The Influences of Eating and Fasting on Inhibitory Control in Bulimia Nervosa: A Computational Neuroimaging Study
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STUDY INFORMATION:

Study Title: The Influences of Eating and Fasting on Inhibitory Control in Bulimia Nervosa: A Computational Neuroimaging Study

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SUMMARY OF THIS RESEARCH STUDY:

This document explains a research study you might be interested in joining. 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.

This research study focuses on an eating disorder called bulimia nervosa (BN). People with this disorder binge eat and then do things like vomiting (also called “purging”) and fasting to try to “undo” the effects of binge eating. Very little is known about what contributes to the development and maintenance of binge eating and purging behaviors. The purpose of this research study is to study changes in brain activation after fasting and eating using a technology called functional magnetic resonance imaging (fMRI) in women with bulimia nervosa and in women who have never had an eating disorder. This study will specifically investigate whether differences in brain activation after fasting and eating are linked to eating-disorder symptoms. This is not a treatment study.

If you choose to participate, you will be asked to complete clinical interviews, medical screening, cognitive tasks, questionnaires, and fMRI scans. In total, the study involves 3 in-person visits and includes approximately 11 hours of procedures. First, you will be asked to complete clinical interviews (about 2.5 hours), either remotely via a HIPAA-compliant videoconference (zoom), or in person at Mount Sinai. The next screening steps must be completed in person, and include a medical evaluation, clinical interviews, questionnaires, a cognitive task, and button-pressing tasks (about 1.5 hours). Between this visit and your second and third visit, you will be asked to complete questionnaires, which take about 1 hour to complete. In the second and third visits (approximately 3 hours each), you will complete two brain scans, called fMRI. You will be asked not to eat or drink anything besides water for the 16 hours before both of these scans. You will be given a standardized meal immediately before one of these scans.

The main risks to you if you choose to participate are (1) pain, bruising, the slight possibility of infection, dizziness, or fainting after the blood draw (if you are in the bulimia nervosa group) (2) risks associated with MRI, and (3) the potential for becoming upset, anxious, or uncomfortable when discussing personal issues, during the computerized tasks, during the fMRI scan, or during fasting. You may also feel some physical discomfort during the fasting periods, including tiredness, hunger, irritability, headaches, general weakness, mild nausea, constipation or diarrhea, bad breath, sleep disturbances, dizziness, or water retention.

Participating in this research will not benefit you. You will receive compensation. 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 an adult woman between the ages of 18 and 35 with a diagnosis of bulimia nervosa, or alternatively, if you are a healthy woman in the same age range who has never had an eating disorder.

Your participation in this research study is expected to last 1-2 weeks. The number of people expected to take part in this research study at the Icahn School of Medicine is 100.

Funds for conducting this research are provided by the National Institutes of Health.

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

DESCRIPTION OF WHAT IS INVOLVED:
If you agree to participate in this research study, the following information describes what may be involved.

Clinical Interviews: *You will be asked to complete clinical interviews about your eating and mood with a member of our research study staff via a HIPAA-compliant videoconference (Zoom) or in person at the Icahn School of Medicine at Mount Sinai. These interviews take approximately 2.5 hours.*

As part of this project’s screening procedures, an **audio** recording will be made of you. Specifically, the clinical interviews conducted as part of screening will be audio-recorded. In any use of the audio recording, your name will not be identified, and the recording will only be associated with a participant ID number that we have assigned to you. You may request to stop the recording at any time or to erase any portion of your recording. The audio recording will be used for this research project for one reason only: to make sure that different individuals who conduct these interviews in our lab ask you questions and score your answers similarly. The audio recording will not be used for any other purpose, and after

the research team has scored the recordings to see how similar interviewers' questions and ratings are (i.e., after the purpose of the audio-recording is fulfilled), the audio recording will be destroyed.

Screening/Medical Evaluation: Members of our research study staff will take a medical history by interview, a physical exam and, if you are in the bulimia nervosa group, basic laboratory tests. Your height and weight will also be measured. In one interview, we will also ask you to solve puzzles and define words. Once the screening information is collected, you will be told if you are eligible to participate. As part of this study, we will have you complete tasks designed to measure your intelligence so that we can make sure our two study groups overall are similar in intelligence. We will not release this information to you.

If you are a participant with bulimia nervosa, we will draw 2 teaspoons of blood for basic laboratory tests for the medical evaluation.

Decision-Making Tasks: We will ask you to complete computer tests of your response style. In these tasks, you will be asked to push buttons with your fingers to respond to the pictures you see on a computer screen. One of these tasks will provide you with practice for a task you will complete at the scanning visits. We will ask you to fill out some brief questionnaires about your mood, hunger and fullness before you start the tasks.

