Study ID #: 07-0529 **Form Version Date:** 10/4/2018

TITLE OF RESEARCH STUDY:

Title: Bio*Me* Biobank Program (Bio*Me*)

PRINCIPAL INVESTIGATOR (HEAD RESEARCHER) NAME AND CONTACT INFORMATION:

Name: Judy Cho, MD
Physical Address: Icahn School of Medicine at Mount Sinai, 1468 Madison Avenue, Annenberg 18-16, New York, New York 10029
Mailing Address: Icahn School of Medicine at Mount Sinai, One Gustave L. Levy Place, Box 1003
New York, New York 10029
Phone: (212)-824-8940

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 that might make you change your mind about participating will be given to you promptly.

PURPOSE OF THIS RESEARCH STUDY:

The purpose of this project is to collect, store and study medical information and blood samples. For example, it will provide a resource for researchers to conduct genetic and molecular studies. This information may be used to advance the medical community's understanding of different diseases, and this understanding may lead to better and more effective treatment options and improvement in quality of life. You may qualify for participation in this project because you are a patient at Mount Sinai.

Funds for conducting this research are provided by the Charles Bronfman Institute for Personalized Medicine at Icahn School of Medicine at Mount Sinai.

LENGTH OF TIME AND NUMBER OF PEOPLE EXPECTED TO PARTICIPATE

Your active participation in this study will take about 30 minutes. If you agree to give additional blood samples as described in the "Description" section of this consent form, it may take about 10 minutes each time you give additional blood samples. The use of your blood samples and data will

be ongoing and your samples will be stored for an indefinite number of years. The number of people expected to participate in this study is 20,000 each year across the Mount Sinai Health System and its affiliates. Any patient who receives care at the Mount Sinai Health System and its affiliates may be eligible to participate.

DESCRIPTION OF WHAT'S INVOLVED:

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

This consent form tells you about the project to help you make your choice on whether or not to take part. Please take the time to read this carefully before making your choice. If you choose to participate in this project, you will be asked to sign this consent. Whether or not you choose to participate in this project, you will receive the same medical care as all patients being followed within Mount Sinai Health System.

The Bio*Me* Biobank Program is set up to store medical information and samples from Mount Sinai Health System patients who have agreed to participate in this project. Bio*Me* freezers are where we freeze and store tubes of blood, which can be studied at a future date. The information collected during this project, including your health and lifestyle information, will be entered into the Bio*Me* Biobank Database. This information will be linked to your medical records and may be used for future research studies. By signing this consent form, you allow the Principal Investigator and other researchers at Mount Sinai (who request and are approved to receive samples) to review and have access to your medical records now and at any time in the future. By signing this consent form, you are giving permission for your medical information including alcohol, drug abuse, psychiatric, and HIV-related information (such as the fact that you have had an HIV-related test, or have HIV infection, HIV-related illness or AIDS, or any information that could indicate that you have been potentially exposed to HIV) to be looked at and used for research purposes as described in this consent.

After your written consent has been obtained, we will ask you to:

- answer a questionnaire about your physical activities, dietary behavior, you and your family's medical history, among other things. You do not have to answer all the questions, and may skip questions that you are uncomfortable answering. It will take about 15-20 minutes to complete this questionnaire.
- have up to 2 tablespoons of your blood drawn. We may coordinate the blood draw to occur at the same time as when you have blood drawn for routine medical care or as part of your participation in approved research studies. You may not have to make any special visits or have unnecessary needle sticks. The blood will be drawn from a vein in the arm.

Your treating physician may ask you to give additional blood samples as part of this research project (no more than 2 tablespoons at a time and up to 6 times per year). These additional blood samples will be drawn from you at routine follow-up visits you have with your treating physician. You do not have to agree to have additional blood drawn from you for this research project. You will be able to continue participating in Bio*Me* as long as you agree to give the first 2 tablespoons of blood.

