STUDY INFORMATION:

Study Title:

Study site(s): Icahn School of Medicine at Mount Sinai, Mount Sinai Hospital, Mount Sinai Beth Israel, Mount Sinai Morningside, Mount Sinai West, New York Eye & Ear Infirmary of Mount Sinai

Principal Investigator (~~Head~~Lead Researcher):

Physical Address:

Mailing Address:

Phone:

SUMMARY OF THIS RESEARCH STUDY:

This document explains a research study ~~is when scientists try to answer a question about something that we don't know enough about.~~ you might be interested in joining. Participation in ~~a research study may or may not directly help you or others. Participation is entirely~~ the study is voluntary. ~~It is completely up to you whether or not you take part.~~ You can ~~also change your mind at any time and it~~agree to join or not. Your decision will not ~~affect~~limit your ability to ~~get medical~~receive care ~~within the~~at Mount Sinai ~~Health System.~~ . You should only agree to take part if you understand the study and if all of your questions about the research study are answered. If you do join the study, the research team must share any new information with you that may change your mind about taking part.

The purpose of this research study is

If you choose to ~~participate~~take part, you will be asked to

~~The~~If you choose to take part, the main risks to you ~~if you choose to participate~~ are

You will not benefit directly from taking part in this research ~~will not benefit you~~.

You may ~~also~~ benefit from ~~participation~~taking part in this research ~~if~~. Some potential benefits are:

Instead of ~~participating~~taking part in this research, you may
If you are interested in learning more about this study, please continue to read below.

STUDY PARTICIPATION ~~IN THIS RESEARCH STUDY:~~:

~~This research study will be fully explained to you by a member of the study team. Feel free to ask all the questions you want before you make a decision 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 may qualify to take part in this research study because

Your participation in this research study is expected to last

There are [insert local enrollment goal] people expected to take part in this research study at [specify by site within MSHS (Mount Sinai Health System)]. If it is a multi-site study, also indicate and [insert overall enrollment goal] people to take part across all sites.

Funds for conducting this research study are provided by

A description of this clinical trial will be available on ~~http://www.ClinicalTrials.gov~~http://www.ClinicalTrials.gov, as required by U.S. Law. This ~~Web site~~website will not include information that can identify you. At most, the ~~Web site~~website will include a summary of the results. You can search this ~~Web site~~website at any time.

~~The number~~

DESCRIPTION OF WHAT IS INVOLVED:

If you agree to take part in this research study ~~across all sites is [overall enrollment goal].~~

~~**DESCRIPTION OF WHAT'S INVOLVED:**~~

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

- Because this ~~project~~research study involves the use of ~~medications~~[study drugs or an investigational medical device], a note ~~of~~must be included in your ~~participation in the~~ electronic medical record~~.~~ ~~That~~ that you are taking part in the research. This way, anyone ~~treating you will be aware of~~involved in your ~~participation and may be able~~medical care will know that you are a study participant, and they can work to avoid any ~~unfortunate~~problems or negative outcomes that could arise if ~~your research participation were unknown~~they do not know.

Randomization

~~The study treatment you get will be chosen~~No one, not you, or anyone from your medical team or from the research team will be able to choose what group you are assigned to or what study

[drug/device/procedure] you get. It will be by chance, like flipping a coin [use the term "pulling names out of a hat" for the case of more than 1:1]. ~~Neither you nor the study doctor will choose what experimental study treatment you get.~~ You will have a(n) [equal/one in three/etc] chance of being given each ~~experimental treatment.~~study [drug/device/procedure]. For double-blinded studies, add: Neither you nor the ~~study~~Lead Researcher or your own doctor will know which ~~experimental~~ study ~~treatment~~[drug/device/procedure] you are getting~~; however,~~. If there is an emergency, they can get this information~~ could be obtained in an emergency.~~. For single blinded studies, add: You will not be told which study ~~treatment~~[drug/device/procedure] you are getting; however, ~~your study doctor~~the Lead Researcher, research team, etc. will know.

Genetic Testing

HIV/AIDS

To take part in this research ~~project we will have to test~~study, your blood will be tested for evidence of HIV~~ infection. HIV is~~, the virus that causes AIDS. ~~It~~People can ~~be transmitted~~ get HIV through unprotected ~~sex (vaginal, anal, or oral sex)~~sexual contact with someone who has HIV, and through contact with blood~~,~~ (as in sharing needles ~~(~~including for piercing, tattooing, ~~drug equipment including needles used to inject~~and injecting drugs). ~~HIV-infected~~ People who are pregnant ~~women~~with HIV infections can transmit HIV to their infants during pregnancy~~ or~~, delivery or while ~~breast feeding.~~breastfeeding. There are treatments for HIV/AIDS that can help ~~an individual~~people stay healthy. ~~Individuals~~People with HIV/AIDS can adopt safe practices to protect uninfected and infected people in their lives from ~~becoming~~getting HIV or getting infected ~~or being infected themselves~~ with a different ~~strains~~strain of HIV.

