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| ***Instructions for developing the consent form:***   1. *Follow all instructions in pink and delete all instructions from the completed consent form. No pink text should remain on your submitted consent form.* 2. *Delete optional text that does not apply to your study.* 3. *If you do not intend to use a color version of the consent form, please make all headers black and bolded.* 4. *Lay language (simple and clear wording understandable to prospective study participants) should be used throughout this document and written close to an 8th grade reading level. Use simple language to help individuals fully understand the research.* 5. *Avoid scientific or medical jargon as much as possible; if not possible, give a short, descriptive explanation. Refer to “Glossary of Lay Terms”:* [*https://www.nccn.org/education-research/nccn-oncology-research-program/informed-consent-language-database*](https://www.nccn.org/education-research/nccn-oncology-research-program/informed-consent-language-database) 6. *Write in the “second person” point of view (you/your) and avoid using “I” or “we” when referring to the research team.* | |
| **STUDY INFORMATION** | |
| **Study Title:**  **Study site(s):** *[Remove any sites not engaging in the research]* **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 (Lead Researcher):** [First Name Last Name, Degree(s)]**Physical Address:** [Hospital/clinic name; e.g., Annenberg 22nd Floor, Room XXX; The location where the research participant should go for study visits; or 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] | |
| **SUMMARY OF THIS RESEARCH STUDY**  *The 2018 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 research participant or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. The information presented here may be discussed in greater detail later in the consent form; however, the information should not be fully duplicated later in the form. Ideally this summary should fit on one page.* ***Please limit this section to no more than 500 words.*** | |
| **Begin with the following statement**  This document explains a research study you might be interested in joining. Participation in the study is voluntary. You can agree to join or not. Your decision will not limit your ability to receive care at Mount Sinai. 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. | |
| **First say…** | **Then Share…** |
| The purpose of this research study is… | *Provide a brief statement of purpose. For example, explain to the participant 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 take part, you will be asked to… | *Provide a brief overview of the major requirements for participants, including:*   * *Number of visits, how long their part in the study will last* * *What will happen in the study, and, if relevant, how it could affect their usual medical care* * *If there are costs that go along with taking part* * *Agree to have data/tissue/blood samples stored for (duration of time)* * *Whether or not there is a payment or a stipend for taking part (details/amounts not included)* |
| If you choose to take part, the main risks to you are… | *Provide a brief summary of the main/most likely and/or most significant risks in lay language – a complete list of all reasonably foreseeable risks should be included in the body of the consent form in the Risks section* |
| **If any of the following conditions apply, add the appropriate information needed** | |
| *If there is no potential for direct benefit to the study participant:*  You will not benefit directly from taking part in this research study. | |
| *If there is potential for direct benefit to the study participant:*  You may benefit from taking part in this research study. Some potential benefits are | |
| *If there are alternatives to taking part in this study, list appropriate alternative procedures or courses of treatment:*  Instead of taking part in this research study, you may | |
| **Conclude this section with the following statement:** | |
| If you are interested in learning more about this study, please continue to read below. | |
| **STUDY PARTICIPATION** | |
| **First say…** | **Then Share…** |
| You may qualify to take part in this research study because… | *[Fill in the reason people are eligible for the research, for example, “you are a healthy person", "you have diabetes,” and “you take insulin.” These descriptions should be brief and not present the entire inclusion/exclusion criteria. Do not repeat the information provided in the summary above.* |
| Your participation in this research study is expected to last | *[months/weeks/years, until a certain event].* |
| 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… | *[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].* |
| 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. | |
| **If the following condition applies, add** | |
| *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 website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time. | |
| **DESCRIPTION OF WHAT IS INVOLVED:**  *This section should explain to the participant what will occur as part of the research. Do not use the word “patient” when referring to an individual taking part in this or any other research study. Alternative terms should be used, such as study participant or research participant.* | |
| **First say…** | **Then Share…** |
| If you agree to take part in this research study, here is what may be involved. | * Where research activities will take place (begin with the appropriate Mount Sinai site. If the participant will need to go/or can choose to go to more than one location for different study visits, make that clear.) If portions of the study will occur at home or remotely, this should be clear * What activities will take place as part of the research study and when they will take place * List experimental procedures and therapies and identify them as experimental. Describe protocol-dictated drugs/biologics and/or devices to be used. Do not imply certainty that an experimental drug/device will ultimately be approved * Description of hospitalizations, outpatient visits and telephone or written follow-up * If blood will be drawn, indicate the amount using both lay and scientific terminology such as teaspoons, tablespoons, or ounces followed by mL in parentheses [2tsp (5ml)]. * If procedures and therapies are performed as part of the individual participant’s clinical care regardless of their research participation, then those procedures or therapies do not necessarily need to be included in great detail. If they are included to provide context, it is important that the participant understands the difference between what is research and what is clinical care * List frequency of procedures and tests and how long visits will take. Consider providing a timeline chart or diagram making it easy to understand the timing of activities and length or time involved in taking part * Indicate who will work with the research participant throughout the research study * *If applicable, include a statement indicating if you will share research results that are relevant to the person’s care, including individual research results, and under what conditions you will share these results.