THE MOUNT SINAI HEALTH SYSTEM
CONSENT FORM TO VOLUNTEER IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION
Icahn School of Medicine at Mount Sinai, Mount Sinai Beth Israel, Mount Sinai Morningside, Mount Sinai West, Mount Sinai Brooklyn, Mount Sinai Queens, New York Eye & Ear Infirmary of Mount Sinai

STUDY 21-01743 **Form Version Date: 12/19/2022**

STUDY INFORMATION:

Study Title: Mount Sinai Million Health Discoveries Program
Principal Investigator (Head Researcher): Alexander W. Charney, MD, PhD
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SUMMARY OF THIS RESEARCH STUDY:

In medicine there are many unanswered questions. A research study is when scientists try to answer a question about something that we don't know enough about. Participation in a research study may or may not directly help you or others. Participation is entirely voluntary. 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 understand how your genes influence your health by collecting clinical information and doing genetic testing on up to one million participants. We will be sharing your genetic and clinical information with others to advance scientific knowledge and we hope that with the information that we learn, we will be able to advance medicine and improve quality of life. It is possible, but not at all certain, that we will find information that is directly useful to yourself and your family.

If you choose to participate, you will be asked to review and sign this consent form to give us permission to collect and use your specimens and data. You will not be required to return to the hospital/doctor's office for any reason and you may choose to participate in future research surveys. Samples can be collected from your routine clinical care or if you choose, through a research visit. The samples will be linked to the medical information in your medical record existing now and in the future, which makes the samples more valuable for research. The collected samples and information will be banked and used for years, or until you stop your participation. There are no costs to you and you will not get paid to participate. In the future, if you choose, we may be able to give you some information that is learned from the research with your samples.

The main risk to you if you choose to participate is the loss of private information. Although your information is stored in a secure and protected way, there is a very small chance that someone could trace it back to you and because this is genetic information, the risk may extend to your blood relatives. As your samples and information will be shared with qualified researchers, it is possible that a study may be conducted that you would not agree to if we had asked. There are no direct benefits to you expected from participating in this research study but the hope is that research done with your specimens will advance medical care for all.

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

PARTICIPATION IN THIS RESEARCH STUDY:

This research study will be fully explained to you through an educational presentation or by a study member. Feel free to ask all the questions you want before you decide about whether or not to participate. Any new information that develops during this research study that might make you change your mind about participating will be given to you promptly.

You are being asked to participate in this research study because you have received medical services in the Mount Sinai Health System. Funds for conducting this research are provided by Mount Sinai. In addition, support for this project is currently coming from Regeneron Genetics Center which will complete genetic sequencing for this study. Outside support for this study may change in the future and you can find a current list of our partners and follow the progress of the study at www.mountsinaimillion.org.

LENGTH OF TIME AND NUMBER OF PEOPLE EXPECTED TO PARTICIPATE:

The time required to participate in this study will be limited to the time needed to review and sign this consent form unless you decide to participate in the surveys or give a research blood sample. The use of your samples and data will be ongoing until you stop your participation. If you agree to be contacted in the future for surveys, surveys will be sent to you for a year or more or until you stop your participation and it may take about 10 minutes each time. If you choose to give a research sample, the time required to participate will be the time it takes to draw a tube of blood. The total number of people expected to take part in this research study is 1,000,000 but this may be changed.

DESCRIPTION OF WHAT'S INVOLVED:

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

Doctor and hospital visits sometimes require patients to give blood samples. Usually, any leftover samples are thrown away after testing. We are asking your permission to keep these leftover samples for research. When leftover samples are not available, we plan to collect blood samples (no more than 10 mL or 2 teaspoons) for research but only when you are already having blood taken for a clinical visit. If you are not having blood taken for a clinical visit, you can come in for a research visit to give a blood sample.

We will ask you to complete a brief questionnaire on race/ethnicity, gender, and education level. To make the research more useful, we will link your samples to the data from your medical record maintained within the Mount Sinai Health System. We will access your entire medical record and

collect information existing now and in future years, and this will include sensitive information such as mental health and reproductive health history.

In general, we will not share samples or information that directly identify you (name, date of birth) with anyone outside of the study team. Instead, we will use a code that links your samples and information with who you are. We will not release that code. Occasionally some information that could indirectly identify you may be provided to researchers, such as a date of birth or a date of an operation. In those cases, the research team will ask the Institutional Review Board (IRB) for permission to use that information. The IRB can give permission for researchers to use and share information that might identify you only if the IRB finds that it will not pose a significant risk to you or your privacy. The IRB is a committee of doctors, scientists, and nonscientists, including people not associated with Mount Sinai, who have the responsibility to protect people who participate in research.

