[Follow all instructions in pink. Delete optional text that does not apply to your study and delete all instructions from the completed consent document. If you do not intend to use a color version of the consent document, please make all headers black and bolded.]

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**STUDY INFORMATION:**

**Study Title:**

#### **Principal Investigator (Head Researcher):** [First Name Last Name, Degree(s)]

#### **Physical Address:** [Hospital/clinic name; Annenberg 22nd Floor, Room XXX; This will usually be the location where the subject should go for study visits; otherwise it can be the PI’s office address]

**Mailing Address:** [e.g. One Gustave L Levy Place Box XXXX, NY, NY 10029]

#### **Phone:** [e.g. 212-XXX-XXXX; this number should reach the research team directly, not be just a general clinic or department number]

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**SUMMARY OF THIS RESEARCH STUDY:**

The revised Common Rule requires that consent forms begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. The intention of this section is to provide potential research participants with a better understanding of the project’s scope, including major risks and benefits, so they can make a more fully informed decision about whether to participate. While using bullet points is not prohibited this section is not intended as a list of isolated facts, but rather should be drafted to promote comprehension. This section has been likened to an “elevator pitch” or a “small talk” summary of your project that would educate, engage and not bore your dinner guests.

This section should include a summary of the purpose of the study, duration of participation, major requirements of the study and any potential benefits. This section should also contain any significant risks of participating in the study. The information presented in this section may be discussed in greater detail later in the consent form; however, the information should not be duplicated later in the form. Ideally this summary should fit on one page.

* Draft language for this section is as follows (instructions in pink):

In medicine there are many unanswered questions. A research study is when scientists try to answer a question about something that we don’t know enough about.  Participation in a research study may or may not directly help you or others. Participation is entirely voluntary. It is completely up to you whether or not you take part. You can also change your mind at any time and it will not affect your ability to get medical care within the Mount Sinai Health System.

The purpose of this research study is [brief statement of purpose in lay language, written at the 8th grade level and avoiding scientific or medical jargon. Document software should be used to test reading level of the consent. For example, explain to the subject the current therapies for the disease and why they are not satisfactory. For non-therapeutic studies, explain the scientific problem. Describe how this research will attempt to solve the problem.].

If you choose to participate, you will be asked to [brief overview of the major requirements for participants in lay language, including:

* Number of visits and duration of participation
* Types of procedures and, if relevant, how standard care will be affected
* Whether there are costs associated with participation
* Mandatory storage of samples
* Whether or not there is compensation (details/amounts not included).].

The main risks to you if you choose to participate are [brief summary of main/most likely and/or significant risks in lay language – a complete list of all reasonably foreseeable risks should be included in the body of the consent form].

If there is no potential for benefit: Participating in this research will not benefit you.

If there is a potential for benefit: You may also benefit from participation in this research if [brief summary of main/most likely benefits].

If there are alternatives to participation: Instead of participating in this research, you may [list appropriate alternative procedures or courses of treatment, if any – this statement may be deleted if there are no alternatives].

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

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**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 [Fill in the circumstance or condition that makes subjects eligible for the research, for example, “you are a healthy individual.”, “you have diabetes and you take insulin.” These descriptions should be brief and not the entire inclusion/exclusion criteria. If additional information is needed to elaborate on the purpose of the study, it should be added here; however, information provided in the summary above need not be reiterated].

Funds for conducting this research are provided by [indicate name of financial sponsor(s) as applicable, and indicate the relationship of the financial sponsor to the study if any (e.g., manufacturer of the drug or device); or, for unfunded studies, Mount Sinai.]

#### For any study that will be registered on ClinicalTrials.gov, please add the following paragraph: A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

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**LENGTH OF TIME AND NUMBER OF PEOPLE EXPECTED TO PARTICIPATE:**

Your participation in this research study is expected to last [months/weeks/years, until a certain event].

The number of people expected to take part in this research study at [specify by site within MSHS] is [local enrollment goal]. If it is multisite study, also indicate: The total number of people expected to take part in this research study across all sites is [overall enrollment goal].

