|  |  |
| --- | --- |
| QMlogo.gif | Yorktown Plaza Ste. 3158120 Old York Rd. Elkins Park, PA 19027Office: 610-940-0488 Fax: 215-359-0630[www.quietmindfdn.org](http://www.quietmindfdn.org)  |

### **PROJECT TITLE:** Efficacy of Infrared Stimulation on Motor Symptoms of Parkinson’s Disease

## **INFORMED CONSENT**

**PARTICIPANT'S NAME AND ADDRESS:**

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

C/S/Z: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Initiation Date: 4/11/17

INVESTIGATOR:

James P. Halper, MD & Marvin Berman, Ph.D., Co-Principal Investigators

Quietmind Foundation 315 Yorktown Plaza Elkins Park, PA 19027

Phone : 610-940-0488 Fax: 215-539-0630

**1. PURPOSE OF THE STUDY**

This study measures whether forearm bradykinesia can be effectively treated using brief (six minute) daily exposure to near infrared light stimulation.

**2. DESCRIPTION OF THE PROJECT**

I understand that I am being asked to participate in research concerning a new approach to improving physical and mental functioning. The Quietmind Foundation (QMF) is a research and educational foundation devoted to bringing neuromodulation techniques into the healthcare mainstream and studying ways to use biofeedback and related technologies to improve motor, cognitive and behavioral problems associated with degenerative brain disorders. This is a single subject study.

**Study location**

Pre/post testing of about 1 hour will be conducted at the QMF offices 521 Plymouth Rd. #106, Plymouth Meeting, PA 19462 or a location to be arranged prior to study initiation. All study related treatment sessions will be conducted at subject’s home over the period of this trial.

**Enrollment and assignment to study conditions**

The study will involve an evaluation conducted either by a member of the Quietmind clinical staff or a qualified neurologist and EEG technician which will take 1 hours to complete**.**  I understand that my medical records may also be reviewed. The evaluation will be repeated quarterly at the Quietmind Foundation offices in Plymouth Meeting, PA or a mutually convenient location. Medical evaluation by a qualified neurologist (Dr. Allan Spiegel, MD) will be conducted to evaluate my condition prior to initiating the study. I will arrange for these periodic assessments to be conducted immediately prior to initiating treatment sessions and again within 3 days of the termination of phototherapy treatments. I give permission to have my treating physicians contacted by the investigator to confirm my diagnosis and inform them of my participation in this research.

Physician Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Telephone: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

### **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 eyes open and closed recordings made of my brainwave activity for up to 8 minutes. The placement and preparation for the recordings may take 10 minutes to complete in addition to the recordings themselves. I will be required to wash my hair twice with clarifying shampoo prior to these assessments.

**Bradykinesia Evaluation:**

I will press buttons on a bar as quickly as I can while keeping my arm in the same relationship to the button press device. I will repeat the process 3 times for 15 seconds each time. I will also be videotaped rising from a chair and walking down a hallway for 10meters and back again.

### **Brain Stimulation Procedure**

NIR Light stimulation sessions will last five minutes and will be conducted daily for 60 consecutive days. I’ll wear the headset and maintain an upward gaze for the duration of the five-minute session with normal blinking. I will need to sit relatively still for the entire treatment period. I’ll inform Dr. Berman of any discomfort so adjustments can be made to assure my comfort during future sessions. I will text or email a digital photograph of myself when the green operating lights are on each time I conduct the treatment.

#### Questions Regarding Participation

What if I am receiving other medications?

I will not be asked to stop or alter my 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 my medicines should be made during this study.

What if I am receiving counseling or psychotherapy?

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

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. You 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.

**3. CONFIDENTIALITY STATEMENT**

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 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 in any way that could compromise my privacy.

**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 and that my participation may be discontinued by the study director Dr. Berman if he determines, in consultation with your primary physician, that the treatment is creating a counter-therapeutic effect.

**6. COSTS STATEMENT**

I understand that if I am accepted as a subject for this study there is no cost to me for participation. Any services that are considered standard of care, e.g., EEG assessments will be billed to my insurance carrier.

**7. INSTITUTIONAL CONTACTS IRB CONTACT**

Researcher conducting this study Institutional Review Board Chairman

Marvin H. Berman, Ph.D., 610-940-0488 Allan Lundy, Ph.D., (215) 820-8100

email marvinberman@quietmindfdn.org email alundy@quietmindfdn.org

**8. TERMINATION STATEMENT**

Either I or the investigator may terminate my participation in the study without my consent after consultation with my physician for which I give unrestricted permission.

**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 - Principal Investigator Date