SAINT LOUIS UNIVERSITY

Research Study Consent Form

STUDY TITLE:	A single center, prospective, double-blinded, randomized, placebo-controlled trial evaluating the efficacy of fractionated carbon dioxide therapy in postoperative lower extremity wound healing

This consent form contains important information to help you decide whether to participate in a research study.

The study staff will explain this study to you. Ask questions about anything that is not clear at any time. You may take home an unsigned copy of this consent form to think about and discuss with family or friends.

- **Being in a study is voluntary – <u>your choice</u>.**
- **If you join this study, you can still <u>stop at any time</u>.**
- **<u>No</u> one can <u>promise</u> that a study will help you.**
- **Do not join this study unless all of your <u>questions</u> are <u>answered</u>.**

After reading and discussing the information in this consent form you should know:

- Why this research study is being done;
- What will happen during the study;
- Any possible benefits to you;
- The possible risks to you;
- Other options you could choose instead of being in this study;
- How your personal health information will be treated during the study and after the study is over;
- Whether being in this study could involve any cost to you; and
- What to do if you have problems or questions about this study.

<u>Please read this consent form carefully.</u>

RESEARCH STUDY CONSENT FORM

Participant:		**IRB #:**	29076
	First Name / Last Name		
Principal Investigator (PI)	Ramona Behshad, M.D	**Contact Phone #**	314-977-9721
	First Name / Last Name Credentials		
Title of Project:	A single center, prospective, double-blinded, randomized, placebo-controlled trial evaluating the efficacy of fractionated carbon dioxide therapy in postoperative lower extremity wound healing		

"You" refers to the person who takes part in the research study.

You are being asked to take part in a research study conducted by Dr. Ramona Behshad and colleagues, because you are having Mohs surgery on your lower leg.

This consent document may contain words that you do not understand. Please ask the research study doctor or research staff to explain anything that you do not understand.

1. WHY IS THIS RESEARCH STUDY BEING DONE?

This study is attempting to determine if a Food and Drug Administration (FDA) approved laser, the Syneron-Candela CO2RE laser, can safely improve how fast your body heals after Mohs surgery on the lower legs. Lasers are devices that produce and shoot a high energy form of light in a controlled way. With FDA approval, doctors have been using lasers to treat conditions like scars and wrinkles for many years. Some physicians have noticed recently that using lasers on long standing wounds helped them heal faster. After Mohs surgery (a surgery to remove some types of skin cancer) on the lower legs you will have some missing tissue (skin, muscle, fat, etc.) where the surgery was done. We refer to that as a postoperative wound. Patients usually have a longer and more difficult time healing lower leg wounds than wounds on other parts of the body. This study will see if the laser treatment after Mohs surgery will help your wound heal faster. The use of the laser in this study is FDA approved. No more than 68 subjects will be enrolled at Saint Louis University.

2. WHAT AM I BEING ASKED TO DO?

Broad Overview:

After the doctor makes sure you are able to participate in the study, you will be placed in group A or group B. Your placement will be random (50/50 chance of being in either group). You will then go for your planned Mohs surgery. Your surgery is not a part of the study and will happen regardless of your choice to participate in this study. After your surgery, if you choose to participate, you will have a real laser treatment or a fake one depending on your group. The fake treatment group is called a placebo group. A placebo group makes sure that the difference we see in 2 groups is because of the laser treatment and not something else. Only

the doctor performing the laser treatment will know which you received. If you receive the real treatment, the doctor will apply the laser to your wound. If you receive the placebo treatment, the doctor will activate the laser and aim it at the floor. You'll be wearing dark safety glasses, your skin will still be numb, and you will hear the laser operating during both fake or real treatments so you will not know which treatment you received. Other research team members will not know which treatment you received. This process is called blinding, and it makes sure that the results are not affected by you or us knowing the treatment you received. If it becomes necessary, the doctor can reveal which group you were in. After treatment, measurements and several different types of pictures will be taken of your lower legs. After the surgery you'll be seen 6 more times and similar measurements will be recorded. Between visits we will ask you to keep a diary of observations about your lower legs.

Required visits:

All visits will take place at SLU Des Peres Dermatology Clinic

1. Initial visit the day of your surgery
2. 1 weeks after your surgery
3. 2 weeks after your surgery
4. 3 weeks after your surgery
5. 4 weeks after your surgery
6. 8 weeks after your surgery
7. 12 weeks after your surgery

If you were not in this study, you would typically follow up with your Mohs surgeon about every 4 weeks after your surgery. By participating in this study, you would be required to have some additional visits in the first 4 weeks following your surgery. Therefore, study visits at 1, 2, and 3 weeks after your surgery are for study purposes only. Visits at the day of your surgery, 4, 8, and 12 weeks after surgery occur regardless of your participation in this study and as a normal part of your care.