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**DESCRIPTION OF WHAT’S INVOLVED:**

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

Tell the subject what to expect using lay language and simple terms. As appropriate, include the following items:

* The site where the research activities will take place (begin with the appropriate Mount Sinai site. If the subject will need to go/or can choose to go to more than one location for different study visits, make that clear.)
* What is being performed as part of the research study
* List experimental procedures and therapies and identify them as such.
* List frequency of procedures and tests. Consider providing a time-line description of the procedures that will be performed. If practical, prepare a time-line chart or schematic to accompany descriptions of procedures and tests for studies that require more than 1 or 2 steps/visits
* Protocol-dictated drugs or biologics to be used
* Protocol-dictated devices to be used
* Hospitalizations, outpatient visits and telephone or written follow-up
* Length and duration of visits and procedures
* If blood will be drawn, indicate the amount in teaspoons, tablespoons, or ounces
* With whom the subject will interact
* Where the research will be done
* When the research will be done
* If procedures and therapies are performed as part of standard clinical care, even if the subject does not take part in the research, they do not necessarily need to be included. If they are included to provide context, identify them as such.
* If applicable, include a statement indicating whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions. Please note that only the results of FDA or New York State approved tests that are performed in a CLIA-certified lab can be shared with participants.
* If your study involves a drug or device: Because this project involves the use of medications or a medical device, it is necessary that we make a note of your participation in the electronic medical record. That way anyone treating you will be aware of your participation and may be able to avoid any unfortunate outcomes that could arise if your research participation were unknown.
* For research involving random group assignment, describe the chances of being assigned to any one group. For example: The study treatment you get will be chosen 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. For double-blinded studies, add:Neither you nor the study doctor will know which experimental study treatment you are getting; however, this information could be obtained in an emergency. For single blinded studies, add: You will not be told which study treatment you are getting; however, your study doctor will know.
* If the research involves genetic testing, refer to the Guidance on Research Involving Genetic Testing, and insert the appropriate language from that document into this section of the consent document. Include a statement to indicate whether or not the results of genetic testing will be shared with participants. If they will be, describe how these results will be shared. Please note that only the results of FDA or New York State approved tests that are performed in a CLIA-certified lab can be shared with participants.
* If your study involves conducting HIV testing for research purposes, the following language must be used: To take part in this research project we will have to test your blood for evidence of HIV infection. HIV is the virus that causes AIDS. It can be transmitted through unprotected sex (vaginal, anal, or oral sex) with someone who has HIV, and through contact with blood, as in sharing needles (piercing, tattooing, drug equipment including needles used to inject drugs). HIV-infected pregnant women can transmit to their infants during pregnancy or delivery or while breast feeding. There are treatments for HIV/AIDS that can help an individual stay healthy. Individuals with HIV/AIDS can adopt safe practices to protect uninfected and infected people in their lives from becoming infected or being infected themselves with different strains of HIV.

By law, positive test results are reported to the NYS Department of Health for epidemiological (the study of the factors determining or influencing the presence or absence of disease) and Partner Notification purposes. If you wish to be tested anonymously you will be referred 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 based on an individual’s HIV status and services are available to help with such consequences. You are free to refuse this test, but if you refuse you will not be allowed to join or remain in this research project.

* If your study requires that participants use birth control during participation, timing and use of birth control is generally dictated by protocol. If this study requires use of contraception, and the sponsor’s template does not provide suggested language for the use of birth control, please insert the appropriate language on birth control, using the following options as a guide:

For Women:

Since you are participating in a research study that involves drugs 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 the study. You should not participate if you are breastfeeding.

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 effective birth control is important. No individual birth control is 100% effective.

Recommended methods of birth control are:

* The consistent use of an approved hormonal birth control (pill/patches, 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
* Sterilization.

Some study drugs interact with hormonal contraceptives and make them less effective or they should not be used with the disease/condition under study. If that is the case, delete the hormonal methods listed above and state why they are not recommended while taking part in the study.

Hormonal birth control, implants, and injections are only considered effective if used properly and started at least one month before you begin the study, continuing throughout the study and for one month [OR insert a longer period of time if required by the protocol] after the end of the 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. If you are unsure whether the method of birth control you use is acceptable to use while participating in this study, you should ask your study doctor before you begin the study. If you are less than one year post-menopausal, there is the potential that you could 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, or in the “month” [OR insert a longer period of time if required by the protocol] following it], it is important that you tell your study doctor immediately. The trial drug may be stopped and a referral may be made to an obstetrician/gynecologist for follow-up. If you plan to become pregnant in the year following a clinical trial, speak with your study doctor.

Should you become pregnant, regardless of the outcome, the sponsor may ask for information on your pregnancy, even if you are withdrawn from the study. Your written consent will be obtained separately in the case that this happens.

