THE GEORGE WASHINGTON UNIVERSITY

WASHINGTON, DC

Informed Consent for Participation in a Research Study

Title of Research Study:

Discovery and Validation of Biomarkers for Lichen Sclerosus

Investigator Contact Information:

Principal Investigator: **Charles Macri, MD 202-741-2510**
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Investigators: **Sidney Fu, MD, PhD 202-994-4767**
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Andrew Goldstein, MD 202-887-0568
The Center for Vulvovaginal Disorders
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Why am I being invited to take part in a research study?

You are being asked to take part in the study because your skin has the appearance of the skin condition called lichen sclerosus (LS), or you have LS as shown in a biopsy

What should I know about a research study?

- Someone will explain this research study to you. You may ask all the questions you want before you decide whether to participate.
- You will not be enrolled in the study if you are pregnant or plan to get pregnant during the study.
- Participation is voluntary; whether or not you take part is up to you.
- You can agree to take part and later change your mind.
- Your decision not to take part or to stop your participation will not be held against you.
- Your decision will not affect the medical care you receive from GWU MFA or The Center for Vulvovaginal Disorders. If you decide not to take part, you can still receive medical care.
- You may take this document home to read or to discuss with your family members or doctor before deciding to take part in this research study.

Who can I talk to if I have questions?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the Study Investigator, Dr. Goldstein at **202-887-0568.**

This research is being overseen by an Institutional Review Board ("IRB"). You may talk to them at 202-994-2715 or via email at ohrirb@gwu.edu if:

- You have questions, concerns, or complaints that are not being answered by the research team or if you wish to talk to someone independent of the research team.
- You have questions about your rights as a research subject.

Why is this research being done?

You are invited to participate in a research study of the skin disease lichen sclerosus (LS). LS is a skin condition of the external genitals (vulva) of women. LS causes vulvar itching, pain, and burning. In addition, LS causes scarring of the vulva which may cause significant lack of sexual pleasure or pain. Lastly, 4-6% of women with LS will develop vulvar cancer.

By engaging in the study, we hope to learn the gene expression file changes in skins affected by LS as compared to normal skins in order to discover the mechanism of the LS, and further to develop effective drugs to treat the condition.

How long will I be in the study?

We expect that you will be in this research study for approximately 30 minutes.

How many people will take part in this research study?

We expect about 58 people will take part in the entire study. We will identify and recruit six (6) families with at least two (2) members in each family with LS. We will ask our patients if they want to ask their family members to participate. These family members must contact the CVVD and let us know that they want to participate in this study and then informed consent will be obtained.

In addition we will recruit forty (40) patients (sporadic) with active lichen sclerosus for this study. Participants must have prior biopsy proven diagnosis of lichen sclerosus and have the signs and symptoms of active lichen sclerosus.

What happens if I agree to be in this research?

After you sign the informed consent, you will be asked details of your medical history as well as the medical history of your family members. Your demographic information, such as name, race, address, date of birth, education level, etc. will be collected along with the information about your medical history and family history. Dr. Goldstein will then perform a thorough examination of your vulva. Dr. Goldstein will then take up to three (3) 4mm skin biopsies, two (2) of skin affected by LS (Only 1 will be taken if you have recently had a biopsy done by Dr. Goldstein which shows a confirmed diagnosis of active LS) and one (1) of non-vulvar skin that is not affected by LS. Only 2 of these biopsies will be used for the research study. One of

the biopsies of the affect skin will be sent to a pathological lab to confirm the diagnosis of LS if you have not already had a biopsy diagnosing you with active LS previously.

Prior to the biopsies, a numbing medication (lidocaine) will be injected in the biopsy sites. After the biopsies, you will get one or two stitches at each biopsy site. These stitches dissolve and do not have to be removed.

One (1) tube of blood (a total of 10ml or 2 teaspoons) will be drawn from a vein in your arm.

The two biopsies for this research study (one of skin affected by LS and one of normal skin) will be placed in liquid nitrogen and transported to the Department of Medicine at George Washington University in Ross Hall, along with blood samples. The other biopsy of the skin affected by LS will be sent to a lab. The three (3) biopsies and blood sample that will be taken will not be charged to you or your insurance.

Your biopsies and blood samples will not be stored with your name but will instead be given a study number. All samples obtained in this study will be processed for RNA, DNA and protein extraction, which will be used for gene expression analysis. Remaining RNA and DNA will be stored in a -80C freezer in Ross Hall of the George Washington University for a period of 5 years for further verification studies, if needed, and then they will be destroyed.

