

## Studying a new therapy for insomnia

IRB00024763

**Where:** Department of Neurology, Piedmont Plaza II Building, 5th floor, Suite 504.

**What For?** To study the effectiveness of a new investigational therapy for moderate to severe insomnia.

**Therapy:** High-resolution, Relational, Resonance-based, Electroencephalic Mirroring (HIRREM™), also known as Brainwave Optimization™, is a noninvasive, innovative type of brain feedback that is intended to facilitate greater balance of brain frequencies which may result in improved symptoms. This study will compare the effects of HIRREM to a placebo given during 10 sessions, of about 90-120 minutes each, over a 3 week period. Participants will then be followed until four months after therapy is completed. Those assigned to placebo will be offered a course of real HIRREM following study completion.

**Testing:** Noninvasive tests include: Blood pressure, heart rate measurement, questionnaires and computer-based tasks, before and after completion of therapy.

**Compensation:** Participants will be compensated for each study visit as well as for sleep diary entries.

**Who May Participate?** People with moderate to severe insomnia, without any of the following:

- Unable, unwilling, or incompetent to provide informed consent
- Physically unable to come to the study visits
- Known obstructive sleep apnea
- Diagnosed periodic limb movement disorder or known restless legs syndrome
- Known seizure disorder
- Known urinary problem (i.e. benign prostatic hypertrophy) which is the likely cause of the sleep disturbance
- Severe hearing impairment (the therapy requires the use of ear buds)
- Diagnosed or suspected posttraumatic stress disorder (PTSD)
- Diagnosed traumatic brain injury (TBI)
- Ongoing treatment with opiate, benzodiazepine, or anti-psychotic medications, antidepressant medications such as SSRI, SNRI, or tricyclics, and sleep medications such as zolpidem or eszopiclone
- Anticipated and ongoing use of recreational drugs or alcohol
- Lack of internet or smart phone access (daily sleep diary will be collected electronically)

**Contact:** For more information and eligibility screening contact study staff at 336-716-9447 or 336-716-9482.