Cognitive Reappraisal Training Targeting Emotion Circuits As a Therapeutic Intervention in Borderline Patients
PI: Harold W Koenigsberg, MD
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## STUDY INFORMATION:

**Study Title:** Cognitive Reappraisal Training Targeting Emotion Circuits As a Therapeutic Intervention in Borderline Patients

**Study site(s):** Icahn School of Medicine at Mount Sinai

**Principal Investigator (Lead Researcher):** Harold W. Koenigsberg, M.D.

**Physical Address:** 1399 Park Avenue, New York, NY 10029

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

**Phone:** 212-585-4642

## SUMMARY OF THIS RESEARCH STUDY:

This document explains the purpose of this research study is to investigate how a 6 week training program in regulating emotion could help those with Borderline Personality Disorder (BPD).

Participation in the study is voluntary. You can agree to join or not. Your decision will not limit your ability to receive care at Mount Sinai. You should only agree to take part if you understand the study and if all of your questions about the research study are answered. If you do join the study, the research team must share any new information with you that may change your mind about taking part.

Borderline Personality Disorder (BPD) is a prevalent, psychiatric condition. One of the most prominent clinical features of BPD is extreme mood shifts occurring in response to external social/emotional events.

If you choose to take part, you will be asked to attend 45 minute meetings, twice a week for 6 weeks with a guide who will help teach techniques to regulate your emotions. We will follow your emotion regulation skills by asking you questions and also by doing brain scans (fMRI) at the beginning and after 6- weeks of training. You will be compensated for the fMRI sessions and questionnaires. We will provide a medical evaluation to be sure you qualify for the study. We will also take a drug screen and pregnancy test (for women) initially and before each brain scan.

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 in 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 will not benefit directly from taking part in this research. However, the results of this study can support the development of new treatments for BPD. If you choose to take part, the main possible risks to you are loss of private information, injury from the blood draw, and side effects from the fMRI machine.

If you are interested in learning more about this study, please continue to read below.

## STUDY PARTICIPATION:

You may qualify to take part in this research study because you are medically healthy and meet criteria for a diagnosis of BPD.

Your participation in this research study is expected to last 6 weeks

One hundred and thirty people are expected to take part in this research study at Icahn School of Medicine

Funds for conducting this research study are provided by The National Institute of Mental Health.

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

## DESCRIPTION OF WHAT IS INVOLVED:

If you agree to take part in this research study, here is what may be involved:

### Screen/Diagnostic Evaluation

In a private office setting at either the Mood and Personality Disorders Program research offices (1399 Park Avenue 3rd Floor, or over HIPAA-Compliant Zoom for remote/social distancing options) you will be asked about any past or present history of psychiatric medications and other drugs (such as alcohol and "recreational drugs" such as marijuana and amphetamines) which affect the brain. You will be asked about your medical and psychiatric history, e.g., epilepsy, head injuries, depression. You will participate in two interviews: 1) an hour screening and 2) one full psychological diagnostic evaluation to screen for any psychological disorders. This can take between 2-3 hours to complete.

You will also 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 Evaluation

If you have not already had one recently through our research group, you will have a medical evaluation with a nurse practitioner at Mount Sinai's Clinical Research Center (1468 Madison Avenue, 1st floor). This will include routine blood tests (complete blood count, metabolic and electrolyte panel, thyroid function tests, and a routine urinalysis. A urine drug screen will be administered in our office (1399 Park Avenue) on the day of your Medical Evaluation. Female participants will also receive a pregnancy test in our office. 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 findings will keep you from further participating in this study. If indicated, laboratory tests may be repeated. If we find that you do not have any significant medical findings, you will be invited to continue to participate in this study. You will also fill out BMEII's (BioMedical Engineering and Imaging Institute- where the fMRI scan takes place) MRI screening questions on this day.

### 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 (1399 Park Avenue). This screening process should take less than 5 minutes. If results are positive, we will cancel and reschedule the appointment once and remind you about abstaining from recreational drug use as this is one of the requirements of the study. We will also have the emotion regulation trainer assess the situation to see if any further intervention is required. 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-Behavioral Battery

On the first day you will be asked to complete some questionnaires about your mood and personality (approximately 1 hour). You do have the option to do this remotely (you will be emailed a link) or in person on paper in our office (1399 Park Avenue).

