Efficacy and Safety of Duobrii in the Management of Acne Keloidalis Nuchae (AKN)

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NCT05608499
Document Date: 7/30/2024

## STUDY INFORMATION:

**Study Title: Efficacy and safety of Duobrii in the management of Acne Keloidalis Nuchae (AKN)**

**Study site: Icahn School of Medicine at Mount Sinai**

**Lead Researcher (Principal Investigator):** Benjamin Ungar, MD

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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 evaluate the effectiveness and safety of Duobrii (study drug) in the management of mild to moderate acne keloidalis nuchae (AKN). AKN is a chronic form of folliculitis (inflamed hair follicles) that mostly affects the scalp.

If you choose to take part, you will be asked to read and sign this consent form before any study tests are done.

- Participate in five (5) in-clinic visits for about 14 weeks, during which time you will not be permitted to participate in other research studies
- Undergo a screening visit in clinic prior to enrollment to determine if you qualify for this study
- Use Duobrii lotion (placebo vs. active) once daily to affected area of scalp for four (4) weeks, after four (4) weeks, you will increase lotion use to twice daily (at least 8 hours apart) for one week. If this increase is tolerated well, you will continue medication for remaining seven (7) weeks. In case there is irritation to area where lotion was applied, you will be instructed to use Bryhali (lotion to reduce skin irritation) for one (1) week. If irritation is healed, you will go back to Duobrii (twice/daily) until the end of the study. However, if irritation returns after resuming Duobrii, participants will alternate between Duobrii and Bryhali. Lastly, if irritation still continues with this new change, you will only use Bryhali until the end of the study.



- Tape strips of your scalp which will be frozen and stored in the freezer until additional funding sources are obtained to cover the expenses associated with processing and analyses of the tape strips.
- Completing questionnaires, having blood samples taken, physical examinations, optional clinical photography, among other study procedures.
- Consent to some of your blood and tissue samples being stored for future use.
- There are no costs to you for participating in this study; however, you will be compensated for your time and effort in participating in this study.

If you choose to take part, the main risks to you are irritation, burning, stinging, itching, dryness, peeling, redness, or pain at the application site with Duobrii.

You may benefit from taking part in this research. Some potential benefits are improvement of your condition or quality of life, reduce itching, redness, and pain at application site.

Instead of taking part in this research, you may decide to pursue other clinical trials or choose no treatment. Alternative treatments for AKN may include steroid injections or surgical removal of lesions.

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

## STUDY PARTICIPATION:

You may qualify to take part in this research study because you are at least 18 years of age and have AKN class I or II (mild to moderate disease).

Your participation in this research study is expected to last 14 weeks.

There are thirty (30) people expected to take part in this research study at the Icahn School of Medicine at Mount Sinai.

Funds for conducting this research study are provided by Bausch Health US, LLC. Bausch Health US, LLC is the manufacturer of the investigational product.

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:

All research visits/activities will be performed only at the Icahn School of Medicine at Mount Sinai, Department of Dermatology. All procedures performed during the study are being done for research purposes only. If screening is successful, patient will continue to their Baseline visit on the same day. The following events will occur during your participation:

**Screening / Visit 1 (30 - 45 minutes):**

- Review informed consent form
- Review Inclusion and Exclusion Criteria
- Record gender, race, ethnicity, and medical history
- Review personal and family history of AKN and other skin diseases
- Record all medications you are currently taking as well as any that were received within 30 days prior to screening, and record all prior therapies for AKN
- Serum Pregnancy Test for participants who have the potential to become pregnant
- Your AKN will be visually evaluated by the study doctor
- Record adverse events (unexpected medical problems that occur during the study) and other medications

**Baseline / Visit 1 (45-60 minutes):**

- Review Inclusion and Exclusion Criteria
- Record any changes to or newly started medications
- Urine sample for a urine pregnancy test for participants who have the potential to become pregnant
- Dermatology Life Quality Index questionnaire
- Clinical photographs
- AKN severity
- Numeric Pain Rating Scale (NRS)
- Clinical Assessment/Lesion Count
- Tape strips (lesional & non-lesional)
- Give study drug and explain instructions
- Record adverse events

**Visits 2, 4, 5 and Early Termination (ET) (45-60 minutes each):**

- Urine sample for a urine pregnancy test for participants who have the potential to become pregnant
- Dermatology Life Quality Index questionnaire
- Clinical photographs



