A Phase I Dose Escalation Study of Harmine in Healthy Subjects
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STUDY INFORMATION: STUDY-20-01329

Study Title: A Phase I Dose Escalation Study of Harmine in Healthy Subjects

Study Site: Icahn School of Medicine at Mount Sinai

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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 test the safety of a drug called *harmine.* Scientists believe that the study drug may be helpful in treating people with diabetes. Naturally occurring unpurified Harmine is found in herbal teas (e.g. Ayahuasca） that have been known to provoke significant hallucinations and other mental effects. It is not known if oral Harmine taken alone will have this effect. This drug has been tested in animals but not yet in people. Harmine has not yet been approved by the FDA so its use in this study is considered investigational. This study tests different doses of the drug to see which dose is safer in people. There will be about 40 people taking part in this study.

Different doses of the study drug *harmine* will be given to several study participants. The first several study participants will receive the lowest dose. If the drug does not cause serious side effects, it will be given to other study participants at a higher dose. The doses will continue to increase for every group of study participants until side effects occur that require the dose to be lowered. Then the study will be stopped. It is therefore very likely that some of the 40 people in this study will have significant and possibly distressing side effects.

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

- Attend a total of three to four visits with a total time commitment of 12 hours.
- Have an I.V. catheter placed in your arm for the purpose of blood sample collection
- Follow a low tyramine diet 3 days before and 3 days after you take the study drug
- Ask a family member or friend to pick you up from the treatment visit

- Agree to have private information/study data/biological samples stored
- Compensation will be provided for your time. There are no costs associated with participation.

If you choose to take part, the main risks to you are

- You may lose time at work or home and spend more time in the hospital or doctor's office than usual
- You may be asked sensitive or private questions which you normally do not discuss

The study drug used in this study may affect how different parts of your body work such as your liver, heart and blood. The study doctor will monitor you and will let you know if changes occur that may affect your health.

There is also a risk that you could have side effects from the study drug. The table below show the most common and the most serious side effects that researchers know about. There might be other side effects that researchers do not yet know about. If important new side effects are found, the study doctor will discuss these with you.

Possible Side Effects of HARMINE

COMMON, SOME MAY BE SERIOUS
● Decreased heart rate ● Decreased blood pressure ● Nausea and vomiting ● Slow tremor of the extremities ● Humming and buzzing noises ● Sense of body vibration ● Numbness ● Reduced sensitivity to light touch

You will not benefit directly from taking part in this research.

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

STUDY PARTICIPATION:

This research study will be fully explained to you by a member of the study team. Feel free to ask all the questions you want before you make a decision about whether or not to participate. Any new information that develops during this research study that might make you change your mind about participating will be given to you promptly.

You may qualify to take part in this research study because you are a healthy person

Your participation in this research study is expected to last up to 8 weeks from screening until the exit visit, but is expected to be less in most cases.

There are 54 people expected to take part in this research study at Icahn School of Medicine at Mount Sinai

Funds for conducting this research study are provided by Mount Sinai and the National Institute of Diabetes and Digestive and Kidney Diseases/NIH/DHHS.

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 participate in this research study, the following information describes what may be involved. Dr. Murrough, Primary Investigator on this project and Director of the Depression and Anxiety Center at Mount Sinai, will be responsible for all trial related medical decisions, including the drug related procedures.

Screening (Visit 0) - Approximately 2.5 hours
You will first come to the study site for a screening visit with the study team, which can be done over the course of 2-3 days if needed. The screening period may last up to 4 weeks but is expected to be less in most cases. At this visit, a thorough psychiatric evaluation will be performed. This may include an interview about your psychiatric history and completing questionnaires about your mood, beliefs, and how you think. Your general health will be assessed by a medical history and physical exam, blood work (up to 3 tablespoons), urinalysis, and vital signs. Your heart function will be assessed using a test called an Electrocardiogram (ECG), which consists of putting stickers on your chest that are able to detect details of your heartbeat. You will also be asked to provide a urine sample that will be tested for the presence of drugs of abuse in your urine. After the visit, the research team will determine if you are a good fit for the study.

