FORM: Request to Rely

The purpose of this form is to provide support for research personnel that are requesting to rely on an external IRB and document the waiver of jurisdiction for external IRBs where there is a master agreement in place. This form is to be completed by one of the research personnel and attached to the RUTH submission. *Submissions with an incomplete HRP-232 form will be returned during pre-review, prior to granting permission to submit to the external IRB.*

basic information

|  |  |
| --- | --- |
| **Basic Study Information** | **Study Details** |
| IRB Number: | Click or tap here to enter text. |
| Study Title:  | Click or tap here to enter text. |
| Mount Sinai PI: | Click or tap here to enter text. |
| Sponsor: | Click or tap here to enter text.  |
| Protocol #: | Click or tap here to enter text. |
| Type of funding: | [ ]  Industry[ ]  Federal PI on grant: Click or tap here to enter text. Grant PI’s institution: Click or tap here to enter text. [ ]  Foundation[ ]  Other Please specify: Click or tap here to enter text. |

1. criteria for use of an external irb

|  |  |
| --- | --- |
| [ ]  Yes [ ]  No | Research is an Industry-sponsored Multi-Center Clinical Trial where all must be true. If all are not true, please submit study for review under the Mount Sinai IRB.1) The Mount Sinai PI is not the overall PI of the Trial 2) The industry-sponsor holds the IND/IDE for the test article (if applicable) |
| [ ]  Yes [ ]  No | Research is federally-funded and use of an sIRB is mandated as part of the grant |
| [ ]  Yes [ ]  No | Research is a major multi-center research consortium projectName of Consortium: Click or tap here to enter text. Attach a copy of the consortium agreement to the submission in RUTH |
| [ ]  Yes [ ]  No | Mount Sinai PI is a collaborator on human research primarily conducted at another organization and PI’s Role does not Include Interaction or Intervention with Subjects |
| [ ]  Yes [ ]  No | Mount Sinai is engaged in the human research solely because it is receiving federal funds |
| [ ]  Yes [ ]  No | The study is not a first-in-human study |
| [ ]  Yes [ ]  No | The study is not planned emergency research |

2. external irb

|  |  |
| --- | --- |
| [ ]  | BRANY - *The Waiver of IRB Oversight will be documented by PPHS on the last page of this form*  |
|  | [ ]  | Mount Sinai FACTS/GCO is responsible for negotiating the contract/agreement *(GCO submission and TE are required)* |
|  | [ ]  | BRANY is responsible for negotiating the contract *(GCO submission and TE are NOT required. Enter BRANY into the TE field in RUTH.)* |
| [ ]  | NCI CIRB.  | *NCI CIRB does not make HIPAA determinations. A standalone HIPAA Authorization must be created and attached to your submission if subjects are being consented. If you are requesting a full or partial HIPAA waiver, fill out the* [HIPAA WIZARD](https://crio-redcap01.mssm.edu/surveys/?s=4JE3E3M9D4) *and attach in RUTH.* |
| [ ]   | Sterling IRB | [ ]  *Sterling IRB Jurisdiction Form\* has been attached in RUTH. Submissions received without this document will be returned.* |
| [ ]  | Advarra | *For these external IRBs, the Waiver of IRB Oversight will be documented by PPHS on the last page of this form.*  |
| [ ]  | WCG/WIRB |
| [ ]  | Alpha IRB |
| [ ]  | Other IRB | Name of external IRB: Click or tap here to enter text. |
|  | Choose all that apply. *If unknown, the external IRB can provide the information/documents. Submissions received without this information will be returned.* |
|  | [ ]  SMART IRB Reliance Agreement will be used[ ]  Reliance will be ceded in SmartIRB online portal[ ]  SmartIRB reliance document(s) is attached in RUTH  |
|  | [ ]  IREx will be used |
|  | [ ]  Institution-specific Reliance Agreement is attached in RUTH. |
|  | [ ]  Institution-specific Local Context Form is attached in RUTH. |
|  | [ ]  Other Please specify: Click or tap here to enter text. |

3. HIPAA Determination

|  |  |
| --- | --- |
| [ ]  Yes [ ]  No | Will the IRB of Record make HIPAA-related determinations? If you answered YES, please move to Section 4.*Most IRBs, including WCG/WIRB, Advarra, BRANY, Sterling, and Alpha, make HIPAA-related determinations.**NCI CIRB does NOT make HIPAA-related determinations.**If unknown, please contact the external IRB to inquire prior to submission.* |
| [ ]  Yes [ ]  No | Are you requesting a waiver of HIPAA authorization? READ BELOW BEFORE YOU ANSWER*You will request a waiver of HIPAA authorization for EITHER of the following reasons:*1. *Your project will NOT obtain informed consent from the subjects with a research consent form including the HIPAA authorization*
2. *You need to access data prior to consenting subjects, e.g. for recruitment screening, retrospective comparison cohort, etc.*

