The Role of 5-Aminolevulinic Acid Fluorescence-Guided Surgery in Head and Neck Cancers: a Pilot Trial
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STUDY INFORMATION:

Study Title: The Role of 5-Aminolevulinic Acid Fluorescence-Guided Surgery in Head and Neck Cancers: a Pilot Trial

Study site(s): Icahn School of Medicine at Mount Sinai, Mount Sinai Hospital, Mount Sinai Union Square, New York Eye & Ear Infirmary of 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 determine the diagnostic performance of 5-ALA and to assess if 5-ALA can be effectively used in FGS for different types of head and neck and skull base cancers.

Treatment for many head and neck cancers involves surgical resection, or removal, of the tumor. A potential complication of surgery is subtotal resection, in which some cancerous material fails to be removed. This is a problem because it can negatively impact patient survival and tumor regrowth after surgery. Because head and neck surgery involves aesthetically sensitive parts of the body and many complicated anatomical structures, it can be difficult for surgeons to ensure total tumor resection while minimizing the amount of healthy tissue they have to remove. Fluorescent-guided surgery (FGS) is a new method used to clearly visualize cancerous tissue during surgery in real-time. Before surgery, a medication that preferentially enters tumor cells is given to the patient. Tumor cells then glow brightly

when exposed to a particular kind of light during surgery, allowing the surgeon to distinguish between healthy and cancerous tissue. One such agent, 5-aminolevulinic acid (5-ALA), has been successfully used by neurosurgeons for FGS of different brain tumors. It is FDA approved and has been shown to be safer and more effective than other types of intraoperative imaging. However, while it shows promise, it has not yet been assessed for use in head and neck cancers.

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

- Attend a standard of care pre-operative visit with your physician where you will learn about the research study and determine if you are willing to participate
- Sign and date this consent, to show your willingness and voluntary participation
- On the day of your surgery, you will receive a single, oral dose of 5-ALA (20mg/kg) 8-12 hours prior to your surgery, which will cause the tumor to glow brightly during surgery.
- Your participation is expected to last 6 weeks. You will have your standard surgery to remove the head and neck tumor
- All other procedures during your surgery and post-operative course will be performed as indicated for your head and neck tumor.
- The study medication will be provided at no cost to subjects.
- Agree to have your private information and study data samples stored for up to six years per Mount Sinai data retention policy.
- Being in this research study will not lead to extra costs to you.
- You will not be paid for participating in this research study.

If you choose to take part, the main risks to you are the potential side effects of 5-ALA. Side effects of 5-ALA administration are uncommon (>=1/1000, <1/100) and include transient nausea and occasional vomiting at 2.5 to 3 hours after receiving the drug, but the chances of these side effects occurring given the low dose used in our study (20mg/kg) are low. Other potential side effects are low blood pressure, your skin being hypersensitive to sunlight up to 24 hours after ingestion, and elevated liver enzyme levels. For 48 hours after your surgery, you will be in subdued light conditions to minimize the chance of any skin-related side effects from 5-ALA. We will also monitor your liver enzymes for 6 weeks after your surgery, and previous studies have shown that liver enzyme elevations have returned to normal in all patients after 6 weeks. Additional risks include all risks in patients normally undergoing surgery for head and neck tumor resection, regardless of participation in this research study. These risks include, but are not limited to, bleeding, infection, scarring, discomfort, complications of anesthesia, nerve injury, and other risks that your surgeon will discuss with you during your routine preoperative visits. Standard consent processes apply to all study subjects, as they are undergoing treatment for their disease. Subjects will be signing a separate clinical consent form, which details these risks in depth.

It is important to know that you may not get any benefit from taking part in this research. Others may not benefit either. However, possible benefits may be improved total surgical removal of the tumor while

minimizing the amount of healthy tissue removed for future patients. Increased total resection of the tumor can potentially decrease the risk of tumor regrowth after surgery. This method of visualizing the tumor during surgery may also be safer and more effective compared to current methods of intraoperative imaging. Others may benefit by the knowledge gained from this research study.

You may choose not to participate without any penalty. Instead of participating in this research, you will receive all standard procedures regardless of whether you choose to take part in this research study.

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 a new or recurrent head and neck or skull base tumor for which surgical resection is indicated and has been planned.

Your participation in this research study is expected to last 6 weeks.

There are 23 people expected to take part in this research study across the Mount Sinai Health System.

Funds for conducting this research study are provided by the Icahn School of Medicine at Mount Sinai.

