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**PROJECT TITLE:**

Clinical Trial: Efficacy of 1072nm Infrared Stimulation on Cognitive Symptoms of Dementia:

**PARTICIPANT INFORMED CONSENT**

**PARTICIPANT:** \_\_\_\_\_

**ADDRESS:** \_\_\_\_\_

**City/State/Zip:** \_\_\_\_\_

**Telephone: (H)** \_\_\_\_\_ **(cell)** \_\_\_\_\_

**INVESTIGATOR:** Jack Lebeau, MD, FACC, Principal Investigator

**1. PURPOSE OF THE STUDY**

This study measures whether problems with executive functioning (including attention, working memory, strategies of learning and remembering, planning, organizing, self-monitoring, inhibition, and flexible thinking) can be effectively treated by repeated brief (6 minute) exposure to 1072nm infrared light stimulation in order to increase cerebral blood flow (CBF) and oxygenation. This particular frequency of light has shown to increase the activity of brain cells and to provide support for the cells' ability to repair and protect itself against further damage.

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**2. DESCRIPTION OF THE PROJECT**

I understand that I am being asked to be a participant in research concerning a new approach to improving mental functioning. The Quietmind Foundation (QMF) is a research and educational foundation devoted to bringing neurofeedback into the healthcare mainstream and studying ways to use biofeedback and related technologies to improve cognitive and behavioral problems associated with degenerative brain disorders.

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Study locations

I understand that I agree to be at the pre/post testing and treatment sessions, which will be conducted at the QMF offices. Treatment sessions may also be provided at other locations pending prior approval by Dr. Lebeau.

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#### Enrollment and assignment to study conditions

The study will involve an evaluation of the participant's cognitive functioning and a recording of my brain activity conducted by a member of the Quietmind staff, which will take 3.5 hours to complete, over a two day period, before and after completing the course of 28 daily stimulation sessions, which will take 15-20 minutes each. I understand that I will be RANDOMLY ASSIGNED (like flipping a coin) to either a treatment group or a placebo (inactive, non-treatment) group. In the placebo group, participants will receive "treatment" that is known to be ineffective (although harmless), but it will follow the same procedure as the active treatment. Neither I, nor the technician working with me, will know which group I am in.

#### Participant Responsibilities

I agree to be responsible to be present and on time for these testing sessions which will consist of paper and pencil testing as well as computerized neuropsychological assessment batteries. I understand that my medical records may also be reviewed. I will be available for up to 28 treatment or placebo sessions, once daily several days a week. These sessions will last about 15-20 minutes. The full evaluation process will be repeated three days after the 28<sup>th</sup> session or as soon as can be arranged. I further agree to complete any assessment instruments as may be required..

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#### EEG recording

During the pre and post treatment evaluation process, I will have a bathing cap containing 19 recording electrodes placed on my head and recordings made of my brainwave activity for 20-30 minutes. The recordings will be done in two segments, one with me keeping my eyes closed and the other eyes open with normal blinking. The placement of the cap and preparation of the sensors for the recordings may take 20-30 minutes to complete in addition to the recordings themselves. I will be required to have my hair washed twice with no residue shampoo, e.g., Neutrogena prior to these assessments and not consume caffeine or other stimulants or nicotine within 6 hours of the testing. Please note that at no time will there be any electrical stimulation of any kind directed into me. These procedures involve only the recording of the body's own naturally occurring electrical activity.

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#### Brain Stimulation Procedure

The light stimulation sessions will last 15 minutes including the placement and removal of the helmet and blood flow measurement headband. During the first part of the session I will have my blood flow measured for two minutes using the headband placed around their forehead. This device will remain in place during the

infrared stimulation portion of the session. I will wear the infrared stimulation headset and maintain an upward gaze for the duration of the session with normal blinking. I will need to sit relatively still for the entire six minute treatment period. The headset will be removed at this point and after another minute there will be another two minute recording of my blood flow using the headband device. I will alert the technician to any discomfort and adjustments will be made to assure my comfort during the session.

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### **Questions Regarding Participation**

#### What if participant is receiving medications?

I will not be asked to stop or alter their current medications as a condition of participation in this study. I understand that if I am currently taking any prescription medications, it will be necessary to stay in contact with my physician to determine whether any changes in their medicines should be made during the course of this study. I agree to be responsible for this.

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#### What if participant is receiving counseling or psychotherapy?

This treatment is not known to evoke emotional responses. If I am currently engaged in counseling or psychotherapy, I will stay in contact with my therapist throughout my participation in this study.

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#### Benefits and risks of participation

The benefit of participating in this study is to improve scientific knowledge about whether this treatment is effective for treating symptoms like those I am experiencing. However, I understand that the experimental nature of this treatment means that there is currently no conclusive scientific evidence that this treatment will improve my symptoms.

This study has the following risks. I may experience a tightness or pressure from the helmet that some people occasionally find uncomfortable and may result in a brief headache. No other negative effects have been reported from the use of this device.

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### **3. CONFIDENTIALITY STATEMENT**

All documents and information pertaining to this research study will be kept confidential in accordance with all applicable federal, state, and local laws and regulations. I understand that data generated by the study may be reviewed by the United States Food and Drug Administration (FDA) and the Quietmind Foundation Institutional Review Board to assure proper conduct of the study and compliance with federal regulations. I understand that the results of this study may be published. If any data are published, I will not be identified by name or any other personal information.

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**4. VOLUNTARY PARTICIPATION STATEMENT**

I understand that my participation in this study is entirely voluntary and that I am free to withdraw from this trial at any time.

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**5. COMPENSATION STATEMENT**

I will receive \$250 compensation when the trial period is completed. If I choose to withdraw from the study I will be compensated on the basis of time invested up to when I withdrew from participation.

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**6. COSTS STATEMENT**

I understand that if I am accepted as a subject for this study, the treatment and tests required by the study will be provided at no cost to me.

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**7. INSTITUTIONAL CONTACTS**

The researchers conducting this study is:

Marvin Berman, Ph. D.

Phone 610-940-0488

email [marvinberman@quietmindfdn.org](mailto:marvinberman@quietmindfdn.org)

**8. TERMINATION STATEMENT**

The investigator may terminate my participation in the study without my consent.

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**10. FINAL STATEMENT AND SIGNATURE**

This study has been explained to me, I have read the consent form and I agree to participate. I have been given a copy of this consent form.

\_\_\_\_\_  
Signature of Participant

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Investigator and Witness

\_\_\_\_\_  
Date