Initial visit (1 hour not counting surgery time):

The screening visit will occur prior to your surgery. You will verify information regarding your name and contact information. We will also ask you about your past medical history (examples of this could include diseases or previous surgeries). You cannot participate in this study if you are younger than 18, are pregnant, are breast feeding, have heart failure, nerve damage in your legs near the treatment area, uncontrolled diabetes, artery disease in your legs, venous disease in your legs, or have a suppressed immune system. After a physician has deemed you appropriate you will sign consent (permission) to participate in the study. You will then undergo your surgery. Because this surgery is independent of our study, details of this procedure will be covered by your Mohs surgeon.

After your Mohs surgery you will go immediately to a laser treatment room. Details are as follows:

1. You will have your eyes covered with an eye shield. This will protect your eyes and make you unable to see.
2. Your lower leg will still be numb from your surgery.

3. If additional numbing medicine is needed, it will be administered at this time.
4. The doctor will begin laser treatment. This procedure will last approximately 10 minutes, but there may be some variation. During this time, you will hear the laser, which sounds like a bee buzzing, and will feel some warmth. Most report minimal discomfort during the procedure. There may be pinpoint bleeding, bruising, and crusting depending upon the area and extent of the treatment. After the treatment, you will be provided with a diary to daily record treatment-related reactions: redness, swelling, pain, itching or color changes following treatment.
5. You will be given instruction on how to care for your surgical site.

After your treatment a separate member of the research team will collect some information about your lower extremities and take some photographs. The following information may be collected. Details on the possible information collected and photographs taken are detailed below:

- We will place a clear piece of grid paper over the site where your surgery was performed. We will trace the wound on the grid paper and use that to measure the size.
- We will use an iPad with an attachment that allows us to record temperature in your wound site. Doing this will be similar to taking a picture.
- We will use a digital camera to take a picture of your lower leg. Your face will not be in this photo.
- We will ask you about how the pain at your surgical site is on a scale of 1-10.
- We will ask you about your quality of life using a questionnaire

1, 2, 3, 4, 8, and 12 week visits (30 minutes):

These visits will be very similar to the visit after your laser therapy. There will be no additional laser treatments or fake laser treatments. All of the same information and pictures will be collected that were collected after your surgery. The only additional information collected will be entries from your diary.

3. HOW LONG WILL I BE IN THE RESEARCH STUDY?

The time you may spend on this research study is 12 weeks.

The research study should be completed by June 2019.

4. WHAT ARE THE RISKS?

There are certain risks and discomforts that may occur if you take part in this research study. Risks relate to both the use of laser energy and to other study procedures performed. Although the majority of patients do not experience these complications, you should discuss each of them with your physician to make sure you understand the risks, potential complications, and consequences of laser skin treatment.

Terms used to describe frequency are as follows:

- Very common: events that occurred in 1 out of 10 patients or more
- Common: events that occurred in 1 out of 100 patients or more but fewer than 1 out of 10 patients
- Uncommon: events that occurred in 1 out of 1000 patients or more but fewer than 1 out of 100 patients

Side effects and risks are listed below:

- Crusting (scaly thickened skin) - Very common side effect after laser treatment, severity varies between individuals, resolves over days

- Color change – Very common side effect. Laser treatments may potentially change the natural color of your skin. Skin redness usually lasts 2 weeks-3 months and occasionally 6 months following laser skin treatment. Uncommonly, treated skin may contain areas that are either lighter or darker than your skin. A visible line separating normal skin and skin treated with lasers can occur.

- Swelling - Very common side effect after laser treatment, severity varies between individuals, self-resolves days to weeks

- Burning sensation - Very common side effect after laser treatment, severity is mild to moderate, self-resolves hours-to-days, with avoidance of harsh alcohol-based personal hygiene products

- Dry skin at treatment site - Common side effect after laser treatment that reverses with a skin moisturizer cream

- Itching at treatment site - Common side effect after laser treatment, severity varies.

- Eye damage - Uncommon side effect, severity varies, eye protection worn during the treatment as provided by our office minimizes damage to your eyes

- Infection - Although infection following laser treatment is uncommon, bacterial, fungal, and viral infections may occur.