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:

- You will attend a standard of care pre-operative visit with your physician where you will learn about the research study and determine if you are willing to participate
- If you are willing to participate, you will sign this informed consent form at the baseline visit

- At the baseline visit, standard pre-operative information will be collected including a medical history, physical exam, tumor imaging, blood tests and labs and a pregnancy test in women of child-bearing potential
- On the day of your surgery, you will receive a single, oral dose of 5-ALA (20mg/kg) 8-12 hours prior to your surgery, which will cause the tumor to glow brightly during surgery.
- You will have your standard surgery to remove the head and neck tumor. During the surgery, a standard surgical operating microscope will be used. In addition to the standard white light that is used in the operating room, a blue light will be switched on to visualize whether the tumor is fluorescent, allowing the surgeon to easily differentiate between healthy and cancerous tissue, and these images will be recorded. Only images will be saved; no tissue will be stored for research purposes.
- All other procedures during your surgery and post-operative course will be performed as indicated for your head and neck tumor. You will undergo routine postoperative care in the hospital and outpatient clinic setting at 48 hours, 2 weeks and 6 weeks after surgery and you will also be monitored for adverse events throughout the course of your care. Data regarding your post-operative course will be recorded until 6 weeks after your surgery.
- Because this research study involves the use of 5-aminolevulinic acid (5-ALA), 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.

Pregnancy

If you can possibly get pregnant, a urine test for pregnancy will be done before you begin the study. Practicing effective birth control is important. No individual birth control is 100% effective.
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, 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 study or in the one month following the end of the study, 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. You should refrain from impregnating a partner and/or donating sperm for a longer period of time than 90 days after the study drug is administered. 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 partner(s) and/or their doctor(s) that you are participating in this clinical trial.

Time and Events Table

Study Assessment or Procedure	Baseline (-60 to day 0 before surgery)	Day 0 (At 5-ALA administration)	Day 0 (prior to surgery)	Within 48h of surgery	Week 2	Week 6
Informed Consent	X					
Demographics and Medical History	X			X	X	X
Physical Exam (vitals, weight, performance status)	X	X		X	X	X
Concurrent Medications	X	X	X	X	X	X
Adverse Events Evaluation	X	X	X	X	X	X
Tumor Imaging	X					
Pregnancy test[d]	X					
Other labs (CMP, CBC, GGT)[a,b,c]	X			X	X	X
5-ALAe		X				

[a.] Albumin, alkaline phosphatase, total bilirubin, bicarbonate, BUN, calcium, chloride, creatinine, glucose, potassium, total protein, SCOT (AST), SCPT (ALT), sodium, gamma glutamyl transpeptidase (GGT)

[b.] Phosphorus, uric acid, creatinine kinase, and amylase will be added as clinically necessary/indicated.

[c.] Repeat only those labs that remain abnormal after 6 weeks unless attributed to other therapy

[d.] Pregnancy test (women of childbearing potential)- part of standard pre-operative protocol

[e.] 5-ALA is dosed as 20mg/kg. Oral administration is one-time only and based on actual weight on day of surgery.

USE OF YOUR DATA AND/OR SAMPLES:

The data and/or samples collected for this study will only be used to complete the study and not banked for future research. 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:

You will be responsible for attending the appropriate postoperative follow-up care that is deemed necessary by your surgeon, calling the study team if you have any side effects, stopping the use of any medications that may interact with 5-ALA as instructed by your physician, using birth control methods as described in the Description of What's Involved section and telling your physician immediately if you become pregnant**.**

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 improved total surgical removal of the tumor while minimizing the amount of healthy tissue for future patients. Increased total resection of the tumor can potentially decrease the risk of tumor regrowth after surgery. This method of visualizing the tumor during surgery may also be safer and more effective compared to current methods of intraoperative imaging. Others may benefit by the knowledge gained from this research study.