Study ID #: 07-0529 **Form Version Date:** 10/4/2018

To protect your privacy and confidentiality, your samples will never be labeled with your name or other type of personal identifier. They will be labeled with a unique series of numbers, which will make it possible to identify you as the donor of the sample if needed.

Your samples may be used for future research including genetic research. Genetic research is the study of your genes which are threadlike particles made of DNA (short for deoxyribonucleic acid). The cells that make up human body tissues contain DNA. DNA is your unique genetic material that carries the instructions for your body's development and function. DNA stores information in the form of a code. DNA is inherited from your parents, will be passed on to your children, and contains the structure and function of all the cells that make up your body. For example, genes control the color of each person's hair and eyes as well as many of the other features that make us different from each other. One of the methods researchers might use to study your sample is called genome sequencing. This allows them to look at some or all of your genetic code. Many diseases can result from changes in a person's genetic material that cause cells to not work properly. Currently, researchers and doctors know some of the genetic changes that can cause disease, but they do not know all of the genetic changes that can cause disease.

Return of Genetic Results

You should not expect to receive genetic results from your participation in Bio*Me*. However, there is a small chance that scientists will find genetic results that are of high medical importance in your sample. In that case, we will attempt to contact you to let you know that you may have a genetic result that is important to your health. We will ask you if you would like to proceed to obtain the genetic result. We will **only** give you genetic results that we think are important to your health, and that have been confirmed in a clinical laboratory. You will be asked to sign a separate clinical genetic testing consent form, as per standard practice, in order to receive the clinical genetic result.

A team of experts, including a population geneticist, a clinical geneticist, and a genetic counselor will determine which genetic research results are of high medical importance and should be returned to Bio*Me* participants. The *number* of disease-associated genes and the *chance* of finding genetic results that are of high medical importance will increase as we continue to learn more about the gene-disease associations in Bio*Me* and elsewhere.

It is possible that you will never be contacted with genetic results. 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.

Do you wish to receive genetic results? (Initial your choice) YES____ NO____

Study ID #: 07-0529 **Form Version Date:** 10/4/2018

Future Research

By signing this consent, you are giving permission for your medical information and samples to be stored and used for future research, related or unrelated to your medical condition, by investigators at Mount Sinai and outside of Mount Sinai. Unless you decide to withdraw from the project, we may keep using your medical information and samples for research indefinitely.

Because the samples will be linked to you, you may request at any time, in writing, that your samples be destroyed and no longer used in future research. However, if we have already shared the samples with other researchers, the samples may not be able to be destroyed. In addition, any research results obtained prior to your withdrawal of consent will not be destroyed. Information about withdrawing from this research program can be found in the "Ending Participation in the Research Study" section of this consent form.

Large-Scale Data Sharing

Some information from the analysis of your coded samples, like your genetic information, and your coded medical information like your age, sex, ethnic background, diagnosis and disease history, may be entered into one or more scientific databases available to other researchers inside and outside of Mount Sinai. There are many different kinds of databases, for example, the National Institutes of Health (NIH), a government agency responsible for health-related research, maintains a restricted database called "dbGAP". Databases, like dbGAP, were created to meet the needs of the medical genetics community by storing medical information from many studies conducted at many different places. Researchers can then study the combined information to learn even more about health and many different diseases. Some of these databases are publicly accessible and some are restricted. Anyone on the Internet can access the information shared in publicly accessible databases. However, only researchers who apply to restricted databases and are approved can access databases, like dbGAP. The Bio*Me* Biobank Program will limit sharing of data to only those databases, which are restricted and require approval to access. Please note that traditionally-used identifying information about you, such as your name, address, telephone number, or social security number, will NOT be put into these scientific databases. However, because your genetic information is unique to you, there is a chance that someone could trace it back to you. The risk of this happening is very small and is explained in the Reasonably Foreseeable Risks and Discomforts section of this consent form. Researchers will always have a duty to protect your privacy and to keep your information confidential.

