A Single-Center, Open-Label, Single-Arm, Phase I Study With Dose Expansion Cohort of Sacituzumab Govitecan in Combination With Cisplatin in Platinum Sensitive Recurrent Ovarian and Endometrial Cancer

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STUDY INFORMATION:

Study Title: A Single-Center, Open-Label, Single-Arm, Phase I Study with Dose Expansion Cohort of Sacituzumab Govitecan in Combination with Cisplatin in Platinum Sensitive Recurrent Ovarian and Endometrial Cancer

Study site(s): Icahn School of Medicine at Mount Sinai, Mount Sinai Hospital, Mount Sinai Chelsea, Mount Sinai West

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SUMMARY OF THIS RESEARCH STUDY:

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 to determine the optimal dose, safety, and effectiveness of sacituzumab govitecan in combination with cisplatin for the treatment of platinum-sensitive, recurrent epithelial ovarian and endometrial cancers.

Trodelvy™ (sacituzumab govitecan-hziy) is approved by the United States (U.S.) Food and Drug Administration (FDA) for the treatment of certain types of breast and bladder cancer, but is not yet approved by the FDA for the treatment of recurrent epithelial ovarian and endometrial cancers.

Cisplatin is FDA-approved for the treatment of advanced ovarian cancer, and is used to treat endometrial cancer.

The combination of these therapies for the treatment of your disease is considered experimental.

Early clinical trials have shown encouraging therapeutic benefit of sacituzumab govitecan plus cisplatin in the treatment of both endometrial and ovarian cancers. Researchers would like to study

this new treatment regimen further because current treatment options are limited for patients with recurrent ovarian epithelial cancer and endometrial cancer.

If you choose to take part, you will be asked to:

- Come to the clinic for approximately 25 visits over the course of 2 years.
- Follow the instructions provided by your study doctor or the study staff to take the study therapies, sacituzumab govitecan plus cisplatin, and undergo the standard tests and evaluations necessary for your medical care.
- Give permission for your previously collected, stored tissue biopsy to be used for research analysis, if available.
- Agree to have your private information, study data, and biological samples stored indefinitely.
- Agree to allow the study team to review the results of your genetic tests. Reviewing this information can help the study team identify which therapies would be most effective in treating your cancer.
- Taking part in this research study may lead to added costs to you, such as additional costs due to travel and time required for study visits. You will not be reimbursed for your travel or time that may be required for study visits. Your insurance may be billed for all or part of the study drug as part of your participation in the study. You or your health insurance company will be responsible for the cost of all standard clinical care services during the research study that you would have received for your condition if you were not enrolled in this study, and also for those services that your study doctor believes are medically necessary to treat you. You will not be paid or compensated for your participation in this study.

If you choose to take part, the main risks to you are the risks associated with the study treatments, sacituzumab govitecan and cisplatin. An additional risk associated with participation in this study may include a breach of confidentiality.

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 improvement in your health condition, and access to medical care that may not be available outside of this study.

Instead of participating in this research, you may choose to receive therapy for your disease without participating in this clinical trial.

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

STUDY PARTICIPATION:

You may qualify to take part in this research study because you have been diagnosed with recurrent epithelial ovarian or endometrial cancer.

Your participation in this research study is expected to last up to 2 years.

There are 42 people expected to take part in this research study at Mount Sinai Hospital, Mount Sinai Chelsea, and Mount Sinai West.

Funds for conducting this research study are provided by Gilead Sciences, Inc.

