Study ID #: 06-0945 **Form Version Date: 4/15/2020**

TITLE OF RESEARCH STUDY:

Title: A Screening Protocol for Adult Patients with Mood and Anxiety Disorders, Chronic Medical Conditions, and Healthy Volunteers

PRINCIPAL INVESTIGATOR (HEAD RESEARCHER) NAME AND CONTACT INFORMATION:

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WHAT IS A RESEARCH STUDY?

A research study is when scientists try to answer a question about something that we don't know enough about. Participating may not help you or others.

People volunteer to be in a research study. The decision about whether or not to take part is totally up to you. You can also agree to take part now and later change your mind. Whatever you decide is okay. It will not affect your ability to get medical care within the Mount Sinai Health System.

Someone will explain this research study to you. Feel free to ask all the questions you want before you decide. Any new information that develops during this research study that might make you change your mind about participating will be given to you promptly.

PURPOSE OF THIS RESEARCH STUDY:

The purpose of this study is to collect data about your symptom patterns and to screen you for participation in other studies within the Depression and Anxiety Center (DAC) at the Icahn School of Medicine at Mount Sinai. This study involves an interview with several members of the study team. It may also involve some or all of the following: a urine toxicity screen, a physical examination, blood work, and some pen and paper tests. The pen and paper tests may be administered via a secure online survey tool.

You may qualify to take part in this research study because you are: (1) at least 18 years old, and (2) not using illegal drugs or abusing alcohol. Furthermore, you (3) have a possible mood or anxiety disorder or chronic medical condition (e.g., chronic fatigue syndrome, Parkinson's disease) or are a healthy volunteer.

Funds for conducting this research are provided by the Icahn School of Medicine at Mount Sinai.

LENGTH OF TIME AND NUMBER OF PEOPLE EXPECTED TO PARTICIPATE

Your participation in this research study is expected to last roughly 3-7 hours, depending on the visit.

The number of people expected to take part in this research study at this site is 5000.

DESCRIPTION OF WHAT'S INVOLVED:

If you agree to participate in this research study, the following information describes what may be involved.

The main part of the study is the Clinical Assessment. You may also be asked to participate in a Medical Clearance Assessment, Neuropsychological Assessment, and to complete a number of Surveys. You may be asked to complete the Clinical Assessment and Surveys in-person, or you may have the option to complete these remotely, using a telehealth platform (VSee) or over the phone.

- **Clinical Assessment** - You will have a diagnostic interview, which means that a study investigator will ask you questions about your psychiatric and medical history, your personal work and education history, and your family history.

- **Medical Clearance Assessment** - You may be asked to give a sample of blood and/or urine for standard lab evaluation (blood and urine tests may include a screen for drugs of abuse, chemistry, complete blood count, thyroid function pregnancy test if appropriate, and medication levels). Also, you may have a physical examination and an EKG. An EKG is an electrical tracing of your heartbeat. For an EKG, you will be asked to lie down while 12 sticky pads are placed on each of your arms and legs and to your chest. The EKG will last about 5 minutes.

- **Neuropsychological Assessment** - You may be asked to complete a neuropsychological assessment. This will consist of a DAC staff member administering various tests of memory and thinking, which takes about one hour.

- **Surveys** – You may be asked to complete a number of surveys about your experiences, behaviors, and symptoms. This will mostly consist of multiple-choice questions that you will complete via a secure computer-based assessment program. You will be given a unique login that will help protect your data.

The purpose of this protocol is for research only, and not to provide medical or psychiatric care. It is important that you understand that treatment will not be offered through this screening protocol. In addition, do not stop any medications you are currently prescribed for the purpose of our evaluation. We will be able to complete your evaluation while you are taking your current medications. We are routinely requesting select patients to sign a release for medical records.

If you wish, we will provide you with all results of screening tests, and will assist you in communicating these results to your primary/referring physician. Should we find any serious medical or psychiatric conditions that require hospitalization we will refer you to the appropriate setting for your care needs.

Should you need to be hospitalized elsewhere, we are not able to pay for this outside of our clinical center. We will however, work with you and your physician to facilitate any necessary hospitalizations occurring outside the Mount Sinai School of Medicine.

Our primary goal at DAC at Mount Sinai is research. Thus, we are unable to provide primary care or individual psychotherapy as part of our screening program. You must continue to have your health care needs met through your own physician and/or psychotherapist while participating in our screening protocol. Your signature on this consent form indicates you understand these conditions and agree to continue your outside care. If you do not have a source of care, we will make the appropriate referrals for you.

