STUDY INFORMATION:

Study Title: Electrophysiologic studies of cognition in epilepsy patients

Study site(s): Icahn School of Medicine at Mount Sinai, Mount Sinai Hospital, Mount Sinai West

Principal Investigator (Lead Researcher): Ignacio Saez, PhD

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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. It is completely up to you whether or not you take part. You can also change your mind at any time and it will not affect your ability to get medical care within the Mount Sinai Health System.

The purpose of this research study is to investigate how people are able to pay attention, remember, speak, make decisions, comprehend language, feel, and think. This research study attempts to understand what brain areas are involved in attention, memory, language, decision-making as well as improve neurosurgical treatment. Another goal for this research is to understand how and why seizures develop. This study is being conducted at Mount Sinai in patients who have electrodes placed on the scalp or surgically inserted into the brain to monitor for or treat seizures.

If you choose to take part, you will be asked to participate during your stay in the Epilepsy Monitoring Unit (typically 3-7 days). In addition, you may be able to fill out questionnaires or carry out one or several computer tasks at home up to 12 months post-discharge. Computer tasks typically range from 10 min - 1 hour and filling out questionnaires typically takes 5-10 minutes. Standard plan of care will not be affected. Your information will be kept confidential, and all tasks and procedures will be explained prior to the start of the study. You will receive monetary compensation for your participation depending on the number of tasks you complete.

If you choose to take part, the main risks to you are:

1. Psychological Risks: Boredom, uncertainty, or fatigue may occur while you are performing cognitive tasks or playing the computer games. If this occurs, you can take a break, or stop playing on the computer at any time.
2. Privacy Risks: Each subject will be assigned a unique identification number, and there will be no reference to your name or any other personal identifier in any subsequent publication. All personal identifiers will be destroyed upon completion of the research and the required storage period. Data files will be stored on a secured server, which will be password-protected and access to data files will be given only to IRB approved research personnel. Video recordings contain identifying facial features and therefore cannot be fully de-identified, but every precaution will be taken to maintain confidentiality.
3. Physical Risk: If you opt to participate in the brain stimulation portion of the study, we will keep electrical simulation at levels known to be safe (i.e. at levels used during standard brain mapping in the epilepsy monitoring unit). As with clinical brain mapping that is part of your evaluation for epilepsy surgery, there is a small chance that the electrical stimulation could cause you to have brief unusual sensations, such as tingling, twitching, or disrupt speech, or even cause a seizure. These effects are temporary and typically end when the stimulation is stopped. You will be monitored during all testing and, if needed, immediately treated for a seizure should the need arise. This is very rare. There are no known side effects of electrical brain stimulation for epilepsy, and similar types of electrical stimulation are routinely done for clinical purposes to identify areas of the brain important for speech, movement, and sensation.

You will not benefit directly from taking part in this research.

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 with epilepsy and are a candidate for scalp or intracranial monitoring (electrodes implanted in the brain to look for seizures).

Your participation in this research study is expected to last until the end of your stay in the epilepsy monitoring unit at Mount Sinai and Mount Sinai West. The duration of your stay will be determined by your doctors, but typically ranges between 3-7 days. In some cases, you will also be asked to perform computer tasks before or after hospital admission as part of the same study for up to 12 months after you're discharged.

There are 200 people expected to take part in this research study at Mount Sinai.

Funds for conducting this research study are provided by Icahn School of Medicine at Mount Sinai. Other funding sources include the National Institutes of Health, Columbia University, and University of California, Davis.

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:

Collection of your EEG and radiology studies: As part of your medical care in the Epilepsy Monitoring Unit at Mount Sinai, continuous brainwave activity (EEG) is collected and analyzed to tell where and when your seizures begin. We are asking your permission to record and store these data, along with radiology images like MRI and CT scans, after all information that could identify you is deleted. Nothing that could identify you will leave Mount Sinai. All the information collected will be confidential and kept encrypted, and password protected, in accordance with Mount Sinai policy.

Cognitive testing: During your stay in the epilepsy monitoring unit, members of our research team will ask you to perform different perception, memory, and cognitive tasks. These will include learning and remembering different types of words, sounds, or pictures, playing simple computer games, and answering questions about different scenarios. These tasks are designed to test different types of thinking and memory. A testing session typically lasts between 10 and 20 minutes but could be longer. Sessions will be offered to you on most days of your hospitalization. You may take breaks and decide to stop or continue at any time. You may be asked to play some of these games remotely, through a computer browser, before your admission or after your discharge from the EMU. If you are required to complete some of the tasks from home (before or after admission) but do not have a computer available to you, the research team will loan you one that you will be expected to return at the end of the study.