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:

If you agree to take part in this research study, here is what may be involved:

- Study visits will be conducted at Mount Sinai Hospital, Mount Sinai Chelsea, and Mount Sinai West.
- The following table shows which procedures and tests will be done during this study, how often they will occur, and the approximate duration of each visit. The evaluations and treatments listed in ***bold italics*** will be done for study research purposes. The other evaluations listed in the table will be performed as part of your routine clinical care, regardless of your research participation. ***Sacituzumab govitecan*** and ***cisplatin*** are the experimental treatments that will be administered as part of this study.
- The study doctor and team will work with you throughout this research study.
- Mutations in genes which produce proteins that help repair damaged DNA (such as mutations in the BRCA1 and BRCA2 genes) are often inherited by, and/or present in the tumors of, patients with your type of cancer. Physicians test patients with your cancer for these types of mutations as part of routine clinical care. Knowing your mutation status can help your physician determine which type of therapy would be most effective in treating your cancer. As part of this research, the study doctor and team will review any mutation studies that have been done previously. The study team will use this information to see if there is a correlation between your mutation status and the way your cancer responds to the study therapy.
- Information about your health status that is gained through the research analysis may be shared with you or your treating provider if deemed clinically significant. However, you will not receive the results of each individual research biospecimen analysis.
- Because this research study involves the use of study drugs, 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.

Evaluations and Treatments	Screening	Treatment (3-week treatment cycles)					Post Treatment	
	Days -28 to 0	Cycle 1-2			Cycles ≥ 3		Final Study Evaluation	Follow-Up Every 3 Months
Procedure\Visit Window	<28 days prior to Cycle 1 Day 1 (C1D1)	-1/+2 days			-1/+2 days		Within 30 days of last dose (+/- 3 days)	+/- 7 days
		Day 1	Day 8	Day 15	Day 1	Day 8		
Informed Consent	***x***							
Eligibility Assessment	***x***							
Medical History	***x***							
Physical Exam with Performance Status Evaluation	***x***	***x***			***x***		***x***	***x***
Vital Signs	***x***	***x***	***x***		***x***	***x***	***x***	***x***
Adverse Event Review		***x***	***x***		***x***	***x***	***x***	***x***
Concomitant Medication Review	***x***	***x***			***x***		***x***	***x***
Complete Blood Count (CBC) with Differential	x	x	x	x	x	x	x	x
Comprehensive Metabolic Profile (CMP)	x	x	x	x	x	x	x	x
CA-125	x	x			x			
Pregnancy Test	x							
HBV and HCV test	x							
PT and PTT	***x***							
CT Scan (chest/abdomen/ pelvis) or PET/CT	x				Every 3 cycles			
Standardized Imaging Review	***x***				***x***			
Pathology Review	x							
Archival Tissue Analysis				***x***				
Sacituzumab govitecan Infusion		***x***	***x***		***x***	***x***		
Cisplatin Infusion		***x***			***x***			
Doctor Visit	***x***	***x***	***x***		***x***		***x***	***x***
Clinical Research Nurse Visit	***x***	***x***	***x***		***x***	***x***	***x***	***x***

Pregnancy

If you can possibly get pregnant, a urine test for pregnancy will be done before you begin the study.

You cannot be included in the study if you are or become pregnant, as the study drugs 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 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).

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 6 months after the last dose of study drug sacituzumab govitecan and cisplatin. 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 become pregnant, or may be pregnant, at any time during the study, or within 6 months after the last dose of study drug sacituzumab govitecan or cisplatin, 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 become pregnant, whether or not you 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 will be asked for additional written consent to share this information if that happens.

USE OF YOUR DATA AND/OR SAMPLES:

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.

YOUR RESPONSIBILITIES IF YOU TAKE PART IN THIS RESEARCH:

If you decide to take part in this research study, you will be responsible for the following things:

- Taking the prescribed medications
- Using birth control methods as described
- Attending study visits
- Calling the study team to notify them of any adverse events or side effects you experience

COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

There may be costs to you for taking part in this study. Your insurance may be billed for all or part of the study drug as part of your participation in the study. Additional costs due to travel and time required for study visits may apply. You will not be reimbursed for your travel or time that may be required for study visits.

You or your health insurance company will be responsible for the cost of all standard clinical care services during the research study that you would have received for your condition if you were not enrolled in this study, and also for those services that your study doctor believes are medically necessary to treat you.

