**FOR CCI USE ONLY**
**Approved by the Beth Israel Deaconess Medical Center Committee on Clinical Investigations:**

BETH ISRAEL DEACONESS MEDICAL CENTER
APPROVED BY THE COMMITTEE ON CLINICAL INVESTIGATIONS
04/11/2022
APPROVAL EXPIRATION DATE

Consent Approval Date: 4/13/2021

Protocol Number: 2019P000344

# INFORMED CONSENT FORM TO TAKE PART IN A RESEARCH STUDY

| |
|---|
| **PARTICIPANT'S NAME:** |
| **TITLE OF RESEARCH PROTOCOL:** Effectiveness of Ablative Fractional 2940 nm Laser Treatment for Vulvar Lichen Sclerosus |
| **PRINCIPAL INVESTIGATOR:** Roger Lefevre, MD |
| **PROTOCOL NUMBER:** 2019P000344 |

## 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?***
We invite you to take part in this research study because you have a history of vulvar lichen sclerosus.

***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.
- Your participation is completely voluntary.
- 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.
- Your refusal to participate will not result in any consequences or any loss of benefits that you are otherwise entitled to receive.
- You can ask all the questions you want before you decide.
- If you choose not to take part, or if you leave the study, your decision will in no way harm your relationship with any member of the research team or any other individuals at Beth Israel Deaconess Medical Center (BIDMC).

***Why is this research being done?***
Lichen sclerosus is a chronic, inflammatory skin condition that is treated with high-dose topical steroids, or in most recent years, laser therapy. Vulvar lichen sclerosus is a type of lesion of the external genitalia, and laser therapy has been approved by the Food and Drug Administration (FDA) to treat lesions of the external genitalia. We are doing this study because there is little data on the effectiveness of laser therapy for lichen

| PARTICIPANT'S NAME: |
|---|
| TITLE OF RESEARCH PROTOCOL: |
| PRINCIPAL INVESTIGATOR'S NAME: |
| PROTOCOL #: |



sclerosus. Knowing whether laser therapy can treat vulvar lichen sclerosus will be especially beneficial for patients who are not eligible for high-dose topical steroids or who have failed prior treatment with topical steroids.

***How long will the research last and what will I need to do?***
If you agree to be in this study, we expect that you will be in this research study for five months. For the first three months, you will undergo monthly laser treatments. We will ask you to return to the clinic for follow-up visits for monitoring to determine the effectiveness of the treatment at one and three months after your last laser treatment. Monitoring involves photos of the affected area and filling out surveys at each visit, as well as a one-time biopsy of the area at the second follow-up visit.

More detailed information about the study procedures can be found under ***"*DESCRIPTION OF STUDY DETAILS*".***

***Is there any way being in this study could be harmful to me?***
In general, there are very few and only minor risks involved in this study. The laser treatment may cause discomfort or light spotting (bleeding from the area where the laser is used); we will use a topical numbing cream to minimize any discomfort. There is a risk of allergic reaction to the topical numbing cream. There also is a rare risk of infection at the biopsy site or from the laser treatment.

There is the potential for loss of confidentiality by participating in this study. Every effort will be made to protect the confidentiality of your identifiable information.

More detailed information about the risks can be found under ***"*RISKS AND DISCOMFORTS*".***

***Will being in this study help me in any way?***
We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include improvement of your vulvar lichen sclerosus and helping others in the future as a result of knowledge gained from the research.

***What happens if I do not want to be in this research?***
Participation in research is completely voluntary. You can decide to participate or not to participate.

Instead of being in this study, you may have the following treatment options:
- High-dose topical steroids
- Intralesional corticosteroids
- Topical calcineurin inhibitors
- Topical progesterone and testosterone
- UVA1 phototherapy
- Oral acitretin

It is important to know that it is possible to get laser therapy even if you do not take part in the study. The laser used in this study (Ablative Fractional 2940 nm Laser) has been approved by the FDA to treat lesions of the external genitalia; vulvar lichen sclerosus is a type of lesion of the external genitalia. Although many doctors in the community use laser therapy to treat lichen sclerosus, not all health insurance companies will pay for this treatment when it is used for lichen sclerosus.

| |
|---|
| PARTICIPANT'S NAME: |
| TITLE OF RESEARCH PROTOCOL: |
| PRINCIPAL INVESTIGATOR'S NAME: |
| PROTOCOL #: |



We recommend that you discuss these and other options with the investigator and your regular doctor so that you can make a well-informed decision about participating in this study.