### Training day and Baseline fMRI session

The second session will be 2 hours long. The first hour is training on the computer task to become familiar with what you will be doing during the scan. The second hour is the fMRI scan session itself.

During this visit, we will familiarize you with the emotion regulation task on the computer that you will perform as we carry out the brain scan (fMRI). This task involves looking at emotional pictures. We will teach you how to do this task and give you practice on a laptop computer. The neutral pictures may include scenes of people interacting or close-ups of peoples' faces. The negative pictures may include violent scenes or images of illness or death (some might be disturbing). If any picture bothers you, you may ask us to turn it off at any time.



For the brain scan, a member of the research team will escort you to the MRI suite in Mount Sinai's Department of Radiology and you will be asked to lie on your back on the scanner table. While you look at the 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. 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. You may notice a spot of white light if you look below the projection screen. Including time to set up the equipment, you will spend about 1 hour in the scanner suite.

**6 week training program**
You will then participate in one of two possible training programs to help you learn how to better regulate your emotional feelings. Each program will include 45-minute sessions twice a week for 6-weeks. We are using 2 different training programs to learn which works better. Each program will be conducted by an emotion regulation trainer in our program. You will be assigned to one or the other program by chance (like by a flip of a coin). With your consent, we will video and audio record each session so that some can be reviewed by a non-Sinai expert in our program, Dr. Bryan Denny, Ph.D of Rice University, to maintain the quality of the emotion training. ***Training sessions can be conducted in person at our offices or remotely via a HIPAA-Compliant Zoom***

**6-week follow-up**
At the end of 6 weeks of training you will have an fMRI scan (1 hr) and some questionnaires (45 min). Each fMRI session follows the same procedure.

**1-month and 4-month follow-up**
1 month and 4 months after your 6-week follow-up visit, you will be contacted by a study team member to complete questionnaires about your mood and personality (approximately 1 hour each). Similar to previous questionnaires, you do have the option to do this remotely (you will be emailed a link) or in person on paper in our office (1399 Park Avenue).

## Pregnancy
If you can possibly get pregnant, a urine test for pregnancy will be done before you begin the study and the pregnancy test will be repeated every FMRI appointment



You cannot be included in the study if you are or become pregnant, as the effects of fMRI scanning upon a fetus are not well known. You also should not be in the study if you are breast feeding as this may change hormone levels.

Unless you are at least one year past menopause or have had a successful operation to make pregnancy impossible, you should use effective birth control. Unless you are sexually abstinent (not having genital sex) the recommended methods of birth control are:

- The consistent use of approved hormonal birth control (pill, patches, or rings),
- An intrauterine device (IUD),
- Contraceptive injection (Depo-Provera),
- Double barrier methods (Diaphragm with spermicidal gel or condoms with contraceptive foam),
- Sexual abstinence (no sexual activity),
- Sterilization (a vasectomy, getting tubes tied, or a hysterectomy).

All birth control methods (other than abstinence and sterilization) are only effective if you use them properly, start them at least one month before you begin the research study, and continue using them throughout the research study and for one month after the research study ends. If you are unsure whether the method of birth control you use is approved to use while you are in this study, you should ask the Lead Researcher before you begin the study. If you are less than one-year post-menopausal, you could still become pregnant.
Should you become pregnant, whether or not you have the baby, the people funding and overseeing the research may ask for information on the pregnancy, even if you are no longer part of the study. You will be asked for additional written consent to share this information if that happens.

## Future Contact:

The researchers may wish to use your personal contact information to contact you in the future. Do you give the researchers permission to **contact you** in the future to request the collection of additional information about you, discuss how your private information, study data and/or samples might be used, or discuss possible participation in another research study?

