Effects of
Meditation on Human Well-being and Function

Informed Consent Form

Protocol # MED02

Version 1.0

Principal Investigator: Dr. Tobias Moeller-Bertram

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE:	Effects of Meditation on Human Well-being and Function
PROTOCOL NO.:	MED02 WCG IRB Protocol #20211477
SPONSOR:	VitaMed Research, LLC.
INVESTIGATOR:	Tobias Moeller-Bertram, MD, PhD, MAS 44630 Monterey Ave. Suite 100 Palm Desert, California 92260 United States
STUDY-RELATED PHONE NUMBER(S):	Tobias Moeller-Bertram, MD Phone Number (Research clinic): 760-656-6116 Phone Number (24 hours): 760-994-7441

SUMMARY

You are being asked to be in a research study. The purpose of this consent form is to help you decide if you want to be in the research study.

You should not join this research study until all your questions are answered.

Things to know before deciding to take part in a research study:

- The main goal of a research study is to learn things to help patients in the future.
- The main goal of regular medical care is to help each patient.
- The decision to join or not join the research study will not cause you to lose any benefits.
- After reading the consent form and having a discussion with the research staff, you should know which parts of the study are being used for research and which are standard medical care.
- Your records may become part of the research record. If that happens, your medical records may be looked at and/or copied by the sponsor of this study and government agencies or other groups associated with the study.

PURPOSE OF THE STUDY

The objective of this study is to describe the effects of meditation on human well-being and function, and to learn in greater detail what effect meditation has on the human organism. We are conducting a study collecting bio-psychosocial readouts, physiologic and molecular measurements. We therefore have a combination of different experimental components. Particularly, we are interested in collecting the following data:

1. Questionnaire data (i.e. demographics, medical history, PROMIS measures)
2. Biological data (i.e whole blood, plasma, serum, and saliva)

3. Physiological readouts (i.e Functional magnetic resonance imaging or functional MRI {fMRI}, heart rate variability, EEG {including 3 arousal states: eyes open, eyes closed, during brief meditation}, physiological readouts from wearables like FitBit, Garmin or Apple Watch)
4. Video/ Audio Recording (i.e. FLIP video): record a 1.5-3 min video at the end of each day of the meditation retreat reflecting on their particular experiences.

Data collection will include Control subjects (not participating in meditation event, or part of Dr. Joe Dispenzas meditation community), novice meditators (little to no prior experience with Dr. Joe Dispenza's meditation) or Dr. Joe Dispenza's meditation cohort as a whole.

This data will be collected as part of one of our study experiments. You may be asked to participate in one or more of the following experiments:

Experiment A: Measuring the effects of meditation on the Healer and Healee; In this study will focus on interactions among Healers and Healees. We are also interested in collecting data among Healers themselves.

Experiment B: Measuring the effects of meditation on the human organism; In this study we will collect data on the effects of meditation on the human organism.

Experiment C: Measuring the effects of meditation within the meditation community; In this study we will collect data within members of Dr. Joe Dispenza's meditation community.

RESEARCH STUDY PROCEDURES

Experiment A: Measuring the effects of meditation on the Healer and Healee; In this study will focus on interactions among Healers and Healees. We are also interested in collecting data among Healers themselves.

The time you spend in this study will be up to 1 year. You will be asked to answer questionnaires collecting information about yourself, your health and well-being. You may be asked these questionnaires before, during, and after the healing event.

If you are receiving a healing, we may be interested in learning more about your disease state. Therefore, we may ask you to give us access to some of your medical information (medical records).

We are also interested in collecting information about your heart coherence. We therefore may ask you to wear a device which can record your heartbeat (HRV device)

In addition, you may also be asked to provide a sample of saliva. For this, you may be asked to gently scrape the inside of your cheek 10-20 times to increase the amount of cells in your saliva. You then will be asked to fill up to two small plastic tubes (2mL each). These samples will allow us to look at how your body functions before and after a healing event.

In some cases, we may also ask you for a small blood sample to be able to measure more in-depth information at how your body functions before and after a healing event. The amount we will collect is similar to a typical blood test given by your doctor.

All of the above information may be collected at multiple timepoints during the study; Before the event, During the event and after the-event. Typical time points to ask for information will be the following: 1, 3, 6, 9, 12 months after the healing event.

Experiment B: Measuring the effects of meditation on the human organism; In this study we will collect data on the effects of meditation on the human organism.