By law, positive test results for HIV/AIDS (as well as other communicable diseases such as hepatitis B, hepatitis C, and syphilis) are reported to the NYS Department of Health ~~for epidemiological (the~~ so they can study ~~of the factors determining or influencing the presence or absence of~~ how people get and transmit the disease~~) and Partner Notification purposes.~~ and notify sexual or needle-sharing partners they may have been exposed. If you wish to be tested anonymously ~~you will be referred~~for HIV/AIDS, the research team can refer you to a public testing center, but you will not be able to be in this study. ~~Please know that~~ New York State law protects the confidentiality of HIV test results and other related information. ~~The law prohibits discrimination~~It is illegal to discriminate against a person based on ~~an individual's~~their HIV status and services are available to help ~~with such consequences.~~if this happens. You are free to refuse ~~this~~ to get an HIV test, but if you refuse you ~~will not be allowed to join or remain in~~ cannot be part of this research ~~project~~study.

Pregnancy

If you can possibly get pregnant, a [specify either blood or urine] test for pregnancy will be done before you begin the study and the pregnancy test will be repeated every [insert week and/or visit time point, or insert similar wording as required by the protocol].
~~For Women:~~

~~Since you are participating~~You cannot be included in ~~a research~~the study ~~that involves drugs~~ if you are or ~~experimental treatment with potential risks to a developing fetus, it is recommended, for your protection, that you not~~ become pregnant ~~for the duration of~~ , as the study~~. You~~ [drug/device/procedure] could harm your fetus. You also should not ~~participate~~be in the study if you are ~~breastfeeding~~producing milk to feed a child as the study [drug/device/procedure] could harm your baby.

~~For research involving pregnancy testing, customize the statement below for this study:~~
~~A [specify either blood or urine] pregnancy test will be done before you begin the study and will be repeated at [insert Week and/or Visit time point, or insert similar wording as required by the protocol].~~ ~~Therefore, practicing~~ Unless you are at least one year past menopause or have had a successful operation to make pregnancy impossible, you should use effective birth control ~~is important. No individual birth control is 100% effective.~~

~~Recommended~~. Unless you are sexually abstinent (not having genital sex) the recommended methods of birth control are:

- The consistent use of ~~an~~ approved hormonal birth control (pill~~/~~, patches, or rings),
- An intrauterine device (IUD),
- Contraceptive injection (Depo-Provera),
- Double barrier methods (Diaphragm with spermicidal gel or condoms with contraceptive foam),
- Sexual abstinence (no sexual ~~intercourse) or~~activity),
- ~~~~Sterilization~~. (a vasectomy, getting tubes tied, or a hysterectomy).

~~Hormonal~~All birth control~~, implants, and injections~~ methods (other than abstinence and sterilization) are only ~~considered~~ effective if ~~used~~you use them properly ~~and started~~, start them at least one month before you begin the research study, ~~continuing~~and continue using them throughout the research study and for one month [OR insert a longer period of time if required by the protocol] after the ~~end of the~~research study~~. You should ask your study doctor if you should continue birth control for longer than 30 days [OR insert a longer period of time if required by the protocol, FDA-approved package insert, or information in the IB] after the end of the study.~~ ends. If you are unsure whether the method of birth control you use is ~~acceptable~~approved to use while ~~participating~~ you are in this study, you should ask ~~your study doctor~~the Lead Researcher before you begin the study. If you are less than one~~-~~year post-menopausal, ~~there is the potential that~~ you could still become pregnant. If you or your partner becomes pregnant, or may be pregnant, at any time [insert the time during which participants are being monitored, e.g. during the ~~trial~~study, or in the "month" ~~[~~OR insert a longer period of time if required by the protocol] following it], ~~it is important that~~ you must tell ~~your study doctor~~a person from the research team immediately. The ~~trial~~ team may stop the study drug ~~may be stopped~~ and ~~a referral may be made~~refer you/your partner to an obstetrician/gynecologist for follow-up. ~~If~~

Should you ~~plan to~~*/your partner become pregnant* ~~in~~*, whether or not you/your partner have the* ~~year following a clinical trial, speak with your study doctor.~~

~~Should you become pregnant, regardless of~~baby, the ~~outcome,~~people funding and overseeing the ~~sponsor~~research may ask for information on ~~your~~the pregnancy, even if you are ~~withdrawn from~~no longer part of the study. ~~Your written consent~~You/your partner will be ~~obtained separately in the case that this~~asked for additional written consent to share this information if that happens.

~~For Men:~~

Semen/Sperm:

Drugs can be found in semen and alter sperm. Since you are ~~participating~~taking part in a study ~~that involves~~using experimental drugs or ~~experimental treatment with potential risks to a developing fetus~~treatments, it is recommended that 1) you use a condom ~~and~~, 2) you do not ~~impregnate~~get a ~~woman~~partner pregnant or expose them to semen, and 3) you do not donate ~~sperm~~semen. These recommendations apply both while you are taking the study drug, and for ~~and additional 90 days~~ 3 months after you stop taking the study drug.This is because levels of the study drug may be present in the sperm and/or ~~seminal fluid~~semen even after you stop taking the study drug. You are encouraged to tell your female partner(s) and/or their doctor(s) that you are participating in ~~a~~this clinical trial.

Future Contact:

The researchers may wish to use your personal contact information to contact you in the future. Do you give the researchers permission to **contact you** in the future to request the collection of additional information about you, discuss how your private information, study data and/or samples might be used, or discuss possible participation in another research study?

Please initial your choice: Yes_____ No_____

If “Yes”, please indicate your preferred method of contact: (initial all that apply)

[ ] Email [ ] Phone [ ] Letter [ ] Text

USE OF YOUR DATA AND/OR ~~**SPECIMENS**~~**SAMPLES**:

OPTION 1:

The ~~private information and/or samples collected as part of this~~ research team will never ~~be used or shared for future research, even if the identifiable information is removed.~~

~~OR~~

~~In the future,~~use or share your ~~identifiable information may be removed from the private information and/~~personal information (such as, name, address, date of birth, social security number), study data and/or samples (blood, tissue, urine, saliva, or ~~samples~~any other body matter) that are collected as part of this ~~research. After this removal, the information~~study for future research, even if your identity is removed. Your data and/or samples ~~could be used for future research studies or shared with other research teams for future research studies. You~~ will ~~not~~only be ~~informed of the details of specific~~used to complete this study and then they will be destroyed.

OR

OPTION 2:
In addition to being used to complete this research ~~that is done with~~ study, your ~~medical~~personal information ~~and biospecimens~~(such as, name, address, date of birth, social security number), study data, and samples (blood, tissue, urine, saliva, or any other body matter.) may also be used and shared for additional (future) research. Before anything is shared, all of your identifying personal information will be removed and it will be replaced with a code. Researchers are not planning on giving you the details of any of this future research nor the results. That means that a research project might be done that you would not consent to if provided with the details of that research project. ~~—~~If you do not want any future research to be done with your data and/or samples, even with your identity removed, please do not sign this consent form or take part in the study.

OR

OPTION 3:
The researchers would like ~~to ask~~ your permission to keep ~~the~~your personal information (such as, name, address, date of birth, social security number), study data and ~~specimens (like~~ /or samples (blood, tissue, ~~hair~~urine, saliva, or any other body matter) ~~collected from you during this study~~ to use ~~them~~or share in future ~~research~~ studies. You can still be part of the study if you do not allow us to use or share them. Please ~~tell us how we may use this material in future research studies.~~ select Yes or No to each of the questions below. To decline all future uses/sharing please select 'No' each time.

(1) Will you allow the researchers to store your ~~information~~data and/or ~~specimens~~samples to use in future research studies?

Please initial your choice: Yes_____ No_____

If ~~no~~you select No, please stop here~~.~~ and move to the next section, **'Your Responsibilities If You Take Part in This Research**' section below."

If yes, please continue to the next question~~.~~

~~**(2)** The researchers can keep~~ and tell us how your personal information, study data and/or ~~specimens stored~~samples may be used in ~~one of two different ways: one way will~~future research studies.

