Study PI: Dr. Jerry Lowder

Study Name: Randomized Controlled Trial of Vaginal Cryotherapy for Pelvic Floor Myofascial Pain

NCT: NCT03885791

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Document: Informed Consent

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Washington University in St. Louis

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INFORMED CONSENT DOCUMENT

Project Title: Randomized controlled trial of vaginal cryotherapy for pelvic floor myofascial pain

Principal Investigator: Jerry Lowder, MD, MSc

Research Team Contact: Haidy Morsy, MD
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This consent form describes the research study and helps you decide if you want to participate. It provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights and responsibilities as a research participant. By signing this form you are agreeing to participate in this study.

- You should read and understand the information in this document including the procedures, risks and potential benefits.
- If you have questions about anything in this form, you should ask the research team for more information before you agree to participate.
- You may also wish to talk to your family or friends about your participation in this study.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

KEY INFORMATION:

This is a research study conducted by Dr. Jerry Lowder having to do with determining whether vaginal cryotherapy is an effective and acceptable treatment option for patients with pelvic floor myofascial pain. You should carefully consider the information in this consent document and discuss it with the research team. You should understand why you might want to participate, or why you might not want to participate. You may choose to participate or not.

If you agree and sign this consent, you will be volunteering to participate in the research study. As a voluntary participant, you will be asked to spend up to 8 weeks in the study. You will need to come to Washington University School of Medicine**.** During that time you will be randomized to a treatment strategy. Both will involve transvaginal application of a device designed to delivery therapy to the muscles of your pelvic floor. You will be given the necessary supplies to undergo this treatment in office or at home. You will be asked to complete surveys and questionnaires, as well as an electronic diary. The main risks to you if you participate are discomfort and embarrassment with the pelvic examination. You may also experience discomfort with the intravaginal tube placement.

We don't expect this study to benefit you directly, but it will help us understand how this intervention can be used to treat others with similar symptoms**.** By volunteering you may help someone else in the future. There is no cost to you and you will be paid a $25 gift card when you complete at least two consecutive weeks of the intervention and following up for a repeat pelvic floor muscle examination for

being a volunteer participant. All of this information will be explained and is listed in more detail in this consent document. The research team must give you a copy of this signed consent document.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We invite you to participate in this research study because you were found to have pelvic floor myofascial pain at the time of your examination by the physician who saw you in clinic today.

The purpose of this research study is to determine whether vaginal cryotherapy is an effective and acceptable treatment option for patients with pelvic floor myofascial pain.

The device being used to administer the cryotherapy is considered investigational, which means that it has not been approved by the U.S. Food and Drug Administration.

WHAT WILL HAPPEN DURING THIS STUDY?

- If you agree to participate in this study you will be randomly assigned (like by a flip of a coin) to one of two possible treatment strategies. Both will involve transvaginal application of a device designed to deliver therapy to the muscles of your pelvic floor.
- This study has two components, and you may choose to participate in one or both of these.
- Part One: immediate therapy today in the office.
    - You will be given the supplies and necessary instructions to self-administer the therapy for 10 minutes.
    - Prior to administering the therapy, you will be asked to complete a short survey about your level of pain or other symptoms.
    - After 10 minutes of therapy, the physician will return to re-examine the pelvic floor.
    - You will be asked to complete a follow up questionnaire at this time.
- Part Two: self-administered therapy done at home on a daily basis.
    - You will be given the supplies and necessary instructions to self-administer the therapy at home for 10 minutes per day.
    - Before leaving clinic, you will be asked to complete three short questionnaires. You may have already completed these prior to your visit. If so, you will not need to do them again.
    - You will be asked to complete a short diary for each session with questions about the time of day, duration of application, pain score before and after application, and other symptoms before and after application. These dairies will be sent electronically through a secure system on a daily basis during study participation.
    - You will return for a follow up examination prior to or concurrently with physical therapy. At this visit, a repeat examination will be performed and you will be asked to complete similar questionnaires to your first visit.
- You will be given the supplies for self-administration of the vaginal therapy. These supplies are often recommended by the physicians and physical therapists at Washington University, even for patients who are not participating in any research studies.
- This study involves the use of surveys and questionnaires. You are free to skip any questions

you would prefer not to answer. A research assistant is available during clinic visits, when the questionnaires are administered, and will be able to answer any questions you have about specific questions.