Questionnaires: You will be asked to complete self-report questionnaires online before your first fMRI study visit. These surveys ask questions about your mood, anxiety, and eating symptoms, temperament, and personality. We anticipate that these questionnaires will take approximately 1 hour to complete.

The above screening procedures might help us determine your eligibility for other studies.

Second and Third Visits: The second and third visits will occur at the BioMedical Engineering and Imaging Institute (BMEII) at the *Icahn School of Medicine at Mount Sinai, and each of these visits will last about 3 hours. You will be asked to not eat or drink anything in the 16-hour period before both of your scheduled scans. At one of the scans, you will be given a standardized meal, which we will ask you to consume within 15 minutes. We will begin scanning procedures within 30 minutes after the entire meal is consumed. For half of the people who take part in this study, they will have this meal before their first scan, and for the other half of the people who take part in the study, this meal will occur before their second scan. When we are scheduling your study visits, we will tell you what scan order has been assigned to you.*

On both scan days, you will be asked to report on your recent food consumption and will also be asked to provide a blood sample via finger prick when you arrive for your scanning visits to confirm (via a glucose test) that you fasted for the required amount of time. If you arrive for any of your scan visits and the tests or you indicate that you did not fast overnight, you will not be scanned. When you arrive for both fMRI scans, you will also be asked to provide a urine sample for pregnancy testing and urine toxicology, a test that will tell us if you have recently used any drugs. You will not be scanned if either of these urine tests are positive.

When you arrive for both fMRI scans, you will be instructed on the fMRI tasks and asked to complete a brief decision-making task and questionnaires about your mood, feelings of tiredness, and hunger and fullness. The task and questionnaires will take approximately 25 minutes.

Functional Magnetic Resonance Imaging (fMRI) Scans: Functional magnetic resonance imaging (fMRI) is a method for measuring the flow of blood in the brain, taking pictures and using a powerful magnet. fMRI does not involve exposure to radiation. However, because a magnet is involved, you must have all metal objects removed from your body before entering the room with the fMRI. People who have metal in the body that cannot be removed (for example, braces, screws in knees) will not be able to participate in the study. Eyeglasses also have to be removed during the brain scan; fMRI safe glasses will be provided for those who do not have contacts to wear in the scanner.

During the scanning session, you will be placed in a large doughnut-shaped machine. You will be asked to lie down on an examination table and will be given headphones that allow you to hear instructions from the technician. Your head will be placed in a special helmet-like “head-holder” to keep your head still. During the scanning procedures, you will be asked to lie as still as possible on the examination table. A head coil that looks like a baseball catcher’s mask will be placed around your head. A mirror attached to the head coil will allow you to see the screen behind you. The examination table will then be moved up and into the machine until only your head is inside the scanner. You will be able to talk to our research staff or technologist anytime you need to during the scan.

Each session consists of several shorter scans (5-10 minutes) all lasting a total of about 90 minutes. You will be asked to relax and lie as still as possible between the short scans. Three of the scans will require you to just relax while we take standard MRI scans, like pictures and movie clips, of your brain and blood flow in your brain. The other two fMRI scans will require you to pay attention to and complete computerized tasks. A response pad will be placed around your right arm before the scan starts. For one of the tasks, you will be looking at a computer screen, and will be asked to push a button or not push a button on the response pad in response to the pictures you see on the screen and sounds you hear through the headphones. You will then do another task in the scanner where you will be asked to press buttons in response to pictures on the screen. These tasks measure how you control your responses and make decisions. This visit will be conducted by trained members of the research team and imaging staff and will take place at the BMEII at the Icahn School of Medicine at Mount Sinai.

On both scan days, after the scanning session is over, we will ask you to fill out some brief questionnaires about your mood, hunger and fullness. This will take an additional 5 minutes. You will also be offered a granola bar snack after scanning is complete.

You will have the opportunity to earn a monetary bonus based on your performance in the decision-making tasks at all study visits. These bonuses can range from $0 to $15 and will be calculated differently for each task you participate in. This calculation will be fully explained to you during the task instructions. Please let the experimenter know if you have any questions about how the bonuses work.

Pregnancy

If you can possibly get pregnant: Since you are participating in a research study that involves a procedure with potential risks to a developing fetus, it is recommended, for your protection, that you not become pregnant for the duration of the study. You should not participate if you are breastfeeding. A urine test for pregnancy will be done before you begin the MRI scanning visit for the study. We will provide the test to make sure that you are cleared to proceed. In the case of a positive pregnancy test, we will stop all research procedures and you will be discontinued from the study. If a pregnancy is identified before the fMRI, we will provide you with referral information for an OB/GYN.