(2) The researchers can store your ~~information~~data and/or ~~specimens~~samples in ~~a way that it is linked to your identity (through the use of a code that can indicate the information came from you personally) and the other way will store your information and/or specimens anonymously~~ one of two ways:

a) Anonymously (no one will know who the ~~information is~~data and/or samples came from). ~~It will not be stored both ways, so~~If you ~~must~~ choose ~~one of these two options. Please note that if~~this option, you ~~choose to have your information and/or specimens stored anonymously, you will not be able to~~ can't change your mind. So, if you wanted to ~~ask for~~have your ~~information~~data and/or ~~specimens to be~~samples destroyed ~~at a future date.~~ in the future, the team could not do it as they would not know which data and/or samples were yours.

b) Linked to your identity (using a code that can show the information came from you personally). In this case you could ask for your data and/or samples to be destroyed in the future if you want that to happen.

How would you like your ~~information~~data and/or ~~specimens~~samples stored? Please initial **ONE** choice~~:~~
below:

I would like my ~~information~~data and/or ~~specimens~~samples stored anonymously _____

I would like my data and/or samples stored with a link to my identity_____
~~I would like my information and/or specimens stored anonymously~~ _____
through the use of a code _____
~~3 can be modified and used in the consent even if banking isn't contemplated, in order facilitate enrollment, etc.~~

(3) Do you give the researchers permission to ~~**contact you** in the future to collect additional information about you, discuss how your information and/or specimens might be used, or to discuss possible participation in another research project? Please initial your choice:~~

~~Yes_____ No_____~~

~~**(4)** Do you give the researchers permission to keep the information and/or specimens indefinitely and use them for future~~ keep the data and/or samples, so they could use them in future studies that are **directly related** to the purpose of the current study?
~~Please initial your choice:~~

Please initial your choice: Yes_____ No_____

(~~5~~4) Do you give the researchers permission to keep the ~~information~~data and/or ~~specimens~~samples

indefinitely ~~and~~, so they could use them for future studies that are **not related** to the purpose of the current study (for example~~,~~ a different area of research)?

Please initial your choice:
Yes No
~~Yes No~~

~~**(5**~~
(4.1) From time to time, researchers outside of medicine and related sciences would like to use ~~this information.~~data and/or samples. This might be in fields such as anthropology, human origins, mapping human migration patterns. Do you give permission for researchers **outside the field of medicine** to use your ~~information and/or specimens outside the fields of medicine and biological sciences?~~ data and/or samples?

Please initial your choice:

Yes_____ No_____

~~**(a)**~~
a. If the future research in a different area can be done without having to know that the ~~information~~data and/or ~~specimens~~samples came from you personally, that will be done. ~~**(b)**~~

b. If the future research in a different area requires that it is known specifically who the ~~information~~ data and/or ~~specimens~~samples came from, then one of the following will be done: ~~**(i)**~~

I. If you allowed the researchers to contact you in the future, they may be able to contact you to explain why your ~~identifiable information~~ data and/or ~~specimen~~samples is needed and what will be done with it. Your permission will be asked to use your ~~information~~data and/or ~~specimens~~samples in that research project.

II. If you do not give permission to be contacted in the future, of if it is found that contacting you is not practical (for example, because you have moved~~,~~), your ~~identifiable~~ data and ~~specimens~~/or samples may still be used. The Institutional Review Board (IRB) will be asked for permission to use the ~~information~~data and/or ~~specimens~~samples linked to your identity. The IRB can give permission for researchers to use and share identifiable health information without contacting you, but only if it determines that sharing the ~~information~~data and/or ~~specimens~~samples will not be more than ~~a~~ minimal risk to you or your privacy. The ~~Institutional Review Board (~~IRB~~)~~ is a committee of doctors and scientists and nonscientists, including people not associated with this hospital or medical school, whose job it is to protect people who participate in research.

~~**(6**~~
(5) Do you give permission to have ~~portions of the specimens~~your data and/or ~~information~~samples given **to other researchers,** including those at Mount Sinai, other ~~academic~~ medical or scientific institutions

and for-~~-~~profit companies, for use in research within the limits you have chosen above? ~~Please initial your choice:~~

Please initial your choice: Yes_____ No_____

~~(~~6~~)~~ Do you give permission to have portions of ~~the specimens~~ your data and/or ~~data~~samples deposited in large public databases (repositories~~, **(explained below**~~) for use in research with the limits you may have chosen above? Please read the paragraphs below which explains repositories, then initial your choice:

~~Yes_____ No_____~~

To do more powerful research, it is helpful for researchers to share ~~information they get~~data and/or samples from ~~studying human samples.~~the people they study. They do this by putting ~~it~~ data and/or samples into a repository. A repository is where something is stored safely for a specified period of time. Data and/or samples from one ~~or more scientific databases, where it is~~study may be stored in a repository along with ~~information~~data and/or samples from other studies. Sample repositories are commonly called biobanks, while data repositories are commonly called databases. . Researchers can then ~~study~~use the ~~combined information~~data and/or samples from multiple studies to learn even more about health and disease. If you agree to take part in this study, some of your genetic and health information might be placed into one or more scientific databases~~. There are many different kinds of scientific~~, but they will not share your direct identifiers (for example, name, address, date of birth). These databases~~; some~~ are maintained by either Icahn School of Medicine at Mount Sinai ~~or~~, another institution, ~~some are maintained by~~ the federal government, ~~and some are maintained by~~ or private companies. ~~For example, the National Institutes of Health (an agency of the federal government) maintains a database called "dbGaP." A~~Any researcher who wants to do a study ~~the information~~using data and/or samples from the repository must apply for permission ~~to use the database. Different databases may have~~. There are different ways of reviewing such requests. Researchers with an approved study may be able to see and use your ~~information~~data, along with that from many other people. Researchers may use your samples for genetic sequencing and other experimental testing. Researchers will always have a duty to protect your privacy and to keep your information confidential, but there are always risks associated with data and/or sample collection and sharing. They are described in more detail in the ~~risks~~Risks section

