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

Study Title:	**Heartfulness meditation: acute and long-term effects on the endocannabinoid signaling system and correlation with psychological outcomes in cyclic vomiting syndrome**
Principal Investigator:	**Thangam Venkatesan, MD**
Sponsor:	**The Ohio State University Wexner Medical Center**

- **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

The following is a short summary to help you decide whether or not to be a part of this study. More detailed information is listed later in this form.

- The purpose of this study is to assess the effects of a guided meditation technique in patients with Cyclic Vomiting Syndrome and also see if this has a change on endocananbinoids in your blood. Endocannabioids are substances that we all produce and helps us stay happy and healthy and can prevent nausea and vomiting.
- If you agree to participate, then you will complete six weeks of guided heart-focused meditation. You will also be asked to come into the clinic for two study visits. At these visits, you will complete questionnaires and have your blood drawn at the beginning and the end of the study.

- Risks associated with participating include a breach of confidentiality, and discomfort from having your blood drawn.

1. Why is this study being done?

Cyclic vomiting syndrome (CVS) is a chronic disorder of gut-brain interaction (DGBI) characterized by episodes of vomiting often triggered by stress. The purpose of this study is to assess the effects of a guided meditation technique called Heartfulness (HFN) Meditation in patients with CVS. You are being asked to participate because you have been diagnosed with CVS.

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

About 80 people will take part in this study.

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

If you choose to participate in this study, then you will complete six weeks of heart-focused meditation with the use of an app. This will be done at home. Each week includes 3 meditation sessions that are about 30 minutes each.

In addition, you will be asked to come into the clinic for two study visits:

- **Visit 1 (Baseline/Week 0):** Introduction to the web app, completion of questionnaires, first meditation session, and a pre- and post-meditation blood draw (about 1.5 tablespoons each).

- **Visit 2 (End-of-Study/Week 6):** Completion of questionnaires, final meditation session, pre- and post-meditation blood draw (about 1.5 tablespoons each).

4. How long will I be in the study?

The time required from you to participate is about 13 hours total. This includes the time required to review this consent form (15 minutes), to complete two study visits (2 hours each), and to complete 18 meditation sessions (30 minutes each). Your overall participation will last up to 6 weeks-8 weeks. However, a study team member may call you for any clarification regarding information pertaining to the study for up to a year.

5. Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

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

The primary risk of this study is loss of confidentiality. However, every effort will be made to protect your personal information.

You may also experience discomfort associated with having your blood drawn.

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

You may or may not benefit from participation in this study. However, the information gained from your participation may help to improve treatment for future patients.

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.

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

There is no cost to participate in this study.

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

You will be compensated $75 at Visit 1; $75 at end of study visit; $100 at completion of at least 14 meditation sessions. You will also be compensated $50 (in-state) or $100 (out-of-state) to assist with travel expenses, as applicable. Therefore, you may receive a total of up to $350 for study participation. This will be paid to you via Visa gift card.

By law, payments to participants are considered taxable income.

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 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 (and bio-specimens) be used or shared for future research?

No.

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

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).

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search the website at any time.

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:
  Laboratory, x-ray, and other test results
  Diaries and questionnaires

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 at which your permission ends. Your information will be used 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 completed.

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 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 study questions, concerns, or complaints, to withdraw consent and HIPAA authorization, or if you feel you have been harmed as a result of study participation, you may contact **Dr. Venkatesan at (614) 293-6255.**

For questions related to your privacy rights under HIPAA or related to this research authorization, please contact the HIPAA Privacy Officer at 650 Ackerman Road, Columbus, OH 43202; or tel: 614-293-6482.

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. Venkatesan at (614) 293-6255.**

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