- AKN severity
- Numeric Pain Rating Scale (NRS)
- Clinical Assessment/Lesion Count
- Tape strips (lesional & non-lesional) – Visit 5 only
- Collect remaining study drug – Visit 5 & Early Termination only
- Record adverse events and medications

**Visit 3 (Phone Visit) and Visit 6 (Follow-Up):**

- Record adverse events and medications
- Assess progress with study drug (visit 3 only)

## Randomization

Because this project involves the use of medications or a medical device, it is necessary that we make a note of your participation in the electronic medical record. That way anyone treating you will be aware of your participation and may be able to avoid any unfortunate outcomes that could arise if your research participation were unknown.

No one, not you, or anyone from your medical team or from the research team will be able to choose what group you are assigned to or what study drug you get. It will be by chance, like pulling names out of a hat. The chances that you will receive study drug vs. placebo is 2:1 or 66.7%. Neither you nor the Lead Researcher or your own doctor will know which study drug you are getting. If there is an emergency, they can get this information. You will not be told which study drug you are getting; however, an unblinded designated drug dispenser will know.

## Pregnancy

If you can possibly get pregnant, a urine test for pregnancy will be done before you begin the study and the urine pregnancy test will be repeated at weeks 4, 8, and 12. Therefore, 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, 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 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_____



## 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.

**(2)** The researchers can store your data and/or samples in the following way:
Linked to your identity (using a code that can show the information came from you personally). In this case you could ask for your data and/or samples to be destroyed in the future if you want that to happen.

I would like my data and/or samples stored with a link to my identity through the use of a code_____

To do more powerful research, it is helpful for researchers to share data and/or samples from the people they study. They do this by putting data and/or samples into a repository. A repository is where something is stored safely for a specified period of time. Data and/or samples from one study may be stored in a repository along with data and/or samples from other studies. Sample repositories are commonly called biobanks, while data repositories are commonly called databases. . Researchers can then use the data and/or samples from multiple studies to learn even more about health and disease. If you agree to take part in this study, some of your genetic and health information might be placed into one or more scientific databases, but they will not share your direct identifiers (for example, name, address, date of birth). These databases are maintained by either Icahn School of Medicine at Mount Sinai, another institution, the federal government, or private companies. Any



researcher who wants to do a study using data and/or samples from the repository must apply for permission. There are different ways of reviewing such requests. Researchers with an approved study may be able to see and use your data, along with that from many other people. Researchers may use your samples for genetic sequencing and other experimental testing. Researchers will always have a duty to protect your privacy and to keep your information confidential, but there are always risks associated with data and/or sample collection and sharing. They are described in more detail in the Risks section.

## 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:

- Go to all scheduled visits
- Follow the study staff's directions about the study
- Tell the study staff about any illnesses or injuries
- Tell the study staff about any changes to your medicines
- Tell the study staff about any side effects or problems that occur during the study
- Tell the study staff if you plan to have any surgery or any other medical treatments or procedures
- You should not receive any live vaccines
- Practice birth control, if applicable, as described in the "Description of What's Involved section."
- If you are female and become pregnant, you must notify the doctor within 24 hours from when you are made aware of the pregnancy.
- You may use any topical prescriptions for your atopic dermatitis (if applicable) during the course of the study, but not on your keloid lesions.

## COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

*If you agree to take part in this research study, we will pay you for your time and effort. You will receive $75 for your screening/baseline as well as your week 12 visit. Additionally, you will receive $50 for visits week 4, week 8, and follow-up. If all visits are completed, you will be compensated a total of $300 in the form of a check.*

*It can take up to 8 weeks to prepare and give you a check 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.

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.

It is possible that products may someday be developed with the help of your data and/or samples, and there are no plans to share any profits from such products with you.

## 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 may be that your AKN improves. Benefits from participation may not continue after the research has ended. This study is not designed to benefit you personally.

