Partners HealthCare System
Research Consent Form

Subject Identification

General Template
Version Date: August 2016

Protocol Title: The Within Scar Randomized Controlled Trial Evaluating Fractional Ablative CO2 Laser to Control and Non-Energy Based Tissue Extraction

Principal Investigator: Jonathan Friedstat, MD

Site Principal Investigator:

Description of Subject Population: All burn patients 18-80 years old, having burn reconstruction with laser or scar lengthening procedures for symptomatic hypertrophic burn scars

About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about taking part in this research study. People who agree to take part in research studies are called "subjects." This term will be used throughout this consent form.

Partners HealthCare System is made up of Partners hospitals, health care providers, and researchers. In the rest of this consent form, we refer to the Partners system simply as "Partners."

If you have any questions about the research or about this form, please ask us. Taking part in this research study is up to you. If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a signed copy of this form to keep.

A description of this clinical trial will be available on *http://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.

Why is this research study being done?

An estimated 450,000 people suffer burn injuries and receive medical treatment annually in the United States alone. Burn survivors are often left with burn scars impact quality of life in many ways. A recent advancement in the treatment of burn scars has been the use of the carbon dioxide

(CO_2) laser to "break up scar tissue." Patients have reported improvements in scar symptoms such as pain, itch, and tightness, as well as improvements in appearance. Although these benefits are clearly visible and easily documented, we do not fully understand how these positive effects occur. We think that the scarring created by burns is the result of the body's producing too much of the scar building "collagen". Not only is too much made, but it is also laid down in a disorderly fashion. Our study aim is to find out the real reason that the laser improves your scars by looking at small samples of the scar before and after treatment. We hope that the information from this study will help to improve our treatments for burn scars in the future. We will also compare the standard laser treatment to a comparable treatment with small 0.5mm punch biopsies.

We are asking you to take part in this study because you have decided to undergo laser or surgical treatment for a burn scar at Massachusetts General Hospital (MGH). About 17 subjects will take part in this study at MGH.

The study is being funded by the Department of Defense (DoD) to help us improve the lives of burn survivors everywhere, both within and outside of the military.

How long will I take part in this research study?

It will take you approximately 12 months to complete this study. We will obtain small samples of your scar during each treatment procedure and at 12 months from your enrollment.

What will happen in this research study?

During the study we will take tissue samples, mostly while you are asleep for your surgical procedures, perform non-invasive, non-painful measurements of your scar and ask you questions and to complete surveys about your burn injury. Any biopsies obtained after laser treatment while you are awake will be done with numbing medication to minimize any pain or discomfort to you and this will occur once at the end of the study.

If you choose to take part in this study, we will ask you to sign this consent form before we do any study procedures.

This is a research study to look at the effect of laser treatment compared to punch biopsies and to no treatment on an area of symptomatic scar. A section of your scar will be selected as the treatment area, inside which three 3cmx3cm areas (each one of the three treatment areas is about a square inch) must fit. Each of those three areas will receive one treatment: laser, many 0.5mm

punch biopsies, or no treatment. The following explains the procedures you will undergo and the timeline. All of this will occur concurrently with a scheduled laser treatment for your scar

The study is broken down into the following phases:

Pretreatment 1:
In the pretreatment phase we will determine which part of your scar will become the "treatment area". The treatment area will include three 3x3 cm^2 areas of scar. Photographs of the treatment area will be taken in clinic, your scar elasticity will be measured, and you will fill out surveys about your scar.

Treatment 1:
This will occur at the same time of your laser treatment in the operating room (OR). **At this time, the treatment area will undergo randomization. This randomization is a process where the same scar will be assigned one of 3 different treatments (no treatment, laser, and 0.5mm punch biopsies). An envelope will contain each of these three treatments and they will be withdrawn one at a time and assigned to the three treatment areas. After one treatment is selected it will not be available again, so each treatment will be used once, one for each 3x3cm area of scar. Those assignments will remain the same for the entire study. Please be aware that if selected for no treatment, some areas of the burn scars will not receive any treatment.**

A 6 mm punch biopsy will be taken from each treatment area for histology and genomic analysis. Then, treatment to each of the treatment areas (one each of laser, 0.5 mm punch biopsy*, and no treatment) will be performed in the operating room (OR).

*In the 0.5mm punch biopsy area, we will be simulating the effects of the laser without using the actual laser. This means that we will be taking many very small punch biopsies from this treatment area. Your surgeon will take 675 very small 0.5mm punch biopsies from about a square inch of your scar. This will look like a lot of really tiny pin pricks. Your doctor will do this under magnification, by hand, while you are asleep in the OR during the rest of your procedure.

Pretreatment 2:
Prior to the second treatment, photographs will be taken again of the treatment area in clinic, you will complete the same surveys as in pretreatment, and your study scar elasticity will be measured in each treatment area. This will be essentially identical to Pretreatment 1.