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. If you become pregnant, or may be pregnant, at any time during the study period, you must tell a person from the research team immediately.

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:

In addition to being used to complete this research study, your personal information (such as, name, address, date of birth, social security number), study data, and samples (blood, tissue, urine, saliva, or any other body matter.) may also be used and shared for additional (future) research. Before anything is shared, all of your identifying personal information will be removed and it will be replaced with a code (i.e., deidentified). Researchers are not planning on giving you the details of any of this future research nor the results. That means that a research project might be done that you would not consent to if provided with the details of that research project.

If you do not want any future research to be done with your data and/or samples, even with your identity removed, please do not sign this consent form or take part in the study.

During and after this study, the study researcher will submit portions of your deidentified data and/or samples to large public databases (repositories) for use in research (e.g., the National Institute of Mental Health Data Archive (NDA) at the National Institutes of Health (NIH)). NDA is a large database where deidentified study data from many NIH studies are stored and managed.

To do more powerful research, it is helpful for researchers to share data and/or samples from the people they study. They do this by putting data and/or samples into a repository. A repository is where something is stored safely for a specified period of time. Data and/or samples from one study may be stored in a repository along with data and/or samples from other studies. Sample repositories are commonly called biobanks, while data repositories are commonly called databases. Researchers can then use the data and/or samples from multiple studies to learn even more about health and disease. If you agree to take part in this study, some of your genetic and health information might be placed into one or more scientific databases, but they will not share your direct identifiers (for example, name, address, date of birth). These databases are maintained by either Icahn School of Medicine at Mount Sinai, another institution, the federal government, or private companies. Any researcher who wants to do a study using data and/or samples from the repository must apply for permission. There are different ways of reviewing such requests. Researchers with an approved study may be able to see and use your data, along with that from many other people. Researchers may use your samples for genetic sequencing and other experimental testing. Researchers will always have a duty to protect your privacy and to keep your information confidential, but there are always risks associated with data and/or sample collection and sharing. They are described in more detail in the Risks section.

Researchers will use a Global Unique Identifier, a computer-generated ID, which cannot be linked back to your identity. This is so any data collected from you is linked to one unique ID, so the NDA and other large data repositories can make sure your data is secure and is not accidentally duplicated if you take part in research at multiple sites.

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:

- *Refraining from using alcohol or any substances you may occasionally use (e.g., marijuana), for at least 7 days prior to scanning,* continuing to take prescribed medications at a stable dose for the duration of your study participation, attending the screening visit, completing online surveys at home, following provided instructions for fasting before scanning visits, and attending scanning visits.
- If applicable, refraining from self-inducing vomiting or taking laxatives or diuretics during the fasting periods before both scans.
- Informing the research team as soon as possible of any changes in medical status, medications, medication doses, or pregnancy status, as they may impact your ability to participate in the fMRI study.
- Informing the research team as soon as possible if you choose to withdraw from the study.

COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

If you agree to take part in this research study, we will pay you up to $310 for your time and effort. If you complete the clinical interviews but are ruled ineligible for continued participation in the study, you will be compensated for $35 for your time. If you pass the clinical interviews and complete the first in-person visit assessments, you will be compensated $60. You will be compensated $100 for each fMRI visit. If you complete all study procedures, including both scan visits, you will receive a $50 bonus, bringing the total to $310. As mentioned above, you will also have the opportunity to earn a bonus from the decision-making tasks, which range from $0 to $15 for each task. The Mount Sinai Finance Department will prepare checks for these visits and they can be mailed to you or picked up on campus. *Checks require some time to be prepared and will be given to you once processed and available.*

If you do not have a social security number (SSN), your payments and reimbursements will be delivered via gift card and/or cash.

You will also be reimbursed for travel/transportation expenses you may incur to come to study visits. Proof of payment must be provided, including all original itemized receipts with your name or a copy of a detailed credit card statement with your name. If you drive to your study visit, you will be reimbursed at the rate of $0.58 per mile (the standard 2019 mileage rate published by the Internal Revenue Service annually), up to 75 miles, and calculated using your place of residence as the address of origination.

Participating in this study will not lead to extra costs to you.

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:

You are not expected to get any benefit from taking part in this research study. Others may not benefit either. However, possible benefits to others include the ability to potentially develop treatments for bulimia nervosa that comes from the information the investigators learn about what is different in the brains of individuals with eating disorders compared to individuals who have never had an eating disorder.