* (Remember, the research team can only share results of FDA or New York State approved tests performed in a CLIA-certified lab) * *If your study involves a drug or device:* Because this research study involves the use of *[study drugs or an investigational medical device],* a note must be included in your electronic medical record that you are taking part in the research. This way, anyone involved in your medical care will know that you are a study participant, and they can work to avoid any problems or negative outcomes that could arise if they do not know. |
| **If any of the following conditions apply, add the appropriate information needed** | |
| **Randomization**  For research involving random group assignment, *include information about multiple study groups that participants can be assigned to.* Describe the chances of being assigned to any one group. For example: 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].* You will have an/a *[equal/one in three/etc.]* chance of being given each study *[drug/device/procedure].*  For double-blinded studies, add:Neither you nor the Lead Researcher or your own doctor will know which study *[drug/device/procedure]* you are getting. If there is an emergency, they can get this information.  For single blinded studies, add: You will not be told which study *[drug/device/procedure]* you are getting; however, the Lead Researcher, research team, etc. will know. | |
| **Genetic Testing**  *If the research involves genetic testing, refer to the* [*Guidance on Research Involving Genetic Testing*](https://icahn.mssm.edu/files/ISMMS/Assets/Research/PPHS/GUIDANCE%20ON%20RESEARCH%20INVOLVING%20GENETIC%20TESTING%20UNDER%20NYS%20LAW.pdf)*, and insert the appropriate language from that document into this section of the consent form.*  *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.*  *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*. | |
| **HIV/AIDs**  *If your study involves conducting HIV testing for research purposes, the following language must be used:*  To take part in this research study, your blood will be tested for evidence of HIV, the virus that causes AIDS. People can get HIV through unprotected sexual contact with someone who has HIV, and through contact with blood (as in sharing needles including for piercing, tattooing, and injecting drugs). People who are pregnant with HIV infections can transmit HIV to their infants during pregnancy, delivery or while breastfeeding. There are treatments for HIV/AIDS that can help people stay healthy. People with HIV/AIDS can adopt safe practices to protect uninfected and infected people in their lives from getting HIV or getting infected with a different 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 so they can study how people get and transmit the disease and notify sexual or needle-sharing partners they may have been exposed. If you wish to be tested anonymously 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. New York State law protects the confidentiality of HIV test results and other related information. It is illegal to discriminate against a person based on their HIV status and services are available to help if this happens. You are free to refuse to get an HIV test, but if you refuse you cannot be part of this research study. | |
| **Pregnancy**  *For research involving pregnancy testing, customize the statement below for this research study:*  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].* | |
| *If the research study requires that participants use birth control during participation, the timing and use of birth control are generally dictated by the protocol. If this research study requires the use of contraception, and the sponsor’s template does not provide suggested language, please insert the appropriate language on birth control, using the following options as a guide.* ***If the sponsor-required language is not gender-inclusive, please revise the language to the following standard:***  You cannot be included in the study if you are or become pregnant, as the study *[drug/device/procedure]* could harm your fetus. You also should not be in the study if you are producing milk to feed a child as the study *[drug/device/procedure]* could harm your baby.  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. Unless you are sexually abstinent (not having genital sex) the recommended methods of birth control are:   * The consistent use of 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 activity), * Sterilization (a vasectomy, getting tubes tied, or a hysterectomy). * *Some experimental study drugs interact with hormonal contraceptives and may render birth control less effective. If that is the case, delete the hormonal methods listed above and state why they are not recommended while taking part in the study.*   All birth control methods (other than abstinence and sterilization) are only effective if you use them properly, start them at least one month before you begin the research study, 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 research study ends. If you are unsure whether the method of birth control you use is approved to use while you are in this study, you should ask the Lead Researcher before you begin the study. If you are less than one-year post-menopausal, 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 study, or in the “month” OR insert a longer period of time if required by the protocol] following it]*, you must tell a person from the research team immediately. The team may stop the study drug and refer you/your partner to an obstetrician/gynecologist for follow-up.  Should you/your partner become pregnant, whether or not you/your partner have the baby, the people funding and overseeing the research may ask for information on the pregnancy, even if you are no longer part of the study. You/your partner will be asked for additional written consent to share this information if that happens. | |
