Study ID #: 120-97 **Form Version Date: 6/18/2020**

TITLE OF RESEARCH STUDY:

Title: **Genetics of Movement Disorders- ADULT**

PRINCIPAL INVESTIGATOR (HEAD RESEARCHER) NAME AND CONTACT INFORMATION:

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WHAT IS A RESEARCH STUDY?

A research study is when scientists try to answer a question about something that we don't know enough about. Participating may not help you or others.

People volunteer to be in a research study. The decision about whether or not to take part is totally up to you. You can also agree to take part now and later change your mind. Whatever you decide is okay. It will not affect your ability to get medical care within the Mount Sinai Health System.

Someone will explain this research study to you. Feel free to ask all the questions you want before you decide. Any new information that develops during this research study which might make you change your mind about participating will be given to you promptly.

Basic information about this study will appear on the website http://www.ClinicalTrials.gov. There are a few reasons for this: the National Institutes of Health (NIH) encourages all researchers to post their research; some medical journals only accept articles if the research was posted on the website; and, for research studies the U.S. Food and Drug Administration (FDA) calls "applicable clinical trials" 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.

PURPOSE OF THIS RESEARCH STUDY:

The purpose of this study is to better understand the genetic basis of movement disorders, such as dystonia, tremor and Parkinson's disease. Information about your medical and family history will be obtained, as well as places of residence, occupations, mood, mental status and activity level. Your medical records may also be examined. You may also be examined and asked to donate a sample of blood (see below) which will be used for analysis of your DNA. DNA is the hereditary material present in all your cells. Information about you, including information we gather from analysis of your DNA,

will be used for the purpose of determining how the disorder may be inherited, to help localize and identify genes that may be responsible for the condition, and to learn about the different ways these genes may be expressed to produce motor and/or non-motor (e.g. cognitive and psychiatric) symptoms. The information will be used for research purposes only, and no information will be disclosed for other purposes. The information collected for the study will not be made a part of your medical records.

You may qualify to take part in this research study because you have a movement disorder, or a family member or friend has a movement disorder.

Funds for conducting this research are provided by The National Institute of Health, The Michael J. Fox Foundation, The Aronov Foundation, The Bigglesworth Family Foundation, The Dystonia Medical Research Foundation, The Bachmann Strauss Foundation, The Empire Clinical Investigator Program, Carol and Joseph Reich, Alan Mirken, Edwin Levy.

LENGTH OF TIME AND NUMBER OF PEOPLE EXPECTED TO PARTICIPATE

Your study visit at Mount Sinai Beth Israel is expected to take between 30 and 45 minutes. If you are asked to complete additional questionnaires or surveys on the phone this could take an additional 30-45 minutes. In addition, you may be re-contacted in the future to provide follow-up information about your health or family history, and you may also be asked whether you would be willing to invite some of your relatives to participate in the study.

So far we have enrolled approximately 6000 people in this study and anticipate that we will enroll 150 to 300 more over the next 5 years.

DESCRIPTION OF WHAT'S INVOLVED:

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

A) Questionnaires: You will be asked questions about your medical history and your family history. This may include filling out questionnaires and telephone or pre-scheduled video interviews. The estimated time required will vary from 30-90 minutes.

B) Exam: You will receive a brief (approximately 10-15 minute) neurological examination.

C) Videotape (optional): Part of your examination will be videotaped. This may be done in person or through a HIPAA approved video platform. The purpose of the videotape recording is for scientific review by other physicians and research staff.

D) Blood sample: You may be asked to submit approximately 2-3 tablespoons of blood. This blood will be used to try to find a gene associated with the movement disorder being studied and to study the function of movement disorder genes. DNA from these samples may also be used anonymously to determine gene frequencies in different populations. You will not share in any financial benefits of these uses and findings. The blood will be obtained by venipuncture, requiring the insertion of a needle into a vein in the forearm. This may be associated with transient sudden pain which will then disappear and may be followed by a black and blue mark. Rarely a second blood sample may be requested. In some cases, you may 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 obtained either by rubbing a cotton swab on the inside of your cheek or by spitting into a plastic tube. Finally, it is unlikely, but possible that we will ask you about donating a tiny skin sample via a procedure in which a doctor will use a specialized skin punch (biopsy) to obtain the sample. It is not necessary to agree to this in order to participate in the rest of the study.