**DETAILED INFORMATION SECTION**

Please read this consent form carefully and ask the investigators or study staff to explain any words or information that you do not clearly understand. Once you read this consent form and understand what your participation in this study will involve, you will be asked to sign this form if you wish to take part. You will be given a signed copy of the form to keep for your records.

**DISCLOSURE OF SPECIAL INTERESTS OF BIDMC AND INVESTIGATORS**

This study is being conducted by Roger Lefevre, MD and is funded by the Department of Obstetrics and Gynecology at BIDMC and Sciton, Inc. The funding agency in this study, Sciton, Inc. is paying BIDMC for a portion of the costs to perform this research. BIDMC and Dr. Roger Lefevre have no additional interests in this research project.

**WHOM TO CONTACT IF YOU HAVE QUESTIONS OR PROBLEMS**

If you have any questions, concerns or complaints about this research or experience any problems, you should contact Dr. Roger Lefevre at (617) 667-4070. If you would like to talk to someone who is not working on the study, you may contact the Human Subjects Protection Office at BIDMC at (617) 975-8500.

**PURPOSE**

This main purpose of this study is to assess the effectiveness of laser therapy to treat vulvar lichen sclerosus, a chronic, inflammatory skin condition. This study will compare the severity of your lichen sclerosus and your symptoms before and after laser treatment. Additionally, this study will evaluate patient satisfaction. The results of this study will determine whether laser therapy is an effective treatment for lichen sclerosus, particularly for those patients not eligible for high-dose topical steroids or who have failed prior treatment with topical steroids.

The laser used in this study (Ablative Fractional 2940 nm Laser) has been approved by the FDA to treat lesions of the external genitalia; vulvar lichen sclerosus is a type of lesion of the external genitalia. Although many doctors in the community use laser therapy to treat lichen sclerosus, not all health insurance companies will pay for this treatment when it is used for lichen sclerosus.

**STUDY PARTICIPANTS**

You have been asked to be in the study because you have vulvar lichen sclerosus.
Approximately 30 people will take part in this study at BIDMC. BIDMC is the only study site.

**DESCRIPTION OF STUDY DETAILS**

If you agree to be in this study, you will be asked to read and sign this consent form. After you sign the consent form, the following things will happen:

1. Research Procedures: If you qualify to take part in this research study, you will undergo the research procedures shown in the table below. At each visit we will apply a numbing cream (topical lidocaine) to the area outside your vagina 20-30 minutes before treatment. We will pass the laser over the area

| PARTICIPANT'S NAME: |
|---|
| TITLE OF RESEARCH PROTOCOL: |
| PRINCIPAL INVESTIGATOR'S NAME: |
| PROTOCOL #: |



of lichen sclerosus twice.

For Visit 1, on the first pass, the depth of the laser will be from 300 to 500 microns, or the thickness of 3 to 5 sheets of paper; the depth will be based on the biopsy that was used to diagnosis the lichen sclerosus. On the second pass, the depth will be 50 microns deeper than the first pass.

For Visit 2, the first pass of the laser will be the same depth as the second pass from the last visit. The second pass will be 50 microns deeper.