| **Semen/Sperm**  Drugs can be found in semen and alter sperm. Since you are taking part in a study using experimental drugs or treatments, it is recommended that 1) you use a condom, 2) you do not get a partner pregnant or expose them to semen, and 3) you do not donate semen. These recommendations apply both while you are taking the study drug, and for 3 months 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 participants refrain from impregnating a partner 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 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 this clinical trial. | |
| **If the study involves future contact, add the following information** | |
| **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 SAMPLES**  The research team must ensure that the consent form and protocol reflect whatever data and/or sample-sharing obligations the funder imposes. If requirements for data and/or sample sharing seem inconsistent with PPHS policy on [Future Use of Research Data and/or Specimens](https://icahn.mssm.edu/files/ISMMS/Assets/Research/PPHS/Future%20Use%20Policy%20(v.%2011.4.19).docx), please contact the PPHS promptly and directly.  *There are THREE possible options you can choose from. The available option(s) depends on whether the research study holds out a prospect of direct benefit to participants, as determined by the IRB.* | |
| **When to use Option 1:**  The data and/or samples collected for this study will only be used to complete the study and not banked for future research. You can select this option for any applicable studies regardless of the prospect of benefit to the participant.  **OPTION 1:**  The research team will never use or share your personal information (such as, name, address, date of birth, social security number), study data and/or samples (blood, tissue, urine, saliva, or any other body matter) that are collected as part of this study for future research, even if your identity is removed. Your data and/or samples will only be used to complete this study and then they will be destroyed. | |
| ***When to use Option 2****:*  *The data and/or samples collected for this study will be used to complete the study and one day the study team may wish to use or share the data and/or samples for future research. This statement can only be used if the study does* ***NOT*** *offer the prospect of direct benefit* ***AND*** *the researcher does not wish to give participants granular control over future uses of data and/or samples. If there is a prospect of direct benefit then you cannot compel (require) future use and you should use Option 3. Likewise, use Option 3 if you wish to offer choices even if it not mandated by policy. In addition, the consent form should include the suggested description and risks of large public repositories as detailed below if you will be sending data and/or samples to such repositories.*  **OPTION 2:**  In addition to being used to complete this research study, your personal information (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*. [Delete any of the following statements that do not apply].* 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.   * *[Please review and consider Question 6 under Option 3. If applicable and appropriate, modify Question 6 to make it a statement (rather than a question).* * *Add relevant additional information here. For example, explicitly saying that future research may involve for-profit, international, non-academic partners; there will be use of a GUID deposition in a large repository*] | |
| **When to use Option 3:**  Use Option 3 if the study offers the prospect of direct benefit and you wish to use or share data and/or samples collected for future research in ways the participant allows. Edit the questions in this option to include only the specific customizations available to the participant. For example, if data and/or samples will always be linked to identity, even with a code, then do not include question 2 and instead state that in a brief description of the data and/or sample banking before asking the questions.  **OPTION 3:**  The researchers would like your permission to keep your personal information (such as, name, address, date of birth, social security number), study data and/or samples (blood, tissue, urine, saliva, or any other body matter) to use or share in future studies. You can still be part of the study if you do not allow us to use or share them. Please select Yes or No to each of the questions below. To decline all future uses/sharing please select ‘No’ each time.  *The following question(s) should be selected and or modified to reflect your protocol. Tailor this section based on whether data and/or samples are collected for the research by removing terms that do not apply. For example, if samples are not collected for the study, delete the word “samples” throughout.*  (1) Will you allow the researchers to store your data and/or samples to use in future research studies?  Please initial your choice: Yes\_\_\_\_\_\_\_\_\_\_\_\_ No\_\_\_\_\_\_\_\_\_\_\_\_\_  If 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 and tell us how your personal information, study data and/or samples may be used in future research studies.  *It is relatively rare, but occasionally researchers find it useful to offer this option to potential participants. You are not obligated to make this offer and may remove this text.*  (2) The researchers can store your data and/or samples in one of two ways:   1. Anonymously (no one will know who the data and/or samples came from). If you choose this option, you can’t change your mind. So, if you wanted to have your data and/or samples destroyed in the future, the team could not do it as they would not know which data and/or samples were yours. 2. 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 data and/or samples stored? Please initial ONE choice below:  I would like my data and/or samples stored anonymously \_\_\_\_\_\_\_\_\_\_\_\_\_\_  I would like my data and/or samples stored with a link to my identity through the use of a code\_\_\_\_\_\_  (3) Do you give the researchers permission to 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: Yes\_\_\_\_\_\_\_\_\_ No\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  (4) Do you give the researchers permission to keep the data and/or samples indefinitely, 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\_\_\_\_\_\_\_\_\_\_  (4.1) From time to time, researchers outside of medicine and related sciences would like to use data and/or samples. This might be in the fields such as anthropology, human origins, mapping human migration patterns. Do you give permission for researchers outside the field of medicine to use your data and/or samples?  