For Men:

Since you are participating in a study that involves experimental drugs or experimental treatment with potential risks to a developing fetus, it is recommended that you use a condom and not impregnate a woman or donate sperm while you are taking the study drug, and for and additional 90 days after you stop taking the study drug [OR insert a longer or shorter period of time if required by the protocol, FDA labeling or the IB. List an exact length of time if the protocol recommends that men refrain from impregnating a woman and/or donating sperm for a longer period of time than 90 days, for example, 180 days or 6 months. Do not list a range of time, for example, 3 to 4 months.]. This is because levels of the study drug may be present in the sperm and/or seminal fluid 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 clinical trial.

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

**The research team must assure that the consent and protocol reflect whatever data sharing obligations that are imposed by the grantor. If the grant seems to require sharing in a manner inconsistent with PPHS policy, please contact the PPHS promptly and directly.**

If your study **is not designed to maintain data or specimens** for any purpose other than the purpose of this study, and those uses are spelled out in the protocol and consent, then you must add one of the following statements. Please note that the second statement can only be used if the original study does not hold the prospect of direct benefit for the participant. If there is direct benefit then you cannot compel future use, but you can ask (see questions below).

Include one of the following statements:

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

OR

In the future, your identifiable information may be removed from the private information and/or samples that are collected as part of this research. After this removal, the information and/or samples could be used for future research studies or shared with other research teams for future research studies. You will not be informed of the details of specific research that is done with your medical information and biospecimens. That means that a research project might be done that you would not consent to if provided with the details of that research project.

OR

If your study will be collecting data and or biospecimens **with the intention of sharing them** in the future, there are 2 paths:

* If the study does not **hold out the prospect of direct benefit** to the subjects then the future uses of data and specimens can be established by the investigator, or granular permission can be asked of participants. If no specific preferences or limitations will be asked, then one of two statements above should be used. The second statement has to be followed with more information, including if the future research will be related or not to a specific purpose, if they will be directly identifiable or linked by a code, if commercial entities may receive the data/specimens. If there is a possibility that there will be data/specimens deposited into a large public repository, or the equivalent, this should be stated or permission asked. The consent should include the suggested description and risks of large public repositories as detailed below.
* If the study **holds out the prospect of direct benefit** to the subjects, then the use of the data and specimens outside the project purpose and description cannot be mandated but can be requested using the following suggested language. Please edit to include only the specific options available. For example, if specimens/data will always be linked to identity, even with a code, then do not include question 2.

The researchers would like to ask your permission to keep the data and specimens (like blood, tissue, hair, or any other body matter) collected from you during this study to use them in future research studies. Please tell us how we may use this material in future research studies.

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

Yes\_\_\_\_\_\_\_\_ No\_\_\_\_\_\_\_\_\_ If no, please stop here. If yes, please continue to the
next question.

(2) The researchers can keep your information and/or specimens stored in one of two different ways: one way will store your information and/or specimens 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 (no one will know who the information is from). It will not be stored both ways, so you must choose one of these two options. Please note that if you choose to have your information and/or specimens stored anonymously, you will not be able to change your mind to ask for your information and/or specimens to be destroyed at a future date.
How would you like your information and/or specimens stored? Please initial ONE choice:

I would like my information and/or specimens stored with a link to my identity\_\_\_\_\_\_\_\_\_\_\_
I would like my information and/or specimens stored anonymously \_\_\_\_\_\_\_\_\_\_\_\_\_

The following question 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 studies that are directly related to the purpose of the current study?
Please initial your choice:

Yes\_\_\_\_\_\_\_\_\_ No\_\_\_\_\_\_\_\_\_\_

(5) Do you give the researchers permission to keep the information and/or specimens indefinitely and 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\_\_\_\_\_\_\_\_\_\_

**(5.1)** From time to time researchers outside of medicine and related sciences would like to use this information. This might be in the field of anthropology, human origins, mapping human migration patterns etc. Do you give permission to use your information and/or specimens outside the fields of medicine and biological sciences? Please initial your choice:

Yes\_\_\_\_\_\_\_\_\_ No\_\_\_\_\_\_\_\_\_\_

(a) If the future research in a different area can be done without having to know that
the information and/or specimens came from you personally, that will be done.
(b) If the future research in a different area requires that it is known specifically who the information and/or specimens came from, then one of the following will be done:
(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 or specimen is needed and what will be done with it. Your permission will be asked to use your information and/or specimens in that research project.
(ii) If you do not give permission to be contacted in the future, or if it is found
that contacting you is not practical, for example, because you have moved, your identifiable data and specimens may still be used. The Institutional Review Board (IRB) will be asked for permission to use the information and/or specimens 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 and/or specimens 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) Do you give permission to have portions of the specimens and/or information given to other researchers, including those at Mount Sinai, other academic institutions and for profit companies, for use in research within the limits you have chosen above? Please initial your choice:

Yes\_\_\_\_\_\_\_\_\_ No\_\_\_\_\_\_\_\_\_\_

(7) Do you give permission to have portions of the specimens and/or data deposited in large public repositories, (explained below) for use in research with the limits you may have chosen above? Please initial your choice:

Yes\_\_\_\_\_\_\_\_\_ No\_\_\_\_\_\_\_\_\_\_

To do more powerful research, it is helpful for researchers to share information they get from studying human samples. They do this by putting it into one or more scientific databases, where it is stored along with information from other studies. Researchers can then study the combined information to learn even more about health and disease. If you agree to take part in this study, some of your genetic and health information might be placed into one or more scientific databases. There are many different kinds of scientific databases; some are maintained by Icahn School of Medicine at Mount Sinai or another institution, some are maintained by the federal government, and some are maintained by private companies. For example, the National Institutes of Health (an agency of the federal government) maintains a database called “dbGaP.” A researcher who wants to study the information must apply for permission to use the database. Different databases may have different ways of reviewing such requests. Researchers with an approved study may be able to see and use your information, along with that from many other people. Researchers will always have a duty to protect your privacy and to keep your information confidential, but there are risks associated with data collection and sharing. They are described in more detail in the risks section.

For research involving biospecimens, indicate whether the research will (if known) or might

include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen.

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**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: [Describe the subject’s responsibilities. Explain what commitment you expect from the subject. For example: taking prescribed medications, using birth control methods as described in the Description of What’s Involved section, avoiding certain medications, attending study visits, calling the study team for certain side effects, etc.]

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**COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:**

If there are no anticipated costs or payments to the subjects, add: You will not be paid for participating in this research study. Being in this research study will not lead to extra costs to you. If time or travel costs to be assumed by subjects, add: You will not be reimbursed for your travel or time that may be required for study visits.

If the research may result in additional costs to the subjects, add: Taking part in this research study may lead to added costs to you. [Describe what these costs are, if known]

When subjects will be paid, add: If you agree to take part in this research study, we will pay you [indicate amount] for your time and effort. [Indicate if the amount is pro-rated for research visit completion and what form the form of the payment will be (e.g. cash, gift card, check). Provide a general indication of when the payment will be provided (e.g. at each visit, at the end of their participation in the study). Be sure the timeframe is general and realistic.]

If the payment will be provided in the form of a check generated by the Mount Sinai Finance department, please include a statement such as: Checks require some time to be prepared and will be given to you once processed and available.

Only if NO payment of any kind will be provided to subjects as part of their participation may this statement be removed: 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.

If any reimbursement will be provided for expenses the subject will incur, such as transportation, indicate what evidence of the expenses the subject needs to provide (receipts). Further guidance is available from the Finance Department.

For studies collecting biospecimens that may be used for profit, one of the following statements must be included:

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

 OR

The samples collected from you as part of this research may be used for commercial profit. You may share in that profit if [Describe potential for participants to share in future profits]

For Department of Defense (DOD) research which targets military personnel and where subjects will be paid, add: You should check with your supervisor before accepting payment for participation in this research.

For studies involving prisoners, add: If you are released from jail before you finish this research study, you should take steps to get insurance or Medicaid coverage. Regular office visits and standard treatment will be billed to you and/or your health insurance. You may continue in the research study after your release from prison. If you move out of the area, we will help you make arrangements to be followed by a physician.

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**POSSIBLE BENEFITS:**

If there are possible benefits to individual subjects from the research, add: It is important to know that you may not get any benefit from taking part in this research. Others may not benefit either. However, possible benefits may be [Describe the potential benefits of participation but do not overstate them – note that benefits from the original summary should not be reiterated unless more detail is needed. First describe any direct benefits to the subject, then any benefits to others. If benefits from participation may not continue after the research has ended, explain that here. For example, an investigational drug provided at no cost during a study may not be available at the end of the research or may no longer be provided at no cost to subject if the drug becomes available for marketing. Monetary reimbursement for participation is not considered a benefit and should be described the Costs/Payments section. Generally speaking enhanced observations and better care because of researcher oversight are not to be listed as a benefit.]