For Visit 3, the first pass of the laser will be the same depth as the second pass from the last visit. The second pass will be 50 microns deeper.

| Visit | Month | Procedures |
|---|---|---|
| 1 | 0 | • Fill out surveys about you and your health<br>• Photographs of the affected area<br>• Laser treatment |
| 2 | 1 | • Fill out surveys about you and your health<br>• Laser treatment |
| 3 | 2 | • Fill out surveys about you and your health<br>• Photographs of the affected area<br>• Laser treatment |

2. Monitoring/Follow-Up Procedures. Procedures performed to evaluate the effectiveness and safety of the research procedures are called “monitoring” or “follow-up” procedures. For this research study, the monitoring/follow-up procedures include those shown in the table below.

| Visit | Month | Procedures |
|---|---|---|
| 4 | 3 | • Fill out surveys about you and your health |
| 5 | 5 | • Fill out surveys about you and your health<br>• Photographs of the affected area<br>• Biopsy of area with lichen sclerosus; the biopsy will be done the same way as the one that was done for clinical purposes to diagnosis your lichen sclerosus |

If you prefer not to come in person for Visit 4 due to concerns over COVID-19, you may have a telehealth visit with your provider instead. In that case, we will ask you to complete the Visit 4 surveys at home, either over the phone or online through a survey link that will be emailed to you.

If you agree to be in this study, you will be in this research study for 5 months.

**Individual Research Results**
Your study doctor will disclose any clinically relevant research results to you, including your biopsy results after laser therapy.

**Information and Biological Samples**

| PARTICIPANT'S NAME: |
|---|
| TITLE OF RESEARCH PROTOCOL: |
| PRINCIPAL INVESTIGATOR'S NAME: |
| PROTOCOL #: |



Your information and biological samples will be used and shared with the sponsor, Sciton, Inc. and the researchers involved in this study to conduct the research. The consent form provides information on who will have access to identifiable information and identifiable biological samples during the study. We also want you to know that your information or biological samples may be stripped of any identifiers (for example your name, medical record number or date of birth) and used for future research studies or distributed to another researcher for future research studies without additional informed consent. BIDMC researchers or other third party researchers may use your information and samples in other scientific research, product testing or commercial development. It is unknown whether a product will ultimately be developed from the research described in this consent form or from any such work that may be performed by BIDMC or other third parties receiving your information or biological samples. In signing this consent form, you are acknowledging and voluntarily consenting to the possibility that your information and biological samples may be used for commercial purposes. For example, your samples and information may be used to develop a new product or medical test to be sold. BIDMC and other researchers may benefit if this happens. There are no plans to pay you if your samples and information are used for this purpose.

If your identifiers are removed, we will not be able to destroy or remove your information or biological samples from distributed information or samples. As part of this research program and as further explained in this form, samples of your tissue and/or information about your medical history may be provided to other researchers and/or outside collaborators.

**RISKS AND DISCOMFORTS**
As a result of your participation in this study, you are at risk for side effects listed in this section. In general, there are very few and minor risks involved in this study. All treatments will be carried out by skilled and trained providers. We will attempt to decrease any discomfort caused by the laser treatment by applying a numbing (topical lidocaine) cream to the outside of the vagina prior to treatment.

You should discuss these with the investigator and with your regular doctor, if you have any questions.

More Common: Light spotting (bleeding from the area outside the vagina where the laser is used)

Less Common: Allergic reaction to topical anesthetic (numbing cream)

Rare: Infection from the biopsy or the laser treatment

**LOSS OF CONFIDENTIALITY**
There is the potential for loss of confidentiality by participating in this study. Every effort will be made to protect the confidentiality of your identifiable information.

**CONFIDENTIALITY**
Information learned about you during this research program will be maintained confidentially by the research staff as described in this form.

Information learned from your participation in this study and from your medical record may be reviewed and photocopied by the Food and Drug Administration (FDA) and/or other federal and state regulatory agencies; the device manufacturer, Sciton; accreditation agencies; the Committee on Clinical Investigations; the Human Subjects Protection Office and others involved in research administration of the BIDMC. Information resulting

| PARTICIPANT'S NAME: |
|---|
| TITLE OF RESEARCH PROTOCOL: |
| PRINCIPAL INVESTIGATOR'S NAME: |
| PROTOCOL #: |



from this study and from your medical record may be used for research purposes and may be published; however, you will not be identified by name in such publications.

