Study ID #: HSM#16-00980/GCO#15-0985 **Form Version Date: 06/29/2020**

TITLE OF RESEARCH STUDY:

Regulating Emotional Responses to Spoken Comments and Visual Images Across the Affective Instability Spectrum: An fMRI Study

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 learn how individuals with different levels of emotionality feel when they hear spoken positive, negative, or neutral statements or see positive, negative or neutral pictures and to what extent they can regulate those feelings by distancing themselves or distracting themselves. We will also measure brain activity as they listen to these statements or look at the pictures and regulate their feelings. The sentences or pictures that we present to you may make you feel positive, negative or neutral.

We will use a functional Magnetic Resonance Imaging (fMRI) scanner to look for changes in brain activity. fMRI is a method that uses a powerful magnet to measure the flow of blood to the brain. The MRI scanner is approved by the Food and Drug Administration and is used routinely. The advantage of using this method of picturing the brain over others is that it involves NO radiation (like in X-rays).

You may qualify to take part in this research study because you are medically healthy and are a more or less emotionally reactive person.

Funds for conducting this research are provided by the National Institute of Mental Health (NIMH). As a study supported by NIMH, this study will share our research data with the NIMH Data Archive (NDA) for use by other scientists. Some of your research data may be shared with the NDA, but it will not include any personally identifiable health information about you.

LENGTH OF TIME AND NUMBER OF PEOPLE EXPECTED TO PARTICIPATE

Your participation is expected to consist of 1 visit that will last about 1 hour and 2 subsequent visits that will each last about 3 hours.

If you have not already had a recent medical evaluation through our group, we will schedule an additional first visit that will include a discussion about your medical history with one of our doctors, and a medical evaluation (described in more detail in the section called Medical Evaluation below). This visit will last about 2hours.

The number of people expected to take part in this research study at this site is 125.

If you enroll in this study you may be contacted to participate in future studies. If you consent to the future studies, the data gathered for research purposes from this study may be used in those future studies.

Do you give us permission to contact you in the future if new studies within our research group become available for which you might be eligible?

Please initial your choice: **Yes_____ No_____**

Do you give us permission to contact you in the future if other research groups' studies become available for which you might be eligible?

Please initial your choice: ***Yes_____ No_____***

DESCRIPTION OF WHAT'S INVOLVED:

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

You will be asked whether you have a history of epilepsy (seizures) or blows to the head, become anxious in small spaces, and/or have surgical clips, pacemakers, metallic prostheses (such as artificial hip or knee), or metal fragments (shrapnel) in your body. If the answer is yes to any of these questions, you may not be able to participate.

Medical History and Evaluation (if indicated)

If you have not already had one recently through our research group, you will have a medical history with one of our doctors in our offices at 1160 5th Ave. A urine drug screen will be administered in our office (1160 5th Ave.) on the day of your Medical History. Female participants will also receive a pregnancy test in our office. If any significant medical conditions are identified during the medical history, and if the research team consequently deems it necessary, we will notify you and you will have a medical evaluation. The medical evaluation will be with a nurse practitioner at Mount Sinai's Clinical Research Center (1184 5th Avenue, 2nd floor). It will include routine blood tests (complete blood count, metabolic and electrolyte panel (SMA-12), TSH, T4), a routine urinalysis, an EKG and a chest x-ray (if indicated). If any significant medical conditions or abnormal results are identified, we will notify you and your physician, who will discuss the findings with you. Some illnesses will keep you from further participating in this study. If needed, laboratory tests may be repeated. If we find that you do not have any significant medical illness, you will be invited to continue to participate in this study.

Pregnancy
If you are a woman of childbearing age, we will give you a urine pregnancy test prior to each fMRI scan. The effects of an MRI on a fetus are not well-studied; therefore, if you are pregnant, you will not be able to continue to participate in this study. Further, if you are sexually active, it is critical that you use an effective form of birth control during this study. If you choose to take birth control pills, the pills must have been started at least one month prior to the study. To take part in this study, women who are sexually active and are able to have children must use an effective means of birth control throughout the study. Acceptable methods of birth control include a barrier method (condoms, diaphragm), hormonal contraceptives (birth control pills, implants [Norplant] or injections [Depo-Provera]), Intrauterine Device (IUD), or abstinence (no sexual activity).

Urine Toxicology
All subjects must complete a urine toxicology (drug) screen on the day of their medical evaluation and again prior to each scan. The urine toxicology screen will be performed by research staff in our offices (1160 5th Ave.). This screening process should take less than 5 minutes. If results are positive, you will not be permitted to continue with the study. The results of this test will not be placed in your clinical medical record, although the research team will keep the result on file in our offices.