If the biopsy sent to the lab does not confirm the diagnosis of LS, then your biopsy samples and blood samples will be destroyed and will not be used for this research study.

What other choices do I have besides taking part in the research?

You do not have to take part in this study if you do not want to participate.

What happens if I agree to be in research, but later change my mind?

You may refuse to participate or you may discontinue your participation at any time without penalty or loss of benefits to which you would otherwise be entitled.

If you change your mind about participating in the research, you may contact the investigator to withdraw the participation of the study. Then your samples will be destroyed but any other data already collected will be maintained.

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

Possible risks, discomforts and inconveniences that you could experience during this study are from the vulvar biopsies and blood draw. These risks or discomforts include pain, bleeding, scarring, infection, and bruising. You will not be able to engage in sexual activity until the biopsies heal in approximately 10-14 days. Other members of your family may also be participating in this study. Therefore some risk to privacy about your condition may exist.

Disease Specific or Genetic Testing

Disease testing and genetic research raises certain questions about informing you of any results. In this study, you will not be getting any results of the testing. Possible risks of knowing results include: anxiety; other psychological distress; and the possibility of insurance and job discrimination. A possible risk of not knowing includes being unaware of the need for

treatment. These risks can change depending on the nature and results of the research and whether there is a treatment or cure for a particular disease. Sometimes patients have been required to furnish information from genetic testing for health insurance, life insurance, and/or a job.

Even with special precautions, there is no absolute protection against discrimination on the basis of disease or genetic information. For this reason, the study Doctors will use the results of this study as research only and not include them in your medical record.

What happens if I believe I am injured because I took part in this study?

The researchers have taken steps to minimize the known or expected risks. In spite of all precautions, you still may experience medical complications or side effects from participating in this study. You should promptly notify the study doctor in the event of any illness or injury as a result of being in the study.

If you believe that you have been injured or have become ill from taking part in this study, you should seek medical treatment from

- The Center for Vulvovaginal Disorders,
- GWU Hospital,
- the GWU Medical Faculty Associates, or
- through your physician or treatment center of choice.

Care for such injuries will be billed in the ordinary manner to you or your insurance company. Your insurance company may not pay for such care because you are participating in a research study.

You will not receive any financial payments from The Center for Vulvovaginal Disorders, GWU, The Gynecologic Cancer Research Foundation (GCRF), GWU Hospital and/or the GWU MFA for any injuries or illnesses. You do not waive any liability rights for personal injury by signing this form.

Will being in this study help me in any way?

You will not receive any benefits from participating in this research.

We hope the information learned from this study will benefit individuals with lichen sclerosus in the future or aid in our understanding of lichen sclerosus.

What happens to my information collected for the research?

To the extent allowed by law, we limit your personal information to people who have to review it. We cannot promise complete secrecy. The IRB and other representatives of this organization may inspect and copy your information.

All records are kept in a secure location at Dr. Andrew Goldstein's clinic, The Center for Vulvovaginal Disorders in Washington, DC in a password protected database, and access is limited to research study personnel.

Except as required by law, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier. The results of this research study may be presented at scientific or medical meetings or published in scientific journals. However, your identity will not be disclosed, unless you give the appropriate authorization.

Tissue Sampling for Research

Research using tissues is an important way to try to understand human disease. You have been given this information because the investigators want to include your tissues in a research project. There are several things you should know before allowing your tissues to be studied.

Your tissues will be stored under a study number and will not be directly linked to your identity.

You have the right to refuse to allow your tissues to be studied now or saved for future study. You may withdraw from this study at any time. The investigators might retain the identified samples, e.g., as part of your routine clinical care, but not for additional research.

You will be told the results of tests that are part of your clinical care, but you will not be told the results of the research tests, including any future research tests.

_____ I **consent** to my samples being saved for future research

_____ I **do not consent** to my samples being saved for future research

Genetic Testing

As part of the analysis on your samples, the investigators will do genetic testing. Genetic research is research that studies genes, including gene characteristics and gene versions that are transmitted by parents to children. Genetic research may include looking at information, such as personal appearance and biochemistry, gene sequences, genetic landmarks, individual and family medical histories, reactions to medications, and responses to treatment. A Federal law, the Genetic Information Nondiscrimination Act of 2008 (GINA), generally makes it illegal for health insurance companies, group health plans, and employers with 15 or more employees to discriminate against you based on your genetic information.