Additional Research

Most of the future research will be done without having to know who you are. This means we will not look up the code to see who the information and sample came from.

In some cases, we may contact you if future research requires that we know who the sample came from or requires collection of additional information about you, for example completing a questionnaire or survey, requires collection of additional samples or enrolling you in another study, which will require signing a new consent form.

Other researchers might apply to do a study for which they may also need to contact you. For example, they may ask you to provide another sample, fill out a survey or do a phone interview. If a study like this is approved, you will be contacted about the study so you can decide if you

want to participate and receive more information. There may be a new consent process just for that study.

In both cases, this means we will have to look up the code to see who the information and sample came from. By signing this consent form, you are giving permission to be contacted in the future about this and other research studies. If we find that contacting you is not practical, for example because you have moved; we may still use your identified blood and medical information. We will first ask the Institutional Review Board for permission. The Institutional Review Board (IRB) is a committee of doctors, scientists, and non-scientists, including people who are not associated with this hospital or medical school. The IRB can give permission to the researcher to use and share your identified health information and the associated sample, but only if the IRB determines that doing this will not present more than a minimal risk to you or your privacy.

It is possible that we may be approached by biotechnology or pharmaceutical companies wishing to do research using your specimens, for the purposes of developing drugs or treatments for medical conditions. In addition to the pharmaceutical and biotechnology companies you may know by name, there are also third party companies that are dedicated to providing these biotechnology and pharmaceutical companies with access to human specimens and related clinical research services for biomedical research and these third party companies are also considered biotechnology and pharmaceutical companies. A commercial product may result from the use of your specimens, but you will not receive any financial benefit.

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:

- Agreeing to having your blood drawn for research purposes
- Answering a family history questionnaire
- Telling the study staff if you decide you do not want to continue participating in Bio*Me*.

COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

If you agree to take part in this research study, we will pay you a total of $20 in cash for your time and effort. You will be given your $20 after you have your blood drawn and you complete the study questionnaire.

There is no extra cost to you or to your insurance company for being a part of Bio*Me*. If you are one of the Bio*Me* participants who obtains genetic results through Bio*Me*, the clinical confirmation of genetic results, study visit for return of results, and genetic counselling will be provided to you free of charge. However, any subsequent clinical appointments or testing that you and/or your family members choose to have done because of your genetic results will be billed to you and/or your health insurance providers.

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 reporting would take place 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.

Study ID #: 07-0529 **Form Version Date:** 10/4/2018

POSSIBLE BENEFITS:

You are not expected to get any benefit from taking part in this research study. Others may not benefit either. However, the results of tests performed on your samples may benefit other people in the future.

You may experience personal benefit by learning about a clinically confirmed genetic result that is of high medical importance. This could also benefit your family members who may be at risk for the same genetic condition.

REASONABLY FORESEEABLE RISKS AND DISCOMFORTS:

Blood draw
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.

Privacy Risks
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 identifiers. Therefore, no one outside of the Bio*Me* research team can access your name. There are procedures in place to further minimize this risk. For example, all data is stored on secured, password-protected servers.

Your name and other information that could directly identify you (such as address or social security number) will never be placed into a public 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 includes 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 also experience other harms, such as stress, anxiety, stigmatization, or embarrassment from revealing information about your family relationships, ethnic background, or health conditions.

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.

Return of Genetic Results
If we tell you that you have a higher chance of having a health problem because of a genetic result, then there is a risk that you might be surprised or upset.

Study ID #: 07-0529 **Form Version Date:** 10/4/2018

Group Risks

Although we will not give researchers your name, we will give them basic information such as your race, ethnic background, 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.

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. Your medical care will not be affected by your decision.

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 the project at any time without any penalty. This will not affect your ability to receive medical care at any of the Mount Sinai Health System hospitals or to receive any benefits to which you are otherwise entitled. If you decide to stop being in the project, please contact the Principal Investigator or the research staff.

