Consent and Authorization Document

Protocol Title: **Efficacy of 1540nm Erbium glass laser to improve benign dermatofibromas**

Study Doctor: **Karen Stolman, MD**

Contact Info: Monday-Friday (8am-5pm) –801-213-4500
After Hours: 801-581-2121 – (Hospital Operator, ask for Dr. Stolman to be paged.)

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BACKGROUND

You are being asked to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether you want to volunteer to take part in this study.

The purpose of the study is to see if the 1540 erbium glass laser is effective in treating dermatofibromas. Dermatofibromas are common benign bumps on the skin, which most often arise on the lower legs. The color of dermatofibromas range from pink to dark brown. They are firm in texture, and the may be painful or itchy. Dermatofibromas are most common in women, but their cause is still unknown. Some doctors believe that dermatofibromas are the skin's reaction to injury, some believe that they are triggered by hormones, and some believe in a combination of both explanations. Dermatologists confirm that the bumps are dermatofibromas by gently pinching the lesions which results in an inward dimpling.

Currently there is not a perfect cure for dermatofibromas. Some treatments may work for some lesions, but not for others. Some of these treatments include: Cryotherapy, shave removals, surgical excision, CO2 laser treatments, and pulsed dye laser treatments. Because these treatments do not work on all dermatofibromas, and some of these treatments will leave a scar, dermatologists would like to see if there are other more effective and lower risk treatments available like the 1540 erbium glass laser. The Erbium glass laser is already widely in use for skin treatments such as: scar treatments, wrinkle treatments, stretch mark treatments, and melasma treatments.

STUDY PROCEDURES

If you decide to participate in this research study you will have 2 to 5 brief clinic visits in four months. The first visit you may have already completed and is called the screening visit. The purpose of the screening visit is to see if you meet all of the qualifications to be a part of the study. If the study doctor determines that you qualify, you will move to the treatment phase of the study. You will receive one treatment with the 1540 erbium glass laser at visit 2 (baseline visit), and one more treatment 4 weeks

later as needed, at visit 3. You will have two follow up visits, 4 and 12 weeks after the last treatment, where the doctor will look at your skin, take photos of the treated lesions, and you will be asked to fill out brief questionnaires. The last two visits where your progress will be evaluated will be no charge office visits. You will have the option of completing these two follow-up visits remotely if you wish. If you are having any side effects, or any changes to your health you should complete the follow-up visits in person. Below are descriptions of what will happen during the study.

- **Informed Consent** – You will be asked to read, discuss and sign this consent form.
- **Inclusion/Exclusion Criteria Review** – The study doctor will check that you meet all of the requirements to continue on the study.
- **Medical History Review -** The study doctor will ask you questions about your medical history, medications, and procedures that you have had in the past. The study doctor will ask you if you are pregnant, breastfeeding, or trying to become pregnant. If you are pregnant, trying to become pregnant or breastfeeding you will not be allowed to participate in this study. If you have any of the following characteristics then you will be excluded from participation in the study: previous treatment of the dermatofibroma, pregnancy/nursing, diabetic, smoker, psoriasis, lupus or other autoimmune disease, history of keloids or poor wound healing.
- **Adverse Event Review –** After the first visit, the study doctor will review any adverse events or side effects since your previous visit while participating on the study.
- **Dermatofibroma Assessment –** The study doctor will examine and assess your dermatofibroma(s).
- **Questionnaires** – You will be asked to fill out some questionnaires about your skin, and rate the pain, itch and color of your dermatofibroma(s). If you choose to complete the two follow-up visits remotely you will complete these surveys through MyChart.
- **Photographs** will be taken of your dermatofibroma(s). These photographs will be taken to help researchers decide if the 1540 erbium glass laser is effective in treating dermatofibromas. You will have photos taken before your first treatment with the laser, before your second treatment, and at both follow up visits. If you choose to complete the two follow-up visits remotely you will take photos as instructed by the study doctor, and upload these photos to MyChart for the study doctor to review. You will not be identified in these photographs. However, if you have any markings on that area of your skin, like a tattoo, those markings may appear in the photographs. The study doctor will own these photographs. The photographs will be used in publications, presentations, brochures, or other ways. The photographs may be used along with text, graphics, or audio materials. You will not be identified by name in any use of the photographs. By signing this consent document, you are giving permission for the study doctor to take this type of photographic images and for the uses described above.
- **Laser Treatment –** You will have laser treatments on the dermatofibromas at visits 2 & 3 during the study. The laser treatment will feel like a rubber band slapping against the skin. This sensation may occur once or twice on the skin. The treatment will only last a few minutes. After each treatment you will need to gently cleanse your skin once daily while bathing. You will need to apply a bland fragrance-free moisturizer like Cetaphil cream to each treated spot twice per day. You must avoid direct sun to the treated spots for the duration of the study as this may

