MedStar Health
Research Institute

Office of Research Integrity
6525 Belcrest Rd, Suite 700
Hyattsville, MD 20782

Approval Notice
Response to Tabled

04-Apr-2018

MedStar Washington Hospital Center
106 Irving Street, NW, Suite 2100 North
Washington, DC 20010

Protocol Number: **2016-144**
PI Name: **Cheryl Iglesia MD**
Protocol Title: **A Randomized Extension Trial Comparing Clobetasol Prioprionate Versus Radiofrequency CO2 Laser for the Treatment of Lichen Sclerosus (eCuRLS)**

Dear Cheryl Iglesia MD,

The **Response to Tabled -** ***(Continuation)*** submission was reviewed by **IRB # 1 Washington** in accordance with full board review procedures on **13-Mar-2018**.

The IRB has approved the submission. You can begin research activities. **The approval is valid from *13-Mar-2018* through *12-Mar-2019***. Any modifications to the IRB-approved protocol and other supporting documents must be reviewed and approved by the IRB prior to implementation.

If the study will continue beyond *12-Mar-2019*, please submit a continuation request form forty-five (45) days prior to *12-Mar-2019* to allow the IRB sufficient time to review and approve the request.

If you have any questions, please contact me at 301-560-2979.

Thank you,

Ashlee Tidwell
Office of Research Integrity

Enclosure: IRB Stamped Informed Consent

IRB number:	2016-144	**Clinical Site IC Version:**	19Sept2016
Project Title:	**A crossover trial comparing Clobetasol Proprionate Versus Fractional CO2 laser for the treatment of Lichen Sclerosus (eCuRLS)**		
Principal Investigator:	Cheryl Iglesia	**Institution:**	MedStar Washington Hospital Center, MedStar Health

MedStar Health Research Institute Informed Consent for Clinical Research

INTRODUCTION

We invite you to take part in **A crossover trial comparing Clobetasol Proprionate Versus Fractional CO2 laser for the treatment of Lichen Sclerosus (eCuRLS)** research study called *eCuRLs*. You were selected as a possible participant in this study because you have lichen sclerosus. Please take your time to read this form, ask any questions you may have and make your decision. We encourage you to discuss your decision with your family, friends and your doctor(s).

WHAT IS THE PURPOSE OF THIS STUDY?

Lichen sclerorus has been traditionally treated with steroid creams such as clobetasol. However, we would like to see if laser treatment can also impact lichen sclerosus and how it compares to steroid cream. This study is being done to compare the effects, good and bad, of **fractional CO2 laser treatment** or **clobetasol proprionate .05% ointment** on you and your lichen sclerosus to see which is better.

WHAT ELSE SHOULD I KNOW ABOUT THIS RESEARCH STUDY?

It is important that you read and understand several points that apply to all who take part in our studies:

- Taking part in the study is entirely voluntary and refusal to participate will not affect any rights or benefits you normally have;
- You may or may not benefit from taking part in the study, but knowledge may be gained from your participation that may help others; and
- You may stop being in the study at any time without any penalty or losing any of the benefits you would have normally received.

The nature of the study, the benefits, risks, discomforts and other information about the study are discussed further below. If any new information is learned, at any time during the research, which might affect your participation in the study, we will tell you. We urge you to ask any questions you have about this study with the staff members who explain it to you and with your own advisors prior to agreeing to participate.

WHO IS IN CHARGE OF THIS STUDY?

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The investigator is Dr. Cheryl Iglesia. The research is being sponsored by Foundation for Female Health Awareness (FFHA) and MedStar Washington Hospital Center Graduate Medical Education Grant (GME). MedStar Health Research Institute is being paid by FHFA and GME to conduct this study with Dr. Cheryl Iglesia as the primary investigator.

WHO CANNOT PARTICIPATE IN THIS STUDY?

You cannot be in this study if any of the following apply to you:

- Male
- Non-English speaking
- Known vulvar cancer
- Pregnancy or planning pregnancy or less than 3 months postpartum
- Current or prior diagnosis of any gynecologic cancer
- Previous pelvic radiation therapy
- Allergy to topical steroid
- Active urinary tract infection, or other vulvar infection
- Pelvic organ prolapse outside the vagina
- Treatment with oral steroids or other medications affecting the immune system
- Treatment with vaginal hormonal or vulvar topical steroid use within the past 2 months
- An IUD or intrauterine device

WHAT IF I AM PRESENTLY PARTICIPATING IN ANOTHER RESEARCH STUDY?

Are you presently participating in any other research studies? Yes ☐ No ☐

If yes, please state which study(ies)_____

While participating in this study, you should not take part in any other research project without approval from the people in charge of each study. This is to protect you from possible injury arising from such things as extra blood drawing, extra x-rays, interaction of research drugs, or similar hazards.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

About **(54)** people will take part in this study, worldwide. **(54)** people will be recruited at this site.