- You will not receive any information on results during the course of your participation.
- This study involves the use of protected health information including your name, date of birth, medical problems, prior surgeries, and pelvic floor myofascial examination scores. This information will be maintained on a secure database that is only accessible to study personnel. The information will only be kept while the study is underway and will be destroyed appropriately at conclusion of the study.

You may be contacted via telephone to follow up if you do not return for the visits at the frequency described above or do not complete the electronic surveys. Three attempts will be made to contact you. If, after the third attempt, the study team is unable to contact you, your participation in the study will be withdrawn. If, at any time, you are no longer interested in participating in the study, please notify the PI or research assistant via the numbers provided above, and your participation will be withdrawn. No future attempts to contact you for study-related reasons will be made.

Will you save my research information to use in future research studies?

We might remove identifiers from your private information and then use the information for future research studies or share them with other researchers for their future research. If this occurs we will not ask you for additional consent for these uses of your information.

Audio Recording/Video Recording/Photographs

One aspect of this study may involve making video recordings or photographs of you. This would be done in order to demonstrate the method for self-administration of the therapy and could be used for future patient education or presentation to other physicians and healthcare providers who treat patients with similar conditions. The video recordings or photographs will NOT include any identifiable images or information and will not include any images of your face.

Participation in the video recordings or photographs is entirely optional, and you are still eligible to enroll in the study, even if you choose not to participate in the making of video recordings or photographs. No video recordings or photographs will be made without your permission.

I give you permission to make video recordings or photographs of me during this study.

_____ Yes **_____ No**
Initials **Initials**

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 165 people will take part in this study conducted by investigators at Washington University.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for up to 8 weeks**:**

- If you choose to just participate in Part One, your participation will require approximately 30-45 minutes and conclude at the end of your clinic visit. You will not be required to undergo any follow up visits.
- If you choose to participate in Part Two (regardless of whether you participate in Part One or not) you will be asked to return for one additional visit prior to or concurrently with your first physical therapy appointment.
    - Visits will range from 15-30 minutes in length
    - You will also be asked to self-administer the therapy for 10 minutes per day between visits

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

The risks of the proposed study primarily include discomfort and embarrassment with the pelvic examination. This risk is not unique to study participants as all new patients undergo a comprehensive pelvic floor myofascial examination. Participants may also experience discomfort or embarrassment with intravaginal tube placement.

Likely / Common

Mild

- Embarrassment with the pelvic examination or intervention
- Discomfort with the pelvic examination or intervention

Breach of Confidentiality

One risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you secure. Please see the section in this consent form titled *"How will you keep my information confidential?"* for more information.

WHAT ARE THE BENEFITS OF THIS STUDY?

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

However, we hope that, in the future, other people might benefit from this study because we will learn how this intervention can be used to treat others with similar symptoms.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

As part of this study you will receive tests and procedures that are similar to what you would receive during routine clinical care of your condition. Your health plan/insurance company will be billed for some or all of these costs, and you will be responsible for any co-pays and deductibles that are normally required by your health plan/insurance. Not all insurance plans cover the costs associated with being in a study. Even if they do, you may be responsible for more out-of-pocket expenses, such as co-pays and deductibles, when there are more tests and procedures or more expensive tests and procedures involved

in the study than if you were to receive routine clinical care outside the study.

If you wish to know whether there are more tests and procedures or more expensive tests and procedures in the study, you should ask your study doctor.

If you wish to know whether your insurance will pay, you should contact them directly, or speak with the study team about obtaining a financial pre-certification prior to enrolling in the study.

WILL I BE PAID FOR PARTICIPATING?