1st Session-Introduction to Study
We will teach you strategies that you will use while viewing pictures and listening to sentences. For down-regulating your emotions, you will learn the distancing and distraction techniques. For up-regulating your emotions, you will learn the enhancing technique. There will be positive, neutral, and negative images/sentences. Then, we will give you a chance to practice on pictures/sentences under the guidance of the research team. This training should take about 1 hour.

fMRI Procedure
On each visit, you will be asked to complete questionnaires related to your emotions in our private offices at Mount Sinai (1160 5th Ave.). These questionnaires will be administered either on a laptop or electronic tablet via RedCap, or by pencil-and-paper. On one day you will look at pictures, and on the other day you will listen to recorded sentences and regulate your emotions as fMRI images are taken.

Before the fMRI scan begins each day, we will again teach you strategies for viewing the pictures and listening to sentences. For down-regulating your emotions, you will learn the distancing and distraction techniques. For up-regulating your emotions, you will learn the enhancing technique. There will be positive, neutral, and negative images/sentences. Then, we will give you a chance to practice on pictures/sentences under the guidance of the research team. This training should take about 30 minutes. Once you have practiced regulating your emotions when listening to some sentences or looking at pictures on a laptop, we will measure your brain activity as you use this strategy while you undergo a brain scan. For the scan, a member of the research team will escort you to the MRI suite in Mount Sinai's imaging center and you will be asked to lie on your back on the scanner table. While you listen to sentences or look at pictures in the scanner, the fMRI machine will take a sequence of images of your head. By computer analysis, this machine creates a visual image of your brain's activity. It is necessary for you to lie very quietly without moving during the scan. You will listen to recorded positive, negative and neutral sentences or look at positive, negative or neutral pictures while in the scanner. We will ask you to listen to each sentence and to use the emotion regulation strategy you were taught. Including time to set up the equipment, you will spend about 2 hours in the scanner suite.

Throughout the scan, we will record small changes in the moisture of your skin ("skin conductance") and your pulse and monitor your eye movements and width of your pupils. To measure skin conductance, we will place small electrodes on two of your fingers or toes, using a small amount of a gel/paste to attach them and to ensure good conductivity between the electrodes and your skin. To measure your eye movements and changes in your pupils, we will use an invisible, infrared beam of light, which you will not be able to feel.

The fMRI pictures of your brain will be routinely reviewed by a doctor. If there are any medically important findings, a study doctor will call you within a few weeks of receiving this information to let you know about the findings. If you wish, we will then send the test results to your primary care doctor. If you do not have a primary care doctor, we can refer you to one. You should know, however, that our research scans are not standard medical tests and are not designed to screen for all possible medical conditions affecting your brain. This test is not what you would receive as part of regular medical care.

Any published reports of this study will not identify you by name. All data collected during this study will be kept strictly confidential.

Data Sharing

To do more powerful research, it is helpful for researchers to share information they get from studying human samples. They do this by putting it into one or more scientific databases, where it is stored along with information from other studies. Researchers can then study the combined information to learn even more about health and disease. There are many different kinds of scientific databases; some are maintained by Mount Sinai, some are maintained by the federal government, and some are maintained by private companies. As a study supported by NIMH, this study will share our research data with the NIMH Data Archive (NDA) for use by other scientists. A researcher who wants to study

the information must apply to the database. Different databases may have different ways of reviewing such requests.

Researchers with an approved study may be able to see and use your information, along with that from many other people. Unless you opt out by initialing below, this study will share research data with the NIMH Data Archive (NDA) for use by other scientists. Once data is deposited, it may be used for research that is not at all related to the current project or related topics. While research data may be shared with the NDA, it will not include any personally identifiable health information about you. No genomic information is being uploaded to the repository. Your name and other information that could directly identify you (such as address or social security number) will never be placed into a scientific database. Researchers will always have a duty to protect your privacy and to keep your information confidential.

I do not want my de-identified data to be shared in a data repository.

Initials:_____

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: attending study visits on time, actively participating in the study tasks, asking the research team or one of its members any questions that you have, and use of effective birth control.

COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

You will not incur any costs for participation in this study.

If you agree to take part in this research study, we will pay you $40 for the singular training session day and $100 per scan. There will be a total of two scan days. Total compensation for the study is $240. You will receive this money in the form of a check. If you do not have a social security number, you will receive petty cash (paper currency). Compensation break-down is as follows:

Single Training Day	$40
First fMRI Study	$100
Second fMRI Study	$100
Total Compensation	**$240**

Checks will be available within two weeks.

You will not be compensated for any medical and laboratory tests you receive through this study, but you will be informed if there are any abnormal findings that are medically important.

Tax law may require the Mount Sinai Finance Department to report the amount of payment you receive from Mount Sinai to the Internal Revenue Service (IRS) or other agencies, as applicable. Generally this reporting would take place if you receive payments that equal $600 or more from Mount Sinai in a calendar year. You would be responsible for the payment of any tax that may be due.

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 may be that your participation in this study will help to provide more information about emotions and their regulation, and may lead to better diagnosis and treatments of people with emotional problems in the future.