POSSIBLE RISKS AND DISCOMFORTS:

- Surgical risk: The therapeutic risks to the study subjects in the prospective cohort will include all risks in patients normally undergoing surgery for head and neck tumors. Standard consent processes apply to all study subjects, as they are undergoing treatment for their disease. Subjects will be signing a separate clinical consent form, which details these risks in depth.
- Risk of loss of private information; this risk always exists, but there are procedures in place to minimize the risk.
- 5-ALA side effects are uncommon (>=1/1000, <1/100) and include transient nausea and occasional vomiting which have been observed following oral administration of high doses of 5-ALA. The incidence of nausea following 30 mg/kg and 60 mg/kg (oral) was 7 and 15%, respectively. No vomiting was observed with the lower dose, while 8% of the patients vomited following the higher dose. In all instances, the nausea was mild and short -lived (less than15 min.) When vomiting occurred, it was mild and occurred only once in each patient. The nausea or vomiting occurred within 2.5 to 3 hours after receiving the drug. Furthermore, given our low study dose of 20 mg/kg, the chance of nausea or vomiting are very low.
- Other potential side effects of 5-ALA are low blood pressure, your skin being hypersensitive to sunlight up to 24 hours after ingestion, and elevated liver enzyme levels. For 48 hours after your surgery, you will be in subdued light conditions to minimize the chance of any skin-related side effects from 5-ALA. We will also monitor your liver enzymes for 6 weeks after your surgery, and previous studies have shown that liver enzyme elevations have returned to normal in all patients after 6 weeks.
- To further reduce the risk of any of these side effects of 5-ALA, your physician will be reviewing your concurrent medications and recommending that you stop any medications that may interact with 5-ALA. These include: use of other substances or medicines that cause a reaction to light (e.g. tetracyclines, sulfonamides, fluoroquinolones, hypericin extracts) for 72h after 5-ALA administration. Patients should avoid exposure of eyes and skin to strong light sources (e.g. operating illumination, direct sunlight or brightly focused indoor light) for 24h after 5-ALA administration. Patients should not be exposed to any medicines or supplements that make the skin more sensitive to sunlight (e.g. sulfa antibiotics, st. John's Wort, coal tar derivatives) up to 2 weeks after 5-ALA administration. Within 24h after 5-ALA administration, other medicinal products that have potentially toxic effects to the liver should be avoided (antibiotics for tuberculosis such as isoniazid, certain antibiotics such as rifampin, St. John's Wort, Kava root). In patients with pre-existing cardiovascular disease, concomitant blood pressure medications should be used cautiously as 5-ALA has been shown to decrease overall blood pressure; your blood pressure will be monitored routinely as part of your regular treatment
- There is a small risk that you will have a serious allergic reaction to 5-ALA, in which case you will immediately be removed from the study and you will be monitored until your side effects have resolved and you have returned to baseline.

- Risk of loss of private information; this risk always exists, but there are procedures in place to minimize the risk.
- In addition to these risks, this research study may hurt you in ways that are not known. The unknown risks could be minor or major (death).
- If 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.

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; this includes your regular planned surgery without the use of 5-ALA.

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. 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.

Withdrawal without your consent: The Lead Researcher, 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. More possible reasons for removal from the study include if you become pregnant, if you are unable to comply with protocol requirements, if you demonstrate disease progression, if your physician judges that continuation of the study would not be in your best interest, if you develop a second malignancy (except for basal cell carcinoma or squamous cell carcinoma of the skin) that requires treatment, which would interfere with this study, if you are lost to follow-up, or if you exhibit a serious allergic reaction to 5-ALA administration.

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 212-241-9410.

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.

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?

- Prior to Surgery: Past medical/surgical history, medications, vital signs (temperature, pulse, respirations, blood pressure), height, weight, Karnofsky performance score, complete Blood Count (CBC) to include white blood cells (WBC), red blood cells (RBC), hemoglobin (HGB), hematocrit (HCT) , MCV, MCHC, WBC differential, platelet count, comprehensive metabolic panel (CMP) to include: albumin, alkaline phosphatase, ALT/SGPT, AST/SGOT, BUN, creatinine, electrolytes (sodium, potassium, calcium, chloride, bicarbonate), glucose, and total bilirubin, pregnancy test (for females of child bearing potential), pre-operative imaging as part of standard operating procedure, gender, race/ethnicity.
- On the day of surgery: physical exam, vital signs, adverse events, images captured during resection, pathology analysis (tumor classification, morphological factors, tumor markers, immunostaining, surgical margins).
- Postoperatively, the following data will be collected (48h, 2 weeks and 6 weeks postoperatively): physical exam, vital signs, labs including albumin, alkaline phosphatase, total bilirubin, bicarbonate, BUN, calcium, chloride, creatinine, glucose, potassium, total protein, SCOT (AST), SCPT (ALT), sodium, gamma glutamyl transpeptidase (GGT), concurrent medications, adverse events.

As part of this study, the research team at the hospital(s) involved in the research will collect your Date of Birth, MRN, First Name, Last Name, Date of Surgery, and Dates of Clinic Visits

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.

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

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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