Treatment Day (Visit 1) - Approximately 8.5 hours
If you are found to be eligible for the study and wish to participate, you will return to the clinic for the treatment day. Because harmine may act similarly in the body as MAO inhibitors, you will be instructed to follow a low tyramine diet, which is recommended for those taking MAO-Is as well. You must follow a low tyramine diet for 3 days before and 3 days after dosing with the study drug. Tyramine is found mainly in foods that are fermented, aged, or spoiled. Eating foods that are high in tyramine while taking certain medications can cause side effects such as high blood pressure, headache, heart palpitations, nausea, vomiting, visual disturbances, and confusion (University of Wisconsin). The study team member will provide a document during consent review at the screening visit outlining the low tyramine diet detailing what foods to avoid. Participants will be systematically reminded 3 days before their scheduled baseline visit to begin adhering to the low tyramine diet, which will be confirmed before dosing begins by the study doctor on treatment day. Additionally, a study team member will systematically remind the participants to abstain from food and drink at least

8 hours before dosing is set to begin, which will also be confirmed by the study doctor on treatment day. Following medical and psychiatric screening, a needle and cannula {intravenous (IV) line} will be placed in a vein by trained personnel to collect blood and monitor the level of metabolites, broken down portions, of study drug. All treatment procedures and monitoring will take place within the Mount Sinai Hospital System. You will be asked to fast overnight, 8 hours prior to treatment, refraining from solid food and non-clear liquids. All procedures will be performed in a private, quiet room. When you arrive, you will need to provide a urine sample to test for the presence of drugs of abuse in your system. Urine samples will be collected by UTox cups that provide immediate results and will not be sent out to MSHS labs.

Next, you will be given an oral dose of harmine and we will begin monitoring your vital signs continuously, including your blood pressure, heart rate, and breathing rate. Immediately following the treatment, you will be repeatedly assessed using self-report rating scales.

During the treatment procedure you will be closely monitored by a study physician. You will also be monitored for a minimum of 8 hour afterwards by study trained personnel. Blood will be collected at eight timepoints over approximately eight hours for analysis. At each of these timepoints, 4mL of blood will be drawn. At the end of the oral administration, you will be asked questions that check for possible side effects of the drug you are receiving and that evaluate your mental state. After at least an 8-hour monitoring period and a check of your vital signs, you will be discharged and you will leave the clinic. You must be picked up from this treatment visit by a family member or friend to ensure your safety. The name and number of the escort home for each individual will be collected upon your arrival at treatment day.

Follow up/Study Exit (Visit 2) – Approximately 1.5 hours
You will return to the clinic 1 day after the treatment day. At this final visit you will be asked questions about your mental and physical health and your general health will be assessed by a physical exam, blood work (up to 3 tablespoons), urinalysis, vital signs, and EKG. Once this visit is over your participation in the study will be complete and you will be considered exited from the study

Because this research study involves the use of an investigational study drug, 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.

Notice Concerning HIV-Related Information

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 urine test for pregnancy will be done before you begin the study and the pregnancy test will be repeated at the morning of your first visit.

You cannot be included in the study if you are or become pregnant, as the study involves drugs or experimental treatment with potential risks to a developing 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 one month 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 trial, you must tell a person from the research team immediately. The team may stop the study drug and refer you/your partner to an obstetrician/gynecologist for follow-up.
Should you/your partner become pregnant, whether or not you/your partner have the baby, the people funding and overseeing the research may ask for information on the pregnancy, even if you are no

longer part of the study. You/your partner will be asked for additional written consent to share this information if that happens.

Semen/Sperm:

Drugs can be found in semen and alter sperm. Since you are taking part in a study using experimental drugs or treatments, it is recommended that 1) you use a condom, 2) you do not get a partner pregnant or expose them to semen, and 3) you do not donate semen. These recommendations apply both while you are taking the study drug, and for 3 months after you stop taking the study drug. 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:

The researchers may wish to use your personal contact information to contact you in the future. Do you give the researchers permission to **contact you** in the future to request the collection of additional information about you, discuss how your private information, study data and/or samples might be used, or discuss possible participation in another research study?

Please initial your choice: Yes_____ No_____

If "Yes", please indicate your preferred method of contact: (initial all that apply)

[ ] Email [ ] Phone [ ] Letter [ ] Text

USE OF YOUR DATA AND/OR SAMPLES:

The 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.

(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.

(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_____

(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_____

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:

- Using birth control methods as described in the Description of What's Involved section
- Avoiding certain medications
    - Discontinue the use of certain over-the-counter (OTC) medications and herbal remedies at least 2 weeks prior to dosing. A study team member will go over any of your current medications that would need to be discontinued at this time.
- Adopting a low Tyramine diet as outlined in the description section and the low tyramine diet document provided by a study team member. On the day of your dosing visit, if you have eaten any of these foods, please let a study team member know
- Attending study visits
- Asking a friend or family member to pick you up from the treatment visit upon discharge from the study doctor

COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

Being in this research study will not lead to research related costs to you. You will not be reimbursed for your travel or time that may be required for study visits.

If you agree to take part in this research study, we will pay you $350 for your time and effort. Payment will be provided at the end of the study.

You will be paid in check *which can take up to 6 weeks to prepare and give you for study participation.* If you do not get a check by then, you can first contact the research team. If further assistance is needed, please contact Mount Sinai's Program for the Protection of Human Subjects at (212) 824-8200.