interfere with healing. It is typical to have redness, swelling, and mild stinging of the treated skin for one to two days after treatment. It is rare to experience worsening of the dermatofibroma after healing from the treatment.

Study Procedures	**Screening Visit (Visit 1)**	**Baseline Visit (Visit 2 – first treatment)**	**Visit 3 (2nd Treatment)**	**Visit 4 (Follow-up #1)**	**Visit 5 (Follow-up #2)**
Week #		Week 0	Week 4	Week 8	Week 12
Informed Consent	X				
Inclusion/Exclusion Criteria Review	X				
Medical History Review	X				
Adverse Event Review		X	X	X	X
Dermatofibroma Assessment	X	X	X	X	X
Questionnaires	X	X	X	X	X
Photographs		X	X	X	X
Laser Treatment		X	X		

RISKS

Study Laser Treatment Risks

With erbium laser skin treatment, it is possible to have temporary redness, swelling, burning, pain, itching. Some less common possible side effects include: persistent redness, discoloration, infection, scarring, no improvement, worsening.

Risks from Research Procedures:

Risks and possible discomforts you might have from the research study procedures include:

- **Questionnaires:** A questionnaire may contain questions that are sensitive in nature. If you have concerns after completing the questionnaire, you should contact your study doctor.
- **Photographs:** Depending on the location of your dermatofibroma you may feel embarrassed about having photographs taken. If you have personal tattoos, there is a chance that you could possibly be identified from the photos. If you have concerns about the photographs, please talk with the study doctor.

UNFORESEEABLE RISKS

In addition to the risks listed above, you may experience a previously unknown risk or side effect.

BENEFITS

We cannot promise any direct benefit for taking part in this study. However, a possible benefit would be that your dermatofibroma would get better. Your participation will help researchers know if the 1540 erbium glass laser works as a treatment for dermatofibromas. We hope that this study will help you, however, this cannot be guaranteed.

ALTERNATIVE PROCEDURES

Currently there is not a cure for dermatofibromas. However, other treatments have been effective for some dermatofibromas. These include: Cryotherapy, shave biopsies, excision of the lesions, CO2 laser treatments, and pulsed dye laser treatments. If you do not want to participate in the study, the study doctor can discuss these alternative procedures with you.

PERSON TO CONTACT

You can ask questions about the study at any time. If you have questions, complaints, or concerns about this study, you can contact the study personnel.

You can contact the study team by telephone during weekday office hours (8am-5pm Monday through Friday) at 801-213-4500. If you think you may have been injured from being in this study, please contact Dr. Karen Stolman at 801-213-4500 from (8am-5pm, Monday-Friday). If outside of normal business hours, please contact Dr. Karen Stolman at 801-581-2121 and have her paged by the hospital operator.

In the event of an emergency, dial 911 immediately.

If you require emergency care, be sure to tell the emergency care provider about your participation in this study. Contact the study doctor or study staff as soon as possible.

Institutional Review Board: Contact the Institutional Review Board (IRB) if you have questions regarding your rights as a research participant. Also, contact the IRB if you have questions, complaints or concerns which you do not feel you can discuss with the investigator. The University of Utah IRB may be reached by phone at (801) 581-3655 or by e-mail at irb@hsc.utah.edu.

Research Participant Advocate: You may also contact the Research Participant Advocate (RPA) by phone at (801) 581-3803 or by email at participant.advocate@hsc.utah.edu.

