Dissecting Oligogenic Biomarkers in Ashkenazi Jews With Parkinson's Disease

PI: Rachel Saunders-Pullman
NCT04668898
Document Date: 2/18/2025

STUDY INFORMATION:

Study Title: Dissecting oligogenic biomarkers in Parkinson Disease

Study site(s): Icahn School of Medicine at Mount Sinai, Mount Sinai Beth Israel

Principal Investigator (Head Researcher): Rachel Saunders-Pullman, MD, MPH, MS

Physical Address: Mount Sinai Beth Israel, 10 Union Square East, Suite 5K, New York, NY 10003

Mailing Address*:* Mount Sinai Beth Israel, 10 Union Square East, Suite 5K, New York, NY 10003

Phone: 888-228-1688

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.

The purpose of this research study is to better understand the genetic causes of Parkinson's disease (PD). Understanding the genetic basis of PD is key to stopping and preventing it in the future. Information about you will be used for the purpose of determining how PD is passed from one generation to the next, to identify genes that are responsible for PD, and to learn how these genes contribute to both motor and/or non-motor (e.g. cognitive and psychiatric) symptoms in PD.

If you choose to take part, you will be asked to:

- Come to Mount Sinai Beth Israel once a year for a 3-4 hour study visit.
- Your participation will last for 1-5 years depending on when you join the study.
- The study visit will include giving information about your medical and family history, a neurological exam and blood and urine sampling.
- There are other parts of the study that are optional but extremely helpful to this effort. They include having your exam videotaped in case we need to re-examine it later on, to have a lumbar puncture, a routine procedure for obtaining a small sample of the fluid that bathes your brain and spine, and to participate in a sleep study.
- You may be asked to complete additional questionnaires or surveys on the phone. This could take an additional 30-60 minutes.
- You may be asked to donate an additional blood sample at a separate visit. This can be coordinated at a time when you are here for your clinical visit if your doctor is at MSBI.
- There are no costs to participate in this study
- You will not be paid for participating
- No medication will be administered in this study

- Samples and data will be stripped of personal identifiers, labeled with a code, and sent to data and biorepositories of the National Institutes of Health, as well as to the study research laboratory at Massachusetts General Hospital. It is possible that Whole Genome Sequencing will be done on your sample.
- The study is funded by the National Institutes of Health (NIH)

If you choose to take part, the main risks to you are those associated with lumbar puncture (LP). Some people have a headache for a day or two following the LP that is generally easily controlled with medication such as Tylenol. Other unlikely risks are minimized by the many precautions we take.

You will not benefit directly from taking part in this research. However, you may benefit by the knowledge that is gained about PD.

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 because you have Parkinson's disease, or a family member or friend has Parkinson's disease, or you are a healthy adult with no family history of Parkinson's Disease.

Your participation in this research study is expected to last up to 5 years. Your study visit at Mount Sinai Beth Israel is expected to take 3-4 hours. If you are asked to complete additional questionnaires or surveys on the phone this could take an additional 30-60 minutes. In addition, you will be re-contacted in the future to provide follow-up information about your health and family history, and you may also be asked whether you would be willing to invite some of your relatives to participate in the study.

There are 190 people expected to take part in this research study at Mount Sinai Beth Israel.

Funds for conducting this research study are provided by The National Institutes of Health 1U01NS094148.

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'S INVOLVED:

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

You will have an annual study visit at Mount Sinai Beth Israel. The visit will last 3-4 hours, and will include some or all of the following activities, depending on your responses below. In addition, you may be asked to have a second blood draw at least one month after your study visit. If you come to MSBI for a regularly scheduled appointment with your doctor this can usually be done on the same day.

A) Questionnaires: You will be asked questions about your medical history and your family history. This will include your filling out questionnaires, completing a memory test, and telephone interviews. The estimated time required will generally be about 30 minutes, but in some cases will be up to 4 hours.

B) Examination: You will receive a brief neurological examination (approximately 10-15 minutes). You will be asked to have a follow-up exam at a later date.

C) Videotape: Part of your examination will be videotaped. The purpose of the videotape recording is for scientific review by other physicians and research staff. Please indicate in the check boxes below whether or not you agree to be videotaped.

D) Samples:

Blood: You will be asked to submit approximately 3-4 tablespoons of blood. This blood will be used to try to find genes associated with Parkinson's disease and to better understand known genes for Parkinson's disease. DNA from these samples will also be used anonymously to determine gene frequencies in different populations. The blood will be obtained by venipuncture, requiring the insertion of a needle into a vein in the forearm.

