

Partners HealthCare System Research Consent Form

General Template
Version Date: August 2016

Subject Identification

Protocol Title: Image guided targeted photoablation of eccrine glands for the treatment of localized hyperhidrosis

Principal Investigator: R. Rox Anderson, MD

Site Principal Investigator:

Description of Subject Population: Subjects with Hyperhidrosis

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?

We would like permission to enroll you as a participant in a research study. The purpose of the study is to evaluate the safety and effectiveness of a dye and laser combination that we hope will help reduce excessive sweating ("perspiration"). Excessive and severe sweating (or perspiration) is a medical condition called "hyperhidrosis."

Despite the large number of options available for the treatment of hyperhidrosis, no treatment is always effective.

Partners HealthCare System Research Consent Form

General Template
Version Date: August 2016

Subject Identification

Lasers have been used in the past to treat parts of the skin such as blood vessels, brown spots, hair, and oil glands. We would like to use a specialized laser in order to target sweat glands. . We hope that by applying a dye that labels the sweat gland before laser treatment, we will be able to use the laser to damage the sweat gland and thus prevent hyperhidrosis.

In this study, we will use a Sciton Joule fractional laser device. This device delivers energy to very small spots in the skin (in this case, the sweat glands), resulting in selective damage to these small spots.

We will also use the Phoresor Iontophoretic Drug Delivery System, which is a device that delivers liquid specifically to the sweat glands by passing a small current over the skin.

This study also involves the use of Methylene Blue, which is considered a drug. This is a dye that creates a small dot in individual sweat glands. The dot is used by the laser in order to target the specific locations of the sweat glands.

The Sciton Joule fractional laser is approved by the U.S. Food and Drug Administration (FDA) for a variety of uses in the skin including skin resurfacing (for treatment of wrinkles) and removal of benign tumors but the Sciton Joule fractional laser is not approved by the FDA to treat hyperhidrosis in particular.

Phoresor Iontophoretic Drug Delivery System is approved by the U.S. Food and Drug Administration (FDA) to for delivery of local anesthetic into the skin while avoiding the use of hypodermic needles , but the Phoresor Iontophoretic Drug Delivery System is not approved by the FDA to deliver methylene blue into the skin.

Methylene blue is lawfully marketed in the US and is indicated for intravenous injection in the treatment of methemoglobinemia. It is not marketed for labeling of sweat glands.

Researchers have used/studied the Sciton Joule Fractional Laser so far in hundreds of patients taking part in research studies, and in thousands of patients for routine clinical use. It has not been used in the treatment of hyperhidrosis.

This is a pilot study. Pilot studies are done on a small group of subjects to learn if a larger study would be useful. We are asking you to take part in this study because you have hyperhidrosis.

15 subjects will be enrolled in this study at the Wellman Center for Photomedicine located at the MGH.

The Sciton Corporation, the manufacturer of the laser involved in this study, has provided the laser to us without charge. However, the company is not paying us to perform the study.

Partners HealthCare System Research Consent Form

General Template
Version Date: August 2016

Subject Identification

How long will I take part in this research study?

It will take you about 6 months to complete this study. You will have a total of 7 visits (including a Screening Visit PLUS the actual 6 study visits).

What will happen in this research study?

If you decide to take part in this study, we will ask you to sign this consent form before we perform any study procedures. Your first visit is called the "Screening Visit", where doctors will make sure you are eligible to take part in the study. If you are still eligible after the Screening Visit, we will ask you to come back to the MGH for 6 study visits. The first of the study visits will be the treatment visit. The remaining five visits will take place at 1, 2, and 4 weeks, as well as at 3 and 6 months, after the treatment visit. Your response to treatment will be assessed at these visits.

Screening Visit [approx 30 minutes]

At the Screening Visit, we will:

- Ask you questions about your medical history
- Do a physical exam

Study Visit 1 [approx 2.5 hours]

The following procedures will take place:

- 1) Two (2) test sites, each measuring 16.8 cm² (about the size of a business calling card), will be mapped on the palms.
- 2) Filter paper will be applied to each of these two sites, and you will be asked to exercise on a stationary bicycle until sweating is observable. The filter paper will then be removed and weighed.
- 3) A dye will be applied to one of the test sites by **iontophoresis** (a technique where a well with dye is placed directly on the skin and a low level electrical current is run to speed up delivery of the dye into the skin). This will create small dots at the locations of the sweat glands.
- 4) Topical anesthetic (numbing medication) will be applied to the treatment site for thirty minutes prior to laser intervention to mitigate pain during the laser procedure. Ice packs will also be used for this purpose during the laser procedure. If these topical measures are not sufficient for control of pain during the laser procedure, you will be offered the option of injected local anesthetic.