Data that are derived from your participation in this screening protocol may be used in publications or in a number of other ways including: to make new theories for future research, for any future DAC research protocols in which you participate, to help inform us on recruitment issues, and to help us understand the qualities of individuals who participate in research.

Permission for Future Contact: If you are eligible for this study and you are interested in participating in future evaluation and treatment studies with DAC, we would like to ask your permission for members of the DAC research team to contact you in the future to let you know about any studies you are eligible for, or to invite you to return for a supplementary assessment session which may include repeating a subset of the assessments you complete today and several additional questionnaires.

Do you give members of the DAC research team permission to contact you in the future in order to tell you about DAC studies you would be eligible for?

_____ I give permission for DAC to contact me in the future for participation in other research studies.

_____ I do not give permission for DAC to contact me in the future for participation in other research studies.

YOUR RESPONSIBILITIES IF YOU TAKE PART IN THIS RESEARCH:

If you decide to take part in this research study you will be responsible for the following things: providing honest information and attendance at agreed upon study visits.

COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

If you agree to take part in this research study, we will pay you a minimum of $25 for your time and effort. Payments are made via check. Payment will be generated by the Mount Sinai Finance department and require up to three weeks to be prepared. You will also be offered a lunch voucher for $5.00 to the Mount Sinai Cafeteria and a $5.50 NYC MTA Metro card at the first screening visit. If your visit occurs remotely, in place of these you will be offered a check for $35, issued by the Mount Sinai Finance department. You will not be reimbursed for your travel or time that may be required for study visits. If you test positive for drugs of abuse (Cocaine, Marijuana, Opiates, Amphetamines, Benzodiazepines) during this screening procedure you will not be compensated for your time.

POSSIBLE BENEFITS:

It is important to know that you may not get any benefit from taking part in this research. Others may not benefit either. However, possible benefits to others may be that you will contribute to a greater understanding of the biology and treatment of mood and anxiety disorders.

REASONABLY FORESEEABLE RISKS AND DISCOMFORTS:

The screening procedures described above may involve the following risks:

- **Blood draw through a needle:** The risks of a blood draw include pain, bruising, and the slight possibility of infection at the place where the needle goes in. Some people feel dizzy or may faint during or after a blood draw.

- **Evaluation**: Participating in a psychiatric evaluation may cause you inconvenience for the time involved or from discomfort in talking about the details of how you feel. You have the right to refuse to answer any question that you do not wish to answer and to withdraw from participation at any time. If you wish, we will make every effort to find you a suitable alternative and pass on the important clinical information we have learned about you to your new clinician.

- **Surveys** – You may be asked to complete a number of surveys about your experiences, behaviors, and symptoms. Answering these questions about how you feel may cause you some emotional discomfort as it can be difficult to think about your mental health and history. You have the right to refuse to answer any question that you do not wish to answer and to withdraw from participation at any time. If you wish, we will make every effort to find you a suitable alternative and pass on the important clinical information we have learned about you to your new clinician.

- **Unknown risks:** Each clinical assessment may involve risks that are currently unforeseeable. As in any medical evaluation you may learn that you have a major or minor medical problem.

- **Loss of information:** Risk of loss of private information; this risk always exists, but there are procedures in place to minimize the risk.

OTHER POSSIBLE OPTIONS TO CONSIDER:

You may decide not to take part in this research study without any penalty. The choice is totally up to you.

IN CASE OF INJURY DURING THIS RESEARCH STUDY:

If you believe that you have suffered an injury related to this research as a participant in this study, you should contact the Principal Investigator, Dr. James Murrough at telephone number 212-585-4640.

ENDING PARTICIPATION IN THE RESEARCH STUDY:

You may stop taking part in this research study at any time without any penalty. This will not affect your ability to receive medical care at any of the Mount Sinai Health System hospitals or to receive any benefits to which you are otherwise entitled.

If you decide to stop being in the research study, please contact the Principal Investigator or the research staff.

You will be notified of significant new findings that might relate to your willingness to continue to participate. If you do not participate in the study, or if you decide to stop your participation in this study, we will destroy any data that we have collected from you.

If you allow us to share samples with other researchers (see section on Description of What's Involved) and you decide not to participate, then we will contact the researchers and they will destroy the samples. The PI may destroy the sample at any time due to funding, space, etc.