E) Second blood sample (optional): You may be asked whether you are willing to come back for a second blood draw (approximately 2-3 tablespoons). Blood from a second draw would also be used to study movement disorder genes, but will be drawn in different tubes and analyzed somewhat differently that the first set of tubes.

F) Ultrasound (optional): You may be asked whether you would be willing to have a test called transcranial ultrasound. This is a painless, risk free procedure which will take about 15 minutes. A clear gel is applied to an ultrasound transducer to help conduct sound waves and then placed at your temple. A machine records the signal frequencies and produces a graph that the physician will analyze.

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

H) Phone interview (optional): You may be asked to do a 1 hour phone interview which involves answering multiple choice type questions about mood and mental health.

I) Phone or video interview (optional): You may be asked to do a 45 to 75 minute phone or video interview which involved answering multiple choice type questions about your experience during the COVID-19 pandemic.

J) Lumbar puncture (optional): You may 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 using a syringe to draw out about 2 tablespoons of fluid. The needle used in this procedure is smaller in diameter than the conventional LP needle and reportedly causes even fewer complications.

The examination, videotaping and blood drawing usually occur in one visit and will take place at the Phillips Ambulatory Care Center of Mount Sinai Beth Israel, or in your home. In addition, parts of the visit, may be conducted by pre-scheduled HIPAA compliant video call. The study visit will be coordinated and conducted by a study coordinator and/or a study physician.

The videotape, video call, ultrasound, additional blood sample, skin punch, phone interview, and lumbar puncture are optional parts of the study. The history, exam and blood/saliva sample are necessary for inclusion in the study. Please indicate below whether you are willing to have the video, ultrasound, skin punch, lumbar puncture, phone interview. Please also indicate whether you would like to learn about the possibility of brain donation for research.

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

B. ❑ 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. ❑ Yes, I agree to the **ultrasound**. (Please initial)_____
❑ No, I do not agree to the ultrasound. (Please initial)_____

D. *If you have been asked to give an additional blood sample please initial your preference below:*

❑ Yes, I agree to the additional blood sample. (Please initial)_____
❑ No, I do not agree to the additional blood sample. (Please initial)_____

E. If you have been asked to give a skin sample please initial your preference below:

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

F. If you have been asked to have a lumbar puncture please initial your preference below:

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

G. If you have been asked if you would be interested in receiving information about brain donation please initial your preference below:

❑ 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)_____

H. *If you have been asked to complete a phone interview about mood and mental health please initial your preference below:*

❑ Yes, I agree to be called for this interview. (Please initial)_____
❑ No, I do not agree to be called for this interview. (Please initial)_____

I. *If you have been asked to complete a phone interview about COVID-19 please initial your preference below:*

❑ Yes, I agree to be called for this interview. (Please initial)_____
❑ No, I do not agree to be called for this interview. (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.

Uses of Samples and Information: 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. The researchers will share samples and information with collaborators at other institutions. If so, your identity will remain unknown to these researchers, with the following exception:

You may be eligible in the future to participate in one of the following optional studies: a separate neuroimaging study with Dr. David Eidelberg at Northwell Health (previously North Shore University Hospital) and/or Dr. Kenneth Marek at The Institute for Neurodegenerative Diseases (IND), a study of non-motor learning with Dr. David Arkadir of Columbia University, or a study of eye movement with Dr. Janet Rucker at New York University. If you enroll in these studies, Drs. Eidelberg, Marek,

Arkadir, and Rucker will request access to and use of your clinical and laboratory information that is obtained in this research study. We will only allow access to this information if you permit us to do so in this form.

Please initial below on the appropriate line below to indicate if you will allow the sharing of your clinical and laboratory information:

❑ Yes, you may share my clinical and laboratory information with Drs. Eidelberg, Marek, Arkadir, and Rucker if I am enrolled in their studies. (Please initial)_____

❑ No, you may not share my clinical and laboratory information with Drs. Eidelberg, Marek, Arkadir, and Rucker if I am enrolled in their studies. (Please initial)_____

If you have or will have deep brain stimulation surgery (DBS) we would like your permission to share your clinical, MRI, and laboratory information with Dr. Jill Ostrem at UCSF and Dr. David Vaillancourt at the University of Florida with whom we are studying the relationship between genes and response to DBS. We will only allow access to this information if you permit us to do so in this form. If you agree, your information will be coded to maintain your confidentiality.