Urine sample: You will be asked to donate a small amount of urine. Your urine will be analyzed to determine whether there are certain chemicals that are unique to individuals with PD or to individuals at risk for PD.

Saliva sample: If you are unable to give blood or are sending samples through the mail, you will be asked to donate a sample containing loose cells from the inside of your mouth from which a small amount of DNA can be extracted. Such a sample is usually obtained by spitting saliva into plastic collection tube and less often by rubbing a cotton swab on the inside of your cheek.

E) Lumbar puncture: You will be asked whether you would be willing to have a lumbar puncture (LP). This is a standard procedure by which we can obtain a sample of cerebrospinal fluid. We do this by first giving an injection of local anesthetic in the lower back and then inserting a special needle into the fluid pocket below the spine to draw out about 1 and a half tablespoons of fluid. This takes about 15 minutes. Please indicate in the check boxes below whether or not you agree to lumbar puncture.

G) Information on brain donation (optional): You may be asked whether you would be willing to receive information about brain donation.

H) Sleep sub-study (optional): You may be asked whether you would be willing to participate in a sleep study. The goal of this study is to better understand sleep disruption in individuals with

Parkinson disease and to evaluate whether light therapy improves sleep. Participants in this sub-study will wear a study watch (called Actiwatch) that measures movement during sleep. A subset of participants will also have a 1 month light therapy trial in which the participant can choose to do any of the following: sit outside for 2 hours every morning, sit inside in front of a light box for 2 hours every morning, or wear goggles fitted with a light for 2 hours every morning.

The videotape, lumbar puncture, sleep study, and information on brain donation are optional parts of the study. The history, questionnaires, exam and blood/saliva and urine samples are necessary for inclusion in the study. Please indicate below whether you are willing to have the video, lumbar puncture and information on brain donation.

Please initial your preference:

A. Videotape:

If you agree to be videotaped, your videotape will be kept indefinitely for scientific review by the Mount Sinai study team. It will not be shared outside the study team unless you give permission to do so on this form (see "use of your data and/or specimens" section).

❑ Yes, I agree to be videotaped. (Please initial)_____
❑ No, I do not agree to be videotaped. (Please initial)_____

B. Video call:

❑ Yes, I agree to a pre-scheduled **HIPAA compliant video call**. (Please initial)_____
❑ No, I do not agree to a HIPAA compliant video call. (Please initial)_____

C. Lumbar puncture:

❑ Yes, I agree to give a lumbar puncture. (Please initial)_____
❑ No, I do not agree to give a lumbar puncture. (Please initial)_____

D. Sleep study:

❑ Yes, I agree to wear the study watch. (Please initial)_____
❑ No, I do not agree to wear the study watch. (Please initial)_____
❑ Yes, I agree to the light therapy trial. (Please initial)_____
❑ No, I do not agree to the light therapy trial. (Please initial)_____

E. Information about brain donation:

❑ Yes, I agree to receive information about brain donation. (Please initial)_____
❑ No, I do not agree to receive information about brain donation. (Please initial)___

If you agreed to receive information and would like to receive a call from the Mount Sinai Brain Bank team to learn more please initial your preference below:

❑ Yes, I would like a member of the brain bank team to contact me.
(Please initial)_____

❑ No, I would not like a member of the brain bank team to contact me. .
(Please initial)_____

There will be no specific genetic results available while you are participating in this study except under extraordinary circumstances where research findings would affect your health or the health of a family member. However, we will notify you if this study leads to the identification of new genes and if clinical testing for these genes becomes available.

If you desire genetic counseling or diagnostic evaluation, you may ask the investigators for a referral, or you may make a separate appointment with one of the investigators in this study for this purpose.

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 SPECIMENS:

This study is being conducted in collaboration with the NIH Parkinson's Disease Biomarkers Program. The information and samples collected for this study will be shared with study collaborators and will also be shared with collaborators at other institutions. In addition, some of the laboratory data generated by this study will be added to web-based databases that are accessed by outside researchers and are a key tool for today's molecular genetics research efforts. If your samples and information are shared, your identity will remain unknown to these researchers.

