Characterizing Pyoderma Gangrenosum Lesion Regression and Remission by IL-36 Receptor Targeting With Spesolimab

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STUDY INFORMATION:

Study Title: Characterizing Pyoderma Gangrenosum Lesion Regression and Remission by IL-36 Receptor Targeting with Spesolimab

Study site(s): Icahn School of Medicine at Mount Sinai at Mount Sinai, Department of Dermatology

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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 assess the feasibility of using spesolimab in participants with moderate to severe pyoderma ganrenosum. This study is not designed to assess effectiveness and safety of spesolimab. The study doctors have achieved a positive response in two patients that have been previously treated with spesolimab. Pyoderma gangrenosum is a rare, inflammatory, autoimmune condition which results in ulceration of skin. The study will also investigate the body's immune response to the spesolimab (when the body detects and defends itself against substances that appear unknown and harmful).

This study is funded by Boehringer Ingelheim Pharmaceuticals, Inc.

Summary of This Study

In total, you will be asked, at minimum, to complete a total of 13 or 15 visits (1 screening visit, 8 or 9 spesolimab treatment visits, 1 endpoint visits, and 4 follow-up visits) which includes physical exams, blood testing and infectious disease testing, completing questionnaires, and photographs of areas of

your skin affected by PG. During each treatment visit, you will receive a 90-minute infusion of spesolimab. It is also possible that your PG or health may improve because you are taking part in this study, but the study is not designed to test this effect.

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 are at least 18 years old and have been diagnosed with moderate to severe pyoderma gangrenosum that has not fully responded to previous treatments that you've tried.

Your participation in this research study is expected to last 12 months. There are 20 people expected to take part in this research study at Mount Sinai Dermatology.

Funds for conducting this research study are provided by Boehringer Ingelheim Pharmaceuticals, Inc, the manufacturer of spesolimab.

DESCRIPTION OF WHAT IS INVOLVED:

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

All research visits/activities will be performed at Mount Sinai and will be for research purposes only.

After signing this consent form, we will ask you about your medical history, any medications you are taking, and all prior treatments for your PG. A research fellow will perform a skin examination to assess your PG. You will also have a physical examination (including measurement of blood pressure and heart rate) and a urine and blood sample will be collected (approximately 3 ¾ tablespoons blood and 3 teaspoons of urine). The blood sample will include a general blood test as well as a test for hepatitis B, hepatitis C, and human immunodeficiency virus (HIV). These tests must be negative to continue to qualify for the study. You will also be screened for tuberculosis via a blood or skin test. A pregnancy test will be performed from the urine collected, if applicable. This test must be negative to continue to qualify for the study.

If you continue to qualify for the study you will return for a baseline visit.

Baseline Visit -Visit 2 (approximately 3 hours):

At the Baseline visit you will be asked to complete a questionnaire; the research fellow will perform a skin examination to assess your PG. You will also have a physical examination (including

measurement of blood pressure and heart rate) and a blood sample will be collected (approximately 2 tablespoons). Urine will be collected (2 teaspoons) for a pregnancy test, if applicable. Photographs of your PG lesions will be also be taken and ulcers will be measured. All efforts will be made to photograph areas that do not include your eyes or any other identifying markers (tattoos). If there are any views that show your eyes or any identifying markers, they will be blacked out in any publication. You cannot participate in the trial if you do not consent for photographs to be taken.

You receive your first study drug through intravenous infusion. An IV infusion is a slow injection of the study drug directly into your vein. It will take about 1-1/2 to 3 hours to give you the study drug. This dose of study drug will be given to you at Visit 2 at the study center or the hospital. The research fellow will discuss this with you. Every participant included in the study will receive treatment with the study drug **.** You will receive study drug at a frequency of every 4 weeks through Week 8, at which time, at the discretion of the investigator, dosing frequency may be increased to every 3 weeks. You will continue to dose every 4 or 3 weeks through Week 28 or 26 (depending on dosing frequency). For the next 26 or 28 weeks, you will return to the study site every 3 or 4 weeks for a study drug infusion.