**MEDICAL RECORD**
A copy of this consent form and information collected during this research may become part of your medical record, if the information is relevant to the care you receive at BIDMC. Medical records are considered permanent records; therefore, information cannot be deleted from the record. Medical records are available to health care professionals at BIDMC and may be reviewed by staff when carrying out their responsibilities, as well as by external parties such as health care insurers and others in certain circumstances. If you are not currently a patient at BIDMC and do not have a medical record at BIDMC, one may be created for you for your participation in this research. You may also be required to register as a patient of BIDMC in order to participate in this research.

**POSSIBLE BENEFITS**
It is not possible to predict whether you will benefit directly from participation in this study. However, your participation may help others in the future as a result of knowledge gained from the research.

**OTHER AVAILABLE OPTIONS**
Taking part in this study is voluntary. Instead of being in this study, you may have the following treatment options:

- High-dose topical steroids
- Intralesional corticosteroids
- Topical calcineurin inhibitors
- Topical progesterone and testosterone
- UVA1 phototherapy
- Oral acitretin
- No treatment

It is important to note that it is possible to get ablative laser therapy even if you do not take part in the study. Many doctors in the community commonly use it to treat lichen sclerosus. Please be aware that not all doctors may agree to use this treatment for you, and that not all health insurance companies will pay for this treatment when it is used for lichen sclerosus.

This research study is not meant to diagnose or treat medical problems not specifically stated in this informed consent document. Participation in this research study does not take the place of routine physical examinations or visits to your regular doctor.

We recommend that you discuss these and other options with the investigator and your regular doctor so that you can make a well-informed decision about participating in this study.

**IF YOU DECIDE NOT TO TAKE PART IN THE STUDY**
Participation in this study is voluntary. You have the right to decide not to take part in this study. If you choose to participate, you have the right to leave the study at any time. Your decision to not participate will not result in any penalties or loss of benefits to you. The investigators will tell you about new information that may affect your willingness to stay in this study.

| |
|---|
| PARTICIPANT'S NAME: |
| TITLE OF RESEARCH PROTOCOL: |
| PRINCIPAL INVESTIGATOR'S NAME: |
| PROTOCOL #: |



If you decide not to participate in the study or decide to leave the study early, your decision will not affect your relationship with the research team or any other individual at BIDMC.

## INVESTIGATORS RIGHT TO STOP THE STUDY

The investigators have the right to end your participation in this study if they determine that you no longer qualify to take part, or if it would be dangerous for you to continue, or if you do not follow study procedures as directed by the investigators. BIDMC or the funding source may stop the study at any time.

## COSTS AND/OR PAYMENTS TO YOU

### COSTS COVERED BY STUDY

You will not be charged for office appointments or treatments that are part of this research study, which includes the three laser treatments and the follow-up biopsy.

### CO-PAYMENT/DEDUCTIBLE STATEMENT

You will be responsible for any co-payments or deductibles that are standard for your insurance coverage.

### PAYMENTS TO YOU:

You will not be paid or reimbursed for your participation in this study.

### COST OF RESEARCH RELATED INJURY:

If you are injured as a direct result of your participation in this study you should contact the Investigator at the number provided under the section “Whom to Call if You Have Questions” in this form. You will be offered the necessary care to treat your injury. You or your insurance company will be billed for medical care and/or hospitalization related to this injury. You will be responsible for all co-payments and deductibles required under your insurance. BIDMC will consider reimbursement of injury related expenses not covered by your insurance on a case-by-case basis. At this time there is no plan to reimburse you for items such as lost wages or lost time from work. By signing this consent form you have not given up any legal rights.

## OTHER IMPORTANT INFORMATION

A description of this clinical trial will be available on 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.

## AUTHORIZATION FOR USE AND DISCLOSURE OF YOUR PROTECTED HEALTH INFORMATION

As part of this study, we will be collecting, using and sharing with others information about you. Please review this section carefully as it contains information about the federal privacy rules and the use and disclosure of your information.

