Informed Consent to Use Intranasal 1070nm Photobiomodulation

[This is an important legal document – All sections MUST be completed by clients and/or their representative before initiating any therapeutic procedure] To be legally valid, consent to participate in any treatment program must be: Informed, Voluntary and the client is Competent to sign the agreement.'

Client Acknowledgement of Capacity to Provide Consent to Treatment:

A person with dementia cannot be assumed to be incapable of making decisions. People with mild to moderate dementia can evaluate, interpret, and derive meaning in their lives unless there is contrary evidence.

Civil Capacities/Competencies (Make your response **by in Boldface)**

1. I have the capacity to consent to therapy and make medical decisions
   Yes No _____ INITIALS
2. I have the capacity to manage my financial affairs
   Yes No _____ INITIALS
3. My finances are managed in a conservatorship
   Yes No _____ INITIALS
4. I live independently and care for self
   Yes No _____ INITIALS
5. I have a guardian Yes No _____ INITIALS
6. I understand that I have been assessed for _____ and I understand
   my present condition Yes No _____ INITIALS

Guardian/POA

I have been involved in a discussion with the relevant health professionals and provide my consent to the treatment of the above-named client. I understand that he/she is unable to give their own consent, based on the criteria set out in this form. I also understand that treatment can lawfully be provided if it is in his/her best interests to receive it.

Name: _____

Relationship to client:_____

Client Consent

There are no known risks associated with the intranasal application of photobiomodulation (PBM) or neurofeedback training (NFT).
There are NO KNOWN or REPORTED SIDE EFFECTS from with the application of PBM unit to the head, nasal cavity and or body
Some individuals may experience warmth as the session proceeds. If the warmth becomes uncomfortable simply remove or reposition the unit to a more comfortable position or remove the device. During the application, I am expected to run the program for up to 30 minutes. This may cause some discomfort and adjustments can be made, please discuss adjusting the protocol with Dr. Berman.

I have been INFORMED of the known risks Yes No _____ INITIALS

Photobiomodulation uses pulsed LED light stimulation. The FDA has not classified these devices but have been determined to be non-significant risk devices by the Quietmind Foundation Institutional Review Board (IRB).

PBM and NFB have both been shown by published research to effectively address cognitive decline by modifying brain electrical activity, improving cerebral blood flow, changing the slope of decline of dementia, improving sleep duration and quality, and improving emotional wellbeing.

I have been INFORMED of the known benefits Yes No _____ INITIALS

I CONSENT TO PARTICIPATE IN THE PROPOSED RSEARCH PLAN OF STIMULATION:

Print Name: _____

Client Signature: _____

PI Signature: _____ Date: __4/30/24