Please initial below on the appropriate line below to indicate if you will allow the sharing of your coded clinical, MRI and laboratory information:

❑ Yes, you may share my coded clinical, MRI and laboratory information with Drs. Ostrem and Vaillancourt. (Please initial)_____

❑ No, you may not share my coded clinical, MRI and laboratory information with Drs. Ostrem and Vaillnacourt. (Please initial)_____

In order to do more powerful research, it is helpful for researchers to share information they get from studying human samples. They do this by putting it into one or more scientific databases, where it is stored along with information from other studies. Researchers can then study the combined information 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. There are many different kinds of scientific databases; some are maintained by institutions, some are maintained by the federal government, and some are maintained by private companies. For example, the National Institutes of Health (an agency of the federal government) maintains a database called "dbGaP." A researcher who wants to study the information must apply to the database. Different databases may have different ways of reviewing such requests. Researchers with an approved study may be able to see and use your information, along with that from many other people. Your name and other information that could directly identify you (such as address or social security number) will never

be placed into a scientific 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. Researchers will always have a duty to protect your privacy and to keep your information confidential.

Your sample or cell line may be used for 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 principal investigator, Dr. Susan Bressman.

CONSENT TO PARTICIPATE IN FUTURE RESEARCH

Is it okay to contact you in the future to see if you are interested in participating in more research that may or may not be related to this study?

Yes ☐ **No** ☐ **DATE and INITIAL**_____

YOUR RESPONSIBILITIES IF YOU TAKE PART IN THIS RESEARCH:

If you decide to take part in this research study you will be responsible for answering questions about your medical and family history, giving a blood or saliva sample, having a neurological exam when possible, 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 participating in this research study. Being in this research study will not lead to extra costs to you. If you are examined at Beth Israel we will pay for your parking expenses, with a maximum reimbursement of $40. If you have your blood drawn for this research study outside Beth Israel we will pay for your blood draw up to a maximum of $50. If you travel to New Haven or Long Island for neuroimaging, you will be reimbursed the cost of your travel up to $100. You will need to provide us with your receipts. 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, the use of your samples may result in new products, tests, or discoveries. You will not receive any financial benefit should this occur.

POSSIBLE BENEFITS:

You may or may not benefit personally from participating in this study. However, benefits to you may include helping future patients or your family by providing important information about the genetics of movement disorders.

REASONABLY FORESEEABLE 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 sample: Persons submitting blood samples may experience transient pain and there may be a black and blue mark at the site at which blood is drawn.

Skin punch: Persons having a skin punch may experience brief pain at the site at which the local anesthetic is injected and may be left with a tiny scar smaller than the tip of a pen at the site of the punch. The punch is usually obtained from the inside of the forearm.
Lumbar Puncture: Persons having lumbar puncture may experience 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 will use a small needle and may prescribe bed rest for one or more hours 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.

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.

Loss of Privacy: There always exists the potential for loss of private information; however, there are procedures in place to minimize this risk.

Your name and other information that could directly identify you (such as address or social security number) will never be placed into a scientific 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.

There is a Federal law called the Genetic Information Nondiscrimination Act (GINA). In general, 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 POSSIBLE OPTIONS TO CONSIDER:

You may decide not to take part in this research study without any penalty. You may also agree to only part of the study; for example you may decline donating a blood sample and/or being videotaped. The choice is entirely up to you.

IN CASE OF INJURY DURING THIS RESEARCH STUDY:

If you believe that you have suffered an injury related to this research as a participant in this study, you should contact the Principal Investigator.

ENDING PARTICIPATION IN THE RESEARCH STUDY:

You may stop taking part in this research study at any time without any penalty. This will not affect your ability to receive medical care at Mount Sinai or to receive any benefits to which you are otherwise entitled.

If you decide to stop participating in the research study please contact the Principal Investigator or the research staff.

If you stop participating 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 wish to withdraw consent for your samples to be used in future research the Principal Investigator and research staff will immediately retrieve and destroy the traceable portions of your sample that have not already been used for research.

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 study doctor, the sponsor or the institution may stop your involvement in this research study at any time without your consent. This may be because the research study is being stopped, the instructions of the study team have not been followed, the investigator

believes it is in your best interest, or for any other reason. If specimens or data have been stored as part of the research study, they too can be destroyed without your consent.