If there are no expected benefits to individual subjects from the research, add: You are not expected to get any benefit from taking part in this research study. Others may not benefit either. However, possible benefits to others include [Describe potential benefits to others but do not overstate them]

For studies involving prisoners, add: Taking part in this research study will not improve your housing or correctional program assignments. Your taking part in this research study will not improve your chance of parole or release.

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**REASONABLY FORESEEABLE RISKS AND DISCOMFORTS:**

Describe each of the following risks and discomforts, as appropriate – note that risks from the original summary should not be reiterated unless more detail is needed*.* When appropriate, it should be clear whether the outcome of certain risks is permanent or can be reversed. The risks of therapies or procedures may be presented in a table form if it provides further clarity.

* Physical risks (for example, medical side effect)
* Psychological risks (for example, embarrassment, fear or guilt)
* Risk of loss of private information; this risk always exists, but there are procedures in place to minimize the risk.
* Describe risks for each relevant procedure (For example, computerized tomography, MRI, survey, etc.) and for each drug, device or biologic that is being studied by the investigation.
* Include relevant risks based on animal and in vitro studies, particularly for Phase I or II trials.
* Describe the probability of risks (frequently, occasionally, or rarely expected). For high-magnitude risks (ones that are life-altering or potentially life-altering, such as visual loss, anaphylaxis, paralysis, and aplastic anemia) explain the ramifications, even if these risks are rarely expected (for example, indicate what might happen to the subject if liver enzyme tests indicate an abnormality, will these effects be reversible.
* Describe risks to those other than the subject, along with corresponding instructions. For example, risk to a nursing infant if the mother is the research subject, risk to sexual partners or family members etc.
* If this study includes blood draw by needle stick, include the following statement: 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.
* If the research involves an investigational product or procedures whose risk profile is not well known, add: In addition to these risks, this research may hurt you in ways that are not known. The unknown risks might be minor or might be major (death).
* If the research involves pregnant women or women of child-bearing potential and investigational products or procedures whose risk profile in pregnancy is not well-known, add: If you are or become pregnant, this research may hurt your baby or your pregnancy in ways that are unknown. The unknown risks might be minor or might be major (death) for the pregnancy. 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.
* 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.
* Legal risks (for example, being reported for child abuse)
* Social risks (for example, damage to your social standing or reputation; possible discrimination)
* Economic risks (e.g. having to pay money out of pocket for research or medical expenses, loss of health insurance, missing work or school)
* If you have included language regarding sharing data/specimens, the following language should be included unless you are certain that the data/specimens will never be used in large-scale research that could result in these types of risks: Group Risks - Although we will not give researchers your name, we will give them basic information such as your race, ethnic group, and sex. This information helps researchers learn whether the factors that lead to health problems are the same in different groups of people. It is possible that such findings could one day help people of the same race, ethnic group, or sex as you. However, they could also be used to support harmful stereotypes or even promote discrimination.
* If sharing data/specimens, include: Privacy Risks - Your name and other information that could directly identify you (such as address, date of birth or social security number) will never be placed into a scientific 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 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 heritage, or health conditions.
* If genetic testing is involved in this project or future use may include genetic research, include: Insurance Risks – There is a Federal law called the Genetic Information Nondiscrimination Act (GINA). In general, this law makes it illegal for health insurance companies, group health plans, and most 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.

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**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.

If there are alternative procedures or courses of treatment that may be helpful to the subject, or if the treatments being studied are available outside of the research, even if not FDA approved for the purpose, add: Instead of being in this research study, your choices may include:

* List alternative procedures. For clinical trials describe the options that you would normally offer patient. If applicable, include supportive care as an option. Do not only state that the study doctor will discuss options.

For clinical trials under FDA jurisdiction, and other studies if applicable, add: The important risks and possible benefits of these alternatives are listed below:

* Describe the important risks and potential benefits of each of the alternative procedures and courses of treatment.

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**IN CASE OF INJURY DURING THIS RESEARCH STUDY:**

Include one of the statements below based on an assessment of the total research risk level

For minimal risk protocols, add: 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.

For protocols involving greater than minimal risk that are Sponsor Initiated(For-Profit), add: If you are injured or made sick from taking part in this research study, medical care will be provided. The sponsor will reimburse your reasonable and necessary medical expenses for diagnosis and treatment of a research-related injury or illness.

**This does not prevent you** from seeking payment for injury related to malpractice or negligence. Contact the investigator for more information.

