Cover Page for Informed Consent Form

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Permission to Take Part in a Human Research Study

University at Buffalo
The State University of New York
University at Buffalo Institutional Review Board (UBIRB)
Office of Research Compliance | Clinical and Translational Research Center Room 5018
875 Ellicott St. | Buffalo, NY 14203
UB Federalwide Assurance ID#: FWA00008824

Adult Consent to Participate in a Research Study.

Title of research study: Objective Assessment of Pain Thresholds in Women with Vulvodynia

Version Date: May 28, 2020 February 28, 2024

Investigator: Vanessa M. Barnabei, MD, PhD, and Tova Ablove, MD

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 take part in a research study because you have been diagnosed with vulvodynia (vulvar pain) or you are a healthy woman without vulvodynia who presents for routine gynecologic care.

What should I 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.

Why is this research being done?

Vulvodynia is a common, chronic disorder that leads to pain of the vulva or the external genitalia. The pain of vulvodynia frequently leads to inability to insert a tampon or have sexual intercourse. The diagnosis of vulvodynia can be difficult to make and is often mistaken for other conditions like yeast infections. Current diagnostic tool is a cotton-tipped swab. This research seeks to use novel diagnostic methods to make the diagnosis of vulvodynia easier and more precise using heat and pain sensors to create a pain map of the vulva. We will do this with women affected with vulvodynia and women who do not have vulvar pain for comparison. We are doing this research so that we may help women who suffer from vulvar pain with faster, more reliable diagnosis.

How long will the research last and what will I need to do?

We expect that you will be in this research study for one hour.

You will be asked to have a pelvic exam, have the vulva (external genitalia) touched with a cotton-tipped swab and have photos taken of the vulva with an infrared camera.

More detailed information about the study procedures can be found under ***"What happens if I say yes, I want to be in this research?"***

Is there any way being in this study could be bad for me?

It is unlikely that you will experience any harm from participating in this study. Having your vulva touched with a cotton-tipped swab may cause some discomfort if you have vulvodynia, but this is a routine part of the exam and evaluation for this condition. If you do not have vulvar pain, you should not experience any discomfort from the swab. The photos will be taken with a camera that will be several inches from your vulva and will not cause pain.

More detailed information about the risks of this study can be found under ***"Is there any way being in this study could be bad for me? (Detailed Risks)"***

Will being in this study help me in any way?

There are no benefits to you by taking part in this research. We cannot promise any benefits to others by you taking part in this research. However, possible benefits to others include helping to advance the understanding of vulvodynia and improving diagnosis and treatment options.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You may choose not to enroll in this study. Your alternative to participating in this research study is to not participate.

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

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at 716-323-0717. You may also contact the research participant advocate at 716-888-4845 or researchadvocate@buffalo.edu.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). An IRB is a committee that provides ethical and regulatory oversight of research that involves human subjects. You may talk to them at (716) 888-4888 or email ub-irb@buffalo.edu if:

- You have questions about your rights as a participant in this research
- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You want to get information or provide input about this research.

How many people will be studied?

We expect about 60 people will be in this research study; 30 with vulvodynia and 30 without the condition.

What happens if I say yes, I want to be in this research?

Prior to your gynecologic exam, either for evaluation of vulvar pain or annual gynecologic exam, you will fill out a history form to make sure that you qualify for the study. The history form will ask about

your medical conditions, including skin conditions and pain conditions, and medications you take. Your medical record in Allscripts electronic medical record will be used to confirm details of your medical history if needed. You will be positioned on the exam table just as you would be for a routine gynecologic exam. A special paper drape with length calibrations (a ruler) will be placed over you so that only your external genitalia are visible. The ruler is there to be able to standardize the image size from one participant to the next for comparison purposes. Pictures will be taken with a special camera (infrared) that can sense areas with different skin temperature. The camera will be on a stand approximately 6 inches from you and controlled remotely. This will last only 5-10 minutes and you must stay still during this phase of testing. You will then be touched gently with a cotton-tipped swab in approximately 15 areas of the vulva and asked to rate your pain on a scale of 0-10, with 0 being no pain and 10 being the worst pain you've ever experienced. Your responses to this will be recorded on a stylized map of the vulva. This testing takes 5-10 minutes.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible to perform the procedures stated above.