A part of the study involves sharing some of the information collected about you and your health condition as well as your biological samples with an international research group including The National Institute of Neurological Disorders and Stroke (NINDS) Parkinson's Disease Biomarkers Program Data Management Resource (PDBP DMR),and The NIH bio-repository at Indiana University. These data and sample repositories are being built in order to create large sets of data and samples to be shared with scientists with the goal of advancing research in Parkinson Disease. The information we collect from you will be added to other data from individuals from around the world. Your information will be stripped of identifiable items and a confidential ID will be added. This ID, called a Global Unique Identifier (GUID), is computer-generated and cannot be linked back to your identity. Using the GUID also ensures that any data collected from you is linked to one unique ID so that it is not accidentally duplicated if you take part in research at multiple sites.

The GUID is generated by entering 9 pieces of information into a secure website. These are first name, last name, middle name or mother's maiden name, gender, day of birth, month of birth, year of birth, city of birth, country of birth. The website generates an ID which does not include any personal information, and the information that was entered is automatically deleted.

Your study data and samples (blood, urine, saliva, spinal fluid, cell line) may be used for future research purposes unrelated to the study for which it was collected. If so, all information will be coded to maintain your confidentiality. Information generated by this research can only be linked to you by way of the above-mentioned code, which is controlled by the Lead Researcher, Dr. Rachel Saunders-Pullman.

A cell line may be developed from your sample. This means that an inexhaustible supply of your DNA will be available for genetic research for many years. DNA is the material from which genes are made. This research may also include deciphering your DNA or genetic code using a process called whole genome sequencing.

As stated above, your videotape will be kept indefinitely by the study team to enable scientific review of your symptoms in the future. It will not be shared with others unless you give permission to do so below. It will not be published without your specific separate consent to do so. If you change your mind about allowing us to keep your videotape in the future, you should contact the principal investigator or her team, so that stored files, including backups, will be permanently deleted.

Please state your preference below:

Use of videotape within Mount Sinai:
❑ Yes, I agree to have my videotape used for training purposes within the Mount Sinai System. I understand that if my videotape is used for this purpose, my videotape will not be altered, and my face will be visible. (Please initial)_____
❑ No, I do not agree to have my videotape used for training purposes within the Mount Sinai System. (Please initial)_____

Use of videotape outside of Mount Sinai:
❑ Yes, I agree to have my videotape used for training and scientific conferences outside the Mount Sinai System. I understand that if my videotape is used for this purpose, the researchers will edit the videotape to obscure or limit views of my face and identifiable features that are not relevant to teaching, but that this may not always be possible. (Please initial)_____

❑ No, I do not agree to have my videotape used for training purposes outside the Mount Sinai System. (Please initial)_____

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. If in the future you wish to withdraw your data and/or samples from the repository you may ask the investigator to do so. They are described in more detail in the Risks section.

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: answering questions about your medical and family history, giving a urine and blood or saliva sample, having a neurological exam, and completing any other parts of the study that you agreed to.

COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

You will not be paid for taking part in this study. Being in this study will not cost you anything extra. If you are examined at Mount Sinai Beth Israel we will pay for your parking expenses, with a maximum reimbursement of $50. If you seek a referral to one of the physicians or genetic counselors in this study for evaluation or genetic counseling, you will be responsible for the charges.

This study is being done by the researchers for academic purposes only, and no financial gains are anticipated. However, it is possible that products may someday be developed with the help of your data and/or samples, and there are no plans to share any profits from such products with you.

Reimbursement for research related expenses:

After you have completed a visit you will need to submit all study related receipts to the study coordinator. *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.

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 you or others include helping individuals with PD or helping your family in the future by providing important information about the genetics of movement disorders.

POSSIBLE RISKS AND DISCOMFORTS:

Psychological - You may experience anxiety as a result of your participation in this study. If you desire, you may ask the investigator for a referral or make an appointment with one of the investigators to address this.

Blood - 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.

Saliva - There is no anticipated risk to this procedure.

Lumbar puncture - The lumbar puncture may cause pain at the site where the needle goes in and the spinal fluid is taken. There is a small risk of infection or bleeding. After the lumbar puncture, you may get a headache. To minimize the risk of a headache, the doctor may prescribe bed rest for 30 minutes after the procedure. If a headache occurs, it is usually mild and can be controlled by bed rest, drinking lots of fluids, and a pain pill, such as Tylenol. Rarely, the headache is severe and may require additional treatment with a "blood patch." In this procedure, a small amount of your own blood is injected into the lumbar puncture site. This procedure is generally effective in stopping the headache. If you agree to lumbar puncture a member of the study team will contact you the day after the procedure to see if you experienced a headache.