We want to collect information before you start a meditation event, and then again after you have finished the meditation event to look for changes. In order to see how long potential changes will last, the time you spend in this study will be up to 1 year. You will be asked to answer questionnaires collecting information about yourself, your health and well-being. You may be asked these questionnaires before, during, and after the healing event. We may ask you to also give us access to some of your medical information (medical records).

We are interested in collecting information about your heart coherence. We therefore may ask you to wear a device which can record your heartbeat (HRV device).

In addition, you may also be asked to provide a sample of saliva. For this, you may be asked to gently scrape the inside of your cheek 10-20 times to increase the amount of cells in your saliva. You then will be asked to fill up to two small plastic tubes (2mL each). These samples will allow us to look at how your body functions before and after a healing event.

In some cases, we may also ask you for a small blood sample to be able to measure more in-depth information at how your body functions before and after a healing event. The amount we will collect is similar to a typical blood test given by your doctor.

We may ask participants to wear a continuous glucose monitor (CGM) that will be fitted before the retreat that will be worn for 14 days to allow data capture during and after the meditation retreat. You will be asked to download software specific for the CGM device onto your mobile phone.

For sub-studies, we will ask participants to submit to Functional magnetic resonance imaging or functional MRI (fMRI). This technique is used to measure and map brain activity in a noninvasive manner.

All of the above information may be collected at multiple timepoints during the study; Before the event, During the event and after the-event. Typical time points to ask for information will be the following: 1, 3, 6, 9, 12 months after the healing event.

Experiment C: Measuring the effects of meditation within the meditation community; In this study we will collect data within members of Dr. Joe Dispenza's meditation community.

We are interested in looking at long-term effects of individuals doing Dr. Joe Dispenza's work on their well-being and function. We will send you questionnaires that you can fill out electronically

at pre-determined time points. assess will either be on a monthly, quarterly, bi-annual, or annual basis. We also are interested in more objective measures of change and therefor may ask you to wear a device like a Fitbit or Apple Watch and allow us to use the data.

For each one of the experiments, you may be asked to answer some or all of the following questions.

- PANAS
- MSQ
- PROMIS-29
- SF-36
- MEQ-30
- GAD-7
- PEG-3
- PSS-10
- PHQ-9
- Perma Profiler
- Primal World Index-18
- Remote Coherence Healing Follow Up Survey (Experiment A – Healees Only)
- PCL-5 (Post Traumatic Stress Disorder (PTSD) Checklist for DSM-5)
- BPI (Brief Pain Inventory), short form

RISKS AND DISCOMFORTS

Questionnaire data collection: The risks and discomforts associated with collection questionnaire data are small. There is a risk of psychological discomfort due to the personal nature of the questionnaires being used. We estimate that the time spent on answering questionnaires could be up to 1 hour depending on amount of questionnaires selected for the experiment.

Physiological data collection: During recording of the EEG, slight headaches in very sensitive individuals may occur. If wearing the EEG equipment on the head cannot be tolerated, the sampling procedure can be stopped immediately. Furthermore, a skin reaction to the electrode adhesive is theoretically possible. The HRV recording equipment is similar to recording a standard 3-lead ECG. Skin reactions to adhesives in the electrode are a theoretical risk. Wearables are commercially available and may be worn around the wrist like a watch. Skin reactions to the wrist band are a theoretical risk. People are at risk for injury from the MRI magnet if they have pacemakers or other implanted electrical devices, brain stimulators, some types of dental implants, aneurysm clips (metal clips on the wall of a large artery), metallic prostheses (including metal pins and rods, heart valves, and cochlear implants), permanent eyeliner, implanted delivery pump, or shrapnel fragments. Welders and metal workers are also at risk for injury because of possible small metal fragments in the eye of which they may be unaware. It is not known if MRI is completely safe for a developing fetus. Therefore, all women of childbearing potential will have a pregnancy test performed no more than 24 hours before each MRI scan. The scan will not be done if the pregnancy test is positive. People with fear of confined spaces (i.e. claustrophobia) may become anxious during an MRI. Those with back problems may have back pain or discomfort from lying in the scanner. The noise from the

scanner is loud enough to damage hearing, especially in people who already have hearing loss. There are no known long-term risks of MRI scans.

Biological data collection: Drawing blood always poses a risk of infection and mild discomfort. These will be mitigated by having the blood draws performed by experienced professionals using standard techniques.