You will be paid for being in this research study. You will need to provide your social security number (SSN) in order for us to pay you. You may choose to participate without being paid if you do not wish to provide your social security number (SSN) for this purpose. You may also need to provide your address if a check will be mailed to you. If your social security number is obtained for payment purposes only, it will not be retained for research purposes.

You will be compensated with a $25 gift card upon completing the study. To qualify for this compensation, you will have to complete at least two consecutive weeks of the intervention and following up for a repeat pelvic floor muscle examination.

WHO IS FUNDING THIS STUDY?

The National Institutes of Health (NIH) is funding this research study. This means that Washington University is receiving payments from the NIH to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from the NIH for conducting this study.

WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?

Washington University investigators and staff will try to reduce, control, and treat any complications from this research. If you feel you are injured because of the study, please contact the investigator at (314) 747-1402 and/or the Human Research Protection Office at 1-(800)-438-0445.

Decisions about whether payment for medical treatment for injuries relating to your participation in research will be made by Washington University. If you need to seek medical care for a research-related injury, please notify the investigator as soon as possible.

HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?

Other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you. We will keep your participation in this research study confidential to the extent permitted by law.

- Government representatives (including the Office for Human Research Protections) to complete federal or state responsibilities

- The U.S. Food and Drug Administration
- The National Institutes of Health (NIH)
- Hospital or University representatives to complete Hospital or University responsibilities
- Information about your participation in this study may be documented in your health care records and will be available to anyone with access to your health care record, including your health insurance company. This information may also be released as part of a release of information request.
- The last four digits of your social security number may be used in hospital or University systems to track billing information for research procedures.
- Washington University's Institutional Review Board (a committee that oversees the conduct of research involving human participants) and the Human Research Protection Office. The Institutional Review Board has reviewed and approved this study.
- Any report or article that we write will not include information that can directly identify you. The journals that publish these reports or articles require that we share your information that was collected for this study with others to make sure the results of this study are correct and help develop new ideas for research. Your information will be shared in a way that cannot directly identify you.

To help protect your confidentiality, we will ensure that only members of the research team have access to your protected health information. Your information will be stored on a secure, password-protected server that is only accessible by members of the research team. You will be assigned a unique study identification number. A password-protected electronic database will be established using REDCap, and only the research team will have access. No results will be presented in a personally identifiable manner.

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.

We will disclose to the proper authorities information shared with us or activities we observe concerning abuse, neglect or harm to others or yourself.

To further protect your privacy, this research is covered by a Certificate of Confidentiality from the federal government. This means that the researchers can refuse to disclose information that may identify you in any legal or court proceeding or to anyone who is not connected with the research except if:

- there is a law that requires disclosure, such as to report child abuse and neglect, or harm to self or others*;*
- you give permission to disclose your information, including as described in this consent form; or
- it is used for other scientific research allowed by federal law.

You have the right to share your information or involvement in this study with anyone at any time. You may also give the research team permission to disclose your information to a third party or any other person not connected with the research.

If information about you or your involvement in this research is placed in your medical record the information may no longer be protected under the Certificate. However, information in your medical records is protected in other ways.

Are there additional protections for my health information?

Protected Health Information (PHI) is health information that identifies you. PHI is protected by federal law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this research, you must give the research team permission to use and disclose (share) your PHI for the study as explained in this consent form. The research team will follow state and federal laws and may share your health information with the agencies and people listed under the previous section titled, "How will you keep my information confidential?"

Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.

The research team will only use and share your information as talked about in this form or as permitted or required by law. When possible, the research team will make sure information cannot be linked to you (de-identified). Once information is de-identified, it may be used and shared for other purposes not discussed in this consent form. If you have questions or concerns about your privacy and the use of your PHI, please contact the University's Privacy Officer at 866-747-4975.

Although you will not be allowed to see the study information, you may be given access to your health care records by contacting your health care provider.

If you decide not to sign this form, it will not affect

- your treatment or the care given by your health provider.
- your insurance payment or enrollment in any health plans.
- any benefits to which you are entitled.

However, it will not be possible for you to take part in the study.