In the future, the study team may want to collect additional health surveys from you which may be about your health, healthcare, lifestyle, and family's health. If you choose to participate, surveys will be emailed or texted (you can choose how surveys are sent below) to you up to 6 times a year until you stop doing them or the study ends. Completing the surveys will take about 10 minutes each time and you may stop participating in the surveys at any time. The surveys are for research purposes only and your responses will not go into your medical chart. If you have any clinical concerns after completing a survey, please report them to your provider, we will not be contacting them directly. While surveys may help strengthen the research, you may participate in this study without participating in the surveys.

Do you wish to participate in additional health surveys? Please initial your choice:

_____ YES, email surveys **_____ YES, text surveys** **_____NO**

Genetic testing for research purposes only:
We will do research on the genes in your blood sample during the course of this study. The research will include genetic sequencing, which is a laboratory process that maps out your genetic information. All living things are made of cells and genes are the part of cells that contain the instructions that tell our bodies how to grow and work. Genes are passed from parent to child and determine physical characteristics such as hair and eye color. Some genes have been associated with different illnesses. We may study just a few areas of your genetic code or perform whole genome studies, in which all or most of your genes can be analyzed. The information learned from this research may be used to advance the medical community's understanding of different diseases which may lead to better and more effective treatment options and improvements in quality of life. The samples provided will be stored for as long as deemed useful for research purposes. The specimen will be assigned a unique ID number to maintain your confidentiality.

USE OF YOUR DATA AND/OR SPECIMENS:

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The researchers would like to ask your permission to contact you in the future to discuss potential participation in another research project. You may participate in this study without choosing to be contacted in the future for another research project.

Do you give the researchers permission to contact you in the future to discuss possible participation in another research project? Please initial your choice:

_____ YES **_____NO**

Will I get results of research done using my samples?

The research tests are done for research purposes only and at this time, we are not planning on returning your individual results back to you, your treating doctor, or anyone else. These results will never go into your medical record. Participating in this study should not replace clinical genetic testing.

However, if experts from the study team decide that genetic results from your sample are of medical importance, we will attempt to contact you to ask if you would like to proceed to obtain the genetic result. If you agree, follow up testing might be needed in a certified clinical lab. Only the genetic results from a certified clinical lab will be shared with you. Genetic results may not be returned for years and it is possible that you will never be contacted with individual research findings. This does not mean that you don't have or won't develop an important health problem. You can also choose not to receive genetic results.

If we find a medically important genetic result, do you wish to be contacted to discuss receiving that result as it may benefit you or your family regarding preventative or clinical care? Please initial your choice:

_____ YES **_____NO**

Data Sharing and Future Use:
A purpose of this research study is to share your samples and information with qualified researchers to help advance medicine. We may share your samples and information with scientists and researchers from the Mount Sinai Health System and its affiliates, other universities, governments, hospitals, health related companies, including for-profit companies, or research institutes throughout the world. We will not ask you for permission to use your samples or information for these studies, and it is possible a study may be conducted that you would not agree to, if we had asked.

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. Your name and other information that

could directly identify you will never be placed into a scientific database. There are many different kinds of scientific databases; some are maintained by Icahn School of Medicine at Mount Sinai or another institution, 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 for permission to use 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. Researchers will always have a duty to protect your privacy and to keep your information confidential, but there are risks associated with data collection and sharing. 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:

- Reviewing and signing the consent form
- Answering a brief questionnaire on race/ethnicity, gender, and education level
- Understanding that this study does not replace clinical testing so if a specific genetic evaluation is required, that should be done outside of this research study
- Reporting any medical concerns to your provider as any information you give us through questionnaires will not be reviewed for weeks or months and can't be used for clinical care

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. You should also know that it is possible that products may someday be developed with the help of your specimens and data, and there are no plans to share any profits from such products with you, regardless of whether your identifiable information is removed.

POSSIBLE BENEFITS:

You are not expected to get any benefit from taking part in this research study. Others may not benefit either. However, if you receive medically important genetic results, you and your family may benefit by learning about the increased risks of the associated medical condition and learning information that would help guide choices regarding preventative or clinical care of the associate medical condition. Research done with the samples and information may lead to a better understanding about disease and what can be done to prevent or treat disease.

REASONABLY FORESEEABLE RISKS AND DISCOMFORTS:

The risks of a blood draw include pain, anemia, 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.

