Cardiovascular Analysis of Post-exertional Malaise

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STUDY INFORMATION:

Study Title: A Cardiovascular Analysis of Post-exertional Malaise

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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 examine why post activity fatigue, also known as post-exertional malaise (PEM) occurs in patients with myalgic encephalomyelitis/chronic fatigue syndrome [CFS] and at what level. PEM is a worsening of your symptoms after even mild physical or mental exertion. The responses of subjects with CFS will be compared to healthy age, activity, and gender matched subjects (control subjects).

If you choose to participate, you will be asked to:

- Undergo an evaluation to determine if you have chronic fatigue syndrome or are an active or sedentary control subject in good health
- Undergo a screening to determine if you have current psychiatric disorders which, if present, would not allow you to participate further
- Complete a Leisure-Time Exercise Questionnaire & Medical History Questionnaire.
- Wear a wristwatch for 18 days, which monitors your activity & sends you 3 daily alerts to provide information about fatigue, brain fog, achy muscles and feeling unrested (CFS and sedentary individuals only)
- Perform cardiopulmonary exercise test (CPET), which takes about 10-15 minutes while breathing through a mouthpiece in order to assess the function of your heart and lungs over two consecutive days for CFS and sedentary controls. Active controls will exercise once.

If you are a CFS subject and choose to participate, you will also be asked to:

- Complete a screening blood draw of about two tablespoons and a physical exam
- Undergo testing to determine your blood volume via an injection of a radio-isotope equivalent to getting a chest X-Ray followed by six collections of about one tablespoon of blood.

- If the blood volume analysis on Day 1 indicates it to be lower than normal, you will receive either saline or no treatment prior to the exercise test on Day 2

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There are no costs associated with this research study.
You will not benefit directly from taking part in this research.

The main risks to you if you choose to participate are development of worse fatigue and other of your symptoms after exercise; called “post-exertional malaise.” Further risks are outlined in a later section of this consent. Participating in this research will not directly benefit you if you are a healthy control. Participation may not benefit CFS subjects, but some patients use the results of this exercise testing to support their complaint of disability and you will be provided testing results if you wish.

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

PARTICIPATION IN THIS RESEARCH STUDY:

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

You may qualify to take part in this research study because you have been diagnosed with Chronic Fatigue Syndrome or are interested in participating as a healthy control.

Funds for conducting this research are provided by the National Institute of Health.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

LENGTH OF TIME AND NUMBER OF PEOPLE EXPECTED TO PARTICIPATE:

CFS and sedentary healthy control participation in this research study is expected to last 2-3 weeks. Active healthy control participation is expected to last for 1 day.
The number of people expected to take part in this research study at Mount Sinai is 160.

DESCRIPTION OF WHAT’S INVOLVED:

If you agree to participate in this research study, the following information describes what may be involved. As outlined in table, only the CFS group will complete a blood draw, fluid infusion, & blood volume analysis. The sedentary healthy control subjects will complete only the 2 day exercise tests and active healthy control subjects will complete only one exercise test. See next section for full details.

Group	Procedure	Day 1	Days 2-8	Day 9	Day 10	Days 11-18
CFS Subjects	Consent	X				
	Questionnaires	X				
	Physical Exam	X				
	Blood Draw	X				
	Stroke Volume			X	X	
	Blood Volume			X	X	
	Fluid Infusion				X	
	CPET			X	X	
	PRO-Diary	X	X	X	X	X
Sedentary Healthy Control Subject	Consent	X				
	Questionnaires	X				
	Physical Exam	X				
	Stroke Volume			X	X	
	CPET			X	X	
	PRO-Diary	X	X	X	X	X
Active Healthy Control Subjects	Consent	X				
	Questionnaires	X				
	Physical Exam	X				
	CPET	X				

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Effective Date: 4/28/2025
End Date:2/24/2026

Intake Procedure. During your first study visit which will be done either face to face or over the phone, information will be taken to determine if you are well or have CFS. You will also complete 3 questionnaires: the Godin Leisure-Time Exercise Questionnaire, to measure your usual physical activity level, the Centers for Epidemiological Study-Depression and the Profile of Mood States which both ask about your mood and magnitude of fatigue. You will then be asked questions to determine if you have a psychiatric illness which, if present, would not allow you to continue in the study. On your first face to face visit, we will do a physical examination to determine if you also have body-wide tenderness.

Blood Draw *(CFS patients only).* During the screening visit, CFS patients will complete a blood draw of about two tablespoons of blood to access common medical causes of fatigue including anemia, hypothyroidism, liver disease, Lyme disease, & rheumatological illness.