Researchers will use a Global Unique Identifier, a computer-generated ID, which cannot be linked back to your identity. This is so any data collected from you is linked to one unique ID, so [name the repository] can make sure your data is secure and is not accidentally duplicated if you take part in research at multiple sites.

Please initial your choice: Yes_____ No_____

Whether or not you have allowed us to share your data and/or samples with [name the repository], the researchers at Mount Sinai will keep data and/or samples collected about you during this research study to use in future research studies consistent with the wishes you expressed above.

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:

COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

You will not be paid for ~~participating~~taking part in this ~~research~~ study. Being in this ~~research~~ study will not ~~lead to~~cost you anything extra~~ costs to you.~~. ~~You~~Researchers will not ~~be reimbursed~~pay you for your travel or the time ~~that may be required~~it will take for you to be in the study ~~visits~~.

~~Taking~~There may be costs to you for taking part in this ~~research~~ study ~~may lead to added costs to you.~~.

If you agree to take part in this ~~research~~ study, ~~we will pay~~ you will be paid [indicate amount] for your time and effort.

~~Checks require some time~~It can take up to ~~be prepared~~6 weeks to prepare and ~~will be given to~~ give you ~~once processed and available~~a check for study participation. If you do not get a check by then, you can first contact the research team. If further assistance is needed, please contact Mount Sinai's Program for the Protection of Human Subjects at (212) 824-8200.

Tax law may require the Mount Sinai Finance Department to report the amount of payment you receive from Mount Sinai to the Internal Revenue Service (IRS) or other agencies, as applicable. Generally, this ~~reporting would take place~~happens if you receive payments that equal $600 or more from Mount Sinai in a calendar year. You would be responsible for the payment of any tax that may be due.

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

~~-~~OR

The samples and/or data collected from you as part of this ~~research~~study may be used for commercial profit. You may share in that profit if

You should check with your supervisor before accepting payment for ~~participation~~taking part in this ~~research~~study.

If you are released from ~~jail~~prison before you finish this ~~research~~ study, you should take steps to get health insurance ~~or~~, such as Medicaid ~~coverage. Regular office~~. Your clinical visits (doctor visits and standard treatment) will be billed to you and/or your health insurance, as this is not part of the research study. You may continue in the research study after your release from prison. If you move out of the area, ~~we will~~ assistance can be provided to help you ~~make arrangements to be followed by~~find a ~~physician~~doctor to care for you.

POSSIBLE BENEFITS:

There is ~~important to know that you~~a chance this study may benefit you, but this is not ~~get any~~ guaranteed. Others may benefit from ~~taking part in this research. Others may not benefit either. However, possible~~what researchers learn from the study. Possible benefits ~~may be~~to you include:

~~You are~~This study is not ~~expected~~designed to ~~get any~~ benefit ~~from taking part in this research study. Others may not benefit either.~~you personally. However, possible future benefits to others include

Taking part in this research study will not improve your housing or correctional program assignments. ~~Your taking~~Taking part in this research study will not improve your chance of parole or release.

~~**REASONABLY FORESEEABLE**~~

POSSIBLE RISKS AND DISCOMFORTS:

- Risk of loss of private information; this risk always exists, but there are procedures in place to minimize the risk.
- 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.
- In addition to these risks, this research study may hurt you in ways that are not known. ~~-~~The unknown risks ~~might~~could be minor or ~~might be~~ major (death).
- If you are pregnant or become pregnant, this research may hurt your baby or your pregnancy in ways that are unknown. The unknown risks ~~might~~could be minor or ~~might be~~ major (death) for the pregnancy. You should not become pregnant or ~~impregnate a woman~~get someone pregnant while ~~on~~you take part in this ~~research~~ study. Please read the acceptable methods of birth control found under the Description of ~~What's~~What Is Involved section of this document.
- ~~For research that involves known risks to an embryo or fetus, add: This drug may harm a pregnancy or fetus in the following ways: [Include any known risks here] You should not become pregnant or impregnate a woman while on this research study. Please read the acceptable methods of birth control found under the Description of What's Involved section of this document.~~

- Group Risks - Although ~~we~~your name will not ~~give~~be given to researchers ~~your name, we will give them~~, basic information such as your race, ethnic group, and sex may be shared. This information helps researchers learn whether the factors that lead to health problems are the same in different groups of people. It is possible that such findings could one day help people of the same race, ethnic group, or sex as you. However, they could also be used to support harmful stereotypes or ~~even promote~~ discrimination.
- Privacy Risks – Your name and other information that could directly identify you (such as an address, date of birth or social security number) will never be placed into a database [if true]. 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 your 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 heritage, or health conditions.
- Insurance Risks ~~–~~- There is a Federal law called the Genetic Information Nondiscrimination Act (GINA). ~~In general, this~~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.~~ . If you decide not to take part, this will not affect the clinical care you receive at Mount Sinai. The choice is totally up to you.

IN CASE OF INJURY DURING THIS RESEARCH STUDY

If you believe that ~~you have suffered an injury related to~~being in this research ~~as a participant in this~~ study has harmed you, you should contact the ~~Principal Investigator~~Lead Researcher. Their contact information is listed at the beginning of this consent form.

