The Ohio State University Combined Consent to Participate in Research and HIPAA Research Authorization

Study Title:	**Cool down with EMBr: Enhancing Menopausal Hot Flash Symptom Reduction after Breast Cancer**
Principal Investigator:	**Sagar Sardesai, MBBS**
Funding:	**The Ohio State University Department of Internal Medicine, Division of Medical Oncology**

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.
- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.
- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

Key Information about This Study

Here is a short summary to help you decide if you want to be a part of this study. More details are listed later in this form.

You are invited to take part in this research study, because you have been having hot flashes for at least 30 days and have a history of breast cancer.

Many kinds of breast cancer treatments can cause these hot flashes. Hot flashes are normally treated with medications, but these can have side effects or not be effective. This is why we are testing a new way to manage bothersome hot flashes for people who have had breast cancer. In this study, we will be trying to figure out if a wrist device (similar to a watch) that can make pulses of cold or heat will help make people with hot flashes more comfortable. The

name of this device is "EMBr Wave generation 2" and other studies have already shown that it can make people more comfortable. We are asking you to be in this study because no one has checked to see if the EMBr Wave could help make hot flashes more comfortable in women who have had breast cancer.

If you choose to join this study, you will be in it for about 56 days. All women who join this study will use the EMBr Wave generation 2 device for 28 days. Compared to the original EMBr Wave, the generation 2 device has the same functionality but improved graphic design and patient compatibility. The women participating in this study will be evenly "randomized" into 2 groups: Group A **will** use the EMBr Wave generation 2 device in their first 28 days on study and **will not** use it in the second 28 days on study (days 29-56). Group B **will not** use the EMBr Wave generation 2 device in their first 28 days on the study, but **will** use the EMBr Wave generation 2 device in the second 28 days of the study (days 29-56).

It is expected that about 50 women will take part in this research study with 25 women in Group A and 25 women in Group B.

We encourage you to take some time to think this over, to discuss it with other people and your primary doctor, and to ask questions now and at any time in the future. Please take as much time as you need to read the consent form. If you find any of the language hard to understand, please ask questions. If you decide to participate, you will be asked to sign this form. We will give you a copy so that you can look at it while you are involved in this research study. If you choose not to participate in this research study, the research doctors will discuss other treatment options with you and/or refer you back to your primary doctor.

1. Why is this study being done?

This research study is a pilot study, which means it is the first time the EMBr Wave generation 2 device is being studied in women with a history of breast cancer who are experiencing bothersome hot flashes.

2. How many people will take part in this study?

It is expected that about 30 women will take part in this research study at the Ohio State University Comprehensive Cancer Centers.

3. What will happen if I take part in this study?

If you decide to take part, this is what will happen:

You will be "randomized" into either Group A (use EMBr Wave generation 2 in the first 28 days of the study) or Group B (use EMBr Wave generation 2 in the second 28 days of the study / days 29-56 of the 56-day study). All women on this study will use the EMBr Wave generation 2 device for 28 days. "Randomized" just means that you are put into a group by

chance, just like pulling a number out of a hat. You will have an equal chance of being placed into Group A or Group B. The only difference between Group A and Group B is when you will use the EMBr Wave generation 2. Each group will use the EMBr Wave generation 2 for the same amount of time.

Before getting your EMBr Wave generation 2 device, you will meet with the research team so you can learn how to work the device and a mobile application that goes with the device. This is what we will call "EMBr Wave orientation." After orientation, you will receive your device.

Before you start using the device, we will ask you to fill out a couple of questionnaires that ask about your hot flashes. You will take these questionnaires again at certain times during the study, as shown in the calendar below. There are no procedures or other medical tests for this study. You will only be asked to take the surveys and to use your EMBr Wave generation 2 device. Research team members may periodically call you on the phone to remind you to complete the study surveys and to see if you are having any problems with the EMBr Wave generation 2 device.

The names of the questionnaires you will take are:

- OCEAN Survey: This survey will ask you about your relatedness with your body and with the world around you, in addition to the way in which you experience emotions.
    - You will take this survey **1 time** at the beginning of your time in the study. This survey will be done either on paper or sent to you by email.
- Daily Hot Flash Score: This will ask you how many hot flashes you had that day and how severe they were.
    - You will take this survey before you start using the EMBr Wave generation 2 device ("baseline")
      AND
    - You will take this survey **1 time per day** for the rest of the study (56 days, when you are using the EMBr Wave generation 2 device and on the days when you are not). This survey will be done either on paper or sent to you by email.
- Hot Flash-Related Daily Interference Scale (HFRDIS): This will ask you about how your hot flashes affect your life.
    - You will take this survey before you start using the EMBr Wave generation 2 device ("baseline")
      AND
    - You will take this survey again **1 time per week** for the rest of the study (56 days) when you are using the EMBr Wave generation 2 and when you are not. This survey will be done either on paper or sent to you by email.
- Satisfaction Survey: This will ask you how much you liked the EMBr Wave generation 2 device and if you thought it helped your hot flash symptoms.