Partners HealthCare System Research Consent Form

General Template
Version Date: August 2016

Subject Identification

- 5) Laser intervention: After 30 to 40 minutes, the test site will be treated with the laser. The following laser will be used in this study: the Sciton Joule Profractional erbium laser. The laser handpiece will be placed on the skin, and energy will be delivered by the laser to the individual small dots on the skin. You will wear goggles as eye protection during the laser treatment.

Study Visits 2 – 6 [approx 1 hour]

You will be asked to return at 1, 2, and 4 weeks, 3 and 6 months after Study Visit 1 for photographs and clinical observation. Each follow-up visit will take 90 minutes. During each visit, the following will take place:

- 1) Filter paper (as described in #2 above) and exercise on a stationary bicycle will be used to measure sweating at each of the test sites.
- 2) *Optional*: If you have a significant (at least 50%) decrease in sweating on the treated side, you may be asked to have a starch-iodine test. An iodine solution is applied to the skin and allowed to dry. Once dry, the area will be dusted with potato flour. You will be asked to exercise on a stationary bike until sweating is observable. In areas of sweating, the potato starch will change to a dark blue color. You may participate in this study even if you decline to have the starch iodine test. It is *optional*. If you agree at this time to have the starch iodine test you may still change your mind at any time during the study.
- 3) *Optional*: Skin punch biopsies will be performed in willing volunteers when appropriate (e.g. at least 50% reduction in sweating). A punch biopsy is a procedure where a small piece of skin, about the size of a pencil eraser, is removed. A local anesthetic (numbing medication) will be injected to remove pain during the biopsy, which is done under sterile conditions. After completing the biopsy procedure the biopsy site will be sutured. You should gently cleanse these areas with soap and water and apply petrolatum or Aquaphor twice daily. Sutures will be removed 10-14 days after the biopsy. A maximum of 4 biopsies will be taken from each subject over the course of the study. You will be paid an additional \$75 for each biopsy that is performed. You may participate in this study even if you decline to provide biopsy samples. It is *optional*. If you agree at this time to provide biopsy samples you may still change your mind at any time during the study.

If you decide to stop taking part in the study, we will ask you to make a final study visit. The final study visit will take about 30 minutes. During this visit, we will do the following:
Photograph the two test sites.

The study doctor may have to take you out of the study. This may happen because:

Partners HealthCare System Research Consent Form

Subject Identification

General Template

Version Date: August 2016

- You experience intolerable side effects from the treatment, such as severe pain.
- You request to be removed from the study.

We will try to keep sensitive information related to the study out of your hospital electronic health record. However, information about serious side effects, serious allergic reactions, or important, unexpected results in imaging studies might become part of your records at the MGH.

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

Risks of Laser Intervention:

- Pain in the form of stinging, heat, or burning sensation.
- Burns (rare)
- Swelling of the skin (common but temporary - improved by applying ice packs)
- Redness of the skin (common but temporary - improved by applying ice packs)
- Pigmentary changes such as darkening or lightening of the skin. Although this is usually temporary, it may be permanent.
- Scarring (rare)
- Miliaria. You may develop small blisters or red bumps on treated areas. This results from the obstruction to the sweat duct.
- Loss of Hair. Treated areas may develop temporary or permanent asymmetric loss of hair.

Risks of Iontophoresis Procedure:

- Tingling or burning sensation
- Staining of the skin. You may develop blue staining of the skin from the iontophoresis procedure which may persist for 4 weeks.

Risks of Biopsy Procedure:

- Infections (rare)
- Scar at biopsy sites

I understand that taking part in skin biopsy is optional and that I may withdraw my consent at any time during the study.

- ☐ YES, I agree in the skin biopsy portion of the study.
- ☐ NO, I do NOT want to take part in the skin biopsy portion of the study.

Partners HealthCare System Research Consent Form

General Template
Version Date: August 2016

Subject Identification

Subject signature

Date

Risks of Iodine Test:

- There may be temporary brown discoloration of the test areas on the skin, which could last up to four weeks.
- As with any drug, an allergic reaction can occur. Allergic reactions can be mild or serious, and can even result in death in some cases. Common symptoms of an allergic reaction are rash, itching, skin problems, swelling of the face and throat, or trouble breathing. Severe reactions such as swelling of the face and throat or trouble breathing have not been reported for the iodine test. If you think you are having an allergic reaction, call the study doctor right away. If you are having trouble breathing, call 911 immediately.

I understand that taking part in the starch iodine test is optional and that I may withdraw my consent at any time during the study.

☐ YES, I agree to take part in the starch iodine test portion of the study and I confirm that I am not aware of an allergy to iodine or potato starch.

☐ NO, I do NOT want to take part in the starch iodine test portion of the study.