If you are injured or made sick from taking part in this ~~research~~ study, you will get medical care ~~will be provided.~~. The ~~sponsor~~group funding this research study will ~~reimburse your~~pay you for any reasonable and necessary medical expenses ~~for diagnosis~~to diagnose and ~~treatment of a~~treat research-related injury or illness.

This does not prevent you from seeking payment for injury related to malpractice or negligence. ~~Contact~~You can contact the ~~investigator~~Lead Researcher for more information.

The Centers for Medicare and Medicaid Services (CMS~~),~~) is the government agency that ~~administers the~~ oversees Medicare and Medicaid~~ programs, has stated that~~. Funding agencies who make payments ~~by a clinical trial sponsor~~ for injuries related to ~~a trial are a form of liability insurance that~~studies must ~~be reported~~report payments to CMS. ~~As a result, if the sponsor pays for any medical expenses to treat a trial-related injury, the sponsor may have an obligation to determine whether you are covered by CMS, and, if you are, the sponsor may be required to make a report to CMS.~~ In order to ~~perform these tasks, the sponsor (or its delegate)~~do this, the funder must have certain ~~individually identifiable~~ information about you, such as your name, date of birth, Social Security Number, ~~CMS Claim Number~~Medicare or Medicaid ID numbers, date of injury, and description of injury. ~~Because the sponsor would not normally receive such identifiable information about you, the sponsor (or its delegate) has agreed~~The funding agency is only allowed to use this information ~~only for~~to report payments related to the ~~purposes described in~~injury should this ~~paragraph~~be necessary or as otherwise specified in the Authorization to Use and Disclose Protected Health Information section, which is included below.

If you are injured or made sick from taking part in this research study, you will get medical care ~~will be provided.~~. Generally, ~~this care~~it will be billed to you or your insurance ~~in the ordinary manner and you~~. You will be responsible for all treatment costs not covered by your insurance, including deductibles, ~~co-payments~~copayments, and coinsurance. ~~This~~This does not prevent you from seeking payment for injury related to malpractice or negligence. ~~Contact~~You can contact the ~~investigator~~Lead Researcher for more information.

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~~. No matter what you choose, your ~~ability to receive medical~~ care ~~at any of the~~and benefits through Mount Sinai ~~Health System hospitals or to receive any benefits to which you are otherwise entitled~~will not be negatively impacted.

If you decide to stop being in the ~~research~~ study, please contact the ~~Principal Investigator~~Lead Researcher or the research staff.

You may also withdraw your permission for the researchers to use and share any of your protected information for research, but you must do so in writing to the Lead Researcher at the address on the first page. Even if you withdraw your permission, the Lead Researcher may still use the information that was already collected if that information is necessary to complete the research study. Your health information may still be used or shared after you withdraw your authorization if you have an adverse event (a bad effect) from taking part in the research study.

If you decide to stop being in the research study, the following may occur:

If you stop being in the research study, ~~already collected~~the research team may not remove information ~~may not be removed from~~they have already placed in the ~~research~~ study database, and ~~will~~may continue to ~~be used to complete the research analysis.~~use that data as part of this study. ~~You~~The research team may ~~be asked~~ask you whether ~~the study doctor~~they can continue to collect information from your ~~routine~~ medical ~~care. If you agree, this data will be handled the same as research data~~record.

If you decide you don't want your ~~samples~~data and/or ~~data~~samples to be used for research anymore, you can contact the researcher and ask to have your ~~samples and/or data removed from future use.~~data and/or samples withdrawn or labeled so that they will not to be used in additional projects or shared. If ~~any samples or~~ your data and/or samples have already been shared with researchers, those researchers will be asked to stop using them. However, if any data and/or samples have already been shared without your identity or a linking code, it won't be possible to retrieve them ~~because no one will know who you are. Samples and data~~. Data and/or samples that have already been used will not be affected by your decision. ~~Any samples and/or~~ If your data ~~that are still linked to your identity by a code the researcher has will be withdrawn so that no future sharing of your samples and/or data will take place. If your~~and/or samples have already been deposited in an external repository, the study team will request that your data and/or samples be removed.

Withdrawal without your consent: The ~~study doctor~~Lead Researcher, the ~~sponsor~~funder or ~~the institution~~Mount Sinai may stop your involvement in this research study at any time without your consent. This may be because the research study is being stopped, the instructions of the ~~study~~research team have not been followed, the ~~investigator~~Lead Researcher believes it is in your best interest, or for any other reason. If ~~specimens or~~ data and/or samples have been stored as part of the research study, they too can be destroyed without your consent. ~~If applicable add: More possible reasons for removal from the study include [add additional reasons why the subject may be withdrawn. Include all withdrawal criteria listed in the protocol. For example, if the protocol states that subjects will be removed from the research if they become pregnant, have tumor progression, or experience certain adverse events, list these here]~~

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~~Lead Researcher at phone number

If ~~you experience~~there is an emergency ~~during your participation in this research, contact [customize as appropriate: e.g. provide an attending physician's number, instruct subjects to~~, please call XXX-XXX-

XXXX or call 911 or go to the emergency room~~, etc.]~~. Let the emergency room staff know you are in a research study so they can contact the Lead Researcher if needed.

~~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~~Researchers sometimes get paid for consulting or ~~similar~~doing 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.~~ companies that produce drugs, biologics or medical devices. If you have questions regarding industry relationships, ~~we encourage~~ you are encouraged to talk ~~your physician/researcher~~to the Lead Researcher or visit our website at http://icahn.mssm.edu/ where Mount Sinai publicly discloses the industry relationships of our faculty.

~~[Add management plan language here, if applicable]~~