*If you answered YES, please complete and attach the document from the* [*HIPAA Wizard*](https://redcap.link/hippa_wizard2) *to your submission in RUTH.* |

4. Required submission documents *Submissions received without this information will be returned. The HRP-503, recruitment materials, questionnaires, and other subject materials do not need to be submitted.*

|  |  |
| --- | --- |
| [ ]  Yes [ ]  N/A | Protocol, grant, or scope of work |
| [ ]  Yes [ ]  N/A | Investigator Brochure and/or Package Inserts for drugs under investigation |
| [ ]  Yes [ ]  N/A | All consent and assent forms that will be used for the study. *Language from Section 6 of this form must be included in all consent forms, as appropriate.* |
| [ ]  Yes | Reliance form(s) *See Section 1.* |
| [ ]  Yes | HRP-232 Form |
| [ ]  Yes | [Ancillary Office Form from RedCap](https://redcap.link/huron_ruth_ancillary) |
| [ ]  Yes [ ]  N/A | PRMC Approval letter *Required for any study involving cancer* |
| [ ]  Yes [ ]  N/A | [Standalone HIPAA form](https://icahn.mssm.edu/files/ISMMS/Assets/Research/PPHS/Research%20HIPAA_authorization_MSHS%20%282.15.19%29.doc) *This is not required for most R2Rs. Required for NCI CIRB studies and any other external IRB that requires that HIPAA language is separate from the* *research consent form.* |
| [ ]  Yes [ ]  N/A | [HIPAA Wizard Form](https://redcap.link/hippa_wizard2) from RedCap *(This is not required for most R2Rs. Please attach based on response to #3 above)* |

