An Oral GnRH Antagonist to Treat Mild Autonomous Cortisol Excess (MACE) Due to Adrenal Adenomas in Postmenopausal Women
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STUDY INFORMATION:

Study Title: An oral GnRH antagonist to treat mild autonomous cortisol excess (MACE) due to adrenal adenomas in postmenopausal women

Study site(s): The Mount Sinai Hospital

Lead Researcher (Principal Investigator): Alice C Levine

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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 if treatment with the study drug Elagolix will improve body weight, waist size, muscle strength, secretion of cortisol (a stress hormone), blood sugar, cholesterol (a fat-like substance found in your blood), and bone quality as well as mood and quality of life in a female patient with mild elevation of cortisol due to overproduction of the hormone by the adrenal gland (an endocrine organ). Many people with adrenal nodules, or non-cancerous growths in the adrenal glands, have mildly elevated cortisol levels. Cortisol is a hormone normally made by the adrenal glands. It is increasingly being recognized that even mild elevations in cortisol levels can negatively impact blood glucose levels, serum cholesterol levels, and weight. This can lead to an increase in risk for heart disease. Our team is trying to determine if the medication Elagolix might be an effective treatment for post-menopausal females with mild elevation of cortisol. Elagolix is a medication used to treat a medical condition called endometriosis, a condition in which the uterine's inner lining tissue is found outside the uterus. The growth of this uterine lining is controlled by reproduction hormones and can be painful but can be effectively treated with Elagolix which limits the release of these hormones. Growth of adrenal adenomas is also thought to be driven by such sex hormones. Therefore, by decreasing production of these hormones, we hope to treat hypercortisolism caused by adrenal adenomas.

If you choose to take part, you will be asked to take Elagolix for 6 months. You will attend 4 visits: before starting Elagolix, and 1 month, 3 months, and 6 months after starting Elagolix. The procedures involved during visits will include a full physical exam, including measurement of vital signs, body weight, and waist circumference (the distance around your waist using a measuring tape), a test of muscle strength called a “sit to stand” test, urine collection, and blood collection via venipuncture. All blood and urine specimens will be discarded once the lab values have resulted. Additionally, at baseline and 6 month study visits, you will have X-rays of the

spine to determine if you have spine fractures and a special X-ray called a DEXA scan to assess your amount of body fat. You will have had a baseline bone density study done and reviewed as part of standard of care for post-menopausal women.

This drug, Elagolix, will be provided to you by the drug manufacturer, AbbVie. You will not have to pay for the drug or the study visits. Taking part in this research study may lead to added costs to you in terms of travel to the visits. There will be no monetary compensation for your time.

If you choose to take part, the main risks to you are cost/time of travel, and low risk of potential adverse effects of the Elagolix as outlined in detail below.

You will not benefit directly from taking part in this research. However, possible benefits may be improvement in blood glucose levels, blood pressure and cholesterol, weight loss, decrease in waist circumference, improvement in bone quality, improvement in muscle strength, and/or improvement in quality of life.

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 a post-menopausal female and have non-cancerous appearing growth in your adrenal gland with mild elevations in your serum cortisol (stress hormone) levels, salivary cortisol levels, and/or urinary cortisol/cortisone levels.

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

There are 12 people expected to take part in this research study at the Mount Sinai Hospital.

Funds for conducting this research are provided by a research grant provided by Abbvie Pharmaceuticals, the manufacturer of the drug.

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'S INVOLVED:

If you agree to participate in this research study, the following information describes what may be involved.

Your medical chart will be reviewed including: results of your baseline bone density and abdominal CT scan or MRI showing an incidentally noted, benign appearing adrenal nodule as well as results of a 24- hour urine free cortisol/cortisone test, a test that determines levels of this hormone in your urine collected over 1 day, 2 midnight salivary cortisol tests, a test that measures the cortisol in your saliva, a dexamethasone suppression test, a blood test that looks at cortisol levels in the blood 12 hours after taking an oral medication, dexamethasone, blood

levels of ACTH, a hormone produced by the brain that tells the adrenal glands to make cortisol, DHEAs, another hormone made by the adrenal glands, vitamin D levels, plasma glucose, a blood test to check sugar levels in your blood at the moment the blood is drawn, and HgA1C, a blood test to see what your blood sugar levels have been on average over the last 3 months. If previously completed, an oral glucose tolerance test will also be reviewed, during which the participants blood is drawn to measure preserved glucose levels both prior to and 2 hours after drinking a glucose solution. These tests are part of the standard work-up of an incidentally noted adrenal nodule, and will be reviewed for the study.