[Provide sponsor language regarding compensation for injury here, as applicable. Please note that Icahn School of Medicine at Mount Sinai (ISMMS) has adopted the position that for-profit sponsors must accept responsibility for the payment for all complications and/or injuries sustained by study subjects as a result of their participation in research.]

If the study funder will pay for research-related injury, include the following information: The Centers for Medicare and Medicaid Services (CMS), the agency that administers the Medicare and Medicaid programs, has stated that payments by a clinical trial sponsor for injuries related to a trial are a form of liability insurance that must be reported 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) must have certain individually identifiable information about you, such as your name, date of birth, Social Security Number, CMS Claim Number, 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 to use this information only for the purposes described in this paragraph or as otherwise specified in the Authorization to Use and Disclose Protected Health Information section, which is included below.

For protocols involving greater than minimal risk that do not have a for-profit sponsor (e.g. NIH), add: **If you are injured or made sick from taking part in this research study, medical care will be provided. Generally, this care will be billed to you or your insurance in the ordinary manner and you will be responsible for all treatment costs not covered by your insurance, including deductibles, co-payments and coinsurance.  This does not prevent you from seeking payment for injury related to malpractice or negligence. Contact the investigator for more information.**

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**ENDING PARTICIPATION IN THE RESEARCH STUDY:**

You may stop taking part in this research study at any time without any penalty. This will not affect your ability to receive medical care at 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 research study, please contact the Principal Investigator or the research staff.   [If procedures for orderly termination of participation by the subject are necessary, describe them. For example, subjects on an investigational drug to treat their diabetes may be switched to an approved drug, subjects in a study of high dose corticosteroids may have their steroid doses tapered, etc. Include any specific withdrawal procedures described in the protocol.]

If there are possible adverse consequences to withdrawing from the research, add: If you decide to stop being in the research study, the following may occur: [Describe the adverse consequences that subjects may experience by unilaterally withdrawing from the research. For example, subjects on a drug to treat their diabetes may experience elevated blood sugars unless they switch to another drug. Subjects in an oncology trial who were getting benefit from the study drug may experience progression off the drug. Subjects in a study of high dose corticosteroids may experience life-threatening symptoms unless the steroid doses are tapered.]

For clinical trials under FDA jurisdiction, add: If you stop being in the research study, already collected information may not be removed from the research study database and will continue to be used to complete the research analysis. [Note: The consent document cannot give the subject the option of having this data removed.] You may be asked whether the study doctor can collect information from your routine medical care. If you agree, this data will be handled the same as research data [Note: If a subject withdraws from the interventional portion of a study and does not consent to continued follow-up of associated clinical outcome information, the investigator must not access the subject’s medical record, or other confidential records requiring the subject’s consent, for purposes related to the study. However, an investigator may review study data related to the subject collected prior to the subject’s withdrawal from the study, and may consult public records, such as those establishing survival status.]

Describe the procedures for withdrawing consent for future use of any data/specimens.

Describe if and how data/specimens can be withdrawn or destroyed. Explain what withdrawal means, (include what will happen to the data and/or specimens and if there are any limitations (if stored without identifiers will you be able to destroy the data, what will happen to data or specimens that have already been shared or used, etc.) and state that no new information will be collected). Modify the below sample statement for accuracy:

If you decide you don’t want your samples and/or data to be used for research anymore, you can contact the researcher and ask to have your samples and/or data removed from future use. If any samples or data have already been shared without your identity, it won’t be possible to retrieve them because no one will know who you are. Samples and data that have already been used will not be affected by your decision. Any samples and/or 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 samples have already been deposited in an external repository, the study team will request that your samples be removed.

Withdrawal without your consent: The study doctor, the sponsor or the institution may stop your involvement in this research study at any time without your consent. This may be because the research study is being stopped, the instructions of the study team have not been followed, the investigator believes it is in your best interest, or for any other reason. If specimens or data have been stored as part of the research study, they too can be destroyed without your consent. 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]

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**CONTACT INFORMATION:**

#### If you have any questions, concerns, or complaints at any time about this research, or you think the research has harmed you, please contact the office of the research team and/or the Principal Investigator at phone number [e.g. 212-659-xxxx; this number should reach the research team directly, not be a general clinic or department number].

If applicable, add: If you experience an emergency during your participation in this research, contact [customize as appropriate: e.g. provide an attending physician’s number, instruct subjects to call 911 or go to the emergency room, etc.].

