

## Participant Consent Form for “Tinnitus Reduction at Brain-Level” trial

(a)(1): Purpose and Procedures: This is a research study intended to assess the effectiveness of training the brain to discriminate between similar tones through a rehabilitation protocol in order to reduce tinnitus perception caused by partial deafness, beyond merely reducing your awareness of the tinnitus. This trial will involve approx. 50-100 people and is “experimental”, meaning that there is a control group. Nevertheless, everyone will get the opportunity to be in the treatment group within the full study time.

If you agree to take part in this research, you will be asked to participate in a 58-day clinical trial of tinnitus reduction. It will require 58 days of rating your tinnitus 1 time per week. For 27 days of that time, you will spend 30-45 min/d listening to tones on a computer and continually marking your observations on a piece of paper that will be provided. 30-45 minutes may be in 15-minute sessions. If you choose, a hearing test may be conducted on you at Baseline and After-Treatment.

If your tinnitus perception improves, you will be asked to participate in an 3-month trial that involves listening to tones 5-10 minutes, 1 or 2 times / week for 3 months, marking your observations on a piece of paper, & rating your tinnitus severity 1 time per week. This will be to determine how little work is required to maintain improvement.

(a)(2)(3)(6): Risks and Benefits: As seen with others who have improved in previous studies, you may experience temporary worsening of your tinnitus early in the program. If you complete the trial, there is a great likelihood that you will have a reduction in your tinnitus, *beyond* merely reducing your *awareness* of the tinnitus. If your tinnitus stays worse, because you discontinued early or for any other reason related to this research, you will not be compensated or provided different treatment to resolve this. Your participation will help researchers and clinicians understand how to better reduce tinnitus and develop more effective treatments.

Previous studies of a similar type have provided an average of 27% in tinnitus reduction to more than 40% of the participants.

(a)(4): Alternative Procedures/Treatments: The most common treatment is counseling or sound-producing devices to help with coping. Hearing aids or cochlear implants may be helpful and “Notched music” has shown results.

(a)(5): Confidentiality: Only the principal researcher (Dr. Jay Hobbs), those assisting with testing and data analysis, and yourself will have access to research results associated with your identity. In the event of publication of this research, no personally identifying information will be disclosed. Information provided at the hearing test will be kept at that office location and will be used only for this research unless otherwise allowed by the participant. Your completed files and hearing results will be kept at the office of Dr. Jay Hobbs and will be used only for this research unless otherwise allowed by the participant. You will be assigned a number that you can use to identify all your records in the notebook.

(a)(7): Who to Contact with Questions: Questions about this research study should be directed to Jay Hobbs, DC, DACNB or Anna at (559) 635-8266. You may receive a copy of this consent form.

(a)(8): Voluntary Participation: Your participation in this research is voluntary. You may refuse to participate or discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled.

Compensation and Cost: You will not have to pay for, nor will receive any monetary benefits for, participating in this research.

I certify that I am 18 years or older and have read (or heard) this form and volunteer to participate in this research study.

\_\_\_\_\_  
(Print) Participant Name

Date: \_\_\_\_\_

\_\_\_\_\_  
Participant *Signature*

\_\_\_\_\_  
(Print) Translator/Reader Name

\_\_\_\_\_  
Translator/Reader Translator/Reader *Signature*

\_\_\_\_\_  
ID Code Assigned by research office

## Nondisclosure Agreement

This Nondisclosure Agreement (the "Agreement") is entered into by and between ("Disclosing Party") Jay Hobbs (operating as Synergy Chiropractic & Natural Health), with its principal offices at Visalia, CA 93277, and ("Receiving Party" your name) \_\_\_\_\_, located at \_\_\_\_\_ (your city, state), for the purpose of preventing the unauthorized disclosure of Confidential Information as defined below. The parties agree to enter into a confidential relationship with respect to the disclosure of certain proprietary and confidential information ("Confidential Information").

**1. Definition of Confidential Information.** For purposes of this Agreement, "Confidential Information" shall include all information or material that has or could have commercial value or other utility in the business in which Disclosing Party is engaged. If Confidential Information is in written form, the Disclosing Party shall label or stamp the materials with the word "Confidential" or some similar warning. If Confidential Information is transmitted orally, the Disclosing Party shall promptly provide a writing indicating that such oral communication constituted Confidential Information.

**2. Exclusions from Confidential Information.** Receiving Party's obligations under this Agreement do not extend to information that is: (a) publicly known at the time of disclosure or subsequently becomes publicly known through no fault of the Receiving Party; (b) discovered or created by the Receiving Party before disclosure by Disclosing Party; (c) learned by the Receiving Party through legitimate means other than from the Disclosing Party or Disclosing Party's representatives; or (d) is disclosed by Receiving Party with Disclosing Party's prior written approval.

**3. Obligations of Receiving Party.** Receiving Party shall hold and maintain the Confidential Information in strictest confidence for the sole and exclusive benefit of the Disclosing Party. Receiving Party shall carefully restrict access to Confidential Information to employees, contractors and third parties as is reasonably required and shall require those persons to sign nondisclosure restrictions at least as protective as those in this Agreement. Receiving Party shall not, without prior written approval of Disclosing Party, use for Receiving Party's own benefit, publish, copy, or otherwise disclose to others, or permit the use by others for their benefit or to the detriment of Disclosing Party, any Confidential Information. Receiving Party shall return to Disclosing Party any and all records, notes, and other written, printed, or tangible materials in its possession pertaining to Confidential Information immediately if Disclosing Party requests it in writing.

**4. Time Periods.** The nondisclosure provisions of this Agreement shall survive the termination of this Agreement and Receiving Party's duty to hold Confidential Information in confidence shall remain in effect until the Confidential Information no longer qualifies as a trade secret or until Disclosing Party sends Receiving Party written notice releasing Receiving Party from this Agreement, whichever occurs first.

**5. Relationships.** Nothing contained in this Agreement shall be deemed to constitute either party a partner, joint venturer or employee of the other party for any purpose.

**6. Severability.** If a court finds any provision of this Agreement invalid or unenforceable, the remainder of this Agreement shall be interpreted so as best to affect the intent of the parties.

**7. Integration.** This Agreement expresses the complete understanding of the parties with respect to the subject matter and supersedes all prior proposals, agreements, representations and understandings. This Agreement may not be amended except in a writing signed by both parties.

**8. Waiver.** The failure to exercise any right provided in this Agreement shall not be a waiver of prior or subsequent rights. This Agreement and each party's obligations shall be binding on the representatives, assigns and successors of such party. Each party has signed this Agreement through its authorized representative.

\_\_\_\_\_  
(Signature)

\_\_\_\_\_  
(Typed or Printed Name)

\_\_\_\_\_  
Date

\_\_\_\_\_  
(Signature)

\_\_\_\_\_  
(Typed or Printed Name)

\_\_\_\_\_  
Date