Treatment 2:
A 3 mm punch biopsy will be taken for analysis from each of the three treatment areas. Then, treatment identical to the Treatment 1 will be performed in the OR.

Pretreatment 3:
Prior to the third treatment in clinic, photographs will be taken of the treatment area, you will complete some surveys, and the study scar elasticity will be measured once again.

Treatment 3:
Same as treatment 2.

Two-month follow-up (+/- one month):
Two months after the third treatment, photos will be taken of your study scar, you will take the same surveys as before, and the study scar elasticity will be measured in each treatment area.

Eight-month follow-up (+/- one month):
Eight months after the third treatment, you will come for your final visit where photographs will be taken of the study scar, you will fill out some surveys, and your study scar elasticity will be measured in each treatment area. Three 6 mm punch biopsies will be taken, one from each of the treatment areas in clinic with local anesthetic. This will conclude your involvement in the study.

Typically the burn scar procedures are performed in the operating room under anesthesia, therefore the first biopsy will also be performed at this time. If your procedure is being performed in the Fraser Outpatient Burn Center, we would use local anesthesia to numb the area being treated and we would collect the punch biopsy at that time. In either case, the location of the biopsy will be closed with 1 or 2 small stitches and a dressing with bacitracin and gauze. Stitches will be removed in 1-2 weeks. The tissue from the biopsies will be used to learn about the histology (the architecture of the tissue) as well as gene expression profiling (which genes are turned on or off). The only specimens that will not stored in Partners, will be tissue for genomic analysis. This will be sent to the University of Texas Southwestern for these particular tests to be completed.

With the reduction to a subject total of 17, all of the samples will be able to go through genetic analysis.

You will also be asked to complete questionnaires about your burn injury and its impact on your life to better understand how our reconstructive treatments are impacting your life. We will also ask you questions about your scar, obtain photographs, and measure the elasticity/flexibility of your skin using a non-painful, non-invasive device that we stick to the outside of your skin.

At any time during the study you may elect to be removed from the study, or you may be removed at the discretion of the attending burn surgeon.

Study information included in your medical record

A notation that you are taking part in this research study may be made in your electronic medical record. Information from the research that relates to your general medical care may be included in the record (for example, list of allergies, results of standard blood tests done at the hospital labs).
Please ask your study doctor if you have any questions about what information will be included in your electronic medical record

It is very important that you notify the study staff if you start any new medications that suppress your immune system. This is extremely important as using these immunosuppressive medications can have an impact on how wounds and laser treatment areas heal.

What are the risks and possible discomforts from being in this research study?

Possible discomfort from this study is related to the punch biopsy procedure itself. This includes:

- Minor, brief pain with injection of local anesthesia (if not performed in the operating room under

general anesthesia)

- Mild discomfort or itching during healing.

Uncommon risks associated with a punch biopsy include:

- Bleeding
- Infection
- Potential for minor scarring at the biopsy site.

Risks of laser include:

- Bleeding
- Scarring
- Open wounds that heal with time
- Infection
- Pain
- Pigment/color changes

These risks will be minimized through proper anesthesia and wound care management procedures which are centered around your comfort and safety.

Additional risks associated with this research study involve privacy/confidentiality issues with

your protected health information. Steps will be taken to ensure confidentiality and privacy during the data sample and data collection process of the study.

Our genetic testing is limited to testing your immune system inflammatory response; we are not testing genes related to other diseases. Genetic information that results from this study does not have medical or treatment importance at this time. However, there is a risk that information about taking part in a genetic study may influence your insurance companies or employers regarding your health. To further safeguard your privacy, genetic information obtained in this study will not be placed in your medical record

Taking part in a genetic study may also have a negative impact on family or other relationships. If you do not share information about taking part in this study, you will reduce this risk.

You may feel sad about your scars or injury, or irritated at completing survey questions.

What are the possible benefits from being in this research study?

By participating in this study there will be no direct benefit to you; however, the valuable information resulting from this trial will guide future therapy for burn scars, ultimately easing the suffering of others.

Can I still get medical care within Partners if I don't take part in this research study, or if I stop taking part?

Yes. Your decision won't change the medical care you get within Partners now or in the future. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive.

Taking part in this research study is up to you. You can decide not to take part. If you decide to take part now, you can change your mind and drop out later. We will tell you if we learn new information that could make you change your mind about taking part in this research study.

What should I do if I want to stop taking part in the study?

If you take part in this research study, and want to drop out, you should tell us. We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

Also, it is possible that we will have to ask you to drop out of the study before you finish it. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

What will I have to pay for if I take part in this research study?