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:

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

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**DISCLOSURE OF FINANCIAL INTERESTS:**

Sometimes, physicians/researchers receive payments for consulting or similar work performed for industry. Effective September 2014 Mount Sinai reviews only payments to an individual totaling more than $5,000 a year per entity when determining potential conflicts of interest. If you have questions regarding industry relationships, we encourage you to talk your physician/researcher or visit our website at http://icahn.mssm.edu/ where Mount Sinai publicly discloses the industry relationships of our faculty.

[Add management plan language here, if applicable]

Add the following statements, as appropriate:

1. For studies paid for in whole or in part by the manufacturer of the drug or device under investigation, the consent form should state: The company sponsoring this research study manufactures the drug/device being tested and so has a financial interest that could be affected by the outcome of this research study.

2. For studies where an investigator holds a financial interest in the company, or in the drug/device under investigation, that could benefit from the trial the consent form should state: One or more researchers has a financial interest that could be affected by the outcome of this research study.

3. For studies where the PI's Department has a financial interest in the drug or device under investigation or in a company that could benefit from the study findings, or receives significant support from the study sponsor, the consent form should state: The Principal Investigator's Department has a financial interest that could be affected by the outcome of this research study or receives significant support from the research study sponsor. [Statements #2 and #3 may be combined in a single statement, when applicable.]

4. For studies where investigators or their Departments are paid on a per-patient enrolled basis, the consent form should state: The costs of doing this research are paid based on the number of patients enrolled.

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**MAINTAINING CONFIDENTIALITY – HIPAA AUTHORIZATION:**

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

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

The following paragraphs must be precise and customized as appropriate:

As part of this research project, the research team at the hospital(s) involved in the research will collect your [At a minimum you should include any of the following if collected: name, address, telephone/fax numbers, dates directly related to the individual (birth, admission, discharge, date of death, etc.), e-mail/internet protocol (IP) addresses or web universal resource locators (URL’s), social security number, medical records number, health plan numbers, account numbers, certificate/license numbers, vehicle identifiers, device identifiers, biometric identifiers, photographic images, other unique codes]

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:

Choose and modify as needed. The first 2 bullets do not need to be included here if they are adequately covered in the description section of the consent:

* taking a medical history (includes current and past medications or therapies, illnesses, conditions or symptoms, family medical history, allergies, etc.)
* doing a physical examination that generally also includes blood pressure reading, heart rate, breathing rate and temperature
* completing the tests, procedures, questionnaires and interviews explained in the description section of this consent.
* reviewing HIV-related information, which includes any information indicating that you have had an HIV related test, or have HIV infection, HIV related illness or AIDS, or any information which could indicate that you have been potentially exposed to HIV. [If you do not intend to access this information for research purposes, delete]
* reviewing genetic tests
* reviewing mental health records [If you include this, your protocol needs to explicitly address this special class of records and appropriate access]
* reviewing alcohol and/or substance abuse records [If you include this, your protocol needs to explicitly address this special class of records and appropriate access this information should also be disclosed in the main consent under the Description Section]
* 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 information being used?

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

Include this statement if applicable, otherwise delete it, unless sharing of research information is not permitted as outlined above, (for example, the results of an experimental test):

The Principal Investigator may also use and share the results of these tests and procedures to treat you in collaboration with others in the Mount Sinai Health System.

The research team and other authorized members of The Mount Sinai Health System (“Mount Sinai”) workforce may use and share your information to ensure that the research meets legal, institutional or accreditation requirements. For example, the School’s Program for the Protection of Human Subjects is responsible for overseeing research on human subjects, and may need to see your information. If you receive any payments for taking part in this study, the Mount Sinai Finance Department may need your name, address, social security number, payment amount, and related information for tax reporting purposes. If the research team uncovers abuse, neglect, or reportable diseases, this information may be disclosed to appropriate authorities.

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

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

Modify this list as appropriate – delete or add items as necessary. For EACH LISTING include a brief description of WHY they will receive the information (the examples below are suggestions only):

* Other collaborating research center(s) and their associated research/clinical staff who are working with the investigators on this project: List all sites; if greater than 6, list the first 6 and add: and other sites available on request. [It is also permissible to reference at this point a website that maintains a current list of sites, as long as the list is printed out and given to the subject at the time this authorization is signed.]
* Research data coordinating office and/or their representative(s) who will be responsible for collecting results and findings from all the centers: [name that group or company]
* Outside laboratory who will be performing laboratory analysis for all the research centers involved in this project: [name that company or organization]
* The commercial sponsor and/or their representative (who will use the results for submissions to the Food and Drug Administration): [name that group or company]
* The sponsoring government agency and/or their representative who need to confirm the accuracy of the results submitted to the government or the use of government funds: [name that agency]
* Contract Research Organization (whose job is to help organizations fulfill their responsibilities in the research and development process): [name that company]
* A Data Safety Monitoring Board or other committee that will monitor the study on an ongoing basis for safety.
* If the research is FDA regulated, add: 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.
* For studies involving prisoners: 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: [name other groups who might receive the PHI, and why; examples may include foreign regulatory agencies, outside firms doing telephone polling, internet hosts, etc.]