You may withdraw your permission for the use and disclosure of any of your protected information for research, but you must request this in writing to the Principal Investigator at the address on the first page that your samples be destroyed and no longer used in future research. However, even if you withdraw your permission please be aware that your withdrawal is not effective for research done while Mount Sinai Health System had your consent. If we have already shared the samples with other researchers, those samples may not be able to be destroyed, and your health information may still be used or shared after you withdraw your authorization if you have an adverse event (a bad effect) from participating in the project. The Bio*Me* Biobank Program may also be terminated at any time and your sample destroyed without informing you. If the Bio*Me* Biobank Program is terminated, any data that was collected can also be destroyed.

Withdrawal without your consent: The study doctor, the sponsor or the institution may stop your involvement in this study at any time without your permission. This may be because the 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 study, they too can be destroyed without your permission.

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 212-824-8940.

This Section For IRB Official Use Only

This Consent Document is approved for use by an Institutional Review Board (IRB)

Form Approval Date: **10/3/2018** **DO NOT SIGN AFTER THIS DATE →** **7/10/2019**

Study ID #: 07-0529 **Form Version Date:** 10/4/2018

This research has been reviewed and approved by an Institutional Review Board. You may reach a representative of the Program for the 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 compensation for work they do for industry. In evaluating potential conflicts of interest, Mount Sinai only reviews total compensation greater than $5,000/year from any entity to an investigator. 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/.

Dr. Tielman Van Vleck (an Associate Computational Scientist in this study) receives financial compensation as a consultant for and owns equity in Clinithink.

Clinithink is a healthcare Information Technology company. The company's Natural Language Processing software is being used to extract information from patient notes and is being utilized for research purposes in this project and across Mount Sinai.

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 **H**ealth **I**nsurance **P**ortability and **A**ccountability **A**ct (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 you name and
-Family History Questionnaire

The research team at the hospital(s) involved in the research will also get information from your medical record from Mount Sinai and from your private doctor(s), if applicable.
- Blood draws

Study ID #: 07-0529 **Form Version Date:** 10/4/2018

The following personal health information will be collected but will not be disclosed or released in connection with this research study.
-Name, Address, Telephone number, medical record number, social security number, date of birth

Why is your protected health information being used?
Your health information and the results of any tests and procedures being collected as part of this research study and for the advancement of medicine and clinical care 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, etc., but would not include any information that would let others know who you are, unless you give separate permission to do so.

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

In almost all disclosures outside of Mount Sinai, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier. Some records and information disclosed may be identified with a unique code number. The 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 Institutional Review Board 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, or a contract research organization, will 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, 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. They 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.

Study ID #: 07-0529 **Form Version Date:** 10/4/2018

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. If you withdraw your permission, please be aware that your withdrawal is not effective for research done while we had your consent. If we have already shared the samples with other researchers, those samples may not be able to be destroyed. Your health information may still be used or shared after you withdraw your authorization if you 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 information in the following box 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.

Study ID #: 07-0529 **Form Version Date:** 10/4/2018

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 (212) 480-2522 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 investigators 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 research information or biospecimens 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 we learn that you or someone else is threatened with serious harm, such as a child or an elderly person being abused, the investigators 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.

Study ID #: 07-0529 **Form Version Date:** 10/4/2018

Signature Block for Capable Adult

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.

DO NOT SIGN THIS FORM AFTER THIS DATE → **7/10/2019**

Signature of subject	Date
Printed name of subject	Time

Person Explaining Study and Obtaining Consent

Signature of person obtaining consent	Date
Printed name of person obtaining consent	Time

Witness Section: For use when a witness is required to observe the consent process, 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*
Printed name of person witnessing consent process	*Time*

This Section For IRB Official Use Only

This Consent Document is approved for use by an Institutional Review Board (IRB)

Form Approval Date: **10/3/2018** **DO NOT SIGN AFTER THIS DATE →** **7/10/2019**