Subject signature

Date

You are NOT eligible to take part in this study if you

- Have a Cardiac Pacemaker
- Have any electrically powered implantable device
- Have a known allergy to lidocaine or methylene blue
- Are taking any of the following categories of psychiatric medications:
 - SSRI (selective serotonin reuptake inhibitors): Examples include citalopram (Celexa), escitalopram (Lexapro or Cipralex), paroxetine (Paxil or Seroxat), fluoxetine (Prozac), fluvoxamine (Luvox), sertraline (Zoloft or Lustral).
 - SNRI (serotonin-norepinephrine reuptake inhibitors): Examples include desvenlafaxine (Pristiq), venlafaxine (Effexor) or venlafaxine XR (Effexor)

Partners HealthCare System Research Consent Form

Subject Identification

General Template

Version Date: August 2016

XR), duloxetine (Cymbalta), milnacipran (Savella), and levomilnacipran (Fetzima).

- MAOI (monoamine oxidase inhibitors): Examples include rasagiline (Azilect), selegiline (Eldepryl or Zelapar), isocarboxazid (Marplan), phelzine (Nardil), tranylcypromine (Parnate).
- TCA (tricyclic antidepressant): Examples include amitriptyline (Elavil), clomipramine (Anafranil), desipramine (Norpramin), doxepin (Sinequan), imipramine (Tofranil), nortriptyline (Pamelor), protriptyline (Vivactil), trimipramine (Surmontil).

The effect of methylene blue on an embryo or fetus (developing baby still in the womb), or on a breastfeeding infant, is unknown but there is some evidence that it may be harmful to a developing baby. Because of these unknown risks, women cannot take part in this study if they are:

- Pregnant
- Trying to become pregnant
- Breastfeeding

If you are a menopausal woman and have not had a period for the past 12 months or more, you will not need to have a pregnancy test. Also, if you have had any well-documented method of surgical sterilization, you will not need to have a pregnancy test. Methods of surgical sterilization include having had a hysterectomy (removal of the uterus with or without the ovaries), bilateral oophorectomy (removal of both ovaries), a tubal ligation (having your tubes tied), or transvaginal occlusion (plugging the opening of the tubes with a coil). All other female subjects must have a negative pregnancy test before starting the study drug.

If you are a female who is sexually active and able to become pregnant, you must agree to use one of the birth control methods listed below. You must use birth control **for the entire study and for at least one month** after your last dose of study drug.

Acceptable birth control methods for use in this study are:

- oral contraceptives (birth control pills)
- contraceptive patch (birth control patch)
- contraceptive ring (birth control vaginal ring)
- condoms
- intrauterine device (such as Paragard or Mirena)

There may be other risks that are currently unknown.

Partners HealthCare System Research Consent Form

General Template
Version Date: August 2016

Subject Identification

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

You may not benefit from taking part in this study. If you receive this laser intervention, it is possible that your hyperhidrosis symptoms will improve during or after the study. It is hoped that results of this study will help people with hyperhidrosis in the future.

What other treatments or procedures are available for my condition?

There are several alternatives for hyperhidrosis. These include:

- pills that function to inhibit sweating among other aspects of bodily function
- topical medications
- surgery to the vagus nerve in the chest
- injections of botulinum toxin
- use of microwaves to destroy the sweat glands by depositing heat into the skin.

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.

Partners HealthCare System Research Consent Form

General Template
Version Date: August 2016

Subject Identification

Will I be paid to take part in this research study?

If you complete all of the study visits (7 in total), we will pay you \$350.

If you are unable to attend every visit, we will pay you \$25 for each visit that you attend.

Subjects who consent to skin biopsies will receive an additional \$75 per biopsy taken.
The maximum payment you may be able to receive from taking part in this study is **\$650**.

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

Study funds will pay for study-related items and services, including the dye, laser treatment, and biopsies. 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.

Partners HealthCare System Research Consent Form

General Template
Version Date: August 2016

Subject Identification

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.

R. Rox Anderson, MD, is the principal investigator for this study. He can be contacted at 617.726.6168.

Yakir Levin, MD, PhD is the person in charge of this research study. You can call him at 650.387.0654 24 hours per day, 7 days per week.

If you have questions about the scheduling of appointments or study visits, call Yakir Levin at 650.387.0654.

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

Partners HealthCare System Research Consent Form

General Template
Version Date: August 2016

Subject Identification

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:

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.

Partners HealthCare System Research Consent Form

General Template
Version Date: August 2016

Subject Identification

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.

Partners HealthCare System Research Consent Form

Subject Identification

General Template
Version Date: August 2016

Subject	Date	Time (optional)
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Consent Form Version: 6; 02/24/2020