Please initial your choice: Yes\_\_\_\_\_\_\_\_\_ No\_\_\_\_\_\_\_\_\_\_   1. If the future research in a different area can be done without having to know that the data and/or samples came from you personally, that will be done. 2. If the future research in a different area requires that it is known specifically who the data and/or samples came from, then one of the following will be done:    1. If you allowed the researchers to contact you in the future, they may be able to contact you to explain why your data and/or samples is needed and what will be done with it. Your permission will be asked to use your data and/or samples in that research project.    2. 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 data and/or samples may still be used. The Institutional Review Board (IRB) will be asked for permission to use the data and/or 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 data and/or samples will not be more than minimal risk to you or your privacy. The 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.     (5) Do you give permission to have your data and/or samples given to other researchers, including those at Mount Sinai, other medical or scientific institutions and for-profit companies, for use in research within the limits you have chosen above?  Please initial your choice: Yes\_\_\_\_\_\_\_\_\_ No\_\_\_\_\_\_\_\_\_\_  *Ask question 6 below if you selected Option 3 and plan to deposit data and/or samples in large public repositories. If Option 2 is being used and it is appropriate, add this language, without making it a question.*  (6) Do you give permission to have portions of your data and/or samples deposited in large public databases (repositories) for use in research with the limits you may have chosen above? Please read the paragraphs below which explains repositories, then initial your choice:  To do more powerful research, it is helpful for researchers to share data and/or samples from the people they study. They do this by putting 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 study may be stored in a repository along with data and/or samples from other studies. Sample repositories are commonly called biobanks, while data repositories are commonly called databases. . Researchers can then use the 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, but they will not share your direct identifiers (for example, name, address, date of birth). These databases are maintained by either Icahn School of Medicine at Mount Sinai, another institution, the federal government, or private companies. Any researcher who wants to do a study using data and/or samples from the repository must apply for permission. There are different ways of reviewing such requests. Researchers with an approved study may be able to see and use your 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 section. [If in the future participants wish to withdraw data and/or samples from the repository, either insert instructions or refer them to the withdrawal section of the consent form.]  If a GUID will be used, insert language here and expand if necessary. NIMH, for example, has good sample language available on their website.  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** | |
| **First say…** | **Then Share…** |
| If you decide to take part in this research study, you will be responsible for the following things: | *[Describe the participant’s responsibilities. Explain what commitment you expect from the participant. For example: taking prescribed medications, continuing ongoing psychotherapy, using birth control methods as described in the Description of What’s Involved section, avoiding certain medications, attending study visits, calling the research team for certain side effects, notifying the clinical treatment team(s), families, sexual partners, etc.]* |
| **COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION** | |
| *If there are no anticipated costs or payments to the participants, add:* You will not be paid for taking part in this study. Being in this study will not cost you anything extra. *If time or travel costs are to be assumed by participants, add:* Researchers will not pay you for your travel or the time it will take for you to be in the study.    *If the research may result in additional costs to the participants, add*: There may be costs to you for taking part in this study. *[Describe what these costs are if known, such as copays, transportation to and from study visits, missing a day of employment, and childcare during study visits]*  *When participants will be paid, add:* If you agree to take part in this study, you will be paid [*indicate amount]* for your time and effort. *[If there are multiple study visits, indicate how the amount will be pro-rated for research visit completion and the form of the payment (e.g., cash, gift card, or 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:* It can take up to 6 weeks to prepare and give you 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.  *This statement may be removed only if NO payment of any kind will be provided to participants as part of their participation:* 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 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.  *If any reimbursement is provided for expenses the participant will incur, such as transportation or childcare, indicate what evidence of the expenses the participant needs to provide (receipts). Further guidance is available from the Finance Department.*  *For studies collecting samples or data that may be used for profit, even if that possibility is remote, one of the following statements must be included:*  It is possible that products may someday be developed with the help of your data and/or samples, and there are no plans to share any profits from such products with you.  OR  The samples and/or data collected from you as part of this study 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 participants will be paid, add:* You should check with your supervisor before accepting payment for taking part in this study.  *For studies involving prisoners, add:* If you are released from prison before you finish this study, you should take steps to get health insurance, such as Medicaid. 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, assistance can be provided to help you find a doctor to care for you. | |
