CONSENT FORM FOR "EFFECTS OF NON-INVASIVE THERAPEUTIC INTERVENTIONS"

Document Date: June 23, 2020

Stanford University

STANFORD UNIVERSITY Research Consent Form

Protocol Directors: Melis Yilmaz Balban, Ph.D.
Andrew Huberman, Ph.D.
David Spiegel, M.D.

IRB Use Only
Approval Date: June 23, 2020
Expiration Date: June 23, 2021

Protocol Title: Behavioral and Autonomic Measurements of the Healthy Human Fear Responses and the Effects of non-invasive Therapeutic Interventions

Breathwork Study: Pilot A

Are you participating in any other research studies? _____ Yes _____No

FOR QUESTIONS ABOUT THE STUDY, CONTACT: The study team at breathworkstudy@stanford.edu.

DESCRIPTION: You are invited to participate in a research study on the effects of therapeutic interventions on psychological and physiological factors. The purpose of this research is to understand the behavioral and internal changes that occur when humans feel stressed or anxious and to test the effects of non-invasive methods (e.g. Breathwork, Mindfulness) on those changes.

If you decide to participate, your participation will be done remotely and can be done through the use of your mobile device or computer. You will be assigned to 2 out of the 4 available interventions. There are 3 breathwork and 1 mindfulness intervention in this study. This means that you will be assigned to one of the three breathwork interventions, and have a 50% chance of being offered mindfulness or another breathwork intervention. Each intervention will last for 28 days, and will take about 10 minutes a day. Each day, you will receive a text containing a link to a secure Stanford server, where you will be able to view a pre-recorded video of the intervention to practice (about 5-7 minutes) and complete a couple of questionnaires before and after the intervention (about 3 minutes).You will also be asked to complete online questionnaires before the start of the first 28 day intervention, and then after the completion of each of the 2 interventions. These questionnaires will take about 3 to 5 minutes at each of the 3 timepoints. We will ship you a WHOOP strap, a lightweight fitness monitor to be worn during you participation in the study. This is a waterproof band that is placed around your wrist to collect physiological data such as heart rate and sleep. Stanford University expects to enroll 125 research study participants

TIME INVOLVEMENT: Your participation in this experiment will take approximately total of 10 hours over about an eight-week period.

RISKS AND BENEFITS: Mindfulness and Breathwork interventions are generally known to be safe and may leave one in positive states such as feeling relaxed and/or alert.

The methods of Breathwork include, but are not limited to, deeper, faster or slower breathing. If you experience any sensations in your body that lead you to believe the process is adversely affecting your health, please stop and contact us. Even though Breathwork is a generally safe, it is not recommended for individuals who are pregnant, have a history of seizures, or glaucoma. If you currently have any of these conditions or experience them after study enrollment, please stop your participation and notify us.

The benefits which may reasonably be expected to result from this study are discovery of a treatment that is easy to implement daily and useful to alleviate emotional disturbances. We cannot and do not guarantee or promise that you will receive any benefits from this study. Your decision whether or not to participate in this study will not affect your grades. The alternative is not to participate.

VOLUNTARY PARTICIPATION: Your participation in this study is entirely voluntary. Your decision not to participate will not have any negative effect on you or your medical care. You can decide to participate now, but withdraw your consent later and stop being in the study without any loss of benefits or medical care to which you are entitled.

COMPENSATION FOR RESEARCH-RELATED INJURY: All forms of medical diagnosis and treatment – whether routine or experimental – involve some risk of injury. In spite of all precautions, you might develop medical complications from participating in this study. If such complications arise, the Protocol Director and the research study staff will assist you in obtaining appropriate medical treatment. In the event that you have an injury or illness that is directly caused by your participation in this study, reimbursement for all related costs of care first will be sought from your insurer, managed care plan, or other benefits program. You will be responsible for any associated co-payments or deductibles as required by your insurance.

If costs of care related to such an injury are not covered by your insurer, managed care plan or other benefits program, you may be responsible for these costs. If you are unable to pay for such costs, the Protocol Director will assist you in applying for supplemental benefits and explain how to apply for patient financial assistance from the hospital.

You do not waive any liability rights for personal injury by signing this form.

COSTS: There is no cost to you for participating in this study, other than basic expenses like the personal time it will take to participate in the study.

PAYMENTS: No payment will be provided for study participation, however, each participant will receive a WHOOP strap to use during, and to keep after completion of study participation. Six-months of WHOOP subscription costs will also be waived. The value of the unit is approximately $350, and $180 for the 6-month subscription.

If the WHOOP straps is damaged during study participation, please contact the study team for repair of the unit. Losing the WHOOP strap will result in end of study participation. The data will be erased from the unit and the 6 month free subscription will be cancelled.

You agree to return the WHOOP strap to Stanford if you are not able to complete your study participation.

_____ _____

Signature of Adult Participant Date

PARTICIPANT'S RIGHTS: You should not feel obligated to agree to participate. Your questions should be answered clearly and to your satisfaction. If you decide not to participate, tell the Protocol Director.