5. Consent language

|  |
| --- |
| This section contains ALL of the language that could be required for a study being reviewed by an external IRB. Not all language below is required for all projects. Instructions are in pink. Suggested/required text is in black. Read each section carefully. Language should be considered and incorporated for any ICFs used for the study. Choose the option in the first column that is appropriate for the Main ICF. *EACH SECTION REQUIRES A RESPONSE.* * “Added by Sinai” indicates that this section has been added by the Mount Sinai team to the submitted ICF(s).
* “Included on template” indicates that the template provided by the sponsor or external IRB contained this information and no change was made to the ICF(s).
* “N/A” indicates that this section is not applicable for this study.
 |
| NYC H+H SITES |
| [ ]  Yes [ ]  No | Is NYC H+H/Queens a site in this study? *Note: NYC H+H Queens and Mount Sinai Queens are NOT the same site.**If NYC H+H/Queens is a site in* *the study, please reach out to PPHS for consent language.* |
| [ ]  Yes [ ]  No | Is NYC H+H/Elmhurst a site in this study?*If NYC H+H/Elmhurst is a site in* *the study, please reach out to PPHS for consent language.* |
| GENERAL INFORMED CONSENT REQUIREMENTS |
| [ ]  Revised by Sinai[ ]  Template ICF uses “participant” | “Participant” is used to refer to the research subject throughout the ICF. |
| [ ]  Revised by Sinai[ ]  Template ICF uses second person | The ICF is written in the “second person” point of view (you/your) and avoid using “I” or “we” when referring to the research team. |
| [ ]  Revised by Sinai[ ]  Template ICF uses Lead Researcher | “Lead Researcher” is used throughout ICF to refer to Principal Investigator. |
| STUDY INFORMATION *(Institutionally required)* |
| [ ]  Added by Sinai team | This text needs to provide the study information at the beginning of the ICF:**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 *(Required per mandated compliance with the Common Rule per NYS law)*** |
| [ ]  Summary added by Sinai team[ ]  Summary included on Template ICF | **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.**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.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 [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 private information/study data/biological 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 [brief summary of 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 there is no potential for direct benefit to the study participant: You will not benefit directly from taking part in this research.If there is potential for direct benefit to the study participant: You may benefit from taking part in this research. Some potential benefits are: [brief summary of main/most likely benefits]. If there are alternatives to taking part: Instead of taking part 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. |
| **CLINICALTRIALS.GOV** |
| [ ]  Added by Sinai team [ ]  Statement included on template ICF on page Click or tap here to enter text.[ ]  This statement is not required. | For clinical trials that require registration on [**http://www.clinicaltrials.gov**](http://www.clinicaltrials.gov)confirm the following statement is included: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 Web site will include a summary of the results. You can search this Website at any time. |
| IF ADDING, INCLUDE THESE IN THE SECTION OF THE ICF WHERE THE PROCEDURES ARE DESCRIBED:1. CLINICALLY RELEVANT RESEARCH RESULTS (Required, when applicable, per mandated compliance with the Common Rule per NYS law) |
| [ ]  Added by Sinai team on page Click or tap here to enter text.[ ]  Statement included on template ICF on page Click or tap here to enter text.[ ]  This statement is not required/applicable. | 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) |
| [ ]  Added by Sinai team[ ]  Statement included on template ICF on page Click or tap here to enter text.[ ]  This statement is not required/applicable. | 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. |
| **2. GENETIC TESTING (Required, when applicable, per NYS law)** |
| [ ]  Added by Sinai team on page Click or tap here to enter text.[ ]  Language included on template ICF on page Click or tap here to enter text.[ ]  Genetic testing in the study does not fit NYS law definition OR no Genetic testing in this study | ***The New York Civil Rights Law § 79-1 has a specific and limited definition of Genetic Test. It only applies to tests of human DNA, chromosomes, genes, or gene products conducted to learn whether an asymptomatic person has a genetic predisposition to a disease or disorder.*** *It does not apply to tests performed on a person with symptoms of the disease or disorder; or tests performed for the purpose of answering a research question, where the ultimate purpose of performing the test is not to identify a genetic variation. An example of such a test would be a test to gauge the efficiency of a diagnostic test by comparing it to another test.** *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 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*
 |
| **3. WHOLE GENOME SEQUENCING *(Required, when applicable, per mandated compliance with the Common Rule per NYS law)*** |
| [ ]  Added by Sinai team on page Click or tap here to enter text.[ ]  Language included on template ICF on page Click or tap here to enter text.[ ]  WGS will not be done | *For research involving biospecimens, include a statement indicating 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.* |
| **4. IF THE STUDY REQUIRES HIV TESTING (Required, when applicable, per NYS law)**  |
| [ ]  Added by Sinai team[ ]  HIV testing will not be done for research purposes | ***If your study involves conducting HIV testing for research purposes, the following language (or equivalent) 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. |
| **5. PREGNANCY****If the sponsor-required language is not gender-inclusive, please revise the language to the following standard:**For research involving pregnancy testing, customize the statement below for this research study: |
| [ ]  Added by Sinai team[ ]  Comparable language is present on template and gender-inclusive. See page Click or tap here to enter text.[ ]  N/A for this 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. |
| **6. SEMEN/SPERM****If the sponsor-required language is not gender-inclusive, please revise the language to the following standard:** |
| [ ]  Added by Sinai team[ ]  Comparable language is present on template and gender-inclusive. See page Click or tap here to enter text.[ ]  N/A for this study | 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. |
| **FUTURE CONTACT**This section is optional. If you do not plan any future contact with study participants, do not add this section. |
| [ ]  Added by Sinai team[ ]  Language included on template ICF on page Click or tap here to enter text.[ ]  Participants will not be contacted in the future. | 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 |
| REASONABLY FORESEEABLE RISKS AND DISCOMFORTSPlease add the following statements when applicable if comparable language is not included in the template consent form: |
| [ ]  Added by Sinai team[ ]  Comparable language included on template ICF on page Click or tap here to enter text.[ ]  N/A for this study | Where private information is being collected (most studies), include the following statement: Risk of loss of private information; this risk always exists, but there are procedures in place to minimize the risk.  |
| [ ]  Added by Sinai team[ ]  Comparable language included on template ICF on page Click or tap here to enter text.[ ]  N/A for this study | 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. |
| [ ]  Added by Sinai team[ ]  Comparable language included on template ICF on page Click or tap here to enter text.[ ]  N/A for this study | 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). |
| [ ]  Added by Sinai team[ ]  Comparable language included on template ICF on page Click or tap here to enter text.[ ]  N/A for this study | If you have included language regarding genetic testing and/or 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.
 |
| [ ]  Added by Sinai tea[ ]  Comparable language included on template ICF on page Click or tap here to enter text.[ ]  N/A for this study | 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. |
| PAYMENT FOR PARTICIPATION (Required when applicable) |
| [ ]  Added by Sinai team[ ]  N/A. Participants will not be paid. | ***If subjects will be paid for participation, in addition to the existing payment information, add the following:***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. |
| DISCLOSURE OF FINANCIAL INTERESTS  |
| [ ]  Added by Sinai team | ***Required to include the following:***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.  |
| [ ]  Added by Sinai team[ ]  N/A. No COI Management Plan for this study. | ***The COI Management plan is provided on a study specific basis and includes specific disclosure language for each study. Include any additional language from the COI management plan as required.*** *Please note that all management plans must be submitted to, and acknowledged, by the external IRB.* |