- This will be taken **1 time** at the end of your time using the EMBr Wave generation 2 device. This survey will be done either on paper or sent to you by email.

Please see the Research Study Calendar on the next page. This gives an overview of when you will take these surveys during the study.

Research Study Calendar:

Informed consent, randomization		
	Group A	**Group B**
Day 0	• Receive EMBr Wave generation 2 • EMBr Wave orientation with introduction to device and mobile application • OCEAN Survey • HFRDIS questionnaire • Daily Hot Flash Score	• OCEAN Survey • HFRDIS questionnaire • Daily Hot Flash Score
Days 1–28	• Daily Hot Flash Score • Device usage assessment	• Daily Hot Flash Score
Days 7, 14, 21, 28	• HFRDIS questionnaire	• HFRDIS questionnaire
Day 28	• Return EMBr Wave generation 2 • Patient satisfaction / perceived efficacy assessment	• Receive EMBr Wave generation 2 • EMBr Wave orientation with introduction to device and mobile application
Days 29–56	• Daily Hot Flash Score	• Daily Hot Flash Score • Device usage assessment
Days 35, 42, 49, 56	• HFRDIS questionnaire	• HFRDIS questionnaire
Day 56		• Return EMBr Wave generation 2 • Patient satisfaction / perceived efficacy assessment

Remember, you will be randomly put into either Group A or Group B. Both groups will use the EMBr Wave generation 2 device for the same amount of time and both groups will take the same surveys the same number of times.

Your medical chart will be reviewed to identify your medical history and what type and stage of cancer you were diagnosed with as well as cancer treatment information and medications you took that affect hot flashes.

4. How long will I be in the study?

You will be in the study for about 2 months (a total of 56 days), but you will only use the EMBr Wave generation 2 for 28 days. Orientation will be before you start using the EMBr Wave generation 2 device. After that, you will take a couple of surveys (described above). You then will use the EMBr Wave generation 2 every day for 28 of the 56 days of the study and you will complete surveys during the study (described above). You will return the EMBr Wave generation 2 device when your 28 days of using it is over. At the end of the study, the research team will collect any remaining paper surveys you finished, and the study team will ask you to complete the final questionnaire about how much you liked the EMBr Wave generation 2, if not already completed electronically.

You need to come to orientation and the meeting at the end of the study so you can return the EMBr Wave generation 2 and finish your surveys, if not already completed. These visits should not take any longer than 1.5 hours. We will try to schedule these study visits when you already have other appointments here so it is easier for you.

5. Can I stop being in the study?

You can leave the study at any time. If you decide to stop being in the study, there will be no penalty to you, and you will have all the same benefits you always have as a patient here. Your decision will not affect your future relationship with The Ohio State University.

You can decide to stop at any time and you may still be treated at your hospital or clinic. Tell your study doctor if you are thinking about stopping or decide to stop. You should talk to the doctor about leaving the study before you decide so that he/she can find out if you are having any difficulties with the EMBr Wave generation 2 device. Another reason to tell your doctor that you are thinking about stopping is so that he/she can talk to you about any other treatments that could help you.

6. What risks, side effects or discomforts can I expect from being in the study?

There are risks to taking part in any research study. One risk is that the EMBr Wave generation 2 device does not help your hot flash symptoms or that it makes your symptoms worse. There is a minimal risk that the EMBr Wave generation 2 device may cause side

effects. Because the EMBr Wave generation 2 device stays on the outside of your body, these risks are small.

In a research study, all of the risks or side effects may not be known before you start the study. **You need to tell your doctor or a member of the study team immediately if you experience any side effects.**

Everyone in the research study will be watched carefully for side effects. If you experience side effects, they may go away after you stop using the EMBr Wave generation 2 device. The side effects listed below are temporary. Appropriate medical care will be provided, if necessary.

Possible risks and discomforts you could experience during this study include:

- **EMBr Wave generation 2 Device**: May cause skin irritation similar to those of watches or bracelets that can be bothersome to some people.

- **Questionnaires:** The questionnaires will ask about your hot flash symptoms and general well-being. If any of the questions make you feel uneasy or embarrassed, you can choose to skip or stop answering any questions that make you uncomfortable.

- **Breach of Confidentiality:** There is a small risk that people who are not connected with this study will learn your identity or your personal information.

7. What benefits can I expect from being in the study?

There is no guarantee that you will receive any benefits from this study. The possible benefit of the EMBr Wave generation 2 device for the treatment of hot flashes in women with a history of breast cancer is not known. By being in this study, you will give doctors more information about how well the EMBr Wave generation 2 device works. It may help doctors understand hot flashes better and may help future patients with hot flashes.