The company sponsoring this research study ~~manufactures~~makes the drug~~/~~ or device (research teams should update the choice depending on the study) being tested and ~~so~~ has a financial interest that could be affected by the outcome of this research study.

The ~~Principal Investigator's Department~~Lead Researcher's department has a financial interest that could be affected by the outcome of this research study or The Lead Researcher's department receives significant support from the research ~~study sponsor. [Statements #2 and #3 may be combined in a single statement, when applicable.]~~funder.

~~The costs of doing~~Researchers and/or their departments receive money from the company sponsoring this research ~~are paid~~ based on ~~the number of patients enrolled.~~how many participants they enroll.

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~~ of this study, some of your private and/or protected health information~~. Consistent with the federal~~ will be obtained, used, and shared with your permission. There is a Federal Health Insurance Portability and Accountability Act (HIPAA~~), we are asking your permission to receive, use and share~~) that ~~information.~~makes sure this is done correctly and safely.

What is protected health information (PHI)?
PHI is the combination of two things:

1. PHI contains information that identifies you. It will be used to contact you and link you to your health information, like name, date of birth, medical record number, and address.
2. PHI also contains health information, including information about your mental and physical health from your visits to doctors or hospitals, or from study visits.

Every time you visit a hospital or your doctor, PHI is created and recorded in your medical record by your healthcare providers. In the same way, the PHI created as part of this study will be linked to who you are and your medical information.

What PHI is collected and used in this research study, and might also be shared with others?
As part of this ~~research project~~study, the research team at the hospital(s) involved in the research will collect your
~~The researchers will also get information from your medical record [include where these records will come from, for example, which hospital or clinic, your private doctor, etc.]~~

During the study, the researchers will gather information by:

- Reviewing and/or taking ~~a~~your medical history (includes current and past medications or therapies, illnesses, conditions or symptoms, family medical history, allergies, etc.)
- ~~doing~~Doing a physical examination that generally also includes blood pressure reading, heart rate, breathing rate, and temperature.
- ~~completing~~Completing the tests, procedures, questionnaires and interviews explained in the description section of this consent.
- ~~reviewing~~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~~Reviewing genetic tests
- ~~reviewing mental health records.~~
- ~~reviewing~~Reviewing mental health records.
- Reviewing alcohol and/or substance abuse records.
- Reviewing psychotherapy notes.
- ~~reviewing psychotherapy notes [If you include this, your protocol needs to explicitly address this special class of records and appropriate access]~~

Why is your ~~protected health~~ PHI being used?

Researchers need the information ~~being used?~~
~~Your personal contact information is important to be able to~~that identifies you so they can contact you during the study. ~~Your~~They need your health information and the results of any tests and procedures being collected as part of this ~~research~~ study ~~will be used for~~to answer the questions posed in the study. The purpose of ~~this~~the study ~~as explained~~is discussed earlier in this consent form. ~~The~~ Before researchers analyze the data, they remove any information that would let others know who you are or that you took part in the study. If researchers publish or present study results ~~of this study could be published or presented~~ at scientific meetings, lectures, or other events, ~~but~~their presentations would not include any information that would let others know who you are, unless you give separate permission to do so.

The ~~Principal Investigator~~Lead Researcher may also use and share the results of these tests and procedures ~~to treat you in collaboration with others in the~~with other healthcare providers at Mount Sinai ~~Health System.~~

who are involved in your care or treatment. The research team and other authorized members of The Mount Sinai Health System ("Mount Sinai") workforce may use and share your information to ensure that the research meets legal, institutional or accreditation requirements. For example~~, the School's~~:

- The Mount Sinai Program for the Protection of Human Subjects is responsible for overseeing research on human ~~subjects,~~participants 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~~PHI?
As part of the study, the ~~Principal Investigator, study~~Lead Researcher, research team and others in the Mount Sinai workforce may disclose your ~~protected health information~~PHI, including the results of the research study tests and procedures, to the following people or organizations: (It is possible that there may be changes to the list during this research study; you may request an up-to-date list at any time by contacting the ~~Principal Investigator~~Lead Researcher.)

- The United States Department of Health and Human Services (DHHS) and the Office of Human Research Protection (OHRP) (the government organization that is responsible for protecting human research participants).
- Other collaborating research center(s) and their associated research/clinical staff who are working with the ~~investigators~~researchers on this project: List all sites; if greater than 6, list the first 6 and add: and other sites available on request.
- Research data coordinating office and/or their representative(s) who will be responsible for collecting results and findings from all the centers:
- Outside laboratory who will be performing laboratory analysis for all the research centers involved in this project:

- The commercial sponsor and/or their representative (who will use the results for submissions to the Food and Drug Administration (the government organization that approves drugs or devices for medical use):
- The sponsoring government agency and/or their ~~representative~~representatives who need to confirm the accuracy of the results submitted to the government or the use of government funds:
- Contract Research Organization (whose job is to help organizations fulfill their responsibilities in the research and development process):
- A Data Safety Monitoring Board or other committee that will monitor the study on an ongoing basis for safety.
- The United States Food and Drug Administration.
- ~~This statement must always be included: The United States Department of Health and Human Services and the Office of Human Research Protection.~~