| ***Add the following statements, as appropriate:*** |
| [ ]  Added by Sinai team[ ]  Comparable language included on template ICF on page Click or tap here to enter text.[ ]  N/A for this study | ***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/device] being tested and has a financial interest that could be affected by the outcome of this research study.  |
| [ ]  Added by Sinai team[ ]  N/A for this study | ***2. 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, for example:*** 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.  |
| [ ]  Added by Sinai team[ ]  N/A for this study | ***3. 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. |
| **IN CASE OF INJURY DURING THIS RESEARCH STUDY (Required)*****The language in the Injury section needs to match what has been agreed to in the contract. Add the Sponsor language regarding compensation for injury after the institutional language, ensuring the language is not contradictory.******Include one of the statements below based on an assessment of the total research risk level:*** |
| [ ]  Added by Sinai team[ ]  Comparable language included on template ICF on page Click or tap here to enter text.[ ]  N/A for this study  | ***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.  |
| [ ]  Added by Sinai team[ ]  Comparable language included on template ICF on page Click or tap here to enter text.[ ]  N/A for this study | ***For protocols involving greater than minimal risk that have a for-profit sponsor, 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. Language referencing a for-profit sponsor charging insurance companies for research related injuries should be removed] |
| [ ]  Added by Sinai team[ ]  Comparable language included on template ICF on page Click or tap here to enter text.[ ]  N/A for this study | 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 the injury should this be necessary or as otherwise specified in the Authorization to Use and Disclose Protected Health Information section, which is included below. |
| [ ]  Added by Sinai team[ ]  Comparable language included on template ICF on page Click or tap here to enter text.[ ]  N/A for this study | ***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. You will be responsible for all treatment costs not covered by your insurance, including deductibles, copayments, 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.** |
| **MAINTAINING CONFIDENTIALITY – HIPAA AUTHORIZATION (Required)** |
| **1. Replace entire existing HIPAA authorization section with the following:**  |
| [ ]  Added by Sinai team[ ]  N/A for this study | 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 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 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 healthcare 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 (DHHS) and the Office of Human Research Protection (OHRP) (the government organization that is responsible for protecting human research participants).Modify the following 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, as long as the list is printed out and given to the participant at the same 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 (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.].
 |
| ***2. Please choose one of the following paragraphs based on whether your study has a Certificate of Confidentiality (CoC). This information should be added after the above HIPAA section. Please note the chosen paragraph must be precise and customized to fit this study****.*  |
| [ ]  Added by Sinai team[ ]  N/A for 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. |
| [ ]  Added by Sinai team[ ]  N/A for this study | **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. |
| **3. *This information should be added after the above HIPAA section.***  |
| [ ]  Added by Sinai team[ ]  N/A for this study | For how long will Mount Sinai be able to use or disclose your PHI? 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 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 us permission to obtain, use or share your PHI?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.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **4. 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 is modified, if this occurs please contact the PPHS promptly. If your study does not have a Certificate of Confidentiality, this section should not be included. |
| [ ]  Added by Sinai team[ ]  Comparable language included on template ICF on page Click or tap here to enter text.[ ]  N/A for this study | 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. |
| **USE OF YOUR DATA AND/OR SPECIMENS** (Required, when applicable, per mandated compliance with the Common Rule per NYS law)***If the study involves collection of data and/or specimens, then future uses for both data and specimens must be accounted for.****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%28v.%2011.4.19%29.docx)*, please contact the PPHS promptly and directly.*  |
| ***OPTION 1 - NO FUTURE RESEARCH******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.*** |
| [ ]  Added by Sinai team[ ]  Comparable language included on template ICF on page Click or tap here to enter text.[ ]  N/A for this study | 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.  |
| ***OPTION 2 – FUTURE RESEARCH LIMITED TO RELATED STUDIES (RELATED=DRUG/DEVICE OR DISEASE UNDER MAIN STUDY)******The data and samples collected for this study will only be used or shared for future research that is related to the product or disease under study. The scope of related future research should be included in the description of the study purpose in the ICF.***  |
| [ ]  Added by Sinai team[ ]  Comparable language included on template ICF on page Click or tap here to enter text.[ ]  N/A for this study | 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 unrelated to ***[the study drug or study device]*** or ***[disease under study]***, even if your identity is removed.  |
| ***OPTION 3 – STUDY OFFERS NO PROSPECT OF DIRECT BENEFIT TO SUBJECTS and FUTURE RESEARCH INTENDED:*** ***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 4. Likewise, use Option 4 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.***  |
| [ ]  Added by Sinai team[ ]  Comparable language included on template ICF on page Click or tap here to enter text.[ ]  N/A for this study | 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 4. 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]
 |
| ***OPTION 4 – STUDY OFFERS PROSPECT OF DIRECT BENEFIT TO SUBJECTS and FUTURE USE INTENDED FOR UNRELATED STUDIES (UNRELATED=NOT RELATED TO THE DRUG/DEVICE OR DISEASE UNDER MAIN STUDY)******Use Option 4 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. If future uses are unrelated to the product or disease under study and there is a prospect of dirct benefit, please use this option.*** ***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.*** |
| [ ]  Added by Sinai team[ ]  Comparable language included on template ICF on page Click or tap here to enter text.[ ]  N/A for this study | 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.  |
| **ENDING PARTICIPATION IN THE RESEARCH STUDY** |
| [ ]  Added by Sinai team | *The language below must be added or replace the language in the template*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. |
| [ ]  Added by Sinai team[ ]  Comparable language included on template ICF on page Click or tap here to enter text.[ ]  N/A for this study | 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.]  |
| [ ]  Added by Sinai team[ ]  Comparable language included on template ICF on page Click or tap here to enter text.[ ]  N/A for this study | 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. |
| [ ]  Added by Sinai team[ ]  Comparable language included on template ICF on page Click or tap here to enter text.[ ]  N/A for this 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.]. |
| [ ]  Added by Sinai team[ ]  Comparable language included on template ICF on page Click or tap here to enter text.[ ]  N/A for this study | 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:
 |
| [ ]  Added by Sinai team[ ]  Comparable language included on template ICF on page Click or tap here to enter text.[ ]  N/A for this study | 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. |
| [ ]  Added by Sinai team[ ]  Comparable language included on template ICF on page Click or tap here to enter text.[ ]  N/A for this study | 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.  |
| **BIOSPECIMENS THAT MAY BE USED FOR PROFIT *(Required, when applicable, per mandated compliance with the Common Rule per NYS law)***For studies collecting biospecimens that may be used for profit, one of the following statements must be included: |
| [ ]  Added by Sinai team[ ]  Comparable language included on template ICF on page Click or tap here to enter text.[ ]  N/A biospecimens not collected for this study. | OPTION 1It 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. |
| [ ]  Added by Sinai team[ ]  Comparable language included on template ICF on page Click or tap here to enter text.[ ]  N/A biospecimens not collected for this study. | **OPTION 2**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] |

