Title: Feasibility and Validation Study of a Standard Phenotyping Assessment Battery (PhAB)

NCT #: NCT03495869

Document date: 11/22/19

Document Type: Informed Consent

RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM

STUDY TITLE: Feasibility and Validation Study of a Standard Phenotyping Assessment Battery (PhAB)

VCU INVESTIGATORS: Lori Keyser-Marcus, Ph.D.
FG Moeller, MD

SPONSOR: National Institute on Drug Abuse (NIDA)

NOTE: In this consent form, "you" always refers to the research participant.

ABOUT THIS CONSENT FORM

You are being invited to participate in a research study. **It is important that you carefully think about whether being in this study is right for you and your situation.**

This consent form is meant to assist you in thinking about whether or not you want to be in this study. **Please ask the investigator or the study staff to explain any information in this consent document that is not clear to you.** You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

Your participation is voluntary. You may decide to not participate in this study. If you do participate, you may withdraw from the study at any time. Your decision not to take part or to withdraw will involve no penalty or loss of benefits to which you are otherwise entitled.

AN OVERVIEW OF THE STUDY AND KEY INFORMATION

The purpose of this study is to try out a battery of tests to see if they might be useful as standard screening and assessment tools in research studies comparing people with and without substance use disorders. We will use the information collected in this study to see which of the surveys and behavior tasks were helpful in making comparisons between the groups. We also are interested in seeing how much time it takes for people to complete the study (from start to finish) and get participant feedback on the study.

In this study, you will be asked to do the following things:
For the behavioral testing portion of the study:

1. Visit this research clinic (CARI) up to 3 times for study visits (one screening visit, one assessment visit and a one month follow up visit)
2. Provide urine samples for drug testing, and (for females only) pregnancy testing.
3. Provide breath samples to test for recent alcohol use and smoking, and have your vital signs (blood pressure, pulse, temperature) taken.
4. Complete surveys and answer questions about your medical history, substance use, mental health, mood, sleep, and attention and concentration.
5. Complete tests on the computer that look at reading, memory, concentration, decision making, and the time it takes you to respond to images presented on the screen.

6. Complete a blood draw (for blood work/labs) and a physical exam, and also answer questions to see if you have any conditions that may prevent you from being able to participate in the MRI portion of the study. This will occur during the initial screening visit.
7. Complete a practice MRI session that will take place in a mock MRI (which is not a real MRI machine) to allow you to practice the same tasks you will do during the real MRI scan. The total time of the practice MRI session will be around 1 hour.

In addition, if you qualify and are interested in participating in the MRI portion of the study, you will be asked to:

8. Complete surveys and answer questions about your recent substance use, sleep, and drug cravings.
9. Complete a MRI scanning session (that will last approximately 1.5 hours)
10. Complete a 1 month follow up visit (only for those with OUD)

Your participation in this study may last up to 9.5 hours (7 hours for screening and behavioral assessment visits) 1.5 hours for the MRI study visit and 1 hour for the follow up visit). Approximately 400 individuals will complete the behavioral testing portion of the study, and approximately 100 individuals will complete the entire study (including the MRI scanning session).

This study will not use your samples to sequence all or part of your DNA.
You do not have to participate in this study if you do not want to.

There are both risks and benefits of participating in research studies.

Risks and Discomforts	Benefits to You and Others
• Participation in research might involve some loss of privacy. There is a small risk that someone outside the study could see and misuse information about you. • The study questionnaires ask personal questions that are sensitive in nature and may make you feel uncomfortable. • This study will ask you questions about personal topics that might be embarrassing to talk about and that could affect your family relationships if this information were to become known	This is not a treatment study, and you are not expected to receive any direct medical benefits from your participation in the study. The information from this research study may lead to a better treatment in the future for people with substance use disorders.

outside of the study. You will also be asked about illegal activities, which could have legal and financial consequences if this information were to become known outside of the study. • You may learn things about yourself that you did not know before and that could affect how you think about yourself. • Other potential discomforts include discomfort from the BP cuff, feeling uncomfortable being weighed and giving urine, and fatigue from the length of the visit. • You may have some pain and a bruise when the blood is drawn. There is also a slight chance of infection. • If you have metal in your body, such as a pacemaker, metal shavings, bullet pieces, or surgical clips, the MRI scan can cause injury to you • You may experience the potential risk of feeling anxious or nervous due to being confined in a small, enclosed space such as the MRI scanner tube. • You may become tired or bored during the MRI testing.	

In general, we will not give you any individual results from the study. If we find something of medical importance to you, we will inform you, although we expect that this will be a rare occurrence.

Please read, or have someone read to you, the rest of this document. If there is anything you don't understand, be sure to ask the study staff.

WHAT WILL HAPPEN IF I PARTICIPATE IN THE STUDY?