You will be scheduled for an initial study visit to which you should arrive not having eaten or drunk anything, except water, in the past 8 hours. This and all following visits will take place in the FPA Endocrine clinic (5 E 98th St 3rd Floor, New York, NY 10029) or the IMA Endocrine clinic at Mount Sinai (17 E 102nd St, New York, NY 10029). During this visit you will have blood drawn for the following tests: serum comprehensive metabolic panel (liver function, kidney function and electrolytes), preserved glucose (blood sugar), insulin level, HbA1c (your average blood sugars over about 3 months), blood cholesterol levels, complete blood count (a test of your blood cell levels), cortisol (a stress hormone), ACTH (a hormone that triggers production of cortisol, DHEAS (a test of adrenal gland function, LH (a sex hormone), estradiol (a sex hormone), 25OH vitamin D (vitamin D level), CTX (a marker of bone breakdown), and osteocalcin (a marker of bone formation). A 2 hour oral glucose tolerance test will be performed as outlined above. A 24 hour urine free cortisol/cortisone test will be performed as outlined above. Approximately 2 teaspoons of blood will be drawn via routine blood drawing practices by a trained member of the research team. These laboratory studies are part of the standard care of a patient being treated for hypercortisolism. Your height, weight, waist circumference and blood pressure will be measured by a member of the study team. You will be asked to complete a test to measure appetite and 3 surveys to assess your quality of life as well as 3 additional questionnaires to assess mood and measure your appetite. This visit will last for about 60 minutes. At the initial study visit you will receive a one-month supply of the study drug, Elagolix. Elagolix is taken twice daily at a dose of 200mg. The dose will not be adjusted. You will take the medication for the full 6 months of your study participation. All participants will receive the study medication. Additionally, at baseline you will have X-rays of the spine to determine if you have spine fractures and a special X-ray called a DEXA scan to assess your amount of body fat.

You will be scheduled for follow-up study visits with a member of the study team at 1 month, 3 months, and 6 months after initiation of Elagolix. At your 1 month visit, you will have blood drawn for a complete blood count and a serum comprehensive metabolic panel, and your blood pressure and weight will be checked. Approximately 1 teaspoon of blood will be drawn at each visit via routine blood drawing practices by a trained member of the research team. These laboratory studies are part of the standard care of a patient being treated for hypercortisolism. Any change in symptoms or any medication side effects will be recorded. You will receive a prescription for a one-month supply of the study drug elagolix. This visit will last approximately 15-30 minutes.

At the 3 month visit, you will arrive not having eaten or drunk anything for the past 8 hours. You will be have blood drawn for the following tests: comprehensive metabolic panel, preserved glucose, insulin level, HbA1c, blood cholesterol levels, complete blood count, cortisol, ACTH, DHEAS. A 2 hour oral glucose tolerance test will be performed as outlined above. A 24 hour urine free cortisol/cortisone test will be performed as outlined above. Approximately 2 teaspoons of blood will be drawn via routine blood drawing practices by a trained member of the research team. Your height, weight, waist circumference (the distance around your waist using a

measuring tape) and blood pressure will be measured by a member of the study team. This visit will last approximately 15-30 minutes.