|  |
| --- |
| Attach completed HRP-232 form in RUTH. *Submissions with an incomplete HRP-232 form will be returned during pre-review, prior to granting permission to submit to the external IRB.* |
| Name of person(s) completing the form | Click or tap here to enter text. | Date | Click or tap here to enter text. |

**THIS SECTION WILL BE COMPLETED BY THE PPHS OFFICE**

**Waiver of IRB Oversight**

In accordance with the existing master service agreement between the Icahn School of Medicine at Mount Sinai (ISMMS) and the external IRB indicated below, ISMMS agrees to waive jurisdiction for the IRB review and continuing oversight of the above-referenced research study to:

|  |  |
| --- | --- |
| [ ]  | Advarra |
| [ ]  | WCG/WIRB |
| [ ]  | BRANY |
| [ ]  | Alpha IRB |

According to the existing master service agreement:

* The external IRB will meet the human subject protection requirements of OHRP and FDA and follow written procedures for review, oversight, and reporting findings.
* The review performed by the external IRB indicated above will meet the human subject protection requirements of FDA and OHRP. The external IRB will follow written procedures for reporting its findings and actions to appropriate officials at Icahn School of Medicine at Mount Sinai. This document must be kept on file by both parties and provided to FDA and OHRP upon request.
* The Icahn School of Medicine at Mount Sinai will be responsible for ensuring compliance with the external IRB’s determinations.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of PPHS Authorized Designee Date

Icahn School of Medicine at Mount Sinai

Program for the Protection of Human Subjects

*Once this form is signed by an appropriate ISMMS PPHS designee, the research personnel will provide it to the external IRB along with other submission materials for IRB approval of the Mount Sinai study site.*