Please initial your choice: Yes_____ No_____

If “Yes”, please indicate your preferred method of contact: (initial all that apply)

[ ] Email [ ] Phone [ ] Letter [ ] Text



## USE OF YOUR DATA AND/OR SAMPLES:

The researchers would like your permission to keep your personal information (such as, name, address, date of birth, social security number), study data and/or samples (blood, tissue, urine, saliva, or any other body matter) to use or share in future studies. You can still be part of the study if you do not allow us to use or share them. Please select Yes or No to each of the questions below. To decline all future uses/sharing please select 'No' each time.

**(1)** Will you allow the researchers to store your data and/or samples to use in future research studies?

Please initial your choice: Yes_____ No_____

If you select No, please stop here and move to the next section, **'Your Responsibilities If You Take Part in This Research**' section below."

If yes, please continue to the next question and tell us how your personal information, study data and/or samples may be used in future research studies.

**(2)** The researchers can store your data and/or samples in one of two ways:

a) Anonymously (no one will know who the data and/or samples came from). If you choose this option, you can't change your mind. So, if you wanted to have your data and/or samples destroyed in the future, the team could not do it as they would not know which data and/or samples were yours.
b) Linked to your identity (using a code that can show the information came from you personally). In this case you could ask for your data and/or samples to be destroyed in the future if you want that to happen.

How would you like your data and/or samples stored? Please initial **ONE** choice below:

I would like my data and/or samples stored anonymously _____

I would like my data and/or samples stored with a link to my identity through the use of a code_____

**(3)** Do you give the researchers permission to keep the data and/or samples, so they could use them in future studies that are **directly related** to the purpose of the current study?

Please initial your choice: Yes_____ No_____

**(4)** Do you give the researchers permission to keep the data and/or samples indefinitely, so they could



use them for future studies that are **not related** to the purpose of the current study (for example a different area of research)?

Please initial your choice: Yes_____ No_____

**(4.1)** From time to time, researchers outside of medicine and related sciences would like to use data and/or samples. This might be in the fields such as anthropology, human origins, mapping human migration patterns. Do you give permission for researchers **outside the field of medicine** to use your data and/or samples?

Please initial your choice: Yes_____ No_____

**a.** If the future research in a different area can be done without having to know that the data and/or samples came from you personally, that will be done.
**b.** If the future research in a different area requires that it is known specifically who the data and/or samples came from, then one of the following will be done:
   I. If you allowed the researchers to contact you in the future, they may be able to contact you to explain why your data and/or samples is needed and what will be done with it. Your permission will be asked to use your data and/or samples in that research project.
   II. If you do not give permission to be contacted in the future, or if it is found that contacting you is not practical (for example, because you have moved), your data and/or samples may still be used. The Institutional Review Board (IRB) will be asked for permission to use the data and/or samples linked to your identity. The IRB can give permission for researchers to use and share identifiable health information without contacting you, but only if it determines that sharing the data and/or samples will not be more than minimal risk to you or your privacy. The IRB is a committee of doctors and scientists and nonscientists, including people not associated with this hospital or medical school, whose job it is to protect people who participate in research.

**(5)** Do you give permission to have your data and/or samples given **to other researchers,** including those at Mount Sinai, other medical or scientific institutions and for-profit companies, for use in research within the limits you have chosen above?

Please initial your choice: Yes_____ No_____

**(6)** Do you give permission for your sessions during your training program with the emotion regulation trainer to be audio and video recorded, so that they may be reviewed by an expert in our program to maintain the quality of the training?

Please initial your choice: Yes_____ No_____



## 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, as described above, 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:

Researchers will not pay you for your travel or the time it will take for you to be in the study.

If you agree to take part in this research study, you will be paid for your time and effort, for a total of up to $435 over 6-8 weeks and the one and four or month follow-ups. The table below indicates how much you will be paid for each part of the study that you participate in.:

| **Session** | **Length** | **Compensation** |
|---|---|---|
| Screening Interview | 1 hr | $25 |
| Clinical Interview | 2-3 hr | $40 |
| 2 Questionnaire Packets | ~1 hr per packet | $25 for each packet |
| Consent & Medical Evaluation Visit | 1 hour | Not compensated for – can keep results of medical evaluation |
| Behavioral Battery | 1 hour | $40 |
| Training day + baseline fMRI session | 2 hour (1 hr training, 1 hour fMRI) | $100 |
| Week 1-Week 6 Training in Cognitive Reappraisal by Distancing with clinical psychologist | 45 minutes, twice a week for 6 weeks | No charge for the training sessions |
| End of Week 6 fMRI + behavioral battery check in | 2 hour (15 min refresher, 45 min battery, 1 hour fMRI) | $100 |
| 1 and 4 month follow-up | 1-2 hours each | $40 for each session |
| Total of 20 visits over 6-8 weeks | 23 ~ 25 hours | $435 |