| **POSSIBLE BENEFITS** | |
| If there are possible benefits to individual participants from the research, add: There is a chance this study may benefit you, but this is not guaranteed. Others may benefit from what researchers learn from the study. Possible benefits to you include: *[Describe the potential benefits of participation but do not overstate them. First describe any direct potential benefits to the participant, then any benefits to others.*   * *If benefits from participation may not continue after the research has ended, explain that here. For example, a study drug provided at no cost during a study may not be available for free, or at all, when the research ends.* * *Please note that monetary reimbursement for participation is* not considered a benefit and should be described in 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 participants from the research (for example, almost all Phase 1 trials) add: This study is not designed to benefit you personally. However, possible future 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. Taking part in this research study will not improve your chance of parole or release. | |
| **POSSIBLE 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 table form if it provides further clarity.*   * Physical risks (for example, medical side effects) * 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. *This can be expanded upon, if pertinent.* * 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. For MRI risks, refer to [*Guidance on Research MRI*](https://icahn.mssm.edu/files/ISMMS/Assets/Research/PPHS/Guidance%20on%20Research%20MRIDec212020.docx). * 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 participant develops aplastic anemia and needs treatment) * Describe risks to those other than the participant, along with corresponding instructions. For example, the risk to a nursing infant if the mother is the research participant, the risk to sexual partners or family members, etc. * If this study includes a 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 study may hurt you in ways that are not known. The unknown risks could be minor or major (death). * If the research either 1) involves persons who can become pregnant or get someone pregnant AND investigational products or procedures whose risk profile in pregnancy is not well-known OR 2) involves known risks to an embryo or fetus add: If you are pregnant or become pregnant, this research may hurt your baby or your pregnancy in ways that are unknown. The unknown risks could be minor or major (death) for the pregnancy. You should not become pregnant or get someone pregnant while you take part in this study. Please read the acceptable methods of birth control found under the Description of What Is 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 (for example, 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/samples, the following language should be included unless you are certain that the data/samples will never be used in large-scale research that could result in these types of risks:   + Group Risks - Although your name will not be given to researchers, 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 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 a relative) to get or keep a job or insurance. If your private information was misused, it is possible you would experience other harms, such as stress, anxiety, stigmatization, or embarrassment from revealing information about your family relationships, ethnic heritage, or health conditions. * 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). 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 OPTIONS TO CONSIDER** | |
| **First say…** | **Then Share…** |
| You may decide not to take part in this research study. 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. | *If there are alternative* procedures or courses of treatment that may be helpful to the participant, or *if the interventions 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. Indicate the risks and potential benefits of each alternative option. For clinical trials, describe the options that you would normally offer patients. If applicable, include supportive care as an option. Do not only state that the study doctor will discuss options. It is permissible to describe related treatments as a group, e.g. Alternative antidepressant treatments with drugs such as fluoxetine (Prozac) have common side effects.* |
| **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 being in this research study has harmed you, you should contact the Lead Researcher. Their contact information is listed at the beginning of this consent form.  *For protocols involving greater than minimal risk that are externally Sponsor Initiated (For-Profit), add:* If you are injured or made sick from taking part in this study, you will get medical care. The group funding this research study will pay you for any reasonable and necessary medical expenses to diagnose and treat research-related injury or illness. **This does not prevent you** from seeking payment for injury related to malpractice or negligence. You can contact the Lead Researcher 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 participants as a result of their participation in research.]  *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, you will get medical care. Generally, it will be billed to you or your insurance 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. You can contact the Lead Researcher for more information.** | |
| If the study funder will pay for research-related injury, include the following information: The Centers for Medicare and Medicaid Services (CMS) is the government agency that oversees Medicare and Medicaid. Funding agencies who make payments for injuries related to studies must report payments to CMS. In order to do this, the funder must have certain information about you, such as your name, date of birth, Social Security Number, Medicare or Medicaid ID numbers, date of injury, and description of injury. The funding agency is only allowed to use this information to report payments related to injury should this be necessary or as otherwise specified in the Authorization to Use and Disclose Protected Health Information section, which is included below. | |
| **ENDING PARTICIPATION IN THE RESEARCH STUDY** | |