In this study you may be asked to attend up to four clinic visits: a screening and mock MRI visit (to be completed today if you decide to be in the study) to see if you qualify to be in the study, an assessment visit (which will be completed within the next week or two) if you qualify for the study, a MRI scanning visit (which will be completed within the next 3 weeks) and a one month follow up visit. At your screening visit, you will be interviewed by the study staff and fill out questionnaires about your medical history, substance use, mood, and mental health. We will also check your vital signs (blood pressure, pulse, and temperature), complete a physical exam (which includes a neurologic exam and medical history), ask you to provide a urine sample to

test for recent drug use, and (if you are female) to see if you are pregnant; and test your breath for recent alcohol use and cigarette use. Finally, we will collect blood samples for routine lab tests. Approximately 1 to 2 tablespoons of blood will be collected. You will also be asked to fill out a standard metal screening checklist to make sure you do not have any metal in your body or conditions that might be dangerous for MRI. If you have ever had any pieces of metal enter your eye, then MRI may be potentially dangerous and you should tell the study staff. Also, if you have a pacemaker or other metal such as bullet pieces in your body, you need to tell the study staff, as these may be dangerous as well. The screening visit should take between 1 and 1.5 hours to complete.

If you qualify for the study, you will then be scheduled to return to the clinic within two weeks for the assessment visit (which will last approximately 4.5 to 5 hours, with breaks included). During the assessment visit, we will check your vital signs (blood pressure, pulse, and temperature), ask you to provide a urine sample to test for recent drug use, and (if you are female) to see if you are pregnant; and test your breath for recent alcohol use and cigarette use. We will ask you to complete interviews with our staff and on the computer about your substance use, mood, mental health, relationships, sleep habits, and your general health and well-being. We will also ask you to complete computer-based tests of memory, concentration, reading, and decision-making. Finally, we will ask you to complete a brief feedback and satisfaction survey about the study.

If you also qualify for the MRI portion of the study, you will be scheduled to return to the clinic within 3-4 weeks for the MRI visit (which will last approximately 2 hours, with a break included). During the MRI visit, we will check your vital signs, ask you to provide a urine sample to test for recent drug use, and (if you are female) to see if you are pregnant; and test your breath for recent alcohol use and cigarette use. If you drink caffeinated beverages we ask that you abstain from these beverages for three hours prior to the scan. We also ask that you do not drink any alcoholic beverages like wine, beer, or liquor prior to the scan on the day of the scan.
If you smoke or use tobacco, we ask that you do not smoke or use tobacco within the one-hour period prior to the scan.

The study doctor will review the results of the scan with you if any structural abnormalities in your brain are indicated and, if needed, you will be referred for treatment outside of this study. The scan will take about 90 minutes. Your blood pressure, heart rate and blood oxygen levels will be measured before, during after the scans by a blood pressure monitor and pulse oximeter.

If you have already participated in the behavioral testing portion of this research study and were invited back for the MRI portion, your involvement will only include providing blood, urine, and breath samples (for laboratory testing, drug testing, and recent use of alcohol and smoking), completing a physical examination and MRI screening, and the mock scanning session and MRI testing session (all described above). You will not have to repeat the screening interviews and behavioral testing visit again.

Participants with OUD who complete the MRI visit will be asked to return to the CARI Clinic for a one-month follow up visit. At this visit you will provide a urine sample for drug screening, complete questionnaires and answer questions about your drug use. You will be asked if we may access your VCU electronic health records to see how you are doing with your treatment.

WILL I BE PAID TO PARTICIPATE IN THE STUDY?

Screening & mock MRI visit: You will be paid up to $115 for completing the screening and mock MRI visit. This includes $40 for the general screening, $25 for MRI screening, and $50 for mock MRI. If you have already completed the general screening portion of the study and are returning to be rescreened for the MRI portion of the study, you can receive up to $75 (which includes $25 for the MRI screening and $50 for the mock MRI.

Behavioral assessment visit: You will be paid $75 for completing the study behavioral assessment visit (which you would have already completed if you are returning to be rescreened for the MRI portion of the study).

MRI scan visit: You will receive $100 for completing the MRI scan visit.

One-month follow up visit: You will receive $40 for completing the follow up visit.

Payment will be in the form of cash. If you complete all portions of the study (screening, behavioral testing, MRI scanning, and 1 month follow-up), you will receive a total of $330. If you are dropped or withdraw before the end of the study, you will be paid a prorated amount of $10 per hour completed in that study visit.

If you have already completed the general screening and behavioral assessment portion of the study and are returning to only complete the MRI screening/scanning portion of the study, you will receive up to $175 for completing both visits.

Total payments within one calendar year that exceed $600 will require the University to annually report these payments to the IRS and you. This may require you to claim the compensation you receive for participation in this study as taxable income. VCU is required by federal law to collect your social security number. Your social security number will be kept confidential and will only be used to process payment.

Please be aware that the investigative team and the University may receive money for the conduct of this study.

CAN I STOP BEING IN THE STUDY?