You will be told of any important new information that is learned during the course of this research study, which might affect your condition or your willingness to continue participation in this study.

PARTICIPANT RESPONSIBILITIES

As a participant, your responsibilities include:

- Follow the instructions of the Protocol Director and study staff.
- Keep your study appointments. If it is necessary to miss an appointment, please contact the Protocol Director or research study staff to reschedule as soon as you know you will miss the appointment.
- Tell the Protocol Director or research study staff about any side effects, doctor visits, or hospitalizations that you may have.
- Tell the Protocol Director or research staff if you believe you might be pregnant.
- Ask questions as you think of them.
- Tell the Protocol Director or research staff if you change your mind about staying in the study.

CONFIDENTIALITY: In order to use the WHOOP to collect physiological data, it is necessary to download WHOOP's smartphone app, which requires standard registration. To limit the risk and protect participants' Personal Healthcare Information (PHI), we, Stanford University School of Medicine, will be providing you, Participant, with de-identified emails for the purpose of this study. However, should you choose to use your existing personal email instead, all interactions with the WHOOP app will be linked and trackable directly to your personal account/email. An IP address (not easily connected to a name, identifies the device you are using) would be used in any web connection. WHOOP records your physiological data and would not formally know that this is a research study or have reason to trace the online

activity back to an individual participant. These recordings are then saved at WHOOP's servers, however WHOOP will block themselves from having access to participants data collected for this study. There is no way to utilize this technology without some potential for the identification of personal information.

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed except as authorized by you or as required by law. However, there is always some risk that even de-identified information might be re-identified.

Identifiers might be removed from identifiable private information and, after such removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you.

Authorization to Use Your Health Information for Research Purposes

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

What is the purpose of this research study and how will my health information be utilized in the study?

This is a research study on emotional states and defensive behavior. The purpose of this research is to understand mechanistically how people respond when certain emotions are evoked by the environment and to test different the effectiveness of different non-ingestible interventions to shift emotional state. Information about your emotional state, your declared psychiatric history or the effect of the interventions might be included in scientific publications or conferences. Your identity will not be revealed.

Do I have to sign this authorization form?

You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study. Signing the form is not a condition for receiving any medical care outside the study.

If I sign, can I revoke it or withdraw from the research later?

If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you must write contact Melis Yilmaz Balban at 299 Campus Drive, Rm 229, Stanford, CA 94305.

What Personal Information Will Be Obtained, Used or Disclosed?

Your health information related to this study, may be used in connection with this research study, including, but not limited to, your name, age and date of birth, demographic information, email, telephone number, mailing address, health

information and declared psychiatric history. Personal identifiers such as name, email and age will not be disclosed or shared with anyone except for the research staff, The Stanford University Administrative Panel on Human Subjects in Medical Research.

Who May Use or Disclose the Information?

The following parties are authorized to use and/or disclose your health information in connection with this research study:

- The Protocol Directors, Drs. Melis Yilmaz Balban, Andrew Huberman, and David Spiegel.
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
- Research Staff on Human Subjects in Medical Research and any other unit of Stanford University as necessary

Who May Receive or Use the Information?

The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- The Office for Human Research Protections in the U.S. Department of Health and Human Services

Your information may be re-disclosed by the recipients described above if they are not required by law to protect the privacy of the information.

When will my authorization expire?

Your authorization for the use and/or disclosure of your health information will end on December 1, 2050 or when the research project ends, whichever is earlier.

_____ _____

Signature of Adult Participant Date

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Print Name of Adult Participant

WITHDRAWAL FROM STUDY

The Protocol Director may also withdraw you from the study without your consent for one or more of the following reasons:

- Failure to follow the instructions of the Protocol Director and study staff.
- The Protocol Director decides that continuing your participation could be harmful to you.
- Pregnancy
- You need treatment not allowed in the study.
- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances.

If you first agree to participate and then you change your mind, you are free to withdraw your consent and discontinue your participation at any time.

If you decide to withdraw your consent to participate in this study, you should notify Dr. Melis Yilmaz Balban at (650) 353-1583.

CONTACT INFORMATION:

If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Protocol Director, Dr. Melis Yilmaz Balban at (650) 353-1583 or yilmel@stanford.edu. You should also contact him or her at any time if you feel you have been hurt by being a part of this study.

Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at (650)-723-5244 or toll free at 1-866-680-2906. You can also write to the Stanford IRB, Stanford University, 1705 El Camino Real, Palo Alto, CA 94306.

Alternate Contact: If you cannot reach Dr. Melis Yilmaz Balban, please contact Dr. Andrew Huberman at (415) 515-0585.

In an event of research related psychological discomfort, please contact Dr. David Spiegel 723-6421 (office) for immediate assistance or Stanford Outpatient Psychiatry Clinic for a consultation (650) 498-9111.

Signing your name means you agree to be in this study and that you will receive a copy of this signed and dated consent form.

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Breathwork Study: Pilot A

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Signature of Adult Participant Date

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