

## **Low Intensity Focused Ultrasound Neuromodulation in Patients with Opioid Use Disorder (OUD) and/or other Substance Use Disorders (SUD)**

### **Who is this study for?**

This study is for people with Opioid Use Disorder (OUD) and/or other Substance Use Disorders (SUD).

### **What is the study about?**

We're exploring if a treatment called low intensity focused ultrasound (LIFU) is safe for people with OUD and/or other SUDs. The device we are using is investigational and is not approved by the FDA to treat OUD or other SUDs. This investigational device is designed to deliver LIFU to specific areas of the brain associated with addiction. The process combines LIFU with Magnetic Resonance Imaging (MRI), and it does not involve any surgery or cutting of the skin.

### **How long does it last?**

The length of this study for participants is approximately 13 months.

### **What is being done?**

Participants are asked to complete various exams, including MRI, CT, urine tox screen, and other clinical assessments to determine their eligibility for the study. Completing all these assessments may take up to 8 hours over one or more days. After participants are deemed eligible and able to safely continue with treatment, they will receive a single LIFU procedure, typically lasting 4-5 hours. Additionally, participants will undergo up to 6 MRI scans and 8 urine tox screens throughout the study, along with other clinical assessments. Following the procedure, participants will spend up to 24 hours in the hospital and will be sent home when the doctor deems it safe. Afterwards, participants are asked to come to WVU for eight or sixteen visits over the next 12-24 months for follow-up. Participants may also be offered an additional optional LIFU procedure.