## POSSIBLE RISKS AND DISCOMFORTS:

**Physical Risks:**

| Risks of Study Drug: Duobrii | |
|---|---|
| Common | • Erythema or redness of skin<br>• A stinging sensation<br>• Abnormal peeling<br>• Itching<br>• Dry Skin<br>• Skin Irritation |
| Infrequent | • Large purple or brown skin blotches<br>• Infection of skin and tissue below the skin<br>• Thinning skin<br>• Inflammation of a hair follicle<br>• Headache<br>• Reaction at application site<br>• Sudden pain at application site<br>• Contact dermatitis<br>• Inflammation of lips |
| Rare | • Insufficiency of the Hypothalamus and Pituitary (hormone regulating) Glands<br>• Addison's Disease – Decreased function of the Adrenal Gland<br>• Glaucoma – An increased pressure in the eye |



| | |
|---|---|
| | • Clouding of the lens of the eye called Cataracts<br>• Inflammation of the skin with blisters<br>• Skin stretch marks<br>• A skin ulcer<br>• Hives<br>• Decreased Pigmentation of the Skin<br>• Central Serous Chorioretinopathy (fluid buildup under the retina)<br>• Increased Sensitivity of the Skin to the sun<br>• Skin discoloration |
| Risks of Rescue Drug: Bryhali | |
| Common | • Burning, stinging, itching, or dryness of treated skin;<br>• Pain where the foam was applied;<br>• Redness or crusting around your hair follicles;<br>• Stretch Marks;<br>• Spider Veins;<br>• Headache; or<br>• Cold symptoms such as stuffy nose, sneezing, sore throat. |

**Additional Risks:**

- **Risks of Photographs:** There is a possibility that you will be able to be identified from photographs for the study. However, steps will be taken to reduce this possibility whenever possible. The photographs will be taken close up and eyes/face, and identifying markers such as tattoos/birthmarks will be avoided whenever possible. Photographs will only be used for publication in medical journals/medical meetings and for teaching purposes.
- **Privacy Risks:** Risk of loss of private information; this risk always exists, but there are procedures in place to minimize the risk. Your name and other information that could directly identify you (such as address, date of birth or social security number) will never be placed into a scientific 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 includes 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 I information was misused it is possible you would also experience other harms, such as stress, anxiety, stigmatization or embarrassment from revealing information about your family relationships, ethnic heritage, or health conditions.



- 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.
- 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.
- Group Risks - Although your name will not be given to researchers, basic information such as your race, ethnic group, and sex may be shared. This information helps researchers learn whether the factors that lead to health problems are the same in different groups of people. It is possible that such findings could one day help people of the same race, ethnic group, or sex as you. However, they could also be used to support harmful stereotypes or discrimination.
- Privacy Risks - Your name and other information that could directly identify you (such as an address, date of birth, or social security number) will never be placed into a database. However, because your genetic information is unique to you, there is a small chance that someone could trace it back to you. The risk of this happening is very small, but may grow in the future. Since the database contains genetic information, a break in security may also pose a potential risk to blood relatives as well as yourself. For example, it could be used to make it harder for you (or a relative) to get or keep a job or insurance. If your private information was misused, it is possible you would experience other harms, such as stress, anxiety, stigmatization, or embarrassment from revealing information about your family relationships, ethnic heritage, or health conditions.

## OTHER OPTIONS TO CONSIDER:

You may decide not to take part in this research study without any penalty. 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. The study doctor will discuss other options and their potential risks and benefits with you before you decide whether you will take part in this study. Instead of being in this research study, your choices may include: other treatments for your condition such as corticosteroid applied to or injected into your skin, or you may choose not to use any treatment at all.

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

- Topical corticosteroids: skin thinning; stretch marks; easy bruising; and enlarged blood vessels.

- Oral corticosteroids: clouding of the lens in one or both eyes; high blood sugar, which can trigger or worsen diabetes; increased risk of infections; thinning bones; and suppressed adrenal gland hormone production
- Retinoids: Photosensitivity which may increase the likelihood of sunburn.

Benefits of topical or oral corticosteroids and retinoids include the possibility that your condition may improve.

## 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. The sponsor will reimburse your reasonable and necessary medical expenses for diagnosis and treatment of a research-related injury or illness.

The sponsor will pay for reasonable and necessary medical treatment of injuries and illness that are a direct result of study procedures and/or study drug that are required by the study protocol and that were done correctly and only because you were in this study.

The sponsor will not cover the costs of your study-related injury or illness if:

- The sponsor and/or the study doctor do not think the condition or injury is a direct result of your being in the study;
- The injury is attributable to the underlying disease or a pre-existing medical condition or the natural progression of an underlying disease;
- The injury was the result of a failure to follow the study protocol or instructions or misconduct by the study staff.

