IMAGING BIOMARKER STUDY - FACT SHEET FOR MAIN STUDY (IMAGING) PARTICIPANTS

The National Institute on Drug Abuse (NIDA), in collaboration with the Federation of State Physician Health Programs (FSPHP), is conducting a research study looking at changes in brain activity in healthcare professionals with a substance use disorder who are participating in a Physician Health Program (PHP) or equivalent. We will use functional magnetic resonance imaging (fMRI) to measure brain activity. The brain imaging done in this study will help us to better understand the effect of drugs on the brain and the changes that take place during the process of recovery or relapse. The goal of this research is to optimize the efficacy of currently available therapeutics by identifying brain biomarkers that can follow treatment progress and predict treatment outcome. The main study consists of 2 target groups:

Group 1 - Cross-Sectional: completed initial treatment more than 2 months ago, but within the last 5 years. This group will complete 1 imaging visit.

Group 2 - Longitudinal: still in initial phase of treatment, but near the end (1-2 months into treatment) at time of joining the study. This group will complete 3 imaging visits over a year.

The imaging visit(s) take place at the NIDA Biomedical Research Center, which is located on the Johns Hopkins Bayview Medical Campus in Baltimore, MD.

General Eligibility

Participants must be:

- between the ages of 21 - 65
- generally healthy with no MRI contraindications*
- diagnosed with severe alcohol or opioid use disorder, or both
- a healthcare professional enrolled in a PHP or equivalent

**Participants who do not meet imaging criteria for the main study may be eligible for the online Addiction Phenotype Characterization arm. Please refer to the study fact sheet for the online Characterization arm for more information.*

Study Commitment

Brief Phone Screening

- You will be asked general questions about your substance use disorder, psychiatric history and medical conditions, which will help determine initial eligibility.

Two Online Video Sessions, Questionnaires, and Medical Records Review

- Online sessions will be conducted via a secure internet connection.
- During the first online session, we will review the screening consent form with you and ask for your verbal consent to ask more detailed questions about your substance use disorder and psychiatric history. This will take about 2 – 3 hours.
- We will then send you questionnaires to fill out online at your convenience (may take up to 4 hours).
- You will also be asked to sign a release of information (ROI) to allow NIDA to access your

medical records.
- Once we receive your medical records and completed questionnaires and determine that you qualify for the study, a second online session will be scheduled.
- During the second online session, we will review the main study consent form with you, which you will be asked to sign and mail to us prior to your (first) imaging study visit to NIDA.

Imaging Study Visit(s)

- You will generally travel to Baltimore the day before the study visit and return home the evening of the study visit. You will stay overnight at an in-patient facility on the Johns Hopkins Bayview Medical Campus.
- Study visits take about 8-10 hours.
- There will be a brief medical assessment at the beginning of the visit.
- There are two MRI sessions during each study visit. Each imaging session will take 2-3 hours.
- A total of about 40-60 mL (3-4 tablespoons) of blood will be collected during the imaging visit(s).
- During the MRI sessions, you will be asked to complete various brain activation tasks.
- One of the tasks will include brief exposure to a small electrical shock to the foot (feels like snapping rubber band) and showing you pictures of alcohol or drugs or both.
- You will also complete some tasks measuring cognitive/behavioral functions outside of the MRI.

Follow up

1-2 business days after your visit we will contact you to assess any visit-related concerns.

Transportation and Compensation

We will pay for or reimburse your transportation to and from study visit(s) and there is no cost to you for the overnight accommodations. You will receive compensation for study participation. You will also receive a picture of your brain on a T-shirt. The total compensation for completing all parts of the study is as follows:

- Cross-sectional Group: between $335 - $405
- Longitudinal Group: between $775 - $905

To learn more or check your eligibility for the study, contact:

Betty Jo Salmeron, M.D.

BSalmeron@nih.gov (preferred)

(443) 740-2651

Visit https://fsphp.memberclicks.net/more-information-about-the-study for additional information, including links to NIDA NRB publications and a description of the NIDA research facilities.

***Participation is completely voluntary, not part of PHP participation or treatment and does not provide any direct benefit. Your participation in this study will not affect your treatment or status in the PHP in any way, positively or negatively.**