What happens if I say yes, but I change my mind later?

You can leave the research at any time and it will not be held against you. If you decide to leave the research, contact the investigator and the investigator will walk you through the withdrawal process.

Is there any way being in this study could be bad for me? (Detailed Risks)

Risks to being in this study include:

1. A small amount of discomfort from being touched with the cotton swab.
2. Loss of confidentiality in the event that your personal medical information, including photos, is viewed by someone other than the investigators.
3. Added time for the study procedures during your visit.

You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay. In some cases, insurance will not pay for services ordinarily covered because these services were performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical or education records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization. Representatives from the Clinical and Translational Science Institute of the Jacobs School of Medicine and Biomedical Sciences, who provided funding for this research, may inspect your information for safety purposes.

The data (information) provided by this study will be kept on password protected computers within the Department of Obstetrics and Gynecology, Jacobs School of Medicine and Biomedical Sciences. Only the study investigators will have access to the study data. The specific information will not be linked directly to you but will be coded to protect your privacy and confidentiality. If identifiers are removed from your identifiable private information or identifiable samples that are collected during this research, that information or those samples could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

The sponsor, monitors, auditors, the IRB, the Food and Drug Administration will be granted direct access to your medical records to conduct and oversee the research. By signing this document you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

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.

Federal law provides additional protections of your medical records and related health information. These are described in the HIPAA section of this document.

Can I be removed from the research without my OK?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include that you have a condition that disqualifies you from participating in this study which may not be known until the exam is performed.

What else do I need to know?

Who is paying for this research?

This research is being funded by The Clinical and Translational Research Center (CTRC) of the Jacobs School of Medicine and Biomedical Sciences at the University at Buffalo.

What medical costs am I responsible for paying?

The tests or procedures required by the research study that would not otherwise be part of your standard care will be covered by the sponsor of this study. The tests or procedures that would be provided to any patient with your condition, regardless of whether he/she was participating in the research study, are considered standard care and will be billed to you or your private or public health insurance company. You will still be responsible for the cost of your usual ongoing medical care, including deductibles and co-payments. If you have any questions about what expenses are covered by the sponsor and what expenses are the responsibility of you or your health insurance provider, please contact a member of the study staff and/or your health insurance provider.

Who will pay for my medical care if participating in this research harms me?

It is important that you tell your study doctor if you feel that taking part in this study has injured you or caused you to become ill.

You will receive medical treatment if you are injured or become ill as a result of this study. Your doctor will explain the treatment options to you and tell you where you can get treatment.

The University at Buffalo and UBMD Obstetrics and Gynecology make no commitment to provide free medical care or payment for any unfavorable outcomes that result from your participation in this research. Medical services will be billed at the usual charge and will be your responsibility or that of your third-party payer but you are not precluded from seeking to collect compensation for injury related to malpractice, fault, or blame on the part of those involved in the research including The University at Buffalo and UBMD Obstetrics and Gynecology. By accepting medical care or accepting payment for medical expenses, you are not waiving any of your legal rights.

Will I get paid for my participation in this research

If you agree to take part in this research study, we will pay you $25 by gift card at the end of your visit for your time and effort.

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What are my alternatives to participating in this research study?

Instead of being in this research study, your choices may include to not participate.

What will happen to my information and samples?

Your information (both identifiable and de-identified) may be used to create products or to deliver services, including some that may be sold and/or make money for others. If this happens, there are no plans to tell you, or to pay you, or to give any compensation to you or your family.

What will I be told about clinically relevant research results?

Most tests done on samples in research studies are only for research and have no clear meaning for health care. If the research with your identifiable information or samples gives results that do have meaning for your health, the researchers will contact you to let you know what they have found.