You must inform your study doctor if you are allergic to local anesthesia (lidocaine) or to Betadine. Although very rare, it is possible to have an allergic reaction to the local anesthetic used for the lumbar puncture. Signs of an allergic reaction include swelling and/or a rash on your skin where the anesthetic was injected. To minimize any possible risk, the lumbar puncture will be done by a staff person who is specifically trained in the procedure.

Actiwatch - There is no anticipated risk to using the Actiwatch.

Light therapy - There is no anticipated risk to this procedure.

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.

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

Your name and other information that could directly identify you (such as an address, date of birth, or social security number) will never be placed into a database. However, because your genetic information is unique to you, there is a small chance that someone could trace it back to you. The risk of this happening is very small, but may grow in the future. Since the database contains genetic information, a break in security may also pose a potential risk to blood relatives as well as yourself. For example, it could be used to make it harder for you (or a relative) to get or keep a job or insurance. If your private information was misused, it is possible you would experience other harms, such as stress, anxiety, stigmatization, or embarrassment from revealing information about your family relationships, ethnic heritage, or health conditions.

Insurance Risks – There is a Federal law called the Genetic Information Nondiscrimination Act (GINA). This law makes it illegal for health insurance companies, group health plans, and most employers of over 15 people to discriminate against you based on your genetic information. However, it does not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

OTHER OPTIONS TO CONSIDER:

You may decide not to take part in this research study. You may also agree to only part of the study; for example you may decline donating a blood sample and/or being videotaped. 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 study, you will get medical care. Generally, this care will be billed to you or your insurance in the ordinary manner and you will be responsible for all treatment costs not covered by your insurance, including deductibles, co-payments and coinsurance. This does not prevent you from seeking payment for injury related to malpractice or negligence. Contact the investigator 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 it may not be possible to remove already collected data and samples from databases and analyses, as they may have already been used in a publication or shared anonymously with study collaborators.

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.

You may be asked whether the investigator can collect information from your routine medical care. If you agree, this data will be handled the same as research data.

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 888-228-1688 (toll free), or 212-844-6053.

If there is an emergency, please 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 protected health information is collected and used in this 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, address, telephone/fax numbers, e-mail, date of birth, other dates if applicable (eg. date of medical visit/procedure, date of death), social security number (for reimbursement/payment), medical records number, photographic images.

The researchers will also get information from your medical record, particularly records from your neurologist(s) or neurosurgeon(s) if applicable.

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.
- reviewing HIV-related information, which includes any information indicating that you have had an HIV related test, or have HIV infection, HIV related illness or AIDS, or any information which could indicate that you have been potentially exposed to HIV
- reviewing genetic tests

The following additional information applies as follows:

- Study participants do not get any genetic results from this study. However, participants will be notified if new tests for movement disorder genes become clinically available.

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 to treat you in collaboration with others in the Mount Sinai Health System.

The research team and other authorized members of The Mount Sinai Health System ("Mount Sinai") workforce may use and share your information to ensure that the research meets legal, institutional or accreditation requirements. For example, the School's Program for the Protection of Human Subjects is responsible for overseeing research on human subjects, and may need to see your information. If you receive any payments for taking part in this study, the Mount Sinai Finance Department may need your name, address, social security number, payment amount, and related information for tax reporting purposes. I*f the research team uncovers abuse, neglect, or reportable diseases, this information may be disclosed to appropriate authorities.*

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.
- 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 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.
- 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).

The following individuals may receive your coded data and/or samples, but not data that identifies you.

- Other collaborating research center(s) and their associated research/clinical staff who are working with the researchers on this project:

Laurie Ozelius, PhD at Massachusetts General Hospital, Ilir Agalliu, MD, PhD and Dr. Cuiling Wang, MD, Albert Einstein College of Medicine, Marta San Luciano,MD, UCSF, Tatiana Faroud, MD, Indiana University, Pramod Mistry, MD, Yale University, Roy Alcalay, MD, Columbia University and other sites available on request.

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 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	Date	Time

_____
Printed Name of Participant

PERSON EXPLAINING STUDY AND OBTAINING CONSENT:

_____	_____	_____
Signature of Consent Delegate	Date	Time

_____
Printed Name of Consent Delegate

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