No other compensation will be offered by the sponsor or Mount Sinai Health System or Biomedical Research Alliance of New York, including for things such as lost wages or discomfort.

The Centers for Medicare and Medicaid Services (CMS) is the government agency that oversees Medicare and Medicaid. Funding agencies who make payments for injuries related to studies must report payments to CMS. In order to do this, the funder must have certain information about you, such as your name, date of birth, Social Security Number, Medicare or Medicaid ID numbers, date of injury, and description of injury. The funding agency is only allowed to use this information to report payments related to the injury should this be necessary or as otherwise specified in the Authorization to Use and Disclose Protected Health Information section, which is included below.

## ENDING PARTICIPATION IN THE RESEARCH STUDY:



You may stop taking part in this study at any time. No matter what you choose, your care and benefits through Mount Sinai will not be negatively impacted.

If you decide to stop being in the study, please contact the Lead Researcher or the research staff. You will be asked to return to the study for a final termination visit (see aforementioned procedures for the Early Termination visit).

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: your condition may return to its original state if you experienced an improvement during the study.

If you decide to 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 +1 212-241-3288.

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

## DISCLOSURE OF FINANCIAL INTERESTS:

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

The company sponsoring this research study makes the drug being tested and has a financial interest that could be affected by the outcome of this research study.

Researchers and/or their departments receive money from the company sponsoring this research based on how many participants they enroll.

## MAINTAINING CONFIDENTIALITY – HIPAA AUTHORIZATION:

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

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

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

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



What PHI is collected and used in this research study, and might also be shared with others?
As part of this study, the research team at the hospital(s) involved in the research will collect your name, address, telephone number, birthdate, e-mail, social security number, blood and tissue samples, and photographic images.

During the study, the researchers will gather information by:

- Completing the tests, procedures, questionnaires and interviews explained in the description section of this consent.
- 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.
- Reviewing HIV-related information, which includes any information indicating that you have had an HIV-related test, or have HIV infection, HIV-related illness or AIDS, or any information which could indicate that you have been potentially exposed to HIV

Why is your PHI being used?
Researchers need the information that identifies you so they can contact you during the study. They need your health information and the results of any tests and procedures being collected as part of this study to answer the questions posed in the study. The purpose of the study is discussed earlier in this consent form. Before researchers analyze the data, they remove any information that would let others know who you are or that you took part in the study. If researchers publish or present study results at scientific meetings, lectures, or other events, their presentations would not include any information that would let others know who you are, unless you give separate permission to do so.

The Lead Researcher may also use and share the results of these tests and procedures with other healthcare providers at Mount Sinai who are involved in your care or treatment. The research team and other authorized members of The Mount Sinai Health System ("Mount Sinai") workforce may use and share your information to ensure that the research meets legal, institutional or accreditation requirements. For example:

- The Mount Sinai Program for the Protection of Human Subjects is responsible for overseeing research on human participants and may need to see your information.
- If you receive any payments for taking part in this study, the Mount Sinai Finance Department may need your name, address, social security number, payment amount, and related information for tax reporting purposes.
- I*f the research team uncovers abuse, neglect, or reportable diseases, this information may be disclosed to appropriate authorities.*

Who, outside Mount Sinai, might receive your PHI?
As part of the study, the Lead Researcher, research team and others in the Mount Sinai workforce may disclose your PHI, including the results of the research study tests and procedures, to the



following people or organizations: (It is possible that there may be changes to the list during this research study; you may request an up-to-date list at any time by contacting the Lead Researcher.)

- The United States Department of Health and Human Services (DHHS) and the Office of Human Research Protection (OHRP) (the government organization that is responsible for protecting human research participants).
- 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): Bausch Health US, LLC
- 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 not be able to access your medical records. This is done to prevent the knowledge of study results from affecting the reliability of the study. Your information will be available should an emergency arise that would require your treating physician to know this information to best treat you. You will have access to your medical record and any study information that is part of that record when the study is over or earlier, if possible. 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.

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**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.

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## 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:*** ○ N/A

*When a witness is required to observe the consent process, it should be documented below (for example, when a study participant 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 |
|---|---|---|---|
| | | | |