After taking the study medication for 6 months you will be scheduled for a final study visit with a member of the study team to which you will arrive not having eaten or drunk anything for the past 8 hours. You will have blood drawn for the following tests: comprehensive metabolic panel, preserved glucose, insulin level, HbA1c, blood cholesterol levels, complete blood count, cortisol, ACTH, DHEAS, LH (a sex hormone), estradiol (a sex hormone), CTX (a marker of bone breakdown), and osteocalcin (a marker of bone formation). A 2 hour oral glucose tolerance test will be performed as outlined above. A 24 hour urine free cortisol/cortisone test will be performed as outlined above. Approximately 2 teaspoons of blood will be drawn via routine blood drawing practices by a trained member of the research team. Your height, weight, waist circumference (the distance around your waist using a measuring tape) and blood pressure will be measured by a member of the study team. You will be asked to complete the same test to measure appetite and 3 surveys to assess your quality of life that you completed at the initial study visit. This visit will last 60-90 minutes. Additionally, 6 month study visits, you will have X-rays of the spine to determine if you have any new spine fractures and a special X-ray called a DEXA scan to assess your amount of body fat.

After this visit you will stop taking Elagolix and your participation in the study will be complete. All blood samples will be discarded according to the routine procedures of the Mount Sinai laboratory once the indicated tests have been performed.

Elagolix interacts with a number of other medications and foods. Patients taking one of these medications on a daily or regular basis should not take Elagolix. You should let your doctor know what medications you are taking. While you are taking Elagolix, you should advise your physicians that you are taking this medication before starting any new medication. If you have questions regarding this information now or during your study participation you may ask a member of the study team.

Clinically relevant research results, including individual research results, will be disclosed to participants, on an ongoing basis. Please note that only the results of FDA or New York State approved tests that are performed in a CLIA-certified lab can be shared with participants.

Because this research study involves the use of Elagolix, 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.

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 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:

1. Attending study visits
2. Taking prescribed dose of Elagolix
3. Avoiding medications that interact with Elagolix
4. Calling the study team to report the side effects listed above

COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

You will not be paid for participating in this research 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:

This study is not designed to benefit you personally. However, possible future benefits to others include improvement in blood glucose levels, blood pressure and cholesterol, weight loss, decrease in waist circumference, improvement in bone quality, improvement in muscle strength, and/or improvement in quality of life. The investigational drug provided at no cost during the study may not be available at the end of the research or may no longer be provided at no cost to you if the drug becomes available for marketing.

POSSIBLE RISKS AND DISCOMFORTS:

The study requires venous blood drawing, a procedure that involves application of a tourniquet (a device which applies pressure to a limb) and blood removal with a needle. 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.

Possible risks include medication side effects. The most common side effects seen with prior use of the drug are hot flashes, night sweats, headache, nausea, insomnia, loss of menses, anxiety, joint pains, depression, mood changes, and a decrease in bone density. These effects are a result of low estradiol, or female sex hormone levels. However, we expect you will not experience most of these effects as you are post-menopausal and thus already have low

estradiol. Other warnings/precautions include suicidal ideation, suicidal behavior, worsening of mood disorders, and liver enzyme elevations which can resolve with discontinuation of the drug. You will be monitored for side effects and adverse reactions of the medication and will receive laboratory screening for any metabolic abnormalities.

This research study includes exposure to radiation from x-rays or gamma rays. This radiation exposure is for research purposes only and is in addition to any radiation needed for your medical care. X-rays and gamma rays from natural or medical sources can damage the genetic material (DNA) in your cells. At low radiation exposures, the body is usually able to repair the damage. Radiation risk is believed to be related to the total lifetime exposure. You should think about your own history of radiation exposure from tests (like x-rays or CT scans) in deciding about the radiation in this study. If you have questions about the total amount of radiation exposure you will be receiving, you should ask your doctor.

The estimated radiation exposure that you will get for this research study will be 2 mSv (an mSv is the scientific unit of measurement for whole body radiation dose also known as the "effective dose"). This is less than the 6.2 mSv that the average person in the United States gets each year from both natural sources like the sun, outer space, air, food, and soil, as well as from medical procedures. The risk from the radiation exposure in this research study is very small.

As with any investigational study, there is a 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).

OTHER OPTIONS TO CONSIDER:

You may decide not to take part in this research study without any penalty. The choice is totally up to you. Instead of being in this research study, your choices may include:

- Treatment of symptoms such as high levels of glucose or sugar in the blood, high blood pressure and high cholesterol individually.
- Evaluation for surgical resection of the adrenal gland containing the adrenal nodule
- Watchful waiting

The important risks and possible benefits of these alternatives are listed below:

- Difficulty treating hyperglycemia, high blood pressure and high cholesterol due to untreated mild elevations in cortisol. This may mean the several medications are required for the treatment of these conditions. Benefits of participating in the study may include control of these conditions with fewer medication side effects.