Weeks 4 through end of treatment (approximately 3 hours each):
The following procedures will be done at each visit:

- We will ask you about any updates to your medical history and medications you are taking
- You will be asked to complete questionnaire(s)
- The research fellow will perform a skin examination to assess your PG and evaluate for any potential side effects of treatment
- You will have a physical examination (including measurement of blood pressure and heart rate)
- Urine will be collected (2 teaspoons) for a pregnancy test, if applicable
- Photographs will be taken of all PG ulcers
- Blood (2 tablespoons) will be collected for standardized tests and possible future use.
- IV infusion of spesolimab over 90 minutes
- If you start to see improvement in your ulcers, the lead investigator/research doctor may decrease other SoC medications that you are on for PG.
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Week 16 Endpoint Visit (approximately 1 hour):

- We will ask you about any updates to your medical history and medications you are taking
- You will be asked to complete questionnaire(s)
- Photographs will be taken of all PG ulcers
- Urine will be collected (2 teaspoons) for a pregnancy test, if applicable
- Blood (2 tablespoons) will be collected for standardized tests and possible future use.
- IV infusion of spesolimab over 90 minutes, if applicable

- Lead Investigator/Research doctor will decide whether you will either enter the follow-up period if you have seen full healing of your ulcer or you may continue with every 3 or 4 week infusions until your ulcers are fully healed.
- If your PG has significantly worsened, you will be discontinued from the study and the study doctor may prescribe Standard of Care (SoC) medications, which are usually given for treating PG. The study doctor will discuss these options with you. You will be asked to complete the 4 follow-up visits to monitor for any side effects.

Follow-Up Visits (the following may occur at some or all of the follow-up visits) (approximately 1 hour):

- We will ask you about any updates to your medical history and medications you are taking
- You will be asked to complete a questionnaire
- The research fellow will perform a skin examination to assess your PG and evaluate for any potential side effects of treatment
- Photographs will be taken of all PG ulcers
- Blood (2 tablespoons) will be collected for possible future use.

If your PG does not improve or worsens during the treatment period, your doctor/dermatologist or the lead investigator may prescribe Standard of Care (SoC) medication(s), which are recommended medication(s) usually given for treating PG. Your doctor/dermatologist or the lead investigator will tell you what SoC medication(s) you will receive.

Because this research study involves the use of the study drug, spesolimab, 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.

HIV/AIDS

To take part in this research study, your blood will be tested for evidence of HIV, the virus that causes AIDS. People can get HIV through unprotected sexual contact with someone who has HIV, and through contact with blood (as in sharing needles including for piercing, tattooing, and injecting drugs). People who are pregnant with HIV infections can transmit HIV to their infants during pregnancy, delivery or while breastfeeding. There are treatments for HIV/AIDS that can help people stay healthy. People with HIV/AIDS can adopt safe practices to protect uninfected and infected people in their lives from getting HIV or getting infected with a different strain of HIV.

By law, positive test results for HIV/AIDS (as well as other communicable diseases such as hepatitis B, hepatitis C, and syphilis) are reported to the NYS Department of Health so they can study how people get and transmit the disease and notify sexual or needle-sharing partners they may have been exposed. If you wish to be tested anonymously for HIV/AIDS, the research team can refer you to a public testing center, but you will not be able to be in this study. New York State law protects the

confidentiality of HIV test results and other related information. It is illegal to discriminate against a person based on their HIV status and services are available to help if this happens. You are free to refuse to get an HIV test, but if you refuse you cannot be part of this research study.

Pregnancy

If you can possibly get pregnant, a blood test for pregnancy will be done before you begin the study and a urine pregnancy test will be repeated every at every treatment and follow-up visit.

You cannot be included in the study if you are or become pregnant, as the study drug 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, implant 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 four months 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 during the study or 4-month follow-up period, 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.

USE OF YOUR DATA AND/OR SAMPLES:

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) 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. All data and samples will always be linked to your identity, using a code, but that code will always remain with the investigators at Mount Sinai and will not be shared outside of the research team members.

(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.

(2) 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_____

(3) 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) 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_____

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:

- You must tell the lead investigator/research fellow if you previously participated in this study, have been in another research study in the past 30 days or are currently in another research study.

- While you are participating in this study, you should not take part in another study without approval from the lead investigator.
- You may only receive spesolimab at this study center. You may harm yourself if you receive spesolimab treatment from multiple providers.
- If you are treated by another doctor, it is important that you tell the study staff about your treatment and what happened.
- You must follow the instructions you are given by the study staff. If you do not follow the instructions, your visit may have to be rescheduled.
- Tell the research fellow or the study staff about all prescription and non-prescription medications, supplements, herbal preparations, or vaccines before you take them.
- Notify the research fellow or study staff if you move and provide your new address and contact information.
- You must continue with one of the outlined birth control methods above.

COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

You will not be paid for taking part in this study. Being in this study will not cost you anything extra. Researchers will not pay you for your travel or the time it will take for you to be in the study.

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 and healing of your PG ulcers.

POSSIBLE RISKS AND DISCOMFORTS:

There are risks to taking part in any research study.

Physical Risks of Spesolimab

As of September 2022, spesolimab is an FDA approved drug for generalized pustular psoriasis (GPP) flares. The listed potential side effects of spesolimab include infections such as urinary tract infections or upper respiratory tract infections, itching, fatigue, or injection site reactions.