You will not be required to pay in order to take part in this research study. Study funds will pay for certain study-related items and services. We may bill your health insurer for, among other things, routine items and services you would have received even if you did not take part in the research. You will be responsible for payment of any deductibles and co-payments required by your insurer for this routine care or other billed care. If you have any questions about costs to you that may result from taking part in the research, please speak with the study doctors and study staff. If necessary, we will arrange for you to speak with someone in Patient Financial Services about these costs.

What happens if I am injured as a result of taking part in this research study?

We will offer you the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the next section of this consent form.

If I have questions or concerns about this research study, whom can I call?

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

Jonathan Friedstat, MD, is the person in charge of this research study. You can call him at (617) 726-3712 [M-F 9-5] or have him paged through the hospital operator at 617-726-2000 [24/7]. You can also call one of our study coordinators, Jennifer Levin and Kristina Chang, at 617-643-2242 [M-F 9-5] with questions about this research study.

If you have questions about the scheduling of appointments or study visits, call our study coordinators at the above number.

If you want to speak with someone **not** directly involved in this research study, please contact the Partners Human Research Committee office. You can call them at 857-282-1900.

You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research

Also, if you feel pressured to take part in this research study, or to continue with it, they want to know and can help.

If I take part in this research study, how will you protect my privacy?

During this research, identifiable information about your health will be collected. In the rest of this section, we refer to this information simply as "health information." In general, under federal law, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use, and share your health information for research and why they may need to do so.

In this study, we may collect health information about you from:

- Past, present, and future medical records
- Research procedures, including research office visits, tests, interviews, and questionnaires

Who may see, use, and share your identifiable health information and why they may need to do so:

- Partners research staff involved in this study

- The sponsor(s) of this study, and the people or groups it hires to help perform this research
- Other researchers and medical centers that are part of this study and their ethics boards
- A group that oversees the data (study information) and safety of this research
- Non-research staff within Partners who need this information to do their jobs (such as for treatment, payment (billing), or health care operations)
- The Partners ethics board that oversees the research and the Partners research quality improvement programs.
- People from organizations that provide independent accreditation and oversight of hospitals and research
- People or groups that we hire to do work for us, such as data storage companies, insurers, and lawyers
- Federal and state agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health, and other US or foreign government bodies that oversee or review research)
- Public health and safety authorities (for example, if we learn information that could mean harm to you or others, we may need to report this, as required by law)
- Other: The DoD will have access to research records as part of its human subjects protection oversight activities. Dr Daniel Driscoll, the independent research monitor, will have access to the research record as part of research oversight and saftey.

Some people or groups who get your health information might not have to follow the same privacy rules that we follow and might use or share your health information without your permission in ways that are not described in this form. For example, we understand that the sponsor of this study may use your health information to perform additional research on various products or conditions, to obtain regulatory approval of its products, to propose new products, and to oversee and improve its products' performance. We share your health information only when we must, and we ask anyone who receives it from us to take measures to protect your privacy. The sponsor has agreed that it will not contact you without your permission and will not use or share your information for any mailing or marketing list. However, once your information is shared outside Partners, we cannot control all the ways that others use or share it and cannot promise that it will remain private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your health information.

The results of this research study may be published in a medical book or journal, or used to teach others. However, your name or other identifying information **will not** be used for these purposes without your specific permission.

Your Privacy Rights

You have the right **not** to sign this form that allows us to use and share your health information for research; however, if you don't sign it, you can't take part in this research study.

You have the right to withdraw your permission for us to use or share your health information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once permission is withdrawn, you cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others.

You have the right to see and get a copy of your health information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.

Informed Consent and Authorization

Statement of Person Giving Informed Consent and Authorization

- I have read this consent form.
- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.
- I understand the information given to me.

Signature of Subject:

I give my consent to take part in this research study and agree to allow my health information to be used and shared as described above.

_____	_____	_____
Subject	Date	Time (optional)

Signature of Study Doctor or Person Obtaining Consent:

Statement of Study Doctor or Person Obtaining Consent

- I have explained the research to the study subject.
- I have answered all questions about this research study to the best of my ability.

Study Doctor or Person Obtaining Consent	Date	Time (optional)

Consent of Non-English Speaking Subjects Using the "Short Form" in the Subject's Spoken Language

Statement of Hospital Medical Interpreter

As someone who understands both English and the language spoken by the subject, I interpreted, in the subject's language, the researcher's presentation of the English consent form. The subject was given the opportunity to ask questions.

Hospital Medical Interpreter	Date	Time (optional)

OR

Statement of Other Individual (Non-Interpreter)

As someone who understands both English and the language spoken by the subject, I represent that the English version of the consent form was presented orally to the subject in the subject's own language, and that the subject was given the opportunity to ask questions.

Name	Date	Time (optional)

Consent Form Version: 12/18/2023