You may also withdraw your permission for the use and disclosure of any of your protected information for research, but you must do so in writing to the Principal Investigator at the address on the first page. Even if you withdraw your permission, the Principal Investigator for the research study may still use the information that was already collected if that information is necessary to complete the research study. Your health information may still be used or shared after you withdraw your authorization if you have an adverse event (a bad effect) from participating in the research study.

Withdrawal without your consent: The study doctor, the sponsor or the institution may stop your involvement in this research study at any time without your consent. This may be because the research study is being stopped, the instructions of the study team have not been followed, the

investigator believes it is in your best interest, or for any other reason. If specimens or data have been stored as part of the research study, they too can be destroyed without your consent.

CONTACT PERSON(S):

If you experience an emergency during your participation in this research, contact 911 or visit your nearest emergency room. If you have any questions, concerns, or complaints at any time about this research, or you think the research has hurt you, please contact the office of the research team and/or the Principal Investigator at phone number 212-585-4640.

This research has been reviewed and approved by an Institutional Review Board. You may reach a representative of the Program for Protection of Human Subjects at the Icahn School of Medicine at Mount Sinai at telephone number (212) 824-8200 during standard work hours for any of the reasons listed below. This office will direct your call to the right person within the Mount Sinai Health System:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You are not comfortable talking to the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

DISCLOSURE OF FINANCIAL INTERESTS:

Sometimes, physicians/researchers receive payments for consulting or similar work performed for industry. Effective September 2014 Mount Sinai reviews only payments to an individual totaling more than $5,000 a year per entity when determining potential conflicts of interest. If you have questions regarding industry relationships, we encourage you to talk your physician/researcher or visit our website at http://icahn.mssm.edu/ where Mount Sinai publicly discloses the industry relationships of our faculty.

MAINTAINING CONFIDENTIALITY – HIPAA AUTHORIZATION:

As you take part in this research project it will be necessary for the research team and others to use and share some of your private protected health information. Consistent with the federal Health Insurance Portability and Accountability Act (HIPAA), we are asking your permission to receive, use and share that information.

<u>What protected health information is collected and used in this study, and might also be disclosed (shared) with others?</u>

As part of this research project, the researchers will collect your Name, Address, Date of birth, Telephone Number, email address, and Social Security Number.

The researchers will also get information from your medical record at Mount Sinai hospital.

During the study the researchers will gather information by:

- taking a medical history (includes current and past medications or therapies, illnesses, conditions or symptoms, family medical history, allergies, etc.)
- possibly doing a physical examination that generally also includes blood pressure reading, heart rate, breathing rate and temperature
- taking a mental health history
- completing questionnaires about your mental health history, including drug and alcohol use, your current emotions, and how you feel about your life.
- collecting a urine sample for a drug screen and a pregnancy test on the day of the medical clearance.
- taking an alcohol or substance abuse history

Why is your protected health information being used?

Your personal contact information is important to be able to contact you during the study. Your health information and the results of any tests and procedures being collected as part of this research study will be used for the purpose of this study as explained earlier in this consent form. The results of this study could be published or presented at scientific meetings, lectures, or other events, but would not include any information that would let others know who you are, unless you give separate permission to do so.

The Principal Investigator may also use and share the results of these tests and procedures to treat you in collaboration with others in the Mount Sinai Health System.

The research team and other authorized members of The Mount Sinai Health System ("Mount Sinai") workforce may use and share your information to ensure that the research meets legal, institutional or accreditation requirements. For example, the School's Program for the Protection of Human Subjects is responsible for overseeing research on human subjects, and may need to see your information. If you receive any payments for taking part in this study, the Mount Sinai Finance Department may need your name, address, social security number, payment amount, and related information for tax reporting purposes. If the research team uncovers abuse, neglect, or reportable diseases, this information may be disclosed to appropriate authorities.

Who, outside Mount Sinai, might receive your protected health information?

As part of the study, the Principal Investigator, study team and others in the Mount Sinai workforce may disclose your protected health information, including the results of the research study tests and procedures, to the following people or organizations: (It is possible that there may be changes to the list during this research study; you may request an up-to-date list at any time by contacting the Principal Investigator.)