Audio recording: For some research tasks, we may ask you to speak words or sentences into a microphone. Your voice will be recorded, and the audio recordings will be kept with your other data. These will not be used outside of research purposes.

Video recording: Video will be recorded during your stay, either as part of the standard of care or an additional video for research purposes. We will analyze these videos as part of the research. The videos will not be used outside of clinical or research purposes.

Microelectrodes: If you decide to participate in the optional micro-wire electrodes sub-study, your surgeon will place depth electrodes that contain fine wires (in addition to the usual contacts) and can

record electrical activity from individual brain cells. As part of your standard treatment, multiple (typically ~7-15) electrodes (wires) will be implanted during surgery. At Mount Sinai, we normally use electrodes from one of several companies: Integra, Ad-Tech, PMT. This study will replace 1 or several of these with a different type of electrode, called a macro-micro electrode. These macro-micro electrodes are similar to standard epilepsy depth electrodes (FDA approved), that also have microelectrodes at the tip. We do not currently use these microelectrodes as standard of care here at Mount Sinai. Both types provide the same information, and have the same risks associated with insertion, but the macro-micro electrodes provide additional data in the form of single-unit recordings of brain activity. These single-unit recordings can record the electrical activity from individual brain cells; however, we do not have enough information to use this extra data to treat patients and are still in the experimental stage. These macro-micro electrodes will only be placed in research subjects and will comprise 1 or several electrodes (typically 2-4) out of a standard electrode insertion. Macro-micro electrodes are almost identical to the currently used electrodes, and will provide the same information to your doctor, with the only difference being they have tiny microelectrodes that come out of the tip.

Brain stimulation: If you decide to participate in the optional brain stimulation, we will carry out brain stimulation in addition to that required for your standard epilepsy evaluation. Stimulating small areas of the brain with small electrical pulses is a normal part of the evaluation for epilepsy surgery in many, but not all patients, depending upon where their seizures are coming from. Stimulation is performed according to guidelines known to be safe. As part of our research, you will undergo brain stimulation studies in addition to those that may be required for your standard epilepsy evaluation. In this case, during some of the cognitive and memory tasks you will be performing, small pulses of electricity will be sent to electrodes in part of your brain, to test whether your task performance is better or worse than without stimulation. In some cases, we will stimulate brain regions which would not otherwise be tested as part of your usual seizure evaluation. The stimulation does not cause pain. Information obtained during these studies may be used to help guide surgery.

You may choose to participate in one, both, or neither components of the sub-study, in addition to the primary research described above.

Optional sub-study using microwire electrodes and/or brain-stimulation to study cognition:

1. Microelectrodes: Participating in this study would allow your surgeon to place depth electrodes that contain fine wires (in addition to the usual contacts) and can record electrical activity from individual brain cells; in contrast, ordinary EEG electrodes record the electrical activity from thousands to millions of cells. These microelectrodes record brain activity that is not picked up by standard electrodes, are FDA approved and do not require extra surgery. This electrode will be removed at the end of your iEEG monitoring along with all the other EEG electrodes.

Would you like to participate in the microwire electrode sub-study?

Yes_____ No_____

2. Brain Stimulation: Stimulating small areas of the brain with small electrical pulses is a normal part of the evaluation for epilepsy surgery in many, but not all patients, depending on where their seizures come from. Stimulation is performed according to guidelines known to be safe. We are asking you to undergo brain stimulation in addition to that which may be required for your standard epilepsy evaluation. Very small pulses of electricity will be sent to electrodes in parts of your brain while you perform cognitive tasks. Electrical responses to this stimulation will be recorded, along with behavioral performance during stimulation.

Would you like to participate in the brain stimulation sub-study?

Yes_____ No_____

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), and study data, 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. 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.

(1) Will you allow the researchers to store your data 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 may be used in future research studies.

(2) Do you give the researchers permission to keep the data, 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_____

(3) Do you give the researchers permission to keep the data 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_____

(3.1) 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.

(4) 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_____

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.

Whether or not you have allowed us to share your data and/or samples with National Institute of Mental Health Data Archive, the researchers at Mount Sinai will keep data and/or samples collected about you during this research study to use in future research studies consistent with the wishes you expressed above.