CONTACT PERSON(S):

If you have any questions, concerns, or complaints at any time about this research, or you think the research has hurt you, please contact the office of the research team and/or the Principal Investigator at phone number 888-228-1688 (toll free), or 212-844-6053.

If you experience an emergency during your participation in this research call 911 or go to the nearest emergency room.

This research has been reviewed and approved by an Institutional Review Board. You may reach a representative of the Program for Protection of Human Subjects at the Icahn School of Medicine at Mount Sinai at telephone number (212) 824-8200 during standard work hours for any of the 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 subject.
- You want to get information or provide input about this research.

DISCLOSURE OF FINANCIAL INTERESTS:

Sometimes, physicians/researchers receive payments for consulting or similar work performed for industry. Effective September 2014 Mount Sinai reviews only payments to an individual totaling more than $5,000 a year per entity when determining potential conflicts of interest. Dr. Susan Bressman is the inventor of a patent related to the genetic diagnosis of primary torsion dystonia. This patent is licensed to Athena Diagnostics, Inc. Both Dr. Bressman and Mount Sinai receive payments related to this Intellectual Property.

If you have questions regarding paid relationships that your physician/researcher may have with industry, we encourage you to talk with him or her, or check for industry relationships posted on individual faculty pages on our website at http://icahn.mssm.edu/.

MAINTAINING CONFIDENTIALITY – HIPAA AUTHORIZATION:

As you take part in this research project it will be necessary for the research team and others to use and share some of your private protected health information. Consistent with the federal Health Insurance Portability and Accountability Act (HIPAA), we are asking your permission to receive, use and share that information.

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

As part of this research project, the 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:

- If you choose to participate in neuroimaging studies being done by Dr. David Eidelberg at Northwell Health (previously North Shore University Hospital) and/or Dr. Kenneth Marek at the IND, the non-motor learning studies being done by Dr. David Arkadir of Columbia University, the eye movement study at NYU Medical Center being done by Dr. Janet Rucker, or the study of deep brain stimulation with Dr. Jill Ostrem at UCSF, and you checked "yes" on the informed consent form for this study, your clinical, genetic, MRI, and laboratory information will be shared with them.

- 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 protected health information being used?

Your personal contact information is important to be able to contact you during the study. Your health information and the results of any tests and procedures being collected as part of this research study will be used for the purpose of this study as explained earlier in this consent form. The results of this study could be published or presented at scientific meetings, lectures, or other events, but would not include any information that would let others know who you are, unless you give separate permission to do so.

The Principal Investigator 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. If the research team uncovers abuse, neglect, or reportable diseases, this information may be disclosed to appropriate authorities.

Who, outside Mount Sinai, might receive your protected health information?

As part of the study, the Principal Investigator, study team and others in the Mount Sinai workforce may disclose your protected health information, including the results of the research study tests and procedures, to the following people or organizations: (It is possible that there may be changes to the list during this research study; you may request an up-to-date list at any time by contacting the Principal Investigator.)

- The following study sponsors: The Michael J. Fox Foundation for Parkinson's Research and the National Instututes of Health and/or their representative, who need to confirm the accuracy of the results submitted and the use of funds.
- The United States Food and Drug Administration, in the event that evidence from this study is used in the review of a future clinical trial.
- The United States Department of Health and Human Services and the Office of Human Research Protection.

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

Laurie Ozelius, PhD and Nutan Sharma, MD, PhD, Massachusetts General Hospital, Ruth Walker, MD, Neil Risch, PhD, Louis Ptacek, MD, Jill Ostrem, MD and Marta San Luciano, MD at UCSF, David Vaillancourt, MD at University of Florida Gainsville, Ritesh Ramdhani, MD, David Swope, MD, and Gregory Pastores, MD at NYU School of Medicine, David Standard, MD and Harrison Walker, MD at University of Alabama, Chiara Sabatti, PhD, at UCLA, Patricia Kramer, PhD, Oregon Health Sciences University, Cuiling Wang, PhD and Susan Hailpern, PhD at Albert Einstein College of Medicine, Gary Heiman, PhD, at Rutgers University, Kirk Wilhelmsen, MD, PhD at University of North Carolina at Chapel Hill, Christine Klein, PhD and Johann Hagenah, PhD at University of Leubeck, Germany, Olaf Riess, MD, at University of Tuebingen, Germany, Seth Pullman, MD, the Clinical Motor Physiology Laboratory, and Maria Felice Ghilardi, MD, Columbia University, Sylvain Chouinard, MD, at Centre Hospitalier de l'Universite de Montreal, Guy Rouleau, MD, and Inge Meijer, MD at McGill University's Center for Research in Neuroscience, Alejandro Schaffer, MD, at the National Human Genome Research Institute, Susan Gross, MD, Albert Einstein College of Medicine/Jacobi Medical Center, Hilla Ben-Pazi, MD at Shaare Zedek Medical Center, Israel.