- The United States Department of Health and Human Services and the Office of Human Research Protection

In all disclosures outside of Mount Sinai, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier unless disclosure of the direct identifier is required by law. Some records and information disclosed may be identified with a unique code number. The Principal Investigator will ensure that the key to the code will be kept in a locked file, or will be securely stored electronically. The code will not be used to link the information back to you without your permission, unless the law requires it, or rarely if the Institutional Review Board allows it after determining that there would be minimal risk to your privacy. It is possible that a sponsor or their representatives, a data coordinating office, a contract research organization, may come to inspect your records. Even if those records are identifiable when inspected, the information leaving the institution will be stripped of direct identifiers. Additionally, when applicable, the monitors, auditors, the IRB, the Office of Human Subjects Protection (OHRP) of the Department of Health and Human Services as well as the Food and Drug Administration (FDA) will be granted direct access to your medical records for verification of the research procedures and data. OHRP and FDA are authorized to remove information with identifiers if necessary to complete their task. By signing this document you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

For how long will Mount Sinai be able to use or disclose your protected health information?

Your authorization for use of your protected health information for this specific study does not expire.

Will you be able to access your records?

During your participation in this study, you will have access to your medical record and any study information that is part of that record. The investigator is not required to release to you research information that is not part of your medical record.

Do you need to give us permission to obtain, use or share your health information?

NO! If you decide not to let us obtain, use or share your health information you should not sign this form, and you will not be allowed to volunteer in the research study. If you do not sign, it will not affect your treatment, payment or enrollment in any health plans or affect your eligibility for benefits.

Can you change your mind?

You may withdraw your permission for the use and disclosure of any of your protected information for research, but you must do so in writing to the Principal Investigator at the address on the first page. Even if you withdraw your permission, the Principal Investigator for the research study may still use your protected information that was already collected if that information is necessary to complete the study. Your health information may still be used or shared after you withdraw your authorization if you should have an adverse event (a bad effect) from being in the study. If you withdraw your permission to use your protected health information for research that means you will also be withdrawn from the research study, but standard medical care and any other benefits to which you are entitled will not be affected. You can also tell us you want to withdraw from the research study at any time without canceling the Authorization to use your data.

If you have not already received it, you will also be given The Hospital's Notice of Privacy Practices that contains more information about how The Hospital uses and discloses your protected health information.

It is important for you to understand that once information is disclosed to others outside Mount Sinai, the information may be re-disclosed and will no longer be covered by the federal privacy protection regulations. However, even if your information will no longer be protected by federal regulations, where possible, Mount Sinai has entered into agreements with those who will receive your information to continue to protect your confidentiality.

If as part of this research project your medical records are being reviewed, or a medical history is being taken, it is possible that HIV-related information may be revealed to the researchers. If that is the case, the following information concerns you. If this research does not involve any review of medical records or questions about your medical history or conditions, then the following section may be ignored.

Notice Concerning HIV-Related Information

If you are authorizing the release of HIV-related information, you should be aware that the recipient(s) is (are) prohibited from re-disclosing any HIV-related information without your authorization unless permitted to do so under federal or state law. You also have a right to request a list of people who may receive or use your HIV-related information without authorization. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the New York State Division of Human Rights at (888) 392-3644 or the New York City Commission on Human Rights at (212) 306-5070. These agencies are responsible for protecting your rights.

Certificate of Confidentiality: To further protect your privacy, the researchers have obtained a Certificate of Confidentiality from the Department of Health and Human Services. This Certificate does not mean that the Department of Health and Human Services approves of this research. Rather, it is intended to ensure that your identity as a participant in this research study will not have to be disclosed as a result from a subpoena, for the purpose of identifying you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings other than to the FDA or OHRP as identified above.

The research staff will not share any of your research information with anyone who is not a member of the research team, including any family members or friends, other than to those identified above. However, you should know that if we learn that you or someone else is threatened with serious harm, such as a child or an elderly person being abused, the investigators may notify the appropriate authorities if necessary to protect you or others. 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. This means that you and your family must also actively protect your own privacy. If an insurer or employer learns about your research participation, and you agree that they can have your

research information, then the researchers may not use the Certificate of Confidentiality to keep this information from them.

Signature Block for Capable Adult

Your signature below documents your permission to take part in this research and to the use and disclosure of your protected health information. A signed and dated copy will be given to you.

DO NOT SIGN THIS FORM AFTER THIS DATE → **1/29/2021**

Signature of subject	Date
Printed name of subject	Time [required if used for FDA documentation purposes]

Person Explaining Study and Obtaining Consent

Signature of person obtaining consent	Date
Printed name of person obtaining consent	Time

Witness Section: For use when a witness is required to observe the consent process,, document below (for example, subject is illiterate or visually impaired, or this accompanies a short form consent):

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

Signature of witness to consent process	*Date*
Printed name of person witnessing consent process	Time