WHAT HAPPENS IF I AGREE TO BE IN THE STUDY?

If you agree to take part in this study, you will be receive either Fractional CO2 laser treatment or clobetasol proprionate 0.05%. If you have already received the laser treatment, you will now receive clobetasol

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proprionate 0.05% steroid treatment. If you have already received clobetasol proprionate 0.05% steroid treatment, you will now receive laser treatment.

You will be asked to fill out questionnaires again. A photo of disease on the vulva will be taken again. The LASER treatment is monthly for 3 months. The topical STEROID therapy, clobetasol propionate .05% ointment is nightly for one month then three times weekly for 2 additional months. At the end of the 6 months, treatment you will be asked to complete follow up questionnaires and another photograph of disease on your vulva will be taken for comparison.

The procedures/treatments in this study that are considered experimental/investigational are: use of the Mona Lisa Fractional CO2 laser for vulvar lichen sclerosus.

For procedures/treatments that are not experimental/investigational,

- The following procedures are part of the research study and would not normally be done as part of your routine care: photo documentation, questionnaires
- The following procedures would normally be done as part of your routine care whether or not you are enrolled in the study: vulvar biopsy, use of clobetasol propionate .05% ointment.

HOW LONG WILL I BE IN THE STUDY?

We think you will be in the study for 6 months.

The investigator may decide to take you off this study if it is believed to be in your best interest, you fail to follow instructions, new information becomes known about the safety of the study, or for other reasons the investigator or sponsor believes are important.

You can stop participating at any time. However, if you decide to stop participating in the study, we encourage you to talk to the investigator and your regular doctor first so they can help you decide what other options may be best for your medical care once you are off study.

If you suddenly withdraw from the study, we may not be able to use any of the information gathered from your participation.

WHAT ARE THE RISKS AND SIDE EFFECTS OF THIS STUDY?

If you decide to participate in this study, you should know there may be risks. You should discuss these with the investigator and/or your regular doctor and you are encouraged to speak with your family and friends about any potential risks before making a decision. Potential risks and side effects related to this study include:

Risks of clobetasol proprionate include skin irritation, burning, rash and change in skin pigmentation. Potential adverse reactions to laser use include ocular laser exposure which will be minimized with the use of protective eyewear with an optical density of 4x the treatment wavelength. Risk to the patient include pain or mild to moderate discomfort, erythema, swelling, blistering, itching, numbness, change in pigmentation, sacarring and burns as well painful intercourse. These risks will be rriinimized with laser use per manufacture instructions with trained personel. All known risks will be disclosed to the participants via the informed consent process. All study participants will be closely monitored post treatment for adverse events.

Risks and side effects ***that may occur*** include:

- Pain and irritation at treatment site
- Bleeding from biopsy site
- Infection at treatment site

Risks and side effects ***that are less likely to occur*** include:

- Swelling
- Blistering
- Itching
- Numbness
- Painful intercourse
- Scarring
- Laser eye injury

Risks and side effects ***that rarely occur*** include:

- Change in pigmentation
- Laser burns
- Change in sexual response, affecting arousal around clitoris and orgasm

Please tell the investigator about all medications including over-the-counter drugs or herbal supplements you are taking, even if you don't think they are important.

Only you can take the study drug. Do not share it with anyone else. It must be kept out of reach of children and persons who may not be able to read or understand the label.

There may also be risks and side effects other than those listed above that we cannot predict. Many side effects go away in a short time after the steroid or laser treamentis stopped, but, in some cases, side effects can be serious, long lasting and/or life threatening. If you have any unwanted side effects, you should ask the

investigator whether there are any medications or other things that may be done to make the side effect less uncomfortable.

For more information about risks and side effects, please ask **Dr. Cheryl Iglesia.**

ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?

You may or may not get any direct benefit from being in this study. We cannot promise that you will experience any benefits from participating in this study. We hope the information learned from this study will benefit others in the future.

WHAT OTHER OPTIONS ARE THERE?

Instead of being in this study, you have these options:

- You always have the option to not be in this study or to refuse any medical treatment.

WHAT ABOUT CONFIDENTIALITY?

Your personal health information (PHI) will be kept private to the extent allowed by law. Study records identifying you will be kept confidential and will not be made publicly available. You will not be identified by name in any publications resulting from this study. You will be asked to sign a separate form that will give permission to the investigator, representatives from government agencies, including the Food and Drug Administration (FDA), institutional review boards, the sponsor and/or the sponsor's representative(s), and certain other people, agencies or entities, to look at and review the records related to this study including your personal health information and the information discovered during this study. This separate form explains in greater detail who will have access to your records, what type of information will be reviewed and for what purposes, how long your permission for others to review and release your records will last, and how you may withdraw your permission if necessary. If you do not wish to sign this permission form you will not be allowed to participate in this study.

