THE MOUNT SINAI HEALTH SYSTEM
CONSENT FORM TO VOLUNTEER IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION

Study ID: STUDY 21-01743 **Form Version Date: 21JUL2023**

STUDY INFORMATION:

Study Title: Mount Sinai Million Health Discoveries Program
Study site(s): Mount Sinai Health System
Principal Investigator (Lead Researcher): Alexander W. Charney, MD, PhD
Principal Investigator Email: alexander.charney@mssm.edu
Study Phone & Email: (212) 659-6793, mountsinaimillion@mssm.edu

This form explains a research study you might be interested in joining. Participation in this study is voluntary and free. You can call (212) 659-6793 or email mountsinaimillion@mssm.edu to ask any question before signing up.

SUMMARY AND PURPOSE OF THIS RESEARCH STUDY:

The purpose of this research study is to understand how genes and environment influence health by collecting participant's clinical and genetic information and sharing that information with researchers to advance medicine and improve quality of life. To participate, you will be asked to review and sign this consent form to give us permission to use your clinical information and samples. You are being asked to participate because you have received care at Mount Sinai. There are 1,000,000 people expected to take part in this research study. Your participation includes reviewing and signing this consent form and voluntarily answering surveys in the future. The use of your samples and data will be ongoing until you stop your participation, and you will not be paid for taking part in this study. Funds for this research are provided by Mount Sinai. Regeneron Genetics Center will complete genetic sequencing for this study. You can find a current list of our partners and follow the study progress at www.mountsinaimillion.org.

DESCRIPTION OF WHAT IS INVOLVED:

If you sign this consent form, Mount Sinai will use the leftover blood samples from your medical care that are usually thrown away for the study. If leftover blood samples are not available, we will collect a research blood sample (no more than 2 teaspoons) at the time of a clinical blood draw or you can choose to give a separate research blood sample. We will study the genes in the samples, including genetic sequencing, along with the information that appears in your medical record, as some genes have been associated with different illnesses. You will be asked to complete a brief questionnaire and may be asked to voluntarily fill out electronic, 5-10 minute health surveys for the study in the future. If study team experts decide that your genetic results are of medical importance, we will ask if you would like to obtain the result, otherwise we will not return your genetic results back to you. By signing this consent form, you give the study team permission to contact you in the future to discuss participating in other research projects. Your samples and data will be kept and studied by Mount Sinai as long as they are useful for research and may be shared with qualified researchers outside of Mount Sinai, including health related for-profit companies and public databases, but will not be linked to your identity. We will use a code that links your samples and information with who you are to maintain your confidentiality.

YOUR RESPONSIBILITIES IF YOU TAKE PART IN THIS RESEARCH:

If you decide to take part in this research study, you will be responsible for reviewing and signing the consent form and answering a brief questionnaire.

POSSIBLE BENEFITS:

You are not expected to get any benefit from taking part in this research study, but the research may lead to a better understanding about disease and what can be done to prevent and treat disease.

POSSIBLE RISKS AND DISCOMFORTS:

The risks of a blood draw include pain, bruising, dizziness, fainting, and the slight possibility of infection at the place where the needle goes in. There is a small risk of loss of private information, this risk always exists but there are procedures in place to minimize this. Although your name will not be given to researchers, basic information such as your race, ethnic group, and gender 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. Your name and other information that could directly identify you (such as an address or date of birth) 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. It is possible that products may 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.

DISCLOSURE OF FINANCIAL INTERESTS:

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

- 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 scientific founder, equity owner, consultant, and advisory board member for Renalytix AI. In addition, Dr. Nadkarni is a co-founder and equity owner of Verici Dx. Renalytix AI, is a public company that develops AI enabled diagnostics for kidney disease progression. Verici Dx, is a public company that develops predictive genetic diagnostics for kidney transplant rejection. Both companies, Renalytix AI and Verici Dx, are based on intellectual property developed by Mount Sinai faculty members and Mount Sinai holds equity in both companies.

While PreciseDx, VericiDx, 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, VericiDx, and Renalytix AI.

MAINTAINING CONFIDENTIALITY – HIPAA AUTHORIZATION:

As part of this study, some of your private and/or protected health information (PHI) will be obtained, used, and shared with your permission. PHI contains information that identifies you, like name and date of birth, and contains health information from your doctors/hospital visits. By signing this form, you agree to release your PHI to the study team to conduct the study.

What PHI is collected and used in this research study, and might also be shared with others? The research team will collect your name, phone number, date of birth, email, zip code, and medical record number. The researchers will also collect information from your Mount Sinai electronic medical records including sensitive information like genetic, mental health, substance abuse, and psychotherapy records. The information collected could have been created before and after the date you sign this form.

Why is your PHI being used? Researchers 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.

Who, outside Mount Sinai, might receive your PHI? In all disclosures outside of Mount Sinai, you will not be identified by name or any other direct personal identifier unless required by law. All identifying information will be removed when the results of this research are published or presented. Information disclosed will be identified with a code with the key to the code stored securely. The code will not be used to link the information back to you without your permission, unless required by law or rarely if the Institutional Review Board (IRB) allows it. Additionally, the IRB, Office of Human Research Protection (OHRP), and the U.S. Department of Health and Human Services (DDHS) will be granted direct access to your medical records for verification of the research. OHRP is authorized to remove identifiable information to complete their task. Once information is disclosed to others outside Mount Sinai, the information may be re-disclosed and may no longer be covered by the federal and state confidentiality laws. However, where possible, Mount Sinai has entered into agreements with those who will receive your information to continue to protect your confidentiality. If the research team uncovers abuse, neglect, or reportable diseases, this information may be disclosed to appropriate authorities. If

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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.

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. 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 participate in the study. 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 record. If you decide to stop being in the study, please contact 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. 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 after you withdraw your authorization if you have an adverse event (a bad effect) from taking the research study.

ENDING PARTICIPATION IN THE RESEARCH STUDY:

You may stop taking part in this study at any time by contacting the research staff. No matter what you choose, your care and benefits through Mount Sinai will not be negatively impacted. You may also withdraw your permission for the researchers to use and share any of your data, samples, and/or protected information for research and you can ask to have your information withdrawn so that it will not to be used in additional projects or shared. If your data and/or samples have already been shared with researchers or an external repository, those researchers/repositories will be asked to stop using them. However, if any data and/or samples have already been shared without 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. The Lead Researcher or Mount Sinai may stop your involvement in this research study and/or destroy your data/samples at any time without your consent.

If researchers are reviewing your medical records, it is possible that they may learn information related to your HIV status. If that is the case, the following information concerns you.

Notice Concerning HIV-Related Information

If you are authorizing the release of HIV-related information, the recipients are prohibited from re-disclosing any non-authorized HIV-related information unless permitted to do so under federal/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.

How the Institutional Review Board (IRB) can help you:

This research has been reviewed and approved by an Institutional Review Board. Please contact a representative of the Institutional Review Board at Mount Sinai at (212) 824-8200 if your questions, concerns, or complaints are not being answered or 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, or you want to get information or provide input about this research.

ADULT PARTICIPANT:

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

Signature of Participant	Printed Name of Participant	Date	Time

PERSON EXPLAINING STUDY AND OBTAINING CONSENT:

Signature of Consent Delegate	Printed Name of Consent Delegate	Date	Time

WITNESS SECTION:

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 participant, and that consent was freely given by the participant.

Signature of Witness	Printed Name of Witness	Date	Time