

Date \_\_\_\_\_

Passed Telephone Screen \_\_\_\_\_

Name \_\_\_\_\_

Screen Failure Code \_\_\_\_\_

Phone \_\_\_\_\_

Comments \_\_\_\_\_

### Telephone Screening Script

#### A MIND-BODY TREATMENT FOR INSOMNIA: INVESTIGATION OF NEUROFEEDBACK TREATMENT OF INSOMNIA

“Hi. This is \_\_\_\_\_ from the National College of Natural Medicine. I understand that you may be interested in participating in our research involving the use of brainwave biofeedback for sleep problems.”

#### How did you hear about the study?

“Do you have 15 minutes for me to tell you about the study and ask you some yes-or-no questions about your health?”

yes

no

- ⇒ If no, “Would you like me to call back at another time?”
  - ⇒ If yes, “When would you like me to call back?”
  - ⇒ If no, “Thank you for your time.”
- ⇒ If yes, continue.

“The purpose of this study is to see whether something called brainwave biofeedback can help people with sleep problems. The study is free and voluntary. If you choose to be part of the study, you'll have to come to the Helfgott Research Institute at the National College of Natural Medicine twice a week for as few as 5 or up to 9 weeks, depending on how you respond to the training. Can you participate for 9 weeks?”

yes

no

- ⇒ If no, “Thank you for your time.”
- ⇒ If yes, continue.

“Before giving you your first treatment, we need to record your sleep patterns by having you wear a small device called an Actiwatch, which looks and feels like a wristwatch. You'll have to wear the Actiwatch for three days at home. Would you be willing to do this?”

Yes

no

- ⇒ If no, “Thank you for your time.”
- ⇒ If yes, continue.

“Also before your first treatment we will study your brainwave function with a test called a quantitative EEG, or 'qEEG'. It is a non- invasive test with no pain . Would you be willing to do this?”

yes

no

- ⇒ If no, “Thank you for your time.”
- ⇒ If yes, continue.

“Let me tell you a little bit about the requirements for participating. There are some medical conditions that would prevent you from participating in the study. May I ask some yes-or-no questions about your health?”

yes

no

- ⇒ If no, “Thank you for your time.”
- ⇒ If yes, continue.

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Do you have difficulty falling asleep?	<b>Yes</b>	<b>No</b>
Do you have difficulty staying asleep?	<b>Yes</b>	<b>No</b>
Do you have problems sleeping even if you have enough time to sleep?	<b>Yes</b>	<b>No</b>
How long have you had problems sleeping? (Answer must be at least 1 month to be eligible)	_____	
How many times per week does your sleep difficulty occur? (Answer must be at least 3 times per week to be eligible)	_____	
Do you feel rested when you awake in the morning?	<b>Yes</b>	<b>No</b>
Does your lack of sleep affect your daytime activities?	<b>Yes</b>	<b>No</b>
Are you between 18 and 65 years of age?	<b>Yes</b>	<b>No</b>
I'm going to ask you 11 more questions. <u>Do not tell me the answers</u> to each individual question but at the end of my list of questions please tell me if you answered "yes" to any of the questions.		
1. Do you work nights?		
2. Have you been treated for a mental disorder within the past year?		
3. Do you drink more than 5 cups or glasses of caffeinated drinks per day?		
4. Do you plan on moving out of the Portland area in the next 3 months?		
5. Are you participating in any other sleep study?		
6. Are you pregnant or nursing or have you delivered in the past three months?		
7. Do you have a history of epilepsy or seizures?		
8. Do you have any serious medical illnesses?		
9. Have you had a serious head injury or stroke within the past year?		
10. Do you take any prescribed sleep medications or any anti-depressant or anti-anxiety drugs?		
11. Would you be <b>unwilling</b> to stop using any over-the-counter sleep medications, herbal sleep remedies, or recreational drugs for 2 weeks prior to and for the duration of the study? ( a 'no' answer would allow inclusion, follow up during the interview would confirm willingness to suspend these.)		

"If your answer is yes to any of these 11 questions, tell me yes."

⇒ If participant meets all screening criteria, continue.

⇒ If participant does not meet all screening criteria state:

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“Unfortunately you can’t participate in the study. Thank you for your time and your interest in the study.”

**For eligible participants:**

“You may be able to participate in the study. In order to fully qualify, you need to have a screening visit with Dr. Barbara Hammer and fill out forms with some questions about your health.”

“If you decide to participate, you’ll have to attend a maximum of 15 sessions of neurofeedback treatments. This will be 2 visits per week for 5-9 weeks. You’ll get one of two types of neurofeedback treatments that we are comparing: either a standard series of treatments or personal treatments designed specially for you based on your first QEEG. You’ll have to avoid making any big lifestyle changes during the study. Also, you can’t start any new treatment for insomnia during the study. Do you want to schedule an appointment for an evaluation?”

Yes

no

⇒ If no, “Thank you for your time.”

⇒ If yes, agree on time and date for appointment, then continue.

“Your first appointment will take about two hours. We will review and sign the consent form together and you will complete forms asking about your sleep patterns and your psychological and medical health.”

“Now, I need your contact information:”

Address \_\_\_\_\_

City \_\_\_\_\_ State \_\_\_\_\_ Zip Code \_\_\_\_\_

Home Phone Number \_\_\_\_\_

Work/Cell Phone Number \_\_\_\_\_

Email Address \_\_\_\_\_

“What is the best way to contact you?” \_\_\_\_\_

“Do you know where we are? I can email or mail you directions.”  
(Provide verbal directions to the NCNM/Helfgott.)

“Do you have any questions?”

“Thank you so much for your time and interest. I will send you a consent form with more detailed information for you to review before our meeting. We will see you at the Helfgott Research Institute on *date at time of appt.*”

“I will call you the day before to remind you of the appointment.”

“Please contact me if you have any questions. My name is \_\_\_\_\_ and I can be reached at \_\_\_\_\_. Thank you.” **[end call]**