For the saliva selection there is the potential of mild discomfort while agitating the inside of your cheek.

NEW INFORMATION

You will be told about any new information that might change your decision to be in this study. You may be asked to read and sign a new consent form if this occurs.

BENEFITS

There may be no direct benefit to you from providing the collected data. However, the data collected may help us understand the effects of meditation on human biology.

COSTS

You will not be responsible for any costs related to study participation. If you experience any adverse events as a result of the study, any additional care needed will be provided to you at no cost to you.

PAYMENT FOR PARTICIPATION

- Research subjects will not be compensated for participation in these studies.
- Research controls may receive a modest form of compensation for participation in these studies.

ALTERNATIVES TO STUDY PARTICIPATION

This is not a treatment study. Your alternative to participating in the study is not to participate in this study.

CONFIDENTIALITY

Your private information and your medical record will be shared with individuals and organizations that conduct or watch over this research, including:

- The research sponsor
- People who work with the research sponsor
- Government agencies, such as the Food and Drug Administration
- The Institutional Review Board (IRB) that reviewed this research

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

We protect your information from disclosure to others to the extent required by law. We cannot promise complete secrecy.

COMPENSATION FOR INJURY

If you are injured or get sick as a result of being in this study, call the Principal Investigator immediately (760-994-7441 24 hours). Your insurance would be billed for any required treatment. No other payment is routinely available from the study doctor or sponsor.

VOLUNTARY PARTICIPATION AND WITHDRAWAL

Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time for any reason or no reason. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled.

Your participation in this study may be stopped at any time by the study doctor or the sponsor without your consent for any reason, including:

- if it is in your best interest
- if you do not consent to continue in the study after being told of changes in the research that may affect you
- if you are not able to comply with your study related responsibilities

If you leave the study before the planned final visit, you may be asked by the study doctor to have some tests or procedures done so that you leave the study safely. Any data previously collected from you prior to withdrawing your consent may still be used.

QUESTIONS

Please contact Tobias Moeller-Bertram, M.D. at 760-656-6116 or 760-994-7441 (24 hours) (Vitamed Research) for any of the following reasons:

- if you have any questions about your participation in this study,
- if you feel you have had a research-related injury, or
- if you have questions, concerns or complaints about the research.

If you have questions about your rights as a research subject or if you have questions, concerns or complaints about the research, you may contact:

WCG Institutional Review Board® (WCG IRB®)
1019 39th Avenue SE Suite 120
Puyallup, WA 98374-2115
Telephone: 855-818-2289
E-mail: researchquestions@wcgirb.com

WCG IRB is a group of people who independently review research.

WCG IRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WCG IRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

Do not sign this consent form unless you have had a chance to ask questions and have gotten satisfactory answers.

If you agree to be in this study, you will receive a signed and dated copy of this consent form for your records.

CONSENT FOR PARTICIPANTS

I have read this consent form (or it has been read to me). All my questions about the study and my part in it have been answered. I freely consent to be in this research study.

I authorize the release of my medical and research records for the purpose of this study.

By signing this consent form, I have not given up any of my legal rights.

Subject/Assigned Representative:

Name (printed) _____

Signature _____ Date _____

Person conducting informed consent discussion:

Name (printed) _____

Signature _____ Date_____

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

What information may be used and given to others?
The study doctor will get your personal and medical information. For example:

- Past and present medical records
- Research records
- Records about phone calls made as part of this research
- Records about your study visits

Who may use and give out information about you?
The study doctor and the study staff.

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.

Your information may be given to:

- The U.S. Food and Drug Administration (FDA),
- Department of Health and Human Services (DHHS) agencies,
- Governmental agencies in other countries,
- Governmental agencies to whom certain diseases (reportable diseases) must be reported, and
- WCG Institutional Review Board (WCG IRB).

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

- to do the research,
- to study the results, and
- to see if the research was done right.

If the results of this study are made public, information that identifies you will not be used.

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.

May I review or copy my information?
Yes, but only after the research is over.

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

This permission will be good until December 31, 2060.

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.

Absolute confidentiality cannot be guaranteed because of the need to give information to these parties. The results of this research study may be presented at meetings or in publications. Your identity will not be disclosed in those presentations.

Subject:

Name (printed) _____

Signature_____ Date_____

Person conducting HIPAA review:

Name (printed) _____

Signature_____Date_____