| You may stop taking part in this study at any time. No matter what you choose, your care and benefits through Mount Sinai will not be negatively impacted.  If you decide to stop being in the study, please contact the Lead Researcher or the research staff.   *[If procedures for orderly termination of participation by the participant are necessary, describe them. For example, participants on an investigational drug to treat their diabetes may be switched to an approved drug, participants in a study of high dose corticosteroids may have their steroid doses tapered, etc.* Include any specific withdrawal procedures described in the protocol.]   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 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 participants may experience by withdrawing from the research. For example, participants withdrawing from a drug trial may face side effects or illness progression off the drug].*  For FDA regulated clinical trials, add: If you stop being in the research study, the research team may not remove information they have already placed in the study database, and may continue to use that data as part of this study. *[Note: The consent document cannot give the participant the option of having this data removed.]* The research team may ask you whether they can continue to collect information from your medical record. *[Note: If a participant withdraws from the interventional portion of a study and does not consent to continued follow-up of associated clinical outcome information, the research team must not access the participant’s medical record, or other confidential records requiring the participant’s consent, for purposes related to the study. However, the research team may review study data related to the participant collected prior to the participant’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 personal information, study data and/or samples.*  *Describe if and how personal information, study data and/or samples can be withdrawn or destroyed.*   * *Include what will happen to the personal information, study data and/or samples.* * *Include any limitations (if stored without identifiers will you be able to destroy the data and/or samples, what will happen to data and/or samples that have already been shared or used, etc.)* * *State that no new information will be collected). Modify the sample statement below for accuracy:*   If you decide you don’t want your data and/or samples to be used for research anymore, you can contact the researcher and ask to have your data and/or samples withdrawn or labeled so that they will not to be used in additional projects or shared. If 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. Data and/or samples that have already been used will not be affected by your decision. If your data 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 Lead Researcher, the funder or 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 research team have not been followed, the Lead Researcher believes it is in your best interest, or for any other reason. If data and/or samples have been stored as part of the research study, they too can be destroyed without your consent. | |
| **CONTACT INFORMATION** | |
| If you have any questions, concerns, or complaints at any time about this research, or you think the research has harmed you, please contact the office of the research team and/or the Lead Researcher at phone number [e.g., 212-XXX-XXXX; this number must provide access to the research team directly and not be a general clinic or department number]. *If applicable, add:*  If there is an emergency, please call XXX-XXX-XXXX or call 911 or go to the emergency room. Let the emergency room staff know you are in a research study so they can contact the Lead Researcher if needed. | |
| **DISCLOSURE OF FINANCIAL INTERESTS** | |
| Researchers sometimes get paid for consulting or doing work for companies that produce drugs, biologics or medical devices. If you have questions regarding industry relationships, you are encouraged to talk 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 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 makes the drug or device *(research teams should update the choice depending on the study)* being tested and has a financial interest that could be affected by the outcome of this research study.  *2. For studies where a member of the research team holds a financial interest in the company, or in the drug/device under investigation, that could benefit from the study, include the FCOI Committee management plan language here.*  *3. For studies where the Institution (Mount Sinai) holds a financial interest in the company, or in the drug/device under investigation, that could benefit from the study, include the FCOI Committee management plan language here.*  *4. 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 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 funder.  *5. For studies where researchers or their departments are paid on a per-patient enrolled basis, the consent form should state:* Researchers and/or their departments receive money from the company sponsoring this research based on how many participants they enroll. | |
| **MAINTAINING CONFIDENTIALITY – HIPAA AUTHORIZATION** | |
| As part of this study, some of your private and/or protected health information will be obtained, used and shared with your permission. There is a Federal Health Insurance Portability and Accountability Act (HIPAA) that 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? Please ensure that this information is consistent throughout the RUTH application.  The following paragraphs must be precise and customized as appropriate:  As part of this study, 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]  During the study, the researchers will gather information by:  Choose and modify as needed.   * Reviewing and/or taking your 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. [If you include this, your protocol needs to explicitly address this special class of records and appropriate access to this information should also be disclosed in the main consent under the Description Section] * Reviewing mental health records. [If you include this, your protocol needs to explicitly address this special class of records and appropriate access to this information should also be disclosed in the main consent under the Description Section]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 to this information should also be disclosed in the main consent under the Description Section] | |