If you sign this form:

- You authorize the use of your PHI for this research
- This authorization does not expire.
- You may later change your mind and not let the research team use or share your information (you may revoke your authorization).
  - To revoke your authorization, complete the withdrawal letter, found in the Participant section of the Human Research Protection Office website at https://hrpo.wustl.edu/participants/withdrawing-from-a-study/ or you may request that the investigator send you a copy of the letter.
    - **If you revoke your authorization:**
      - The research team may only use and share information already collected for the study.
      - Your information may still be used and shared as necessary to maintain the integrity of the research, for example, to account for a participant's withdrawal from the research study or for safety reasons.
      - You will not be allowed to continue to participate in the study.

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Can we contact you by email?
We would like to contact you by email for the purposes listed below. Some of these emails may contain health information that identifies you.

- Transmission of daily survey questions. These will come directly from the secure REDCap database.

Only the research team will have access to your email communications. We will only communicate by email to send you the information listed above. If you have any questions or need to contact us for an urgent or emergent situation, please contact the research team member identified at the top of this document.

You should be aware that there are risks associated with sending your health information via email.

- There is always a risk that the message could be intercepted or sent to the wrong email address. To avoid sending messages to the wrong email address, the first email we send you will be a test message to ensure we have the correct email address.
- When using any computer you should be careful to protect your username and password. Make sure you log-out before getting up from the computer.
- If you share a home computer with other family members, and do not want them to know you are participating in this study make sure you provide an email address that only you can access.
- Your employer will have access to any email communications sent or received on any electronic devices used for work or through a work server.

Do you agree to allow us to send your health information via email?

_____ **Yes** _____ **No**
Initials **Initials**

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. Any data that was collected as part of your participation in the study will remain as part of the study records and cannot be removed.

If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

What if I decide to withdraw from the study?

You may withdraw by telling the study team you are no longer interested in participating in the study or you may send in a withdrawal letter. A sample withdrawal letter can be found at https://hrpo.wustl.edu/participants/withdrawing-from-a-study/ under Withdrawing from a Research Study.

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Will I receive new information about the study while participating?

If we obtain any new information during this study that might affect your willingness to continue participating in the study, we'll promptly provide you with that information.

Can someone else end my participation in this study?

Under certain circumstances, the investigator might decide to end your participation in this research study earlier than planned. This might happen for no reason or because your condition changes or worsens, you are or become pregnant, or because funding for the research study ends.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Jerry Lowder, MD (314) 747-1402 or Haidy Morsy, MD (314) 747-1402**.** If you experience a research-related injury, please contact: Jerry Lowder, MD (314) 747-1402 or Haidy Morsy, MD (314) 747-1402.

If you have questions, concerns, or complaints about your rights as a research participant, please contact the Human Research Protection Office 1-(800)-438-0445, or email hrpo@wustl.edu. General information about being a research participant can be found on the Human Research Protection Office web site, http://hrpo.wustl.edu. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by agreeing to participate in this study. As a participant you have rights and responsibilities as described in this document and including:

- To be given enough time before signing below to weigh the risks and potential benefits and decide if you want to participate without any pressure from the research team or others.
- To understand all of the information included in the document, have your questions answered, and receive an explanation of anything you do not understand.
- To follow the procedures described in this document and the instructions of the research team to the best of your ability unless you choose to stop your participation in the research study.
- To give the research team accurate and complete information.
- To tell the research team promptly about any problems you have related to your participation, or if you are unable to continue and wish to stop participating in the research study.

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Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a signed and dated copy of this form.

Do not sign this form if today's date is after $STAMP_EXP_DT.

_____ _____

(Signature of Participant) (Date)

_____

(Participant's name – printed)

Statement of Person Who Obtained Consent

The information in this document has been discussed with the participant or, where appropriate, with the participant's legally authorized representative. The participant has indicated that they understand the risks, benefits, and procedures involved with participation in this research study.

_____ _____

(Signature of Person who Obtained Consent) (Date)

_____

(Name of Person who Obtained Consent - printed)