Study Consent

Title: Miradry Treatment for Focal Axillary Hyperhidrosis (MiraDry Tx)

NCT02295891

IRB00036743

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If you are using Epic for this study, fax a copy of the signed consent form to 410-367-7382.

Patient I.D. Plate

RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

Protocol Title: MiraDry Treatment for Secondary Psychopathology in Focal Axillary Hyperhidrosis

Application No.: IRB00036743

Sponsor: Miramar Labs, Inc.

Principal Investigator: Dr. Malcolm V. Brock
600 North Wolfe Street
Johns Hopkins Hospital
Baltimore, MD, 21287
Phone: 410-955-4408
Address: Blalock 240

1. What you should know about this study:

- You are being asked to join a research study. This consent form explains the research study and your part in the study.
- Please read it carefully and take as much time as you need.
- Ask your study doctor or the study team to explain any words or information in this informed consent that you do not understand.
- You are a volunteer. If you join the study, you can change your mind later. You can decide not to take part or you can quit at any time. There will be no penalty or loss of benefits if you decide to quit the study.
- During the study, we will tell you if we learn any new information that might affect whether you wish to continue to be in the study.
- If you receive routine medical treatment (including medical or laboratory tests) in the study or if you are taking part in the study at the Clinical Research Unit, information about your research study participation will be included in your medical record, which is used throughout Johns Hopkins. Doctors outside of Johns Hopkins may not have access to this information. You can ask the research team to send this information to any of your doctors.
- When Johns Hopkins is used in this consent form, it includes The Johns Hopkins University, The Johns Hopkins Hospital, Johns Hopkins Bayview Medical Center, Howard County General Hospital, Johns Hopkins Community Physicians, Suburban Hospital, Sibley Memorial Hospital and All Children's Hospital.
- The Johns Hopkins School of Medicine Institutional Review Board (IRB) sometimes reviews studies that are conducted at other institutions. These other institutions are solely responsible for conducting

the study safely and according to the protocol that the Johns Hopkins IRB has approved. Information about how to contact the investigator at the institution that is responsible for the study is included in this form. When another institution is conducting the study, the word "we" in this consent form may include both Johns Hopkins and the participating institution.

- 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.
- If you would like to review the information for this study, or a summary of the results, ask the study team doctor for the ClinicalTrials.gov study registration number.
- During this study, you will not have access to certain medical information and test results collected for study purposes. If an emergency occurs while you are in the study, medical information needed for your treatment can be made available to your study physician and other physicians who treat you. When the study is completed, all the information in your medical record will be available to you.

2. Why is this research being done?

This research is being done to evaluate the effectiveness of the non-invasive (not requiring the introduction of instruments into the body) miraDry device in reducing the psychological distress or anxiety of people with hyperhidrosis (or excessive underarm sweat).

Excessive sweating due to hyperhidrosis has been shown to have profound effects on patients' physical and mental quality of life, with functional impairments negatively impacting work productivity, daily activities, willingness to participate in social situations, and personal relationships.

MiraDry ® is approved by the U.S. Food and Drug Administration (FDA) for the treatment of axillary hyperhidrosis. MiraDry ® is a non-invasive procedure that uses microwave energy for the reduction or removal of the underarm sweat glands.

People aged between 18 and 29 years, with localized hyperhidrosis primarily in the underarms who have decided to undergo the miraDry procedure as part of standard clinical care may join.

How many people will be in this study?

About 24 people are expected to take part in this study.

3. What will happen if you join this study?

You have already completed a short Hyperhidrosis Disease Severity Scale (HDSS) as a part of the prescreening process to measure the severity of your hyperhidrosis.

If you agree to be in this study, we will ask you to do the following things:

You will schedule an appointment with behavioral medicine during which you will be asked to complete a survey evaluation done only for the purpose of this research. This survey evaluation will ask about your quality of life and any anxiety or depression you may be experiencing.

You will also be asked to schedule two miraDry appointments about 3 months apart. The miraDry appointments will be done as part of your standard clinical care. At each of these appointments, you will be asked to complete the above surveys again.

A follow up survey will take place between 6 months and 1 year after your first miraDry visit. An in-person follow up visit is optional because the survey can be administered over phone, through the mail, or electronically if you are unavailable for a study visit.

How long will you be in the study?
You will be in this study for about one year.

4. What are the risks or discomforts of the study?

The miraDry procedures will be done as part of standard care and not part of this research.

The only risks of this research are that you may become bored when completing the research surveys, and that information about you may become known to people outside this study

5. Are there benefits to being in the study?

There is no direct benefit to you from being in this study. The miraDry procedure is not part of this research, but part of your standard care.

If you take part in this study, you may help others in the future.

6. What are your options if you do not want to be in the study?

You do not have to join this study. If you do not join, your care at Johns Hopkins will not be affected.

7. Will it cost you anything to be in this study?

You will have a minimum of one visit with the behavior medicine specialist/psychologist as part of the study. You will be responsible for payment associated with this behavior medicine appointment because it is a part of the standard care at Johns Hopkins Hospital for people with hyperhidrosis

Information about the appointment will be submitted to your insurance as a health and behavior consultation under the medical diagnosis of hyperhidrosis. As needed, the behavior medicine clinic will obtain necessary pre-authorizations.

