Consent Form
University of Oklahoma Health Sciences Center (OUHSC)
Title: A Device to Prevent Female Urinary Stress Incontinence
Sponsor: Watkins-Conti Products, Inc
Robert E. Hurst, PhD, Principal Investigator

This is a clinical trial (a type of research study). Clinical trials include only patients who choose to take part in them. Please take your time to make your decision. Discuss this with your family and friends.

Why Have I Been Asked To Participate In This Study?
You are being asked to take part in this trial/study because you have been diagnosed as having stress urinary incontinence (SUI), which is that you sometimes leak urine when you move in certain ways, exercise, laugh, cough or engage in actions of daily living.

Why Is This Study Being Done?
The purpose of this study is to test whether the Yoni.Fit device will prevent or at least substantially reduce SUI in women and whether women will wish to use it.

What is the Status of the Device Involved in this Study?
The Yoni.Fit is an investigational device that is not approved by the US Food and Drug Administration.

How Many People Will Take Part In The Study?
About 50 people will take part in this study, all of whom will participate at this location.

What Is Involved In The Study?
When you appear for your appointment, you will be asked to void and will be given a liter bottle of water that you will need to drink over the course of the next 15-20 minutes. You will then fill out 4 short questionnaires that we will use to determine how severe your incontinence is. You will also fill out a short health questionnaire that mostly will be used to confirm that you are eligible for the study.

An hour after you have finished drinking your bottle of water, you will be shown how to use the Yoni.Fit. You will then be given the device and a pad, both of which you take to a restroom where you will insert the device as instructed and slip the pad into your underwear. In a private room, you will then perform the following challenges. (a) Stand from sitting 10 times. (b) Cough vigorously while standing. (c) Bend down to pick up small object. (d) Perform ten jumping jacks.

You will then return to the restroom, remove the pad and place it into a sealable plastic bag, place in a new pad, remove the Yoni.Fit and return it and the used pad in its sealed bag to the study coordinator. You will then repeat the challenges without the Yoni.Fit in place and return the second pad in the sealed bag to the Study Coordinator. Half of the patients will perform the challenges in the opposite order without the Yoni.Fit in place first and with the device in place second. You will then fill out a short exit questionnaire. Following this, you are done and will receive a gift card worth $100 as compensation for your time.

How Long Will I Be In The Study?
We think that you will be in the study for an hour and a half to two hours. There may be unanticipated circumstances under which your participation may be terminated by the investigator without regard to your consent, including if you are unable to perform the physical challenges. You can stop participating in this study at any time. However, if you decide to stop participating in the study, you will no longer be eligible to obtain the gift card.

What Are The Risks of The Study?
The risks of the study are minimal. It is possible you may experience some discomfort from inserting the Yoni.Fit. There is a very small risk that you could develop a urinary tract infection.

Are There Benefits to Taking Part in The Study?
If you agree to take part in this study, there likely will not be direct medical benefit to you. We hope that the information learned from this study will help the sponsor to manufacture an effective device to prevent or minimize incontinence. If you are interested, we will put your name on the list for more extensive trials in the future in which you will be allowed to use the Yoni.Fit for an extended period of time.

What Other Options Are There?
Your only other option is not to participate.

What about Confidentiality?
Efforts will be made to keep your personal information confidential. You will not be identifiable by name or description in any reports or publications about this study. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. You will be asked to sign a separate authorization form for use or sharing of your protected health information.

There are organizations outside the OUHSC that may inspect and/or copy your research records for quality assurance and data analysis. These organizations include the US Food & Drug Administration and other regulatory agencies, Watkins-Conti Products, Inc. The OUHSC Human Research Participant Program office, the OUHSC Institutional Review Board, and the OUHSC Office of Compliance may also inspect and/or copy your research records for these purposes.

What Are the Costs?
There is no cost to you if you participate in this study.

Will I Be Paid For Participating in This Study?
You will receive a gift card worth $100 at the completion of the study to compensate you for your time.

What Are My Rights As a Participant?
Taking part in this study is voluntary. You may choose not to participate. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled.
If you agree to participate and then decide against it, you can withdraw for any reason and leave the study at any time.

You have the right to access the medical information that has been collected about you as a part of this research study.

Whom Do I Call If I have Questions or Problems?

If you have questions, concerns, or complaints about the study or have a research-related injury, contact the Principal Investigator, Dr. Robert E. Hurst (405-271-3930). If you have a medical question related to your incontinence, you may call either of the referring physicians, Dr. Gennady Slobodov, Department of Urology (405-271-6452) or Dr. Lieschen Quiroz, Department of Obstetrics and Gynecology (405-271-9493).

If you cannot reach the Investigator or wish to speak to someone other than the investigator, contact the OUHSC Director, Office of Human Research Participant Protection, at 405-271-2045.

For questions about your rights as a research participant, contact the OUHSC Director, Office of Human Research Participant Protection at 405-271-2045.

Signature:

In the future, researchers involved with this project may need more information about you, or may ask if you are willing to participate in other research studies. Please check below to indicate whether or not you may be contacted within the next few years by the investigator conducting this study. If you agree to be re-contacted, you may still change your mind about providing additional information, or in participating in other research studies in the future.

_____I may be re-contacted for information or a future study.

_____ I may not be re-contacted for information or future study.

Subject Signature:_____ Date:_____

By signing this form, you are agreeing to participate in this research study under the conditions described. You have not given up any of your legal rights or released any individual or entity from liability for negligence. You have been given an opportunity to ask questions. You will be given a copy of this consent document.

I agree to participate in this study:

_____	_____	_____
PARTICIPANT SIGNATURE (age ≥18) (*Or Legally Authorized Representative)*	Printed Name	Date
_____	_____	_____
SIGNATURE OF PERSON OBTAINING CONSENT	Printed Name	Date