POSSIBLE RISKS AND DISCOMFORTS:

Study questions. We will be asking you many questions concerning your feelings, emotions and behaviors throughout the course of the study. Sometimes people can feel uncomfortable discussing their personal issues. You might also find some assessment tasks challenging. If for any reason you do not want to share your feelings or emotions on certain issues or have difficulty completing certain tasks, you can let our research staff know and they will stop the study. You may decline to answer any question.

Targeted advertising. If you saw our study's advertisement in your Facebook or Instagram account, or in the ads section of a Google search, the information that you provided to these online platforms (specifically, gender, age, location, and interests) may have matched your profile with our advertisement. As a result of clicking on our ad, there is a possibility that you could be shown additional advertisements related to eating disorders, given how Facebook/Instagram and Google use your behavior to target you with future ads. Facebook, Instagram (owned by Facebook), and Google provide their users with control over how they are targeted with ads and what ads they see. Therefore, when you agree to these platforms' user agreements, you consent to be targeted by various types of advertisements, including our ad. You can change your user settings in these online platforms to adjust your advertisement preferences. In order to best target the population we are recruiting for this study, the researchers conducting the study are working with a digital marketing company that created our study-specific website and our ads, and adjusts our ad targeting settings. However, note that neither the digital marketing company that works with us nor our research team has any access to your personally identifiable information during ad targeting. In addition we cannot capture any of this information when you click on our study's ad.

Fasting and standardized meal. There is a potential risk that fasting might make you feel distressed or uncomfortable. On "fasted-state" scan days, you will have fasted for a total of approximately 18 hours (since you are not eating during the scan), and on fed-state scan days, you will fast for approximately 16 hours before having the standardized meal just before the scan. During the fasting periods, you may get symptoms similar to those you get after skipping a meal, including tiredness, hunger, irritability, headaches, general weakness, or mild nausea. Past studies that asked participants to fast for 16 hours or more a day for several weeks have documented the following additional possible side effects: constipation or diarrhea, bad breath, sleep disturbances, dizziness, water retention. You will be provided with a list of potential physical symptoms during the fast In the event of minor side effects, we ask you to contact the research team, but if more severe problems occur, or if

you feel sick or uncomfortable continuing to fast, stop fasting and eat something first, then contact the research team. If you call us after business hours, our voicemail will remind you of these instructions. In addition, this voicemail will instruct you to eat something if you are unsure about whether your symptoms are mild enough to keep fasting. Study staff will speak with you at the conclusion of both scan visits if you are upset or uncomfortable. If you start to feel very upset or distressed as a result of fasting for the study, you will be asked to notify research staff immediately, and will be encouraged to stop fasting and discontinue study participation. In addition, although the standardized meal before the fed-state scan is a normal-sized meal, you may be upset if you feel that you have overeaten during this meal. A member of the staff will be present during the standardized meal, and will be available to you if you do become upset.

Loss of private information. This risk always exists, but there are procedures in place to minimize the risk. Loss of your private information could impact future insurability, employability, or reproduction plans, or have a negative impact on family relationships, and/or result in stigmatization or civil/criminal liabilities. To minimize these risks, you will be assigned a study code number so that you will not be identified by your name. This study code will be used to identify your data and other study-related activities. The information linking your personal identity to this code number and your study records will be stored in locked and encrypted research files at the Icahn School of Medicine at Mount Sinai (separately from your research records). In addition, your personal information will not appear in publications that might result from this study or be disclosed to a third party without your written permission. However, information may be given without your written permission to the Icahn School of Medicine at Mount Sinai Institutional Review Board (IRB).

If you tell a study staff member or indicate on any of your assessments that you feel like hurting or killing yourself, research staff will ask you more questions about your thoughts. Based on your responses, staff may provide you with help to get treatment. This may include again providing you with information about treatment options, encouraging you to pursue treatment, working with you to contact your doctor or mental health provider, or working with you on a plan that may include getting you to a hospital for safety. This may be upsetting, and may require that we breach your confidentiality in order to keep you safe.

MRI scan. The risks from the MRI scan are considered to be minimal. The scanner makes a loud, banging noise while it is taking “pictures.” You will be given a set of earplugs to help with the noise.

Some people may experience claustrophobia, or a feeling of anxiety. You may experience some discomfort or fatigue from lying still in a confined space during imaging. There are no known effects from exposure to magnetic fields (MRI), but the MRI scans could cause you to feel hot, and the rapid switching of the magnetic field could cause a tingling sensation in your arms and legs. If you experience such sensations, you may stop the study at any time by pressing a button that will immediately notify the research staff that you would like to exit the scanner. You will be in voice contact with the research staff at all times during the fMRI scanning. The MRI operation is automatically disabled if FDA guidelines are exceeded.

