**PROJECT TITLE: Bellabee PEMF therapy: Open Label Case Series**

## **INFORMED CONSENT**

**PARTICIPANT'S NAME:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

INVESTIGATOR(s):

Marvin Berman PhD
Quietmind Foundation
267-481-3987

**1. PURPOSE OF THE STUDY**

 This research will investigate the effects of a 2-month Pulsed Electromagnetic Frequency (PEMF) stimulation with the Bellabee on anxiety related symptoms and associated brainwave activation.

**2. DESCRIPTION OF THE PROJECT**

 I understand that I am being asked to participate in research concerning the connection of PEMF relative to anxiety-related symptoms. I understand participation and adherence to the requirements below will help establish data to understand if there is a link between the PEMF protocol provided to me as part of the research and improved anxiety symptoms and/or brainwave activation.

Study location

 Subjects will self-administer the treatment at home for two months according to the protocol they and their treatment providers determine. We are restricting participation to within the USA.

Enrollment and action required by participant

 The study will require the following actions:

1. Enroll in the trial by signing the informed consent and purchasing the Bellabee device.
2. Undergo two (2) brain activity assessments using Quantitative Electroencephalographic measurements of 19-channels of scalp acquired EEG activity. The qEEG is a diagnostic tool used to detect brain activity by wearing a cap (that looks similar to a shower or bathing cap) connected to a computer to capture the information.
3. Follow instructions I will receive from Quietmind Foundation staff and/or the local investigators to properly complete **(1-3)** above and related actions in connection with the study.

#### 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 on any prescription medications, prescribed or recommended diets, it will be necessary to disclose them to Dr. Thompson and stay in contact with my physician to determine if any changes to these should be made during this study.

Benefits and risks of participation

There are no known significant risks associated with participation in this research.

I understand that the possible benefits of participation in this research include full reimbursement for the cost of the Bellabee device after completing the entire study Although these possible positive outcomes have been identified using other electromagnetic stimulation techniques, there is no guarantee that you will obtain any benefit in terms of your symptoms from this treatment. My participation in the current study will help to scientifically validate the potential for the Bellabee to be a useful intervention for anxiety-related symptoms.

Possible adverse reactions to PEMF include a temporary worsening of symptoms and possible dizziness or nausea. If such symptoms occur, I will stop using the device and contact my provider or Quietmind Foundation staff to discuss my continued participation. Participation will be discontinued if I develop a medical condition that can influence my symptoms, or if I have a history of seizure, any cardiac abnormalities problems, have an implanted pacemaker, or are currently abusing drugs or alcohol. I will continue with my other treatments and not begin any new treatments other than the use of the Bellabee.

**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 NeuroField Neurotherapy Inc, and the United States Food and Drug Administration (FDA) 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.

**4. VOLUNTARY PARTICIPATION STATEMENT**

 I understand that my participation in this study is entirely voluntary and that I am free to withdraw from the study at any time without penalty.

**5. COMPENSATION STATEMENT**

 I understand that I will receive no monetary compensation from my participation in the study. I will have my purchase price of $89 refunded on receipt of the 2nd QEEG report. I may withdraw from the study at any time before completion and no refund will be issued unless the unit is returned in good working condition.

**6. INSTITUTIONAL CONTACTS**

 If I have any questions about research-related issues, I may contact Marvin H Berman PhD 267-481-3987. If I have any complaints about the manner in which this study is being conducted, or wish to speak with a person not directly involved, I may contact Allan Lundy, PhD, at Allan.Lundy@comcast.net, or 215-820-8100. Dr. Lundy is the Chairperson of the Quietmind Foundation Institutional Review Board, which has approved this study.

**7. STANDARD INJURY STATEMENT**

 I understand that if I sustain an injury as a result of participation in this study, only physicians' fees and medical expenses not covered by my medical and hospital coverage will be paid. Compensation for such injuries is not available. I understand that I have not waived any of the legal rights that I would otherwise have as a participant in an investigational study.

**8. COSTS STATEMENT**

 I understand that if I am accepted as a subject for this study, the PEMF protocolwill be made available at no cost as my purchase price will be refunded on completion of the study.

**9. TERMINATION STATEMENT**

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

**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.

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#  Signature of Participant Date

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 Signature of Investigator Date