Please choose one of the following paragraphs based on whether your study has a Certificate of Confidentiality (CoC). Please note the chosen paragraph must be precise and customized to fit this study.

For studies with no CoC: In all disclosures outside of Mount Sinai, you will not be identified by [name, social security number, address, telephone number, or any other direct personal identifier] unless disclosure of the direct identifier is required by law. Some records and information disclosed may be identified with a unique code number. The Principal Investigator will ensure that the key to the code will be kept in a locked file, or will be securely stored electronically. The code will not be used to link the information back to you without your permission, unless the law requires it, or rarely if the Institutional Review Board allows it after determining that there would be minimal risk to your privacy. It is possible that a sponsor or their representatives, a data coordinating office, a contract research organization, may come to inspect your records. Even if those records are identifiable when inspected, the information leaving the institution will be stripped of direct identifiers. Additionally, when applicable, the monitors, auditors, the IRB, the Office of Human Subjects Protection (OHRP) of the Department of Health and Human Services as well as the Food and Drug Administration (FDA) will be granted direct access to your medical records for verification of the research procedures and data. OHRP and FDA are authorized to remove information with identifiers if necessary to complete their task. By signing this document you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

OR

For studies with a CoC [Please note that effective 10/1/17, all NIH-funded studies active as of 12/31/16 were granted a CoC and consent forms should be updated accordingly]:

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.

For how long will Mount Sinai be able to use or disclose your protected health information? [A specific duration can be given, but has to be consistent with FDA, faculty handbook, and other guidelines.] Otherwise, just insert this sentence: Your authorization for use of your protected health information for this specific study does not expire.

Will you be able to access your records?

Use this paragraph for blinded studies or other studies where access will be denied in order to protect the integrity of the research; otherwise delete it: During your participation in this study, you will not be able to access your medical records. This will be 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 is not required to release to you research information that is not part of your medical record.

Use this paragraph for open label studies and other studies for which access will not be denied; otherwise, delete it: During your participation in this study, you will have access to your medical record and any study information that is part of that record. The investigator is not required to release to you research information that is not part of your medical record.

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

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

Can you change your mind?

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

If subjects are not patients of the Mount Sinai Health System site engaging in this research, and the information being gathered remains solely in the research record, the need to give out a Notice of Privacy Practices is eliminated and the following sentence can be removed (when in doubt leave the following sentence in, and give out the Notice of Privacy Practices to those who have not received it during the course of clinical care): If you have not already received it, you will also be given The Hospital’s Notice of Privacy Practices that contains more information about how The Hospital uses and discloses your protected health information.

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

If as part of this research project your medical records are being reviewed, or a medical history is being taken, it is possible that HIV-related information may be revealed to the researchers. If that is the case, the following information concerns you. If this research does not involve any review of medical records or questions about your medical history or conditions, then the following section may be ignored.

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**Notice Concerning HIV-Related Information**

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

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If your study does not have a Certificate of Confidentiality, delete this section. If you have a COC, Leave the following paragraph exactly as it is. Please note that effective 10/1/17, all NIH-funded studies active as of 12/31/16 were granted a CoC and consent forms should be updated accordingly. Sometimes NIH request that this language be modified, if this occurs please contact the PPHS promptly.

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 information or biospecimens 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 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.

[Omit the signature page if there is no written documentation of consent.]

**[Ensure that the signature page fits on one page and signature lines are not broken up]**

**ADULT PARTICIPANT:**

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

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Signature of subject Printed Name of Subject Date Time

[required if used for FDA documentation purposes]

**PERSON EXPLAINING STUDY AND OBTAINING CONSENT:**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_**

Signature of consent delegate Printed Name of consent delegate Date Time

**WITNESS SECTION:**

When a witness is required to observe the consent process, it should be documented below (for example, when subject is illiterate, visually impaired, or this document accompanies a short form consent).

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

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Signature of Witness Printed Name of Witness Date Time