The following individuals are collaborators who run specialized testing in person. If you participate in this testing your identity will be known to them:

David Eidelberg, MD, North Shore University Hospital, Kenneth Marek, MD at The Institute for Neurodegenerative Disorders (IND), David Arkadir, MD, PhD, Columbia University Janet Rucker, MD, NYU Medical Center,

In all disclosures outside of Mount Sinai, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier unless disclosure of the direct identifier is required by law. Some records and information disclosed may be identified with a unique code number. The Principal Investigator will ensure that the key to the code will be kept in a locked file, or will be securely stored electronically. The code will not be used to link the information back to you without your permission, unless the law requires it, or rarely if the Institutional Review Board allows it after determining that there would be minimal risk to your privacy. It is possible that a sponsor or their representatives, a data coordinating office, a contract research organization, may come to inspect your records. Even if those records are identifiable when inspected, the information leaving the institution will be stripped of direct identifiers. Additionally, when applicable, the monitors, auditors, the IRB, the Office of Human Subjects Protection (OHRP) of the Department of Health and Human Services as well as the Food and Drug Administration (FDA) will be granted direct access to your medical records for verification of the research procedures and data. OHRP and FDA are authorized to remove information with identifiers if necessary to complete their task. By signing this document you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

For how long will Mount Sinai be able to use or disclose your protected health information? Your authorization for use of your protected health information for this specific study does not expire.

Will you be able to access your records?

During your participation in this study, you will have access to your medical record and any study information that is part of that record. The investigator is not required to release to you research information that is not part of your medical record.

Do you need to give us permission to obtain, use or share your health information?

NO! If you decide not to let us obtain, use or share your health information you should not sign this form, and you will not be allowed to volunteer in the research study. If you do not sign, it will not affect your treatment, payment or enrollment in any health plans or affect your eligibility for benefits.

Can you change your mind?

You may withdraw your permission for the use and disclosure of any of your protected information for research, but you must do so in writing to the Principal Investigator at the address on the first page. Even if you withdraw your permission, the Principal Investigator for the research study may still use your protected information that was already collected if that information is necessary to complete the study. Your health information may still be used or shared after you withdraw your authorization if you should have an adverse event (a bad effect) from being in the study. If you withdraw your permission to use your protected health information for research that means you will also be withdrawn from the research study, but standard medical care and any other benefits to which you are entitled will not be affected. You can also tell us you want to withdraw from the research study at any time without canceling the Authorization to use your data.

If you have not already received it, you will also be given The Hospital's Notice of Privacy Practices that contains more information about how The Hospital uses and discloses your protected health information.

It is important for you to understand that once information is disclosed to others outside Mount Sinai, the information may be re-disclosed and will no longer be covered by the federal privacy protection regulations. However, even if your information will no longer be protected by federal regulations, where possible, Mount Sinai has entered into agreements with those who will receive your information to continue to protect your confidentiality.

If as part of this research project your medical records are being reviewed, or a medical history is being taken, it is possible that HIV-related information may be revealed to the researchers. If that is the case,

the following information concerns you. If this research does not involve any review of medical records or questions about your medical history or conditions, then the following section may be ignored.

Notice Concerning HIV-Related Information

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

_____

Signature Block for Capable Adult

Your signature below documents your permission to take part in this research. A signed and dated copy will be given to you.

DO NOT SIGN THIS FORM AFTER THIS DATE → **11/30/2020**

Signature of subject | Date and Time

Printed name of subject

Person Explaining Study and Obtaining Consent

Signature of person obtaining consent | Date and Time

Printed name of person obtaining consent

Witness Section: For use when a witness is required to observe the consent process and document below (for example, subject is illiterate or visually impaired, or this accompanies a short form consent):

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

Signature of witness to consent process | *Date and Time*

Printed name of person witnessing consent process