This law generally offers the following protections:

- Health insurance companies and employer-based group health plans may not request your genetic information that we get from this research.

- Health insurance companies and employer-based group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.

- Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

- All health insurance companies and group health plans must follow this law. All employers with 15 or more employees must follow this law as of November 21, 2009. The protections offered by GINA apply regardless of when the research that obtained the genetic information was conducted, even if prior to the effective date.

Be aware that this law does not protect you against discrimination on the basis of your genetic information by companies that sell life insurance, disability insurance, or long-term care insurance.

How will my privacy and health information be protected?

The Health Insurance Portability and Accountability Act (HIPAA) requires that researchers and health care providers protect the privacy of information that identifies you and relates to your past, present and future physical and mental health or conditions, or the provision of health care. If you agree to participate in this research, protected health information will be used and shared with others for purposes of the study. Below is more detailed information about how your health information will be shared and protected. By signing this form, you are allowing the people and groups that are listed in the next paragraphs to use your health information for this research study. Your information will only be used or shared as explained in this authorization form.

The use and release of protected health information is for the purpose of collecting data for this study.

Protected Health Information to be shared:

- This consent form;
- Demographic information (like your name, date of birth, etc.);
- Information about your medical history from your medical records and your doctor's office;
- Information obtained from you to be used in the Study as a result of tests or procedures;
- Results of physical examinations
- Laboratory results obtained on specimens collected from you (like blood, urine, tissue);
- Interviews with you conducted by members of the Research Team;
- Other data created or collected during this study.

Who may disclose your protected health information: The researcher and the other members of the research team may obtain your individual health information from:

- The Center for Vulvovaginal Disorders

- And from hospitals, clinics, health care providers, and health plans that provide health care to you during the study.

By signing this form, you allow the use, sharing, copying, and release of your protected health information in connection with this study to:

- The members of the research team;
- Other healthcare providers such as labs which are part of the study;
- Institutional officials who are responsible for compliance;
- GWU Institutional Review Board ("IRB") or its authorized representatives, as well as representatives of the Office of Human Research Protections (OHRP) who may review your records to ensure that your rights as a research subject are protected.
- The sponsor of the study and any contractors or partners it may have. (research monitors and auditors), and
- Accrediting agencies and legal counsel

Some of the tests in this study are being done as part of your regular care. These test results will be used both to treat you and to complete this research. The test results from the routine biopsy will be recorded in your medical record. Results of tests and studies done solely for this research study and not as part of your regular care will not be included in your medical record.

Once your health information has been disclosed to others outside of the hospitals and medical practices, the information may no longer be covered by the federal regulation that protects privacy of health information.

Not signing this form or later canceling your permission will not affect your health care treatment outside the study, payment for health care from a health plan, or ability to get health plan benefits. However, if you do not give permission to use your health information, you may not take part in this study because your health information is needed in order to conduct this study.

This Authorization does not have an expiration date.

However, you may cancel this authorization at any time. Even if you cancel this authorization, the researchers may still use the protected health information they already have about you; however, no new health information or new biological specimens will be collected from you after you cancel your permission.

To cancel your permission, you will need to send a letter to ***Dr. Andrew Goldstein*** stating that you are canceling your authorization. This letter must be signed and dated and sent to this address: ***The Center for Vulvovaginal Disorders, 3 Washington Circle, NW, Suite 205, Washington, DC 20037*****.**

Are there any costs for participating in this research?

There will be no additional costs to you as a result of taking part in this study. However, you are responsible for all routine medical care for your condition (the care you would receive whether or not you were in this study).

Will I be paid for my participation in this research?

There is no payment provided for participating in this study.

What else do I need to know?

This research is being funded by a grant from The Gynecologic Cancer Research Foundation (GCRF). Dr. Goldstein is the president of GCRF.

May we contact you about future studies that may be of interest to you?

____ Yes ____ No {please initial one choice}

Signature Block for Adult

By signing below, you agree that the above information has been explained to you and you have had the opportunity to ask questions. You understand that you may ask questions about any aspect of this research during the course of the study and in the future. Your signature documents your permission to take part in this research. Your signature documents your permission to take part in this research.

_____

Printed name of subject

_____ _____

Signature of subject Date

_____ _____

Signature of person obtaining consent Date