- Bleeding – It is common to have some minor bleeding at the site receiving laser treatment. This will stop shortly after the treatment with application of a tight bandage.

- Scarring - Although normal healing after a procedure is expected, abnormal scars may occur both in the skin and deeper tissues. Uncommonly, keloid scars may result. Scars may be unwanted or a different color than the surrounding skin. Additional treatments such as corticosteroid injections may be needed to treat scarring.

- Burns – Uncommonly, laser energy may produce burns. Nearby skin and surrounding structures, including the eyes, may be injured or permanently damaged by the laser beam. Burns are rare as an effect of the heat produced within the tissues by laser energy. Additional treatment such as topical ointments and prescribed oral antibiotics may be necessary to treat laser burns.

- Laser smoke (plume) – Uncommonly laser smoke may represent a possible hazard to your health. A smoke evacuator (a device that removes smoke fumes) attached to the laser will be utilized to minimize your exposure.

- Pain – Uncommonly, short-term pain (such as a burning or stinging sensation) may occur after laser skin treatment procedures

- Allergic reactions – It is common to have local allergies to tape, topical and local anesthetics, and topical ointments. Uncommonly, reactions affecting all of your organs, which are serious may result from drugs used during medical procedures and prescription medicines. Allergic reactions may require additional treatment.

- Delayed Healing - Uncommonly, it may take longer than anticipated for healing to occur after laser treatments. Skin healing may result in thin, easily injured skin. This is different from the normal redness in skin after a laser treatment.

- Topical and/or local anesthesia - Topical and/or local medication used to numb the treatment area prior to the laser treatment may be offered. Some anesthetic agents contain epinephrine, which may cause short-term moderate anxiety, fear or an uneasy feeling, restlessness, shaking, weakness, dizziness, sweating, rapid or abnormal heart beats, increased blood pressure, pale skin, nausea and vomiting, headache, and/or difficulty breathing. These symptoms are more likely in people with high blood pressure or an overactive thyroid. Excessive doses of epinephrine may cause severe high blood pressure, stroke, and irregular heartbeats, which can lead to death.

- Additional Treatment or Surgery Necessary - There are many variable conditions which influence the long-term results of laser skin treatments. Even though risks and complications occur infrequently, the risks cited are the ones that are particularly associated with these procedures. Other problems and risks can occur but are even more uncommon. Should problems occur, procedures, surgery, or other treatments may be necessary.

- Loss of confidentiality – Although there is always the possibility of a loss of confidentiality, every effort will be made to protect your research data.

- Some questions in the questionnaire may make you feel uncomfortable. You may choose not to answer any question with which you feel uncomfortable.

In the past, treating areas with a history of skin cancer with a laser has been avoided. This was avoided due to the increased risk of cancer or other complications associated with the treatment. However, the laser in this study works in a very different way. There have never

been any reported problems using this laser in an area with a history of skin cancer. This laser is also Food and Drug Administration (FDA) approved for the treatment of skin cancer.

If a complication occurs, you should contact the study doctor immediately who will use her medical judgment to do whatever is necessary to treat you.

The research team is willing to discuss any questions you might have about these risks and discomforts.

5. ARE THERE BENEFITS TO BEING IN THIS RESEARCH STUDY?

You may or may not benefit from this research study. Your wound may heal faster, stay the same, or heal slower. Even though you may not receive any benefit, society may benefit in the future because of what the researchers learn from this study.

6. WHAT OTHER OPTIONS ARE THERE?

You may choose not to be in this research study. If you do not participate in this study it will NOT affect your medical care, and you will continue to receive the highest quality of care available. If you do not participate your surgical site will be left to heal on its own without any additional therapies. This is the standard way that wounds from Mohs surgeries heal.

7. WILL MY INFORMATION BE KEPT PRIVATE?

The results of the research study may be published but your name or identity will not be revealed and your record will remain private. In order to protect your information, Dr. Behshad will assign a study number to your information, and maintain your study documents in locked cabinets in a secure, locked office. Electronic information is kept and transmitted on secure password protected systems with safety firewalls that limit access to authorized study personnel. Digital photographs are maintained on a secure memory device that will be placed in a locked box that only research members have access to. When pictures are accessed on a computer it will be on a password protected system with safety firewalls and access limited to study personnel. Information shared will not include your name or contact information.