There is a small risk of loss of private information, this risk always exists but there are procedures in place to minimize the risk. The information, as well as the specimens stored for the purposes of the research, does not contain your name or other direct identifiers, they will be coded. Further, all data is stored on secured, password-protected servers.

The use of large databases, especially of genetic data, increases the privacy risks and has additional risks:

- Privacy Risks - Your name and other information that could directly identify you (such as email or phone number) will not 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 small but has been growing. Since the database includes genetic information, a break in security may also pose a potential risk to blood relatives as well as yourself. If your private information was misused it is possible you would also experience other harms, such as stress, anxiety, stigmatization, or embarrassment from revealing information about your family relationships, ethnic heritage, or health conditions.
- Group Risks - Although we will not give researchers your name, we will give them basic information such as your race, ethnic group, and sex. This information helps researchers learn whether the factors that lead to health problems are the same in different groups of people. It is possible that such findings could one day help people of the same race, ethnic group, or sex as you. However, they could also be used to support harmful stereotypes or even promote discrimination.
- Insurance Risks – 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 larger employers 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.
- Genetic Testing Risks: In general, results from studies that use data collected as part of this research will be preliminary, and the clinical implications of any findings may not be understood for years. Therefore, unless our expert team believes it is medically important, individual study results will not be shared with you or your healthcare providers.

OTHER POSSIBLE OPTIONS TO CONSIDER:

You may decide not to take part in this research study without any penalty. The choice is totally up to you.

IN CASE OF INJURY DURING THIS RESEARCH STUDY:

If you believe that 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 within the Mount Sinai Health System or to receive any benefits to which you are otherwise entitled. If you decide to stop being in the research study, please contact the Principal Investigator or the research staff.

If you decide you don't want your samples and/or data to be used for research anymore, you can contact the research staff and ask to have your samples and/or data removed from future use. We will ask that any shared samples or data that are still linked by a code and have not yet been used by the outside researcher, be withdrawn so that no future sharing of your samples and/or data will take place. If any samples or data have already been shared without a linking code, it won't be possible to retrieve them because no one will know who you are. Samples and data that have already been used will not be affected by your decision. If your samples have already been deposited in an external repository, the study team will request that your samples be removed.

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 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 Principal Investigator at phone number (212) 659-6793.

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 the 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. If you have questions regarding industry relationships, we encourage you to talk your physician/researcher or visit our

website at http://icahn.mssm.edu/ where Mount Sinai publicly discloses the industry relationships of our faculty.

Dr. Carlos Cordon-Cardo (a co-Investigator in this study) is a founder, equity owner, and Chair of the Scientific Advisory Board for PreciseDx. PreciseDx provides artificial intelligence (AI) guided pathology diagnostics to improve patient outcomes. The Icahn School of Medicine at Mount Sinai holds equity in PreciseDx.

Dr. Girish Nadkarni (a co-Investigator in this study) is a founder, equity owner, consultant, and advisory board member for Renalytix AI. Renalytix AI, Inc. is a public company that develops AI enabled diagnostics for predicting progression of kidney disease. The Icahn School of Medicine at Mount Sinai holds equity in Renalytix AI.

While PreciseDx and Renalytix AI are not directly involved in this study, future research collaborations are possible. In addition, the data collected may influence the business decisions and business objectives of PreciseDx and Renalytix AI.

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 shared with others? As part of this research project, the research team at the hospital(s) involved in the research will collect your name, telephone number, date of birth, email, zip code, and medical record number. The researchers will also collect information from your electronic medical records that are held by Mount Sinai Health System. Some of this information can be particularly sensitive. The information collected could include information created before and after the date you sign this form.

During the study the researchers will gather information by:

- completing the tests, procedures, questionnaires and interviews explained in the description section of this consent.

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**.** 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 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 United States Department of Health and Human Services and the Office of Human Research Protection.

In all disclosures outside of Mount Sinai, you will not be identified by name 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 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 law requires it, or rarely if the Institutional Review Board (IRB) 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, 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 protected health information? Your authorization for use of your protected health information for this specific study does not expire.

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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 to not 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 Mount Sinai's Notice of Privacy Practices that contains more information about how Mount Sinai 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.

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ADULT PARTICIPANT:

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

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

PERSON EXPLAINING STUDY AND OBTAINING CONSENT:

_____	_____	_____	_____
Signature of consenter	Printed Name of consenter	Date	Time

WITNESS SECTION:

When a witness is required to observe the consent process, it should be documented below (for example, when subject is illiterate, visually impaired, or this document 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	Printed Name of witness	Date	Time