You can stop being in this research study at any time. Leaving the study will not affect your medical care, employment status, or academic standing at VCU or VCU Health. Tell the study staff if you are thinking about stopping or decide to stop.

Your participation in this study may be stopped at any time by the investigator without your consent. The reasons might include:

- the investigator thinks it necessary for your health or safety

- you are found to not be eligible for the study
- the sponsor has stopped the study
- you have not followed study instructions
- administrative reasons require your withdrawal

HOW WILL INFORMATION ABOUT ME BE PROTECTED?

VCU and the VCU Health System have established secure research databases and computer systems to store information and to help with monitoring and oversight of research. Your information may be kept in these databases but are only accessible to individuals working on this study or authorized individuals who have access for specific research related tasks.

Identifiable information in these databases are not released outside VCU unless stated in this consent or required by law. Although results of this research may be presented at meetings or in publications, identifiable personal information about participants will not be disclosed.

Personal information about you might be shared with or copied by authorized representatives from the following organizations for the purposes of managing, monitoring and overseeing this study:

- The study Sponsor, representatives of the sponsor and other collaborating organizations
- Representatives of VCU and the VCU Health System
- Officials of the Department of Health and Human Services

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Website will include a summary of the results. You can search this Web site at any time.

If you tell us that you may hurt yourself or someone else, the law says that we must let people in authority know.

There are no plans to share any money or profits with you if the use of your sample(s) results in inventions or discoveries that have commercial value.

Future Research Studies

In the future, identifiers might be removed from the information you provide in this study, and after that removal, the information could be used for other research studies by this study team or another researcher without asking you for additional consent.

Certificate of Confidentiality

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project under the following circumstances: child or elder abuse or neglect, harm to self or others.

HOW WILL MY HEALTH INFORMATION BE USED AND SHARED DURING THIS STUDY?

As part of this research study, we will ask you to share identifiable health information with us and/or permit us to access existing information from your healthcare records. New health information may also be created from study-related tests, procedures, visits, and/or questionnaires. This type of information is considered "Protected Health Information" that is protected by federal law.

What type of health information will be used or shared with others during this research?
The following types of information may be used for the conduct of this research:

☒ Information about drug and alcohol use. This may include information about your drug treatment from your medical records, if applicable.

☒ Information about mental and physical health conditions

☒ Urine drug screen, and breath samples for recent alcohol use and smoking

Who will use or share protected health information about me?
VCU and VCU Health are required by law to protect your identifiable health information. By consenting to this study, you authorize VCU/VCU Health to use and/or share your health information for this research. The health information listed above may be used by and/or shared with the following people and groups to conduct, monitor, and oversee the research:

- Principal Investigator and Research Staff
- Health Care Providers at VCU Health
- Institutional Review Boards
- Study Sponsor
- Government/Health Agencies
- Others as Required by Law

Once your health information has been disclosed to anyone outside of this study, the information may no longer be protected under this authorization.

When will this authorization (permission) to use my protected health information expire?
This authorization will expire when the research study is closed, or there is no need to review, analyze and consider the data generated by the research project, whichever is later.

Statement of Privacy Rights
You may change your mind and revoke (take back) the right to use your protected health information at any time. However, even if you revoke this authorization, the researchers may still use or disclose health information they have already collected about you for this study. If you revoke this Authorization you may no longer be allowed to participate in the research study. To revoke this Authorization, you must write to the Principal Investigator.

WHO SHOULD I CONTACT IF I HAVE QUESTIONS ABOUT THE STUDY?

If you have any questions, complaints, or concerns about your participation in this research, contact:

Dr. Lori Keyser-Marcus or Dr. FG Moeller
PO Box 980059
Richmond VA 23298-0059
Phone: 804-828-3686

The researcher/study staff named above is the best person(s) to call for questions about your participation in this study.

If you have general questions about your rights as a participant in this or any other research, you may contact:

Virginia Commonwealth University Office of Research
800 East Leigh Street, Suite 3000
Box 980568
Richmond, VA 23298
Telephone: (804) 827-2157

Contact this number to ask general questions, to obtain information or offer input, and to express concerns or complaints about research. You may also call this number if you cannot reach the research team or if you wish to talk to someone else. General information about participation in research studies can also be found at http://www.research.vcu.edu/irb/volunteers.htm.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

STATEMENT OF CONSENT

I have been provided with an opportunity to read this consent form carefully. All of the questions that I wish to raise concerning this study have been answered. By signing this consent form, I have not waived any of the legal rights or benefits to which I otherwise would be entitled. My signature indicates that I freely consent to participate in this research study. I will receive a copy of the consent form for my records.

Signature Block	
_____ Participant Name (Printed)	
_____ Participant's Signature	_____ Date
_____ Name of Person Conducting Consent Discussion (Printed)	
_____ Signature of Person Conducting Consent Discussion	_____ Date
_____ Principal Investigator Signature (if different from above)	_____ Date