The Saint Louis University Institutional Review Board (the Board that is responsible for protecting the welfare of persons who take part in research), and other Saint Louis University officials may review your research study records. The Food and Drug Administration (FDA) may also review your research study records, including your medical record. State laws or court orders may also require that information from your research records be released.

A description of this study and study results will be available on *http://www.ClinicalTrials.gov,* as required by U.S. Law. This website will not include information that can identify you. You can search this website at any time.

8. WHAT ARE THE COSTS AND PAYMENTS?

You will not receive compensation for your participation.

Supplies to cover your surgical site (tape, bandage etc.) will be given to you free of charge. There will be no cost to you. The cost associated with laser treatment will be paid for by the Dermatology department.

Because your Mohs surgery provides standard treatment and follow-up tests for the disease or condition being studied, insurance carriers ordinarily cover the costs. You should check with your insurance company to verify that they cover standard of care procedures. You will be responsible for any costs not covered by your insurance company including any co-payments and/or deductible.

9. WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS RESEARCH STUDY?

If you believe that you are injured as a result of your participation in the research study, please contact the research study doctor and/or the Chairperson of the Institutional Review Board as stated in section 10.

You will receive necessary medical treatment in the event that an injury results because of your participation in this research. The University will have the right to determine whether an injury is related to your participation in this study or happened because of your medical condition or other reasons which are not related to this study. If the injury is due to participation in the research, you will not have to pay for the cost of this treatment unless your injury is due to your own failure to follow the study doctor's instructions. There are no plans for Saint Louis University to pay for the costs of any additional care. You have not waived your legal rights by signing this form. If you have questions, please call the Saint Louis University General Counsel's office at 314-977-5767.

10. WHO CAN I CALL IF I HAVE QUESTIONS?

If you have any questions or concerns about this research study, or if you have any problems that occur from taking part in this research study, you may call Dr. Ramona Behshad at 977-9721. You may also reach the study team at 314-256-3454. For questions after hours, you may call the Saint Louis University switchboard at 314-577-8000 and ask for the dermatologist on-call. That doctor will know how to contact a member of the research team.

If you have questions, concerns or complaints about your rights as a research participant and would like to talk to someone not on the research team, please contact the Saint Louis University Institutional Review Board (IRB) at 314-977-7744 or irb@slu.edu.

11. WHAT ARE MY RIGHTS AND WHAT ELSE SHOULD I KNOW AS A RESEARCH STUDY VOLUNTEER?

Your participation in this research is voluntary. You may choose not to be a part of this research. There will be no penalty to you if you choose not to take part. You may leave the research study at any time. The research study doctor or research study staff will let you know of any new information that may affect whether you want to continue to take part in the research study.

If you decide to withdraw from the study you should contact the study staff immediately. If you decide to withdraw, you will be asked to return for a final study visit. If you end the study early, the investigators or study staff may ask you some questions about being in the study. To help you leave the study safely, the investigators may ask you to participate in more tests.

The study doctors can stop your participation at any time without your consent for the following reasons:
• If it appears to be medically harmful to you;
• If you fail to follow directions for participating in the study;
• If it is discovered that you do not meet the study requirements;
• If the study is canceled; or
• For administrative reasons, including competitive enrollment - the target number of subjects has entered the study.

12. AM I SURE THAT I UNDERSTAND?

I have read this consent document and have been able to ask questions and state any concerns. I have been asked if I wish to speak directly to the researcher or research study doctor responsible for this research study. The research team has responded to my questions and concerns. I believe I understand the research study and the potential benefits and risks that are involved.

Statement of Consent
I give my informed and voluntary consent to take part in this research study. I will be given a copy of this consent document for my records.

_____
Print Name of Participant

_____ _____
Signature of Research Participant (18 and over) Date

SAINT LOUIS UNIVERSITY – INSTITUTIONAL REVIEW BOARD – APPROVAL STAMP

This form is valid only if the IRB's approval stamp is shown below.

IRB #: 29076
Approved: 06-05-18
Expires: 06-04-19
Board #: 1
Saint Louis University

I certify that I have explained to the above individual(s) the nature and purpose of the research study and the possible benefit and risks associated with participation. I have answered any questions that have been raised and the subject/patient has received a copy of this signed consent document.

Signature of Consenting Research Team Member	**Date**
First Name / Last Name *Credentials*	
Printed Name of Consenting Research Team Member	

NOTE: The Principal Investigator or Research Team Member that signs here must be authorized in the IRB-approved protocol to obtain informed consent and must sign at the SAME time on the same day as the above signatures are obtained.