*You will be compensated in the form of checks. Checks are requested after each visit. Checks require some time to be prepared and will be given to you once processed and available. It can take up to 6 weeks to prepare and give you a check for study participation.* If you do not get a check by then, you can first contact the research team. If further assistance is needed, please contact Mount Sinai's Program for the Protection of Human Subjects at (212) 824-8200.

A mailing address and Social Security number is needed to process the checks. If you wish not to share that information or do not possess a social security number, we have the option to compensate in the form the Amazon gift cards, which will be available for pick up at our offices after completed study visits.

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 happens 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:

This study is not designed to benefit you personally. However, possible future benefits to others include that your participation in this study will help to provide more information about brain function in the BPD, and may lead to better treatment in the future.

## POSSIBLE RISKS AND DISCOMFORTS:

Participating in a full diagnostic evaluation and collecting information about past and current psychological symptoms, even when done by a highly trained investigator/clinician, can potentially stir up feelings of fear, sadness, anger, and even self-destructive thoughts. You will be encouraged to proceed at a rate that is comfortable for you and take breaks as needed. During and after the information is obtained, you may ask questions or talk about your feelings in order to help you leave the study visit in the most comfortable state as possible

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

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.

MRI scanning involves the use of a magnet and radio frequency energy. Therefore, patients who have implanted metal devices, such as pacemakers, certain aneurysm clips, or shrapnel or metal in the eye are at risk. You will complete a screening form to identify the presence of metal, but if you have any



question that you may have metal in the body, you should inform the technologist or investigators before entering the magnet room. If you have metal in your body that you are unable to remove, the safety team will determine whether you will be able to undergo MRI scanning safely. Because of the strong magnetic field associated with the scanner, it is rare, but possible, that a metallic object could fly through the air toward the scanner and hit you. To reduce this risk, everyone in the vicinity of the magnet will remove all metal from their clothing or pockets when in the scanning environment.

To create images MRI employs radio waves. These waves are not harmful, however, MRI scanners do produce loud noises when these waves are generated. To minimize discomfort, you will be provided with disposable earplugs or headphones that help suppress external noise levels but do not eliminate the noise so that you can have voice communication with the scanner operator. Some individuals may also experience a feeling of claustrophobia (fear of being trapped in a narrow place) during scanning, but if you become uncomfortable, the machine may be stopped at any time during the scan upon your request.

Other risks of MRI that rarely occur include neurostimulation effects, such as muscle twitches and tingling sensations, due to the rapid switching of magnetic fields, and a slight increase in body temperature that may occur in the presence of radio frequency energy. These are very unlikely under current operational guidelines. In the very remote event that the magnet loses its magnetism, helium gas in the magnet will escape. The room is designed with ventilation systems to prevent accumulation of these gases. Should this occur, you will immediately be brought out of the magnet room.

Emotional Distress: answering questions about your moods and your personality may bring up uncomfortable memories and/or may cause you distress. We will attempt to minimize your experienced distress by using trained interviewers and by offering you the opportunity to skip any questions that you consider disturbing

There are no known risks during pregnancy to having an MRI. There may be risks that are unknown. Current FDA guidelines state that safety has not been established for imaging the fetus.

The machine settings used for this special MRI are not chosen to pick up structural changes in the brain, for example: masses or bleeding. However even research MRI scans may reveal unexpected finding(s). Should this occur, the finding(s) will be considered by the appropriate personnel and the PI will inform you if necessary. These possible finding(s) may or may not be significant and may lead to anxiety about your condition and to further work-up by your physician and may result in additional cost to you.

