You or your insurance company will be financially responsible for this emergency medical treatment, continuing medical care and/or hospitalization. OhioHealth Corporation has no funds set aside to compensate you in the event of injury or illness.

FUNDING ENTITY RESPONSIBILITY:

You may be at risk of being injured from participating in this research study. If injury occurs, treatment will be available.

The funding entity (CONMED) will not pay for the costs associated with emergency care and treatment. You or your insurance company will be financially responsible for this emergency medical treatment, continuing medical care and/or hospitalization.

COMPENSATION?

You will receive no payment for taking part in this study.

WHAT INFORMATION WILL BE COLLECTED FROM ME FOR USE IN THE STUDY?

The medical information that will be collected from you if you take part in this study includes:

- Information obtained from procedures used to determine your eligibility to take part in the research study, including a routine medical history and physical exam.

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- Information that is created or collected from you during your participation in the study, including your over-all medical condition, the results of your surgery, blood tests, and study questionnaires.
- Information contained in your underlying medical records related to your medical history and treatment prior to this study

The above information may identify you by name, address, telephone number, social security number, health plan number, study number, date of birth, dates relating to various medical procedures, or other identifying information.

WHAT ABOUT CONFIDENTIALITY?

If you sign this form and take part in this study, the study staff will be authorized to use the information described above to carry out the purposes of the research study. The study staff will also be authorized to disclose the information described above to all of the following parties involved in the research study:

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as:

- OhioHealth Institutional Review Board (IRB)
- Funding Entity (CONMED Corporation)
- The U.S. Food and Drug Administration (FDA) and other government agencies.
- The Department of Health and Human Services Office of Human Subject Research Protections
- The Centers for Medicare and Medicaid Services (CMS)
- The financial agent for CMS
- OhioHealth Research and Innovation Institute Office of Regulatory Compliance

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Once your information is disclosed to the study funding entity, the IRB or the government agencies described above, there is a potential that your medical information will be re-disclosed and will no longer be protected by federal privacy regulations.

If we publish the information we learn from this study in a medical journal, you will not be identified by name or in any other way.

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

DO I HAVE THE RIGHT TO DECLINE AUTHORIZATION?

You have the right to decline to sign this authorization to use/disclose your medical information. If you decline, you will not be able to take part in this research study. Except as described herein, if you decline to sign this authorization, your rights concerning treatment, payment for

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services, enrollment in a health plan or eligibility for benefits will not be affected.

How Long Will My Authorization Remain In Effect?

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.

Can I Withdraw My Authorization?

You may withdraw your authorization at any time by sending a written request to the Principal Investigator at:

Ronney Abaza, MD, FACS
OhioHealth Dublin Methodist Hospital
7450 Hospital Drive, Suite #300, Dublin, OH 43016

If you withdraw your authorization:

- Your participation in the study will end
- The study staff will stop collecting your medical information

Your medical information that has already been used and disclosed prior to withdrawing your authorization remains a part of the research study data.

While the research study is in progress, your access to your study records will be temporarily suspended. Afterwards, you have the right to see and copy the medical information collected from you in the course of the study, for as long as that information is maintained by the study staff and other entities subject to federal privacy regulations.

What Are My Rights as a Participant?

Your doctor has answered your questions. You can ask your doctor questions at any time.

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled.

We will tell you about important new information that may affect your health, welfare and willingness to stay in this study.

Whom Do I Call if I Have Questions or Problems?

For questions about the study or a research-related injury, contact the study doctor, Dr. Ronney Abaza, at 614-566-1250.

For questions related to your privacy rights under HIPAA or related to this research

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authorization, please contact the OhioHealth Corporation Office of Ethics and Compliance at 614-544-4200.

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 the Office of Research Compliance at 614-544-4200 or the Office of Regulatory Compliance at 614-566-1748.

STATEMENT OF CONSENT AND AUTHORIZATION

I hereby freely and voluntarily consent to take part in the research study described above. This consent is given based on the verbal and written information provided and the understanding that I am medically and physically qualified to take part in this study. I am free to ask questions at any time.

I have the option to decline to take part or to withdraw from the study at any time without incurring any penalty or loss of benefits otherwise available, including medical care at this institution.

My signature below indicates that I voluntarily agree to take part in this study and that I authorize the use and disclosure of my information in connection with the study. I will receive a signed copy of this consent and authorization form.

_____	_____	_____
Patient Signature	Date	Time
_____	_____	_____
Research Coordinator/ Person Obtaining Consent	Date	Time
_____	_____	
Investigator Signature	Date	

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