Table of compensation broken down by study visit

Study Visits	Compensation
Visit 1 (Screening)	$75
Visit 2 (Treatment visit)	$200
Visit 3 (Follow-up/Study Exit)	$75
Total	**$350**

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.

POSSIBLE BENEFITS:

This study is not designed to benefit you personally. However, possible future benefits to others include the finding of a new drug that may help people with diabetes.

POSSIBLE RISKS AND DISCOMFORTS:

Risks of harmine

Previous studies examining the use of harmine have documented side effects of the drug such as nausea, vomiting, slow, coarse, spontaneous tremor of the extremities, humming and buzzing noises, 'waviness' of the environment, 'sinking' sensations of the body, subjective sense of body vibration, numbness and reduced sensitivity to light touch. Hallucinations are also possible. Blood pressure and heart rate are expected to drop, with or without symptoms such as light headedness and are expected to recover after 30 minutes. Given the study design it is expected that some significant side effects will be experienced by some subjects in this study. Please note that expected side effects are based on studies conducted several decades ago and therefore there may be unforeseen risks that we don't yet

know about**. I**n 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).

Psychological risks associated with clinical interviews

During the clinical interviews, you may become tired or upset about the questions. If this happens, you should tell the interviewer/study personnel and they will stop the examination. Depending upon how you feel, you may then 1) take a rest period and resume later, 2) reschedule for a later appointment or 3) decide not to finish the exam.

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.
Intravenous catheter insertion

The insertion of the IV catheter may cause momentary discomfort. To minimize this, only experienced Depression and Anxiety Center (DAC) personnel will perform the procedures involved.

Pregnancy risks

If you are or become pregnant, this research may hurt your baby or your pregnancy in ways that are unknown. The unknown risks might be minor or might be major (death) for the pregnancy. You should not become pregnant or impregnate someone while on this research study. Please read the acceptable methods of birth control found under the Description of What's Involved section of this document.

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

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.

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 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) 241-6539 .

If there is an emergency during your participation in this research, 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.

Drs. Robert De Vita and Andrew Stewart (Co-Investigators in this study) are named co-inventors on pending patent applications related to novel DYRK1A inhibitors, including harmine. These are filed through the Icahn School of Medicine at Mount Sinai and are currently unlicensed.

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 the following:

- Name, Address, Telephone number, and Social Security Number

- Mental health history, including specific information regarding your history of mental illness and alcohol or substance abuse history which will become part of your research record

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.)

- A Data Safety Monitoring Board or other committee that will monitor the study on an ongoing basis for safety.

- The United States Department of Health and Human Services and the Office of Human Research Protection.

- The United States Food and Drug Administration

- The National Institute of Diabetes and Digestive and Kidney Diseases/NIH/DHHS

In almost all disclosures outside of Mount Sinai, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier. Some records and information disclosed may be identified with a unique code number. The Lead Researcher will ensure that the key to the code will be kept in a locked file or will be securely stored electronically. The code will not be used to link the information back to you without your permission, unless the Institutional Review Board (IRB) allows it after determining that there would be minimal risk to your privacy. The Certificate of Confidentiality obtained from the Department of Health and Human Services will not be used to prevent disclosure to local authorities of child abuse and neglect, or harm to self or others. It is possible that a sponsor or their representatives, a data coordinating office, a contract research organization, may come to inspect your records. Even if those records are identifiable when inspected, the information leaving the institution will be stripped of direct identifiers. Additionally, *OHRP, as well as the Food and Drug Administration (FDA) will be granted direct access to your medical records for verification of the research procedures and data. OHRP and FDA are authorized to remove information with identifiers if necessary to complete their task. By signing this document, you are authorizing this access.* The results of this research may be published. However, your name and other identifying information will be kept confidential.

For how long will Mount Sinai be able to use or disclose your PHI?
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) 306-5070. These agencies are responsible for protecting your rights.

Certificate of Confidentiality: To further protect your privacy, the researchers have obtained a Certificate of Confidentiality from the Department of Health and Human Services. This is intended to ensure that your identity as a participant in this research study will not have to be disclosed as a result from a subpoena, for the purpose of identifying you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings other than to the FDA or OHRP as identified above.

The research staff will not share any of your personal information, study data and/or samples with anyone who is not a member of the research team, including any family members or friends, other than those identified above. However, you should know that if it is learned that you or someone else is threatened with serious harm, such as a child or an elderly person being abused, the research team may notify the appropriate authorities if necessary to protect you or others. A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. This means that you and your family must also actively protect your own privacy. If an insurer or employer learns about your research participation, and you agree that they can have your research information, then the researchers may not use the Certificate of Confidentiality to keep this information from them.

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

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

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

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

Signature of Witness	Printed Name of Witness	Date	Time