If you are pregnant or become pregnant, this research may hurt your baby or your pregnancy in ways that are unknown. The unknown risks could be minor or major (death) for the pregnancy. You should not become pregnant or get someone pregnant while you take part in this study. Please read the



acceptable methods of birth control found under the Description of What Is Involved section of this document.

The skin conductance measurement involves minimal discomfort. To take this measurement, however, a small amount of a gel/paste is used to attach the electrodes to your skin. There is a small possibility that you will be allergic to this gel/paste and have some itching, redness, or skin sensitivity where it is applied.

Some of the pictures of people, places and things that you will be shown 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 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 pictures we plan to show.

## OTHER OPTIONS TO CONSIDER:

You may decide not to take part in this research study. If you decide not to take part, this will not affect the clinical care you receive at Mount Sinai. The choice is totally up to you.

## IN CASE OF INJURY DURING THIS RESEARCH STUDY

If you are injured or made sick from taking part in this research study, you will get medical care. Generally, it will be billed to you or your insurance. You will be responsible for all treatment costs not covered by your insurance, including deductibles, copayments, and coinsurance. This does not prevent you from seeking payment for injury related to malpractice or negligence. You can contact the Lead Researcher for more information.

## ENDING PARTICIPATION IN THE RESEARCH STUDY:

You may stop taking part in this study at any time. No matter what you choose, your care and benefits through Mount Sinai will not be negatively impacted.

If you decide to stop being in the study, please contact the Lead Researcher or the research staff

You may also withdraw your permission for the researchers to use and share any of your protected information for research, but you must do so in writing to the Lead Researcher at the address on the first page. Even if you withdraw your permission, the Lead Researcher 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 taking part in the research study.

If you decide you don't want your data and/or samples to be used for research anymore, you can contact the researcher and ask to have your data and/or samples withdrawn or labeled so that they will not to be used in additional projects or shared. If your data and/or samples have already been shared with researchers, those researchers will be asked to stop using them. However, if any data and/or samples have already been shared without your identity or a linking code, it won't be possible to retrieve them. Data and/or samples that have already been used will not be affected by your decision. If your data and/or samples have already been deposited in an external repository, the study team will request that your data and/or samples be removed.

Withdrawal without your consent: The Lead Researcher, the funder or Mount Sinai 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 research team have not been followed, the Lead Researcher believes it is in your best interest, or for any other reason. If data and/or samples have been stored as part of the research study, they too can be destroyed without your consent.

## CONTACT INFORMATION:

If you have any questions, concerns or complaints at any time about this research, or you think the research has harmed you, please contact the office of the research team and/or the Lead Researcher at phone number 212-585-4642

If there is an emergency, please call 888-836-4443 or call 911 or go to the emergency room. Let the emergency room staff know you are in a research study so they can contact the Lead Researcher if needed.

## DISCLOSURE OF FINANCIAL INTERESTS:

Researchers sometimes get paid for consulting or doing work for companies that produce drugs, biologics or medical devices. If you have questions regarding industry relationships, you are encouraged to talk to the Lead 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 part of this study, some of your private and/or protected health information will be obtained, used, and shared with your permission. There is a Federal Health Insurance Portability and Accountability Act (HIPAA) that makes sure this is done correctly and safely.



What is protected health information (PHI)?
PHI is the combination of two things:

1. PHI contains information that identifies you. It will be used to contact you and link you to your health information, like name, date of birth, medical record number, and address.
2. PHI also contains health information, including information about your mental and physical health from your visits to doctors or hospitals, or from study visits.

Every time you visit a hospital or your doctor, PHI is created and recorded in your medical record by your healthcare providers. In the same way, the PHI created as part of this study will be linked to who you are and your medical information.

What PHI is collected and used in this research study, and might also be shared with others?

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As part of this study, the research team at the hospital(s) involved in the research will collect your Name, Address, Telephone 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 Icahn School of Medicine at Mount Sinai.

- 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:

- Reviewing and/or taking your medical history (includes current and past medications or therapies, illnesses, conditions or symptoms, family medical history, allergies, etc.)
- Doing a physical examination that generally also includes blood pressure reading, heart rate, breathing rate, and temperature, and blood tests.
- Completing the tests, procedures, questionnaires and interviews explained in the description section of this consent.