- If you are a prisoner, your medical and/or research records may also be given to officials and agencies within the criminal justice system when necessary and permitted by law.
- Others:

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~~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, ~~the Office of Human Subjects Protection (OHRP) of the Department of Health and Human Services~~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. ~~We may publish the~~The results of this research~~.~~ may be published. However, ~~we will keep~~ your name and other identifying information will be kept confidential.

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~~Lead Researcher will ensure that the key to the code will be kept in a locked file~~,~~ or will be securely stored electronically. The code will not be used to link the information back to you without your permission, unless the Institutional Review Board (IRB) allows it after determining that there would be minimal risk to your privacy. The Certificate of Confidentiality obtained from the Department of Health and Human Services will not be used to prevent disclosure to local authorities of child abuse and neglect, or harm to self or others. It is possible that a sponsor or their representatives, a data coordinating office, ~~or~~ a

contract research organization, ~~will~~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, ~~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~~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~~The results of this research~~.~~ may be published. However, ~~we will keep~~ 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?~~PHI? Your authorization for use of your ~~protected health information~~PHI for this specific study does not expire.

Will you be able to access your records?
During your participation in this study, you will not be able to access your medical records. This ~~will be~~is done to prevent the knowledge of study results from affecting the reliability of the study. Your information will be available should an emergency arise that would require your treating physician to know this information to best treat you. You will have access to your medical record and any study information that is part of that record when the study is over or earlier, if possible. The ~~investigator~~research team is not required to release ~~to you~~ research information to you that is not part of your medical record.

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~~research team is not required to release ~~to you~~ research information to you that is not part of your medical record.

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

Can you change your mind?
~~You~~ If you decide to stop being in the study, please contact the Lead Researcher or the research staff. The research team may ask you whether they can continue to collect information from your medical record. You will also have to decide if you wish to limit the continued use of the information collected during the study. Under US privacy laws you may also withdraw your permission for the researchers to use and ~~disclosure of~~share any of your protected information for research, but you must do so in writing to the ~~Principal Investigator~~Lead Researcher at the address on the first page.

Even if you withdraw your permission, the ~~Principal Investigator for the research study~~Lead Researcher may still use ~~your protected~~the information that was already collected ~~if that information is necessary,~~ but only to complete ~~the~~this research 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~~taking part in 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~~PHI.

It is important for you to understand that once information is disclosed to others outside Mount Sinai, the information may be re-disclosed and will no longer be covered by the federal privacy protection regulations. ~~However, even if your information will no longer be protected by federal regulations~~However, 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~~researchers are reviewing your medical records ~~are being reviewed, or a~~asking questions about your medical history ~~is being taken~~or conditions, it is possible that ~~HIV-related~~ they may learn information ~~may be revealed~~ related to ~~the researchers.~~ your HIV status. If that is the case, the following information concerns you. ~~If this research does~~researchers are not ~~involve any review of~~reviewing your medical records or asking questions about your medical history or conditions, then you may ignore 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.~~

Certificate of Confidentiality: To further protect your privacy, the researchers have obtained a Certificate of Confidentiality from the Department of Health and Human Services. This is intended to ensure that your identity as a participant in this research study will not have to be disclosed as a result from a subpoena, for the purpose of identifying you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings other than to the FDA or OHRP as identified above.

The research staff will not share any of your ~~research~~personal information~~, study data and~~/or ~~biospecimens~~samples with anyone who is not a member of the research team, including any family members or friends, other than ~~to~~ those identified above. However, you should know that if ~~we learn~~it is learned that you or someone else is threatened with serious harm, such as a child or an elderly person being abused, the ~~investigators~~research team may notify the appropriate authorities if necessary to

protect you or others. A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. This means that you and your family must also actively protect your own privacy. If an insurer or employer learns about your research participation, and you agree that they can have your research information, then the researchers may not use the Certificate of Confidentiality to keep this information from them.

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

This research has been reviewed and approved by an Institutional Review Board (IRB). You may reach a representative of the Mount Sinai Program for Protection of Human Subjects at telephone number (212) 824-8200 during regular work hours (Monday-Friday, 9am-5pm, excluding holidays) for any of the reasons listed below. This office will direct your call to the right person within the Mount Sinai Health System:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You are not comfortable talking to the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

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

_____ _____ _____ _____

Signature of ~~subject~~ Participant | Printed Name of ~~Subject~~Participant | Date | Time

PERSON EXPLAINING STUDY AND OBTAINING CONSENT:

_____ _____ _____ _____

Signature of ~~consent delegate~~Consent Delegate | Printed Name of ~~consent delegate~~Consent Delegate | Date | Time

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

_____ _____ _____ _____

Signature of Witness | Printed Name of Witness | Date | Time