YOUR RESPONSIBILITIES IF YOU TAKE PART IN THIS RESEARCH:

If you decide to take part in this research study, you will be responsible for completing the computer games, either during your hospital stay, during research visits (which can be scheduled to coincide with your normal care visits), or at home.

COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

Being in this study will not cost you anything extra. You or your health plan will be billed for the costs of routine medical care you receive during the study. These costs may include operating room fees,

pharmacy charges, treatments, hospitalization, scans, etc. You will be expected to pay for the usual deductibles and co-payments, and for any routine care that is not covered. Only the costs of research or experimental procedures will be paid by the study. The study will provide:

- Macro-micro electrodes
- Study specific cognitive testing
- Equipment for remote testing (i.e. laptop or tablet), if necessary

If you agree to take part in this research study, you will be compensated for your time and effort. You will receive a minimum of $10 for each task you successfully complete. In some cases, there will be an additional payment that will vary depending on how well you do on the task. Payment will be provided at the end of the study in the form of a gift card.

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 using this research to help us develop new treatments for people with seizures or other disorders.

POSSIBLE RISKS AND DISCOMFORTS:

Psychological Risks: Boredom, uncertainty, or fatigue may occur while you are performing the cognitive tasks or playing computer games. If this occurs, you can take a break, or stop playing on the computer at any time.

Physical Risks: If you opt in for the electrical stimulation portion of the study, electrical stimulation will be kept at levels known to be safe (i.e. at levels used during standard brain mapping in the epilepsy monitoring unit). As with clinical brain mapping that is part of your evaluation for epilepsy surgery, there is a small chance that the electrical stimulation could cause you to have brief unusual sensations, such as tingling, twitching, or disrupt speech, or even cause a seizure. These effects are temporary and typically end when the stimulation is stopped. You will be monitored during all testing and, if needed, immediately treated for a seizure should the need arise. This is very rare. There are no known side effects of electrical brain stimulation for epilepsy, and similar types of electrical stimulation is routinely done for clinical purposes to identify areas of the brain important for speech, movement, and sensation. If you opt-in to the microelectrode portion of the study, there is no additional risk of intracerebral

hemorrhage or tissue injury compared with the standard clinical macro electrodes. There are no reports of any ill effects from these FDA-approved electrodes for clinical EEG recording.

Risk of loss of private information: This risk always exists, but there are procedures in place to minimize the risk. Each subject will be assigned a unique identification number and there will be no reference to your name or any other personal identifier in any subsequent publication. All personal identifiers will be destroyed upon completion of the research and the required storage period. Data files will be stored on a secured server, which will be password-protected and access to data files will be given only to IRB approved research personnel.

Group Risks: Although your name will not be given to researchers, basic information such as your race, ethnic group, and sex may be shared. 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 discrimination.

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 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.

If you are injured or made sick from taking part in this study, you will get medical care. The group funding this research study will pay you for any reasonable and necessary medical expenses to diagnose and treat research-related injury or illness. 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 stop being in the research study, the research team may not remove information they have already placed in the study database, and may continue to use that data as part of this study. The research team may ask you whether they can continue to collect information from your medical record.

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 212-523-8829.

If there is an emergency, contact the PI at 212-523-8829 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. For non-emergency issues you can call the Mount Sinai Hospital Operator (212) 523-4000, tell the Operator you are participating in a research study, and you wish to talk to the Neurosurgery Resident on call.

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 research project, the research team at the hospital(s) involved in the research will collect your name, contact information, and date of birth. The researchers will also get the following information from your Mount Sinai medical record: electronic medical record number, medical history, co-morbidities, and brain imaging.

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.).
- Completing the tests, procedures, questionnaires, and interviews explained in the description section of this consent.
- Analyzing EEG recordings of your brain.
- Reviewing mental health records and psychotherapy notes.

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.)

- 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: including UC Berkeley, UC Davis, UC Irvine, Columbia University, NY University and others sites available on request.
- An Independent Safety Monitor that will monitor the study on an ongoing basis for safety.
- 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 not be able to access your medical records. This is done to prevent the knowledge of study results from affecting the reliability of the study. Your information will be available should an emergency arise that would require your treating physician to know this information to best treat you. You will have access to your medical record and any study information that is part of that record when the study is over or earlier, if possible. 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.

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 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

PERSON EXPLAINING STUDY AND OBTAINING CONSENT:

Signature of Consent Delegate	Printed Name of Consent Delegate	Date	Time

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