- Surgical procedures always involve risks including infection, bleeding and death. Benefits include surgical cure of mild hypercortisolism and improvement in resulting metabolic derangements without the use of medications.

IN CASE OF INJURY DURING THIS RESEARCH STUDY:

If you are injured or made sick from taking part in this research study, medical care will be provided. Generally, this care will be billed to you or your insurance in the ordinary manner and you will be responsible for all treatment costs not covered by your insurance, including deductibles, co-payments and coinsurance. This does not prevent you from seeking payment for injury related to malpractice or negligence. Contact the investigator for more information.

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.

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. The study medication Elagolix will be stopped and you will be referred to your Primary care doctor or endocrinologist for further evaluation for the need for treatment of any elevations in blood glucose, high blood pressure, high cholesterol or overweight.

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

If you decide to stop being in the research study, the following may occur: return of previous elevations in blood glucose requiring treatments, elevations in blood pressure requiring antihypertensive medications, elevations in cholesterol requiring medications, weight gain.

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.

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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.

If there is an emergency, please call 212-241-3422. or call 911 or go to the emergency room. Let the emergency room staff know you are in a research study so they can contact the Lead Researcher if needed.

DISCLOSURE OF FINANCIAL INTERESTS:

Researchers sometimes get paid for consulting or doing work for companies that produce drugs, biologics or medical devices. If you have questions regarding industry relationships, you are encouraged to talk to the Lead Researcher or visit our website at http://icahn.mssm.edu/ where Mount Sinai publicly discloses the industry relationships of our faculty.

The company (Abbvie, Inc.) sponsoring this research study manufactures the drug being tested and so has a financial interest that could be affected by the outcome of this research study.

MAINTAINING CONFIDENTIALITY – HIPAA AUTHORIZATION:

As part of this study, some of your private and/or protected health information will be obtained, used, and shared with your permission. There is a Federal Health Insurance Portability and Accountability Act (HIPAA) that makes sure this is done correctly and safely.

What is protected health information (PHI)?
PHI is the combination of two things:

1. PHI contains information that identifies you. It will be used to contact you and link you to your health information, like name, date of birth, medical record number, and address.
2. PHI also contains health information, including information about your mental and physical health from your visits to doctors or hospitals, or from study visits.

Every time you visit a hospital or your doctor, PHI is created and recorded in your medical record by your healthcare providers. In the same way, the PHI created as part of this study will be linked to who you are and your medical information.

What PHI is collected and used in this research study, and might also be shared with others?

As part of this research project, the researchers will collect your name, address, telephone/fax numbers, dates directly related to the individual medical records number, health plan numbers

The researchers will also get information from your medical record at the Mount Sinai Hospital and if applicable your private doctor.

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.
- If the research team uncovers abuse, neglect, or reportable diseases, this information may be disclosed to appropriate authorities.

Who, outside Mount Sinai, might receive your PHI?

As part of the study, the Lead Researcher, research team and others in the Mount Sinai workforce may disclose your PHI, including the results of the research study tests and procedures, to the following people or organizations: (It is possible that there may be changes to the list during this research study; you may request an up-to-date list at any time by contacting the Lead Researcher.)

- The United States Department of Health and Human Services (DHHS) and the Office of Human Research Protection (OHRP) (the government organization that is responsible for protecting human research participants).
- Outside laboratory who will be performing laboratory analysis for all the research centers involved in this project: Quest diagnostics and ACL Laboratories

- The commercial sponsor and/or their representative (who will use the results for submissions to the Food and Drug Administration (the government organization that approves drugs or devices for medical use): Abbvie
- The sponsoring government agency and/or their representatives who need to confirm the accuracy of the results submitted to the government or the use of government funds: FDA
- -Contract Research Organization (whose job is to help organizations fulfill their responsibilities in the research and development process): IRB
- 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.
- The United States Department of Health and Human Services and the Office of Human Research Protection.

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) 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:

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