Why is your PHI being used?
Researchers need the information that identifies you so they can contact you during the study. They need your health information and the results of any tests and procedures being collected as part of this study to answer the questions posed in the study. The purpose of the study is discussed earlier in this consent form. Before researchers analyze the data, they remove any information that would let others know who you are or that you took part in the study. If researchers publish or present study results at scientific meetings, lectures, or other events, their presentations would not include any information that would let others know who you are, unless you give separate permission to do so.



Who, outside Mount Sinai, might receive your PHI?
As part of the study, the Lead Researcher, research team and others in the Mount Sinai workforce may disclose your PHI, 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 Lead Researcher.)

- The United States Department of Health and Human Services (DHHS) and the Office of Human Research Protection (OHRP) (the government organization that is responsible for protecting human research participants).
- Other collaborating research center(s) and their associated research/clinical staff who are working with the researchers on this project: The James J Peters Veterans Affairs Medical Center, since this study is carried out in collaboration with the Bronx VAMC
- The sponsoring government agency and/or their representatives who need to confirm the accuracy of the results submitted to the government or the use of government funds: **The National Institutes of Health**
- A Data Safety Monitoring Board or other committee that will monitor the study on an ongoing basis for safety.
- Others: Dr. Bryan Denny, our collaborator at Rice University, Houston, Texas.

In almost 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. Some records and information disclosed may be identified with a unique code number. The Lead Researcher 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 Institutional Review Board (IRB) allows it after determining that there would be minimal risk to your privacy. The Certificate of Confidentiality obtained from the Department of Health and Human Services will not be used to prevent disclosure to local authorities of child abuse and neglect, or harm to self or others. 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, *OHRP, 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.* The results of this research may be published. However, your name and other identifying information will be kept confidential.

For how long will Mount Sinai be able to use or disclose your PHI? Your authorization for use of your PHI 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 research team is not required to release research information to you that is not part of your medical record.

Do you need to give the researchers permission to obtain, use or share your PHI?
NO! If you decide not to let the research team obtain, use or share your PHI, 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?
If you decide to stop being in the study, please contact the Lead Researcher or the research staff.
The research team may ask you whether they can continue to collect information from your medical record. You will also have to decide if you wish to limit the continued use of the information collected during the study. Under US privacy laws you may also withdraw your permission for the researchers to use and share any of your protected information for research, but you must do so in writing to the Lead Researcher at the address on the first page.

Even if you withdraw your permission, the Lead Researcher may still use the information that was already collected, but only to complete this 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 taking part in the research study.

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 PHI.

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, where possible, Mount Sinai has entered into agreements with those who will receive your information to continue to protect your confidentiality.

If researchers are reviewing your medical records or asking questions about your medical history or conditions, it is possible that they may learn information related to your HIV status. If that is the case, the following information concerns you. If researchers are not reviewing your medical records or asking questions about your medical history or conditions, then you may ignore the following section.

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**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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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 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 personal information, study data and/or samples with anyone who is not a member of the research team, including any family members or friends, other than those identified above. However, you should know that if it is learned that you or someone else is threatened with serious harm, such as a child or an elderly person being abused, the research team 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.

## How the Institutional Review Board (IRB) can help you:

This research has been reviewed and approved by an Institutional Review Board (IRB). You may reach a representative of the Mount Sinai Program for Protection of Human Subjects at telephone number (212) 824-8200 during regular work hours (Monday-Friday, 9am-5pm, excluding holidays) 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 participant.
- You want to get information or provide input about this research.

## ADULT PARTICIPANT:

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

| Signature of Participant | Printed Name of Participant | Date | Time |
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## PERSON EXPLAINING STUDY AND OBTAINING CONSENT:

| Signature of Consent Delegate | Printed Name of Consent Delegate | Date | Time |
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## *WITNESS SECTION:*

*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 participant, and that* consent was freely given by the participant.

| Signature of Witness | Printed Name of Witness | Date | Time |
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