Information, that does not include personally identifiable information, concerning this clinical trial has been or may be submitted, at the appropriate and required time, to the government-operated clinical trial registry data bank, which contains registration, results, and other information about registered clinical trials. This data bank can be accessed by you and the general public at www.ClinicalTrials.gov. Federal law requires clinical trial information for certain clinical trials to be submitted to the data bank.

A Data Safety and Monitoring Board, which is a group of experts not connected to the study, will be reviewing the data from this research throughout the study. We will tell you about the new information from this or other studies that may affect your health, welfare, or willingness to stay in this study.

WILL I BE PAID FOR PARTICIPATING IN THIS STUDY?

You will not be paid for being in this study. Materials and information obtained from you in this research may be used for commercial or non-commercial purposes. It is the policy of MedStar Health Research Institute, MedStar Health, Inc. and its affiliated entities not to provide financial compensation to you should this occur.

WHAT ARE THE COSTS?

You do not have to pay anything to be in this study. However, if taking part in this study leads to procedures or care not included in the study, it may lead to added costs for you or your insurance company. You will not be charged for appropriate tests, procedures, medications, etc. that are part of this research study.

However, you, or your insurance company, will be charged for any other portion of your care that is considered standard of care. You may be responsible for any co-payments and deductibles that are standard for your insurance coverage during each office visit. This may include: cost for steroid cream, baseline vulvar biopsy, and follow up study visits to monitor treatment.

WHAT IF I'M INJURED OR BECOME ILL DURING THE STUDY?

We will make every effort to prevent injuries or illness from occurring while you are in the study. In the case of an injury, illness, or other harm occurring to you during, or resulting from, the study, you should seek medical treatment. You should also contact the study doctor as soon as possible. You or your insurance company will be charged for any continuing medical care and/or hospitalization that are not a part of the study.

If you suffer an injury related to the study drug or study procedures, the reasonable costs of necessary medical treatment of the injury will not be reimbursed by the Foundation for Female Health Awareness to the extent these costs are not covered by your insurance or other third party coverage.

No funds have been set aside, by the MedStar Health Research Institute, MedStar Health, or its affiliated entities to repay you in case of injury, illness, or other harm occurring during, or resulting from the study, and their current policies do not provide for payments for lost wages, cost of pain and suffering, or additional expenses. By agreeing to this you do not give up your rights to seek compensation in the courts.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

- You have the right to be told about the nature and purpose of the study;
- You have the right to be given an explanation of the exactly what will be done in the study and given a description of potential risks, discomforts, or benefits that can reasonably be expected;

- You have the right to be informed of any appropriate alternatives to the study, including, if appropriate, any drugs or devices that might help you, along with their potential risks, discomforts and benefits;
- You have the right to ask any questions you may have about the study;
- You have the right to decide whether or not to be in the study without anyone misleading or deceiving you; and
- You have the right to receive a copy of this consent form.

By signing this form, you will not give up any legal rights you may have as a research participant. You may choose not to take part in or leave the study at any time. If you choose to not take part in or to leave the study, your regular care will not be affected and you will not lose any of the benefits you would have received normally. We will tell you about new information that may affect your health, welfare, or willingness to be in this study.

WHO DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or a research-related injury, contact the investigator, Joanna Peterson, clinical research nurse coordinator, at (202)-877-0526. If you are having a medical emergency, you should call 911 or go directly to the nearest emergency room.

For questions about your rights as a research participant, contact the MedStar Health Research Institute. Direct your questions to the Office of Research Integrity at:

Address:	MedStar Health Research Institute 6525 Belcrest Rd. Suite 700 Hyattsville, MD 20782	Telephone: Toll Free: Fax	(301) 560-2912 (800) 793-7175 (301) 560-7336

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SIGNATURES

As a representative of this study, I have explained the purpose, the procedures, the possible benefits and risks that are involved in this research study. Any questions that have been raised have been answered to the individual's satisfaction.

Signature of Person Obtaining Consent _____ Date of Signature _____

Printed Name of Individual Obtaining Consent: _____

I, the undersigned have been informed about this study's purpose, procedures, possible benefits and risks, and I have received a copy of this consent. I have been given the opportunity to ask questions before I sign, and I have been told that I can ask other questions at any time. I voluntarily agree to be in this study. I am free to stop being in the study at any time without need to justify my decision and if I stop being in the study I understand it will not in any way affect my future treatment or medical management. I agree to cooperate with Dr. Cheryl Iglesia and the research staff and to tell them immediately if I experience any unexpected or unusual symptoms.

Participants signature _____ Date of Signature _____

Printed Name of Participant _____

As the Principal Investigator (or his designee) for this research study, I attest that the participant has voluntarily agreed to be part of this study, the risks and benefits of the study have been fully explained, and any questions have been addressed to the participant's satisfaction.

Principal Investigator's Signature _____ Date of Signature _____