### PROTECTED HEALTH INFORMATION [PHI]

By signing this informed consent document, you are allowing the investigators and other authorized personnel to use and disclose health information about you. This may include information about you that already exists (for example: your medical records and other sources of health information, demographic information, the results of any laboratory tests, and mental health records if applicable such as questionnaires about your mood and wellbeing), as well as any new information generated as part of this study. This is your Protected Health Information.

| |
|---|
| PARTICIPANT'S NAME: |
| TITLE OF RESEARCH PROTOCOL: |
| PRINCIPAL INVESTIGATOR'S NAME: |
| PROTOCOL #: |



**PEOPLE/GROUPS AT BIDMC WHO WILL SHARE AND USE YOUR PROTECTED HEALTH INFORMATION**

Your Protected Health Information may be shared with and used by investigators working on this study, including the supporting research team (such as research assistants and coordinators, statisticians, data managers, laboratory personnel, pharmacy personnel, and administrative assistants), and may also be shared with and used by other health care providers at BIDMC who have treated you in the past and have information relevant to the research, or who provide services to you in connection with the research. Your Protected Health Information may also be shared with the members and staff of the Committee on Clinical Investigations of BIDMC, which is responsible for reviewing studies for the protection of the research subjects, so that it can carry out its oversight responsibilities with respect to the study.

**PEOPLE/GROUPS OUTSIDE OF BIDMC TO WHOM YOUR PROTECTED HEALTH INFORMATION WILL BE DISCLOSED (SHARED) AND WHO MAY USE YOUR PROTECTED HEALTH INFORMATION**

We will take care to maintain confidentiality and privacy about you and your Protected Health Information. We may share your Protected Health Information with the following groups so that they may carry out their duties related to this research study:

- The funding source and/or sponsor of this study, Sciton, Inc, and, where applicable, the people and companies that the funding source and/or sponsor use to oversee, administer, or conduct the research (for example, clinical research organizations are companies that are sometimes hired by research sponsors to help manage and run a clinical research study)
- The other hospitals and medical centers taking part in this study and research collaborators at those institutions.
- Other research collaborators and supporting research team members taking part in this study
- Any external health care providers who provide services to you in connection with this research
- Laboratories not affiliated with BIDMC that are involved in conducting tests related to the research
- Statisticians and other data monitors not affiliated with BIDMC
- The members and staff of any other IRBs (beyond the BIDMC Committee on Clinical Investigations) that oversee the research
- Centralized data collectors
- Your health insurance company
- The Food and Drug Administration [FDA], the Department of Health and Human Services [DHHS], the National Institute of Health [NIH], the Office for Human Research Protections [OHRP], and other federal and state agencies that may have jurisdiction over the research
- Hospital and Clinical Research Accrediting Agencies
- Data and Safety Monitoring boards that oversee this study (if applicable)

Those who receive your Protected Health Information during the course of the research may not be required by the federal privacy regulations to protect it, and they may make further disclosures to others and use your information without being subject to penalties under those laws.

**PURPOSE: WHY WE ARE USING AND SHARING YOUR PROTECTED HEALTH INFORMATION**

The reason for using and sharing your Protected Health Information is to conduct and oversee the current, secondary, and future research described in this Informed Consent Document. There are many other reasons beyond the research for which BIDMC may use or disclose your Protected Health Information. Not

| PARTICIPANT'S NAME: |
|---|
| TITLE OF RESEARCH PROTOCOL: |
| PRINCIPAL INVESTIGATOR'S NAME: |
| PROTOCOL #: |



all of these reasons require your express written authorization. For example, we will use and share your Protected Health Information to ensure that the research meets legal, institutional and accreditation requirements and to conduct public health activities. The various ways in which BIDMC may use and disclose your protected health information without your authorization are explained in a document called the Notice of Privacy Practices. If you have not received a copy of BIDMC's Notice of Privacy Practices, please ask us for one and review it before signing this form. In addition to signing this document, you may also be asked to sign a BIDMC General Agreement form acknowledging that you have received the BIDMC Notice of Privacy Practices.

