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TITLE OF RESEARCH STUDY:

Regulating Emotional Responses to Spoken Comments and Visual Images Across the Affective Instability Spectrum: An fMRI Study (Development of the Stimulus Sets)

PRINCIPAL INVESTIGATOR (HEAD RESEARCHER) NAME AND CONTACT INFORMATION:

Name: Harold W. Koenigsberg, M.D.

Physical Address: 1160 5th Avenue, Suite 108, New York, NY 10029

Mailing Address: One Gustave L Levy Place Box 1228, NY, NY 10029

Phone: 212-241-4459

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 evaluate how individuals respond to images and recordings of positive, negative, and neutral verbal sentences. The sentences and images may make you feel positive, negative, or neutral. The ratings made by you and other participants will be analyzed for reliability and then used to develop a stimulus set of sentences and images.

You may qualify to take part in this research study because you are medically healthy and have no history of a mental disorder.

Funds for conducting this research are provided by the National Institute of Mental Health (NIMH).

LENGTH OF TIME AND NUMBER OF PEOPLE EXPECTED TO PARTICIPATE

Your participation is expected to consist of 1-3 visits that will each last about 2 hours.

The number of people expected to take part in this research study at this site is 100.

DESCRIPTION OF WHAT'S INVOLVED:

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

Urine Toxicology
All subjects must complete a urine toxicology (drug) screen. 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. The result of the urine toxicology (drug) screen will not include identifiable information.

Overview of Study Procedures
You will be asked to listen and rate your reactions to positive, negative, and neutral sentences or positive, negative, or neural pictures, or both during your visits. Each sentence or picture will be presented to you on a laptop computer, where you will also enter your rating by pressing one of the keys to rate how these sentences or pictures make you feel. Each visit will include four runs separated by short breaks. The sentences and images will be presented to you on a laptop computer in a private room within our research office at Mount Sinai (1160 5th Ave.). The negative sentences and images may include content about situations that are upsetting. Each session will take about 2 hours. You can decide whether to participate in one, two, or three sessions. If you have previously participated in this study, you are only eligible to complete two sessions. If you become uncomfortable at any time during the study procedure, you can discontinue your study participation.

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, and asking the research team or one of its members any questions that you have.

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 $50 per session for your time and effort. Thus, you will earn $50-$150 depending upon the number of sessions you complete. 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).. Checks require some time to be prepared and will be available within two weeks. Compensation break-down is as follows:

Development Day 1	$50

Development Day 2 (optional)	$50
Development Day 3 (optional)	$50
Total Possible Compensation	**$150**

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:

There will be no direct benefit to the individual subject. 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:

Some of the sentences and images 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 images 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 and images. If you become uncomfortable or upset, you can discontinue your study participation.

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.

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

As part of this research project, the researchers will collect your Name, Address, Telephone number, Email Address, and Social Security Number.

During the study the researchers will gather information by:

- a urine sample for a drug screen before study procedures for all participants
- procedures described in this consent including listening to sentences and rating how they make you feel

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 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.

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