REASONABLY FORESEEABLE RISKS AND DISCOMFORTS:

The fMRI procedure involves minimal discomfort and the risk involved is small. Some people have claustrophobic reactions in MRI scanners. An individual will be present to reassure you and aid you in relaxing, but should you wish, the MRI scanning can be stopped immediately. The MRI scan can also be performed at a later date.

The MRI machine is a very large magnet that is always on. It is very dangerous to approach the MRI if you are carrying or wearing any kind of metallic or magnetic object (such as jewelry, belt, keys or coins). To ensure your safety, one of the study doctors, research coordinators, or the MRI technician will escort (bring) you to the MRI scanner to make sure you are free of these materials and that you are safe. If you have any surgical clips or metallic prostheses (such as artificial hip or knee), pacemakers, or shrapnel (metal fragments) in your body, you may not be able to participate in this study.

No short term risks have been reported for MRI. MRI does not involve exposure to radiation as occurs with X-rays. There are no known risks to having an MRI during pregnancy. There may be risks that are unknown.

Some of the sentences or pictures that will be presented have been selected to produce an emotional response. They may make you feel happy, sad, angry, disgusted, or neutral. It is possible that you will find some sentences or pictures unpleasant or disturbing. To help ensure that you do not have an unpleasant experience, we will discuss with you the general content of the sentences we plan to play for you.

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.

There always exists the potential for loss of private information; however, there are procedures in place to minimize this 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 Dr. Koenigsberg at telephone number (212) 241-4459.

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 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 should 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 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, Dr. Koenigsberg at phone number (212) 241-4459.

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 following reasons:

- 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>

Data from this study may be submitted to the National Institute of Mental Health Data Archive (NDA). NDA is a data repository run by the National Institute of Mental Health (NIMH) that allows researchers studying mental illness to collect and share de-identified information with each other. A data repository is a large database where information from many studies is stored and managed. De-identified information means that all personal information about research participants such as name, address, and phone number is removed and replaced with a code number. With an easier way to share, researchers hope to learn new and important things about mental illnesses more quickly than before.

During and after the study, the researchers will send de-identified information about your health and behavior and in some cases, your genetic information, to NDA. Other researchers nationwide can then file an application (NDA Data Use Certification) with the NIMH to obtain access to your de-identified study data for research purposes. Researchers must be approved by a Data Access Committee (DAC) to access this data. Experts at the NIMH who know how to protect health and science information will look at every request carefully to minimize risks to your privacy. Your de-identified data will be shared with the NDA unless you opt out and request that the information be

withdrawn. Once data is deposited, it may be used for research that is not at all related to the current project or related topics.

You may not benefit directly from allowing your information to be shared with NDA. The information provided to NDA may help researchers around the world treat future children and adults with mental illnesses so that they have better outcomes. NIMH will also report to Congress and on its web site about the different studies that researchers are conducting using NDA data. However, you will not be contacted directly about the data you contributed to NDA.

You may decide later that you do not want to share your information using NDA. If so, contact the researchers who conducted this study, and they will tell NDA, which can stop sharing the research information. Your data will be removed from future data distributions, however, NDA cannot take back information that was shared before you changed your mind. If you would like more information about NDA, this is available on-line at http://data-archive.nimh.nih.gov/.

As part of this research project, the researchers will collect your Name, Address, Telephone number, Email Address, Medical Record Number, and Social Security Number. Medical History information collected as part of this study will be used in this study and kept by Dr. Koenigsberg and his research team. Medical Record Information obtained during this research study about your medical health will be kept in a record at the General Clinical Research Center at The Mount Sinai Health System.

- Information from a physical examination that generally also includes blood pressure reading, heart rate, breathing rate and temperature

During the study the researchers will gather information by:

- a thorough medical examination, including an electrocardiogram, which is a recording of the electrical activity of the heart, and the drawing of up to three tablespoons of blood, which will be used to obtain standard medical screening tests
- a urine sample and pregnancy test before scanning for all females
- a urine sample for a drug screen before scanning for all participants
- tests, procedures, questionnaires and interviews described in this consent, including fMRI scans of your brain that will take pictures of the structure of your brain and the areas of your brain that are active while you look at pictures

<u>Why is your protected health information being used?</u>

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 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 sponsoring government agency and/or their representative who need to confirm the accuracy of the results submitted to the government or the use of government funds: The National Institutes of Health.
- United States Department of Health and Human Services and the Office of Human Research Protection.
- The James J Peters Veterans Affairs Medical Center, since this study is carried out in collaboration with the Bronx VAMC
- The Human Studies Subcommittee and/or the Committee on Research and Development of the James J Peters Veterans Affairs Medical Center who provide oversight to insure that the rights of human subjects are protected in this study, since this study is carried in collaboration with the James J Peters VA Medical Center.

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.

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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 → **8/23/2021**

Signature of subject	Date
Printed name of subject	Time

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