Dr. Dmitriy Zamarin (a researcher in this study) is a consultant for Gilead Sciences, the study sponsor and developer of the study drug (sacituzumab govitecan).

If you have questions regarding paid relationships that your physician/researcher may have with industry, you are encouraged to talk with your physician/researcher, or check for

POSSIBLE BENEFITS:

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 improvement in your health condition, and access to medical care that may not be available outside of this study.

POSSIBLE RISKS AND DISCOMFORTS:

Risks of Trodelvy™ (sacituzumab govitecan-hziy)

Sacituzumab govitecan is given intravenously (through a vein in your arm)

There are risks involved with taking sacituzumab govitecan. Seek urgent medical attention if you notice any of the following serious side effects while being given or after you are given sacituzumab govitecan.

The most common adverse reactions (incidence ≥25% or 25/100 people) in patients with metastatic triple-negative breast cancer are:

- Nausea
- Neutropenia (low white blood cell count)
- Diarrhea
- Fatigue
- Anemia (low red blood cell count)
- Vomiting
- Alopecia (hair loss)
- Constipation
- Rash
- Decreased Appetite
- Abdominal Pain

Allergic Reactions (very common, occurring in more than 1 in 10 people) including Infusion Related Reactions

Sometimes people have allergic reactions during or after sacituzumab govitecan infusion, which can be severe or life-threatening. This includes infusion related reactions (common, occurring in 1 to 10 in 100 people), which occur when your body reacts negatively to medicines given through an infusion. This also includes an anaphylactic reaction (uncommon, occurring in up to 1 in 100 people), which is a serious allergic reaction that may cause an itchy rash, throat or tongue swelling, shortness of breath, vomiting, lightheadedness, low blood pressure, or death if not promptly treated.

Neutropenia or Low white blood cell count (very common, occurring in more than 1 in 10 people)

This is a condition where you have too few neutrophils, a type of white blood cell, in your blood, resulting in an increased risk of infections. Fever may also occur with neutropenia (common, occurring in 1 to 10 in 100 people) and may be a sign of infection, which may require antibiotics or other medicines. Neutropenic colitis (inflammation of a part of the large intestine with neutropenia, common) may also occur and be associated with infection.

Infections that occur when you have neutropenia can be severe, life-threatening, or fatal. Fatal infections associated with neutropenia are rare and have mostly been seen early on in treatment, within the first 4 doses. Although this is not a complete list, you may be at higher risk for fever with neutropenia if you:

- Are 65 years of age or older
- Have difficulty completing everyday activities
- Have had too few neutrophils in the past
- Have one or more other health conditions, including but not limited to heart disease, kidney problems, or liver issues

If you are at an increased risk for fever with neutropenia, it is recommended that you receive an additional type of drug called granulocyte colony-stimulating factor (G-CSF) to help lower the risk of infection associated with neutropenia. Please speak with your doctor about whether you should receive this additional drug to lower the likelihood of this side effect while taking sacituzumab govitecan.

Possible signs and symptoms of neutropenia or neutropenic infections include:

- Cough or shortness of breath
- Fever
- Chills or sweating
- Sore throat, sores in the mouth, or a toothache
- Stomach pain
- Pain near the anus
- Pain or burning when urinating or urinating often
- Diarrhea or sores around the anus

Diarrhea (very common, occurring in more than 1 in 10 people)

Diarrhea can be severe. Dehydration due to diarrhea has been seen in people getting sacituzumab govitecan, and in some severe cases, has resulted in acute kidney injury (sudden kidney damage).

Nausea and Vomiting (very common, occurring in more than 1 in 10 people)
Nausea and vomiting can be severe. Please talk to your doctor about what medications or other supportive measures you can take to help prevent and treat nausea and vomiting when you are taking sacituzumab govitecan.

Patients who have the UGT1A1*28 Gene
Some patients may be genetically more likely to have certain side effects from the medicine. If you have the UGT1A1*28 gene, you may be more likely to develop neutropenia (with or without fever) earlier than in patients without this gene. You may also be more likely to develop low levels of red blood cells (anemia) or other side effects after being given sacituzumab govitecan than those who do not have the gene. Inform your doctor if you know you have the UGT1A1*28 gene.