**NO EXPIRATION DATE – RIGHT TO WITHDRAW AUTHORIZATION**

Your authorization for the use and disclosure of your Protected Health Information in this Study shall never expire. However, you may withdraw your authorization for the use and disclosure of your Protected Health Information at any time provided you notify the Principal Investigator in writing. If you would like to take back your authorization so that your Protected Health Information can no longer be used in this study, please send a letter notifying the Principal Investigator of your withdrawal of your authorization to Dr. Roger Lefevre at 330 Brookline Ave., Boston, MA 02215. Please be aware that the investigators in this study will not be required to destroy or retrieve any of your Protected Health Information that has already been used or disclosed before the Principal Investigator receives your letter, and they are permitted to continue to use and disclose your previously collected information as necessary to complete the research.

**REFUSAL TO SIGN**

Your clinical treatment may not be conditioned upon whether you sign the Authorization for Research. However, if you choose not to sign this informed consent document and authorization for the use and disclosure of your Protected Health Information, you will not be allowed to take part in the research study.

**RIGHT TO ACCESS AND COPY YOUR PHI**

If you wish to review or copy your Protected Health Information as it is made part of your medical record, you may do so after the completion or termination of the study by sending a letter to the Principal Investigator requesting a copy of your Protected Health Information. You may not be allowed to inspect or copy your Protected Health Information until this study is completed or terminated.

**ADDITIONAL CONTACT FOR QUESTIONS OR CONCERNS**

You may contact the Human Subjects Protection Office at [617] 975-8500 in the event that you would like to obtain information or to offer input about the research study. This office is independent of the investigator or investigator's research staff and can also assist with questions relating to your rights as a participant in research, which may include questions, concerns or complaints about your participation in the study.

| |
|---|
| PARTICIPANT'S NAME: |
| TITLE OF RESEARCH PROTOCOL: |
| PRINCIPAL INVESTIGATOR'S NAME: |
| PROTOCOL #: |



**THE FOLLOWING PARAGRAPHS CONTAIN SOME STANDARD INFORMATION WHICH GENERALLY APPLIES TO INDIVIDUALS PARTICIPATING IN A RESEARCH STUDY.**

**CONSENT FORM FOR CLINICAL RESEARCH**

I have read the previous page[s] of the consent form and the investigator has explained the details of the study. I understand that I am free to ask additional questions.

If I wish additional information regarding this research and my rights as a research subject, or if I believe I have been harmed by this study, I may contact the Human Subjects Protection Office (HSPO).

I am aware that this is a research project and that unforeseen side effects may occur.

I understand that the BIDMC has no formal program for compensating patients for medical injuries arising from this research. Medical treatment will be provided for injuries at the usual charge to me or to my insurer unless payment is otherwise provided for in this consent form.

I understand that participation in this study is voluntary and I may refuse to participate or may discontinue participation at any time without penalty, loss of benefits, or prejudice to the quality of care which I will receive.

I acknowledge that no guarantees have been made to me regarding the results of the treatment involved in this study, and I consent to participate in the study and have been given a copy of this form.

_____ _____

Signature of Subject or Legally Authorized Representative (Parent if the subject is a minor) — Date

_____

Relationship of Legally Authorized Representative to Subject

***The subject has been given the opportunity to read this consent form and to ask questions before signing, and has been given a copy.***

_____

SIGNATURE OF INVESTIGATOR/Co-Investigator DATE

_____

PRINT INVESTIGATOR'S/Co-Investigator's NAME

***A signing co-investigator must be listed on the study's approved Research Staffing Form at the time of consent.***

| |
|---|
| PARTICIPANT'S NAME: |
| TITLE OF RESEARCH PROTOCOL: |
| PRINCIPAL INVESTIGATOR'S NAME: |
| PROTOCOL #: |



## THE FOLLOWING SECTIONS ARE NOT NEEDED FOR ALL STUDIES AND SHOULD BE UTILIZED AS INDICATED:

***If the subject is able to speak and understand English but is not able to read or write***

I was present during the entire oral presentation of the informed consent and witnessed the subject's agreement to participate in the study.

Signature of Witness: _____

Printed Name of Witness: _____

Date: _____

***If the subject is able to understand English but is not physically able to read or write or see***

I was present during the entire oral presentation of the informed consent and witnessed the subject's agreement to participate in the study.

Signature of Witness: _____

Printed Name of Witness: _____

Date: _____