You may become dizzy or experience a metallic taste in your mouth if you move your head quickly in the magnet, so we will remind you several times to move slowly when entering and exiting the scanner.

It is possible that a metal object could accidentally fly into the magnet and cause you harm, but steps are taken to make sure no magnetic metal objects are near the MRI. If you have any metal clips or plates in your body, or a pacemaker, you should tell the investigator about it. MRI may not be appropriate under some of these conditions: A cardiac pacemaker; metal fragments in eyes, skin, body; heart valve replacement, brain clips, venous umbrella; being a sheet-metal worker or welder; aneurysm surgery, intercranial bypass, renal, aortic clips; prosthetic devices such as middle ear, eye, joint, or penile implants, joint replacements; hearing aid, neurostimulator, insulin pump; IUD; being pregnant or trying to become pregnant; shunts/stents, metal mesh/coil implants; metal plate/pin/screws/wires, or any other metal implants; permanent eyeliner or eyebrows.

Glucose finger prick. You may feel uncomfortable when we prick your finger for two drops of blood to confirm that you are in a fasted state when you arrive to your scan visits. We have a firm policy to only attempt finger pricks/blood draws a maximum of two times on one occasion. For participants in the bulimia nervosa group, 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.

Data sharing. Group Risks - Although we will not give researchers your name, we will give them basic information such as your race, ethnic group, and sex. This information helps researchers learn whether the factors that lead to health problems are the same in different groups of people. It is possible that such findings could one day help people of the same race, ethnic group, or sex as you. However, they could also be used to support harmful stereotypes or even promote discrimination.

If you are currently in treatment for your eating disorder, the fasting protocol could interfere with your ongoing treatment. That treatment team should be aware of your participation in this study. With this consent, you are asked to inform the treatment provider, but you also provide us permission to contact your treatment provider(s) to inform them that you will be taking part in this study, and that participation requires two fasting periods that range from 16-18 hours. We will provide you with two copies of written pre-scan instructions, which outline the details of these fasting periods. We request that you review these instructions with your treatment provider(s).

There might be some currently unforeseeable risks associated with this study. You will be promptly notified if any new information develops during the conduct of this research study which may cause you to change your mind about continuing to participate.

For those who can become pregnant: If you are or become pregnant, this research may hurt your baby or your pregnancy in ways that are unknown. The unknown risks might be minor or might be major (death) for the pregnancy. You should not become pregnant while in this research study. Please read the acceptable methods of birth control found under the Description of What's Involved section of this document.

OTHER 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 being in this research study has harmed you, you should contact the Lead Researcher. Their contact information is listed at the beginning of this consent form.

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. More possible reasons for removal from the study include becoming pregnant or worsening of symptoms that would interfere with participation (for example, becoming suicidal or developing an illness that requires intensive treatment).

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) 824-9545.

If there is an emergency, please call 911 or go to the emergency room.

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?
As part of this study, the research team at the hospital(s) involved in the research will collect your name, address, telephone number, birth date, e-mail address, social security number (SSN), and medical records number (MRN) for communication, scheduling, and payment purposes.

During the study, the researchers will gather information by:

- taking a medical history (includes current and past medications or therapies, illnesses, conditions or symptoms, family medical history, allergies, etc.) – doing a physical examination that generally also includes blood pressure reading, heart rate, breathing rate and temperature

- 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.

The Lead Researcher may also use and share the results of these tests and procedures with other healthcare providers at Mount Sinai who are involved in your care or treatment. 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 Mount Sinai Program for the Protection of Human Subjects is responsible for overseeing research on human participants 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.
- I*f the research team uncovers abuse, neglect, or reportable diseases, this information may be disclosed to appropriate authorities.*

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.)

- Other collaborating research center(s) and their associated research/clinical staff who are working with the investigators on this project: Columbia University, the University of California, San Diego, Trinity College Dublin, and other sites available on request.
- 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 Institute of Mental Health.
- The United States Department of Health and Human Services and the Office of Human Research Protection.

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.

Notice Concerning HIV-Related Information

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

Certificate of Confidentiality:

To further protect your privacy, the researchers have obtained a Certificate of Confidentiality from the Department of Health and Human Services. This 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 and to the use and disclosure of your protected health information. A signed and dated copy will be given to you.

_____	_____	_____	_____
Signature of subject	Printed Name of Subject	Date	Time

PERSON EXPLAINING STUDY AND OBTAINING CONSENT:

_____	_____	_____	_____
Signature of consent delegate	Printed Name of consent delegate	Date	Time