Pregnancy and Lactation
Based on how sacituzumab govitecan works, it may cause harm to an unborn baby, such as birth defects or death, when given to a pregnant woman. Sacituzumab govitecan contains a component that targets rapidly dividing cells, which may damage the genetic information within a cell, including cells that become sperm, and therefore may harm an unborn baby (including mutations and birth defects). The effects of sacituzumab govitecan in women trying to get pregnant or are pregnant have not been studied at this time.

As there is potential of harm to an unborn baby, individual of childbearing potential in this study should not be pregnant or become pregnant and must agree to the contraception requirements for the study.

Avoid pregnancy and breastfeeding while taking sacituzumab govitecan, and for 3 months (90 days) after discontinuing treatment, as the drug may cause harm to the fetus or newborn.

Older Patients
In previous clinical studies with HR+/HER2- breast cancer and bladder cancer, patients who were 65 years and older stopped sacituzumab govitecan due to harmful effects at higher rates compared to younger patients. However, overall, there were no differences in effectiveness.

Antibody Risks

Antibodies are protective proteins made by your immune system. Your body may develop its own antibodies against the sacituzumab govitecan that is given in this study. In previous studies of patients treated with sacituzumab govitecan, there was a low number of patients who developed antibodies and the development of antibodies is not expected to impact the effect of sacituzumab govitecan.

Additional Risks

Other harmful effects reported in previous studies with sacituzumab govitecan in more than 1 out of 10 people include:

- Low amount of red blood cells, also called anemia, which may cause fatigue or may require a blood transfusion
- Low amount of white blood cells
- Decreased number of a type of white blood cell called “lymphocytes”
- Constipation
- Pain in the abdomen
- Fatigue (tiredness), feeling weak and having no energy
- Urinary tract infection which may cause frequent and painful urination
- Weight loss
- Decreased appetite
- Low blood magnesium
- Low potassium
- Low phosphate level
- Dehydration (when your body does not have as much water and fluid as it should)
- Joint pain
- Headache
- Dizziness
- Shortness of breath with or without exercise
- Cough
- Itching
- Hair loss
- Rash

In addition, in previous studies with sacituzumab govitecan, 1 to 10 in 100 people had these side effects:

- Decreased number of a type of blood cell that helps to clot blood (platelet), causing bruising and/or bleeding

- Infection of the lungs
- Inflammation of the mouth and lips
- Indigestion
- Digestive disease in which stomach acid irritates the food pipe lining
- Swelling of the abdomen
- Upper abdominal pain
- Inflammation of the lining of the large intestine
- Chills
- Pain
- Upper respiratory tract infection, common cold
- Severe infection throughout the body
- Increase in an enzyme called alkaline phosphatase, which may be a sign of a bone or liver problem
- Increase in length of time it takes for a blood clot to form
- High blood level of an enzyme called blood lactate dehydrogenase
- Low blood sodium
- Low calcium level
- High blood sugar level
- Change in sense of taste
- Difficulty sleeping
- Increase in levels of protein in the urine
- Bleeding from the nose
- Runny nose
- Nasal congestion
- Dry skin
- Rash which may look flat and discolored or small and raised and may be itchy
- Darkening of the skin
- Small, raised, acne-like bumps usually on the face, scalp, chest, or upper back
- Low blood pressure

In previous studies with sacituzumab govitecan, 1 to 10 in 1000 people had this side effect:

- Inflammation of the lining of the small intestine

Please talk to your study doctor for more details on side effects.