Some subjects receiving spesolimab in studies for other conditions reported: dizziness, double vision, and temporary loss of consciousness. These were thought to be possibly related to spesolimab. Some subjects that were enrolled in studies for other conditions and were receiving either spesolimab or placebo (product that does not contain any active ingredients) have reported the following: joint

pain, fever, low white blood cell count or platelet count, elevated liver tests, and enlargement of liver and/or spleen.
If you receive study drug, then side effects may occur. Some of those side effects can be treated. Some side effects may go away when you stop taking the study drug. Some side effects can be mild, but others may continue longer or become permanent. Some may be life-threatening or fatal. In addition, the concurrent use of SoC medications for PG have not been studied in combination for spesolimab. Thus, concurrent use of a Soc medication and spesolimab may lead to both known side effects such as infection and unknown side effects that have not been studied.

The effects of spesolimab on sperm, a pregnancy, a fetus, or a nursing child are not known. 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.

All drugs have a potential risk of causing an allergic reaction, which (if not treated quickly) could become life-threatening. You child should get medical help right away or call your local emergency number and contact the lead investigator/study doctor and/or research fellow if you think you are having a serious allergic reaction: trouble breathing or wheezing; Swelling of the face, mouth, lips, gums, tongue, or neck; Rash, hives, or blisters; Dizziness and fainting; a fast pulse/heart beat; and/or or sweating.

In addition to these risks, this research study may hurt you in ways that are not known. The unknown risks could be minor or major (death).

Risk of loss of private information:
This risk always exists, but there are procedures in place to minimize the risk.

Risks of Blood Draw:
The risks of a blood draw include pain, bruising, and the slight possibility of infection at the place where the needle goes in. Some people feel dizzy or may faint during or after a blood draw.

Risks of Intravenous Infusion
Receiving study drug by IV infusion may result in an infusion reaction with symptoms such as fever, flushing of the skin, itching, rash or a decrease in blood pressure. You will be monitored by the study doctor for signs of an adverse reaction during the infusion. Infusion reactions typically resolve after stopping or slowing down the infusion, sometimes additional medication is required. Other risks of infusion include damage to blood vessels, swelling in the area of IV insertion, bruising at site of insertion, inflammation of the veins, infection, skin death, and possible development of an abscess. Further, a blood clot or an air bubble could form, which could block a blood vessel in another part of

your body.

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. 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.

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. *Commonly used alternatives are prednisone, cyclosporine, adalimumab and infliximab. However, these are not treatments without serious side effects and must be discussed with your doctor.*

IN CASE OF INJURY DURING THIS RESEARCH STUDY

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.
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

WITHDRAWAL: 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 will be asked to return all study drug and for your safety, you will be asked to complete the Early Termination Visit tests (as described in the description section of this form).

If you decide to stop being in the research study, any improvements in your PG may be lost or worsen.

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 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. You may inform the study team in writing at any time if you choose to withdraw your consent for future use of any personal information, study data and/or samples.

If you decide you don't want your data and/or samples to be used for research anymore, you can contact the Lead 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 212-241-7568 or 212-241-3288.
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.

In the past, Dr. Saakshi Khattri (the Lead Researcher in this study) has been a paid consultant for Boehringer Ingelheim (the study sponsor and developer of the study drug, spesolimab).

Dr. Mark Lebwohl (a Researcher in this study) is a paid consultant for Boehringer Ingelheim.

Dr. Khattri and Dr. Lebwohl also receive financial compensation as consultants from other companies that research and develop therapies used in the treatment of dermatologic conditions.

If you have questions regarding paid relationships that your physician/researcher may have with industry, we encourage you to talk with him or her, or check for industry relationships posted on individual faculty pages on our website at http://icahn.mssm.edu/.

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, social security number, and photographic images.

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, 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

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).
- Our collaborator on this study, Boehringer Ingelheim Pharmaceuticals Inc., and their representatives or business partners, including those in other countries. Any reference to the collaborator includes their research partners and service providers including companies belonging to the collaborator, and any person or company that acquires them or the rights to the study drug (spesolimab). The research team will send study data and results to Boehringer Ingelheim Pharmaceuticals Inc. Information sent to Boehringer Ingelheim Inc. will not include information that directly identifies you (such as your name and Social Security number) and will be coded with a participant identification number. In the future, Boehringer Ingelheim Pharmaceuticals Inc and their representatives, may continue to use coded health information that is collected as part of this study. Boehringer Ingelheim Pharmaceuticals Inc may share information from the study with regulatory agencies.
- 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?
You will have access to your medical record and any study information that is part of that record at any point during or after the study has ended. 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) 306-5070. 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

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