| Why is your PHI being used?  Researchers need the information that identifies you so they can contact you during the study. They need your health information and the results of any tests and procedures being collected as part of this study to answer the questions posed in the study. The purpose of the study is discussed earlier in this consent form. 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 at scientific meetings, lectures, or other events, their presentations 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 Lead Researcher may also use and share the results of these tests and procedures with other health care providers at Mount Sinai 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 Mount Sinai Program for the Protection of Human Subjects is responsible for overseeing research on human 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 PHI?  As part of the study, the Lead Researcher, research team and others in the Mount Sinai workforce may disclose your 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 Lead Researcher.)   * The United States Department of Health and Human Services and the Office of Human Research Protection (the government organization that is responsible for protecting human research participants)   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 researchers 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, if the list is printed out and given to the participant 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 center*s:* *[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 (the government organization that approves drugs or devices for medical use): *[name that group or company]* * The sponsoring government agency and/or their representatives 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 * 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 Lead Researcher will ensure that the key to the code will be kept in a locked file, or will be securely stored electronically. The code will not be used to link the information back to you without your permission, unless the law requires it, or rarely if the Institutional Review Board (IRB) allows it after determining that there would be minimal risk to your privacy. It is possible that a sponsor or their representatives, a data coordinating office, a contract research organization, may come to inspect your records. Even if those records are identifiable when inspected, the information leaving the institution will be stripped of direct identifiers. Additionally, when applicable, the monitors, auditors, the IRB, OHRP, as well as the Food and Drug Administration (FDA) will be granted direct access to your medical records for verification of the research procedures and data. OHRP and FDA are authorized to remove information with identifiers if necessary to complete their task. By signing this document you are authorizing this access. The results of this research may be published. However, your name and other identifying information will be kept confidential.  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 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, 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, *OHRP, as well as the Food and Drug Administration (FDA) will be granted direct access to your medical records for verification of the research procedures and data. OHRP and FDA are authorized to remove information with identifiers if necessary to complete their task. By signing this document, you are authorizing this access.* The results of this research may be published. However, your name and other identifying information will be kept confidential | |
| For how long will Mount Sinai be able to use or disclose your PHI?  *[A specific duration can be given, but must be consistent with FDA, faculty handbook, and other guidelines.] Otherwise, just insert this sentence:* Your authorization for use of your PHI 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 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 research team is not required to release research information to you 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 research team is not required to release research information to you that is not part of your medical record. | |
| Do you need to give the researchers permission to obtain, use or share your health information?  NO! If you decide not to let the research team obtain, use or share your PHI, you should not sign this form, and you will not be allowed to 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?  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 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, but only to complete this 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 participants 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 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, where possible, Mount Sinai has entered into agreements with those who will receive your information to continue to protect your confidentiality.  If researchers are reviewing your medical records or asking questions about your medical history or conditions, it is possible that they may learn information related to your HIV status. If that is the case, the following information concerns you. If researchers are not reviewing your medical records or asking questions about your medical history or conditions, then you may ignore the following section. | |
| **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. | |
| *If your study does not have a Certificate of Confidentiality (CoC), 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 requests 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 personal information, study data and/or samples with anyone who is not a member of the research team, including any family members or friends, other than those identified above. However, you should know that if it is learned that you or someone else is threatened with serious harm, such as a child or an elderly person being abused, the 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:   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 participant. 5. You want to get information or provide input about this research*.*   *[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 study and to the use and disclosure of your protected health information. A signed and dated copy will be given to you.  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_**  Signature of Participant Printed Name of Participant Date Time  *[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 participant, and that consent was freely given by the participant.  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_**  Signature of Witness Printed Name of Witness Date Time | |