8. What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

If you decide not to take part in this study, you have other choices. For example:
- You may choose to have the usual approach for management of hot flashes
- You may choose to take part in a different study, if one is available.

9. What are the costs of taking part in this study?

The EMBr Wave generation 2 device will be provided to you for free. You will be expected to return this device at the end of the study.

The only cost associated with this study will be travel to the medical center to receive and return your EMBr Wave generation 2 device.

10. Will I be paid for taking part in this study?

You will not receive payments for taking part in this study.

11. What happens if I am injured because I took part in this study?

If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Wexner Medical Center. The study doctor's name and phone number are listed at the bottom of this consent form.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

12. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of research participants.

13. Will my de-identified information be used or shared for future research?

No.

14. Will my study-related information be kept confidential?

We will work to make sure that no one sees your survey responses without approval. But, because we are using the Internet, there is a chance that someone could access your online responses without permission. In some cases, this information could be used to identify you. Your data will be protected with a code to reduce the risk that other people can view the responses.

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

Your study records will NOT be shared with or available to Embr Labs, the company that makes the EMBr Wave generation 2.

If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic, or physician's office records. Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information.

During the research study, you will be told about newly discovered side effects or important findings, which may affect your health or decision to keep being in the study. You may be asked to sign a new consent form that shows that you have been told about new information about this research study.

Study information that could have to do with your health may be placed in your medical record where authorized employees may see the information. Further, authorized requests for your records (medical record release for continuity of care) may result in research-related information being released.

Please talk to your study team, or contact the Office of Responsible Research Practices at 614-688-8641, if you have questions.

You may also be asked to sign a separate Health Insurance Portability and Accountability Act (HIPAA) research authorization form if the study involves the use of your protected health information.

15. HIPAA AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

I. What information may be used and given to others?

- Past and present medical records;
- Research records;
- Records about phone calls made as part of this research;
- Records about your study visits;
- Information that includes personal identifiers, such as your name, or a number associated with you as an individual;
- Information gathered for this research about:
    - Medical History
    - Physical exams
    - Laboratory, x-ray, and other test results
    - Diaries and questionnaires
    - The diagnosis and treatment of a mental health condition
- Records about any study drug you received;

II. Who may use and give out information about you?

Researchers and study staff.

III. Who might get this information?

- The sponsor of this research. "Sponsor" means any persons or companies that are:
    - working for or with the sponsor; or
    - owned by the sponsor.
- Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information;
- If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic, or physician's office record.

IV. Your information <u>may</u> be given to:

- The U.S. Food and Drug Administration (FDA), Department of Health and Human Services (DHHS) agencies, and other federal and state entities;
- Governmental agencies in other countries;
- Governmental agencies to whom certain diseases (reportable diseases) must be reported; and
- The Ohio State University units involved in managing and approving the research study including the Office of Research and the Office of Responsible Research Practices.

V. Why will this information be used and/or given to others?

- To do the research;
- To study the results; and
- To make sure that the research was done right.

VI. When will my permission end?

There is no date when your permission ends. Your information will be used for an unlimited amount of time / indefinitely. This is because the information used and created during the study may be analyzed for many years, and it is not possible to know when this will be complete.

VII. May I withdraw or revoke (cancel) my permission?

Yes. Your authorization will be good for the time period indicated above unless you change your mind and revoke (cancel) it in writing. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the researchers. If you withdraw your permission, you will not be able to stay in this study. When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

VIII. What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study and receive research-related treatment. However, if you are being treated as a patient here, you will still be able to receive care.

IX. Is my health information protected after it has been given to others?

There is a risk that your information will be given to others without your permission. Any information that is shared may no longer be protected by federal privacy rules.

X. May I review or copy my information?

Signing this authorization also means that you may not be able to see or copy your study-related information until the study is completed.

16. Who can answer my questions about the study?

For questions, concerns, or complaints about the study you may contact Dr. Sagar Sardesai at (614) 293-0066.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Office of Responsible Research Practices at 1-800-678-6251.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact Dr. Sagar Sardesai at (614) 293-0066.

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this combined consent and HIPAA research authorization form**.**

Printed name of participant	**Signature of participant**
	AM/PM
	Date and time
Printed name of person authorized to consent for participant (when applicable)	**Signature of person authorized to consent for participant (when applicable)**
Relationship to the participant	**AM/PM** **Date and time**

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent	**Signature of person obtaining consent**
	AM/PM
	Date and time

Witness(es) - *May be left blank if not required by the IRB*

Printed name of witness	**Signature of witness**
	AM/PM
	Date and time
Printed name of witness	**Signature of witness**
	AM/PM
	Date and time