HIPAA: Authorization for the Use and Disclosure of Identifiable Health Information for Research Purposes

This section describes information about you and about your health that will be obtained by the researchers when you participate in the research study. By signing this form, you are agreeing to permit the researchers and/or other parties (described in detail below) to have access to this information and to use or disclose it for the purposes of the research described in this document. If there are any parts of this form that you do not understand, please be sure to ask us for further clarification.

A. What individually identifiable health information will be collected about you as part of this research study?

_xx_ Information from your full medical records: Name, DOB, MRN, date of visit, age, medications, medical conditions, number of pregnancies and type of delivery, race.
_ xx_ New Health Information created from study related tests, procedures, visits, and/or questionnaires as described in this consent form.

B. Who is authorized to create or provide this information for research use?

_xx__ UBMD Clinical Practice Plan(s) (identify): Obstetrics and Gynecology
_xx__ Principal Investigator or designee

C. Who is authorized to receive the information from the information providers identified in (B)?

__√__ Principal Investigator or designee

D. With whom may your protected health information be shared?

Your health information may be shared with others outside of the research group for purposes directly related to the conduct of this research study or as required by law, including but not limited to:

_xx_ Clinical staff not involved in this research study who may become involved in your care if it is potentially relevant to your treatment

_xx_ The sponsor of this research study, the Clinical and Translational Research Center (CTRC) of the Jacobs School of Medicine and Biomedical Sciences, University at Buffalo.

_ xx_ The organization(s) responsible for administering this research, the Research Foundation of SUNY, University at Buffalo.

Your information may also be shared with individuals or entities responsible for general administration, oversight and compliance of research activities. Examples of this include the institution's Privacy and Security Officers or other internal oversight staff, Safety Monitoring Boards, an Institutional Review Board, The Research Foundation of the State University of New York, University at Buffalo Foundation Services, and accrediting bodies, or with certain government oversight agencies that have authority over the research including the Department of Health and Human Services (HHS), the Food and Drug Administration (FDA), the National Institutes of Health (NIH), and the Office of Human Research Protections (OHRP). Your information may also be shared with other entities as permitted or required by law. All reasonable efforts will be used to protect the confidentiality of your individually identifiable health information that may be shared with others as described above.

Although safeguards are in place to prevent accidental disclosure of your information beyond the purposes described above, the information disclosed through this authorization is no longer protected by HIPAA. There is the potential for this information to be re-disclosed by the recipient(s). After such a disclosure, the information may no longer be protected by the terms of this authorization against further re-disclosure.

E. How long are the information providers listed in (B) authorized to provide your information for this research project?

_xx__ a. This authorization has no expiration date. The researchers may continue to rely on this authorization to obtain and use protected health information about you unless you revoke this authorization in writing.

_xx__ d. Your protected health information will go into a database that will be maintained indefinitely. Any future study using this information that falls outside the scope of this current study will be required to follow guidelines designed to govern access to that information and to protect the privacy of that information. The researchers may continue to rely on this authorization to acquire protected health information about you unless you revoke this authorization in writing.

F. What are your rights after signing this authorization?

You have the right to revoke this authorization at any time. If you withdraw your authorization, no additional efforts to collect individually identifiable health information about you will be made. You should know, however, that protected health information acquired using this authorization prior to its withdrawal may continue to be used to the extent that the investigator(s) have already relied on your permission to conduct the research. If you choose to withdraw this authorization, you must do so in writing to the following individual(s):

Vanessa M. Barnabei, MD, PhD
Department of Obstetrics and Gynecology
Jacobs School of Medicine and Biomedical Sciences
1001 Main Street, Buffalo, NY 14203

If you send us a request to withdraw your authorization, we will forward that request to the institutions we have shared it with in order to collect your individually identifiable health information.

G. What will happen if you decide not to sign this authorization?

Refusing to sign this authorization will not affect the present or future care you receive at this institution and will not cause any penalty or loss of benefits to which you are otherwise entitled. If you decide not to sign this authorization, you will not be able to participate in the research study.

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Signature Block for Capable Adult

Your signature documents your permission to take part in this research. By signing this form you are not waiving any of your legal rights, including the right to seek compensation for injury related to negligence or misconduct of those involved in the research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	