You are responsible to pay a total of $1,800 for two miraDry ® treatments. You will be responsible for the portion not covered by your insurance. Depending on the insurance, participants may be responsible for a co-pay, co-insurance, or meeting an existing deductible for the medical coverage.

If you have not yet met your deductible, then the entire cost of the appointment may be applied toward the deductible, which will depend on your individual insurance plan. An exact estimate cannot be provided, as the rates are regulated by the state of Maryland and therefore variable.

This visit will not be billed as a mental health appointment with a psychiatric diagnosis; rather, this visit will be billed as a medical/physical health appointment with a medical diagnosis.

8. Will you be paid if you join this study?

No.

9. Can you leave the study early?

- You can agree to be in the study now and change your mind later.
- If you wish to stop, please tell us right away.
- Leaving this study early will not stop you from getting regular medical care.

If you leave the study early, Johns Hopkins may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities**.**

10. How will your privacy be protected?

We have rules to protect information about you. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form you provide your permission, called your "authorization," for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records. This could include information about HIV and genetic testing, or treatment for drug or alcohol abuse or mental health problems.

The research team will know your identity and that you are in the research study. Other people at Johns Hopkins, particularly your doctors, may also see or give out your information. We make this information available to your doctors for your safety.

People outside of Johns Hopkins may need to see or receive your information for this study. Examples include government agencies (such as the Food and Drug Administration), safety monitors, other sites in the study and companies that sponsor the study.

We cannot do this study without your authorization to use and give out your information. You do not have to give us this authorization. If you do not, then you may not join this study.

We will use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside Johns Hopkins who receive your information may not be covered by this promise or by the federal Privacy Rule. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee that your information will not be re-disclosed.

The use and disclosure of your information has no time limit. You may revoke (cancel) your permission to use and disclose your information at any time by notifying the Principal Investigator of this study by phone or in writing. If you contact the Principal Investigator by phone, you must follow-up with a written request that includes the study number and your contact information. The Principal Investigator's name, address, phone and fax information are on page one of this consent form.

If you do cancel your authorization to use and disclose your information, your part in this study will end and no further information about you will be collected. Your revocation (cancellation) would not affect information already collected in the study, or information we disclosed before you wrote to the Principal Investigator to cancel your authorization.

11. What treatment costs will be paid if you are injured in this study?

Johns Hopkins does not have a program to pay you if you are hurt or have other bad results from being in the study. However, medical care at Johns Hopkins is open to you as it is to all sick or injured people.

- If you have health insurance: The costs for any treatment or hospital care you receive as the result of a study-related injury will be billed to your health insurer. Any costs that are not paid for by your health insurer will be billed to you.

- If you do not have health insurance: You will be billed for the costs of any treatment or hospital care you receive as the result of a study-related injury.

By signing this form you will not give up any rights you have to seek compensation for injury.

12. What other things should you know about this research study?

a. What is the Institutional Review Board (IRB) and how does it protect you?

The Johns Hopkins Medicine IRB is made up of:

- Doctors
- Nurses
- Ethicists
- Non-scientists
- and people from the local community.

The IRB reviews human research studies. It protects the rights and welfare of the people taking part in those studies. You may contact the IRB if you have questions about your rights as a participant or if you think you have not been treated fairly. The IRB office number is 410-955-3008. You may also call this number for other questions, concerns or complaints about the research.

b. What do you do if you have questions about the study?

Call the principal investigator, Dr. Malcolm Brock at 410-955-4408. If you wish, you may contact the principal investigator by letter or by fax. The address and fax number are on page one of this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 410-955-3008.

c. What should you do if you are injured or ill as a result of being in this study?

If you think you are injured or ill because of this study, call Dr. Malcolm Brock at 410-955-4408 during regular office hours.

d. What happens to Data that are collected in the study?

Johns Hopkins and our research partners work to understand and cure diseases. The data you provide are important to this effort.

If you join this study, you should understand that you will not own your data, and should researchers use them to create a new product or idea, you will not benefit financially.

13. What does your signature on this consent form mean?

Your signature on this form means that:

- you understand the information given to you in this form
- you accept the provisions in the form
- you agree to join the study

You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

Signature of Participant	(Print Name)	Date/Time

Signature of Person Obtaining Consent	(Print Name)	Date/Time

NOTE: **A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT; IF YOU ARE USING EPIC FOR THIS STUDY A COPY MUST BE FAXED TO 410-367-7382; IF YOU ARE NOT USING EPIC A COPY MUST BE PLACED IN THE PARTICIPANT'S MEDICAL RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).**

ONLY CONSENT FORMS THAT INCLUDE THE JOHNS HOPKINS MEDICINE LOGO CAN BE USED TO OBTAIN THE CONSENT OF RESEARCH PARTICIPANTS. IF THIS CONSENT FORM DOES NOT HAVE A JOHNS HOPKINS MEDICINE LOGO, DO NOT USE IT TO OBTAIN THE CONSENT OF RESEARCH PARTICIPANTS.