Interactions with Other Drugs

Avoid taking medications used in general anesthesia and for sedation while taking sacituzumab govitecan, as this may increase your risk of experiencing adverse reactions**.**

Risks of Cisplatin

Cisplatin is given intravenously (through a vein in your arm)

The most common adverse reactions are:

- Nephrotoxicity (kidney injury)
- Peripheral Neuropathy (weakness, numbness, or pain, usually in the hands and feet)
- Nausea
- Vomiting
- Myelosuppression (decreased blood cell production) occurs in 25-30% or 25-30 out of 100 people
- Ototoxicity (tinnitus, hearing loss) occurs in 40-60% or 40-60 out of 100 people

The following less common reactions have also been observed:

- Ocular toxicity (impairment of eye function)
- Secondary malignancy (a new cancer may result)

Hypersensitivity (Allergic) Reaction may occur.

<u>Pregnancy and Lactation</u>

Avoid pregnancy and breastfeeding while taking cisplatin and study drug sacituzumab govitecan, and for 6 months after the last dose of study drug sacituzumab and cisplatin govitecan, as the drugs may cause harm to the fetus or newborn.

<u>Other risks:</u>

- The combination of the study drugs sacituzumab govitecan and cisplatin at the doses given in this trial may be associated with additional risks, including worsening of the risks for either of these drugs when given alone, and may pose new risks that may not yet be known to us.
- Risk of loss of private information; this risk always exists, but there are procedures in place to minimize the risk.
- This research study may hurt you in ways that are not known. The unknown risks could be minor or major (death).
- If you are pregnant or become pregnant, this research may hurt your baby or your pregnancy in ways that are unknown. The unknown risks 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.
- 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 - 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.
- 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:

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.

Instead of being in this research study, your choices may include surgery and the standard chemotherapies that are given for your disease.

Side effects of surgery may include pain, infection, bleeding, blood clots, swollen legs, bladder and bowel problems and symptoms of menopause, including hot flashes or vaginal dryness.

Side effects of chemotherapy may include: nausea, vomiting, loss of appetite, loss of hair, hand and foot rashes, mouth sores, infection (from low white blood cell counts, also called leukopenia), easy bruising or bleeding (from low blood platelet counts. also called thrombocytopenia), fatigue (from low red blood cell counts and other reasons, also called anemia), kidney damage, nerve damage, hearing loss, and secondary cancer development.

IN CASE OF INJURY DURING THIS RESEARCH STUDY

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.

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

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

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

- You may no longer have access to the study treatment sacituzumab govitecan.
- Your disease may progress while off the study treatment

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. The

research team may ask you whether they can continue to collect information from your medical record.

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 (212) 824-8591.

If there is an emergency, please 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.

The company sponsoring this research study, Gilead Sciences, Inc., makes Trodelvy™ (sacituzumab govitecan), the drug being tested, and has a financial interest that could be affected by the outcome of this research study.

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?

As part of this study, the research team at the hospital(s) involved in the research will collect your name, address, telephone number, birthdate, dates of admission and discharge, date of death (if death occurs), e-mail address, social security number, medical record number, and health plan numbers.

During the study, the researchers will gather information by:

- 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 and procedures 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.
- Reviewing genetic tests.

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.

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.
- I*f 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).
- The funding sponsor and/or their representative (who may use the results for submissions to the Food and Drug Administration (the government organization that approves drugs or devices for medical use): Gilead Sciences, Inc.
- The United States Food and Drug Administration.

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.

For how long will Mount Sinai be able to use or disclose your PHI?
Your authorization for use of your PHI for this specific study does not expire.

Will you be able to access your records?
During your participation in this study, you will have access to your medical record and any study information that is part of that record. The 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 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 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) 416-0197. These agencies are responsible for protecting your rights.

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

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

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

ADULT PARTICIPANT:

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

Signature of Participant	Printed Name of Participant	Date	Time

PERSON EXPLAINING STUDY AND OBTAINING CONSENT:

Signature of Consent Delegate	Printed Name of Consent Delegate	Date	Time

----------FOR IRB USE ONLY----------

Study ID: STUDY-23-00832 **Form Version Date: 03February2025**

WITNESS SECTION:

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

_____	_____	_____	_____
Signature of Witness	Printed Name of Witness	Date	Time