RESEARCH-RELATED INJURY

If you are injured from being in this study, medical care is available to you at the University of Utah, as it is to all sick or injured people. The University of Utah has not set aside any money to pay the costs for such care. The University will work with you to address costs from injuries. Costs would be charged to you or your insurance company (if you have insurance), to the study sponsor or other third party (if applicable), to the extent those parties are responsible for paying for medical care you receive. Since this is a research study, some health insurance plans may not pay for the costs. By signing this consent form you are not giving up your right to pursue legal action against any parties involved with this research.

The University of Utah is a part of the government. If you are injured in this study, and want to sue the University or the doctors, nurses, students, or other people who work for the University, special laws may apply. The Governmental Immunity Act of Utah is a law that controls when a person needs to bring a claim against the government, and limits the amount of money a person may recover. See sections 63G -7-101 to -904 of the Utah Code.

VOLUNTARY PARTICIPATION
Research studies include only people who choose to take part. You can tell us that you don't want to be in this study. You can start the study and then choose to stop the study later. We will still give you medical care and answer any questions you have. Your decision will not affect your relationship with your doctor or the study team in any way.

If you want to stop being in this study, please let the research doctor know. That way you can find out what should be done about your normal medical care outside of the study.

RIGHT OF INVESTIGATOR TO WITHDRAW PARTICIPANTS
In the event that a participant experiences the following adverse effects before the final treatment, that participant will continue in the study, for data collection, but will be asked to withdraw from further laser treatments: *Scar, blistering, infection, worsening of symptoms or appearance of lesions.*

A participant that newly acquires one of the exclusion criteria will be asked to withdraw from the study (for example: pregnancy).

COSTS AND COMPENSATION TO PARTICIPANTS
All 5 study visits and related study procedures performed at the visits will be free of charge to you.

NUMBER OF PARTICIPANTS
We expect to enroll 40 participants into this study.

AUTHORIZATION FOR USE OF YOUR PROTECTED HEALTH INFORMATION
Signing this document means you allow us, the researchers in this study, and others working with us to use some information about your health for this research study.

This is the information we will use and include in our research records:

- Demographic and identifying information like name, address, and telephone number
- Related medical information about you like current and past medical conditions, allergies, current and past medications or therapies, and information from physical examinations, such as blood pressure reading, heart rate, temperature, and lab results
- All tests and procedures that will be done in the study

How we will protect and share your information:

- We will do everything we can to keep your information private but we cannot guarantee this. Study information will be kept in a secured manner and electronic records will be password protected. Study information may be stored with other information in your medical record. Other doctors, nurses, and third parties (like insurance companies) may be able to see this

information as part of the regular treatment, payment, and health care operations of the hospital. We may also need to disclose information if required by law.

- In order to conduct this study and make sure it is conducted as described in this form, the research records may be used and reviewed by others who are working with us on this research:
    - Members of the research team and University of Utah Health Sciences Center;
    - The University of Utah Institutional Review Board (IRB), which reviews research involving people to make sure the study protects your rights;
- If we share your information with groups outside of University of Utah Health Sciences Center, we will not share your name or identifying information. We will label your information with a code number, so they will not know your identity.
- If you do not want us to use information about your health, you should not be part of this research. If you choose not to participate, you can still receive health care services at University of Utah Health Sciences Center.

What if I decide to Not Participate after I sign the Consent and Authorization Form?

You can tell us anytime that you do not want to be in this study and do not want us to use your health information. You can also tell us in writing. If you change your mind, we will not be able to collect new information about you, and you will be withdrawn from the research study. However, we can continue to use information we have already started to use in our research, as needed to maintain the integrity of the research.

This authorization does not have an expiration date.

CONSENT

I confirm that I have read this consent and authorization document and have had the opportunity to ask questions. I will be given a signed copy of the consent and authorization form to keep.

I agree to take part in this research study and authorize you to use and disclose health information about me for this study, as you have explained in this document.

_____
Participant's Name

_____ _____
Participant's Signature Date

_____
Name of Person Obtaining Authorization and Consent

_____ _____
Signature of Person Obtaining Authorization and Consent Date