PRO-Diary (CFS patients and sedentary healthy controls only). You will use a wrist-mounted computer, that records your daily activity and alerts you three times a day to record how you are feeling. This includes severity of fatigue, feeling unrested, muscle achiness and brain fog. You will record your feelings within the wrist-mounted computer. You will use this device for 8 days before the exercise test (CPET), during the 2 days of exercise testing, and for an additional 8 days thereafter.

Blood Volume Determination (BVA) *(CFS patients only).* This test takes approximately 60 minutes and involves a 1 minute intravenous infusion of a radioactive chemical compound. Please see risk section for more details on the minimal radiation risk. One teaspoonful of blood will be taken at baseline, 12, 18, 24, 30, & 36 minutes after infusion. This test is only for CFS patients and will be done before exercise testing on both visitdays.

CPET. This Cardiopulmonary Exercise Test (CPET) will be done on two back-to-back days for CFS and sedentary control subjects and only on one day for active control subjects. Ten chest electrodes (stickers) will be used to monitor your heart rate throughout the test. You will be seated on an electronic stationary bicycle, with the seat height adjusted for optimal performance. You will wear a nose-clip and breathe through a mouthpiece, so we can sample the air you exhale. We will collect resting measurements for 3 minutes and then you will begin bicycle exercise starting with no resistance to pedaling. You will be instructed to maintain a certain pedaling speed. Every 2 minutes, the resistance will be increased. This will occur until you feel that you cannot continue. Once a maximum limit has been reached, we will remove the resistance and collect recovery measurements for 3 minutes. Blood pressure, oxygen levels, & how much exertion you perceive doing will be measured at each stage. Heart rate will be monitored continuously. The test usually lasts about 30 minutes.

Method for Assessing Stroke Volume. Before the start of the exercise, non-invasive patches will be placed on your back and connected to a device which sends small electric pulses into your chest and then monitors their return (bioreactance). This measures how well your

heart pumps blood (cardiac output). These electrodes remain on your back throughout exercise and every minute a cardiac output is generated. This measurement will also be made before and during exercise on the day 2 CPET.

Fluid Replacement *(CFS group only).* The results of the first blood volume analysis will determine if you will be eligible for the fluid replacement experiment before the Day 2 exercise test. Based on the results from the 1st test, a coin flip will determine if you will receive a liter of either normal saline or no infusion at all over 60 minutes; we are doing it this way so we can learn if the saline infusion restores your blood volume toward normal. You will not know whether you received fluids or not, as the infusion will be hidden from view. The 2nd exercise test will start immediately after the fluid replacement.

Pregnancy

CFS group: If you can possibly get pregnant, a urine test for pregnancy will be done before your first BVA. You cannot be included in the study if you are pregnant, as the radioisotope could harm your fetus. You also should not be in the study if you are producing milk to feed a child as the radioisotope 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)

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 SPECIMENS:

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 information and/or specimens to use in future research studies?

Yes_____No_____If no, please stop here. If yes, please continue to the next question.

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.

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(2) The researchers can store your data and/or samples in one of two ways:

a) Anonymously (no one will know who the data and/or samples came from). If you choose this option, you can't change your mind. So, if you wanted to have your data and/or samples destroyed in the future, the team could not do it as they would not know which data and/or samples were yours.

b) 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.

How would you like your data and/or samples stored? Please initial **ONE** choice below:

I would like my data and/or samples stored anonymously _____

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

(3) Do you give the researchers permission to keep the data and/or samples, so they could use them in future studies that are **directly related** to the purpose of the current study?

Please initial your choice: Yes_____No_____

(4) Do you give the researchers permission to keep the data and/or samples indefinitely, so they could use them for future studies that are **not related** to the purpose of the current study (for example a different area of research)?

Please initial your choice: Yes_____No_____

(4.1) From time to time, researchers outside of medicine and related sciences would like to use data and/or samples. This might be in the fields such as anthropology, human origins, mapping human migration patterns. Do you give permission for researchers **outside the field of medicine** to use your data and/or samples?

Please initial your choice: Yes_____No_____

a. If the future research in a different area can be done without having to know that the data and/or samples came from you personally, that will be done.

b. If the future research in a different area requires that it is known specifically who the data and/or samples came from, then one of the following will be done:

I. If you allowed the researchers to contact you in the future, they may be able to contact you to explain why your data and/or samples is needed and what will be done with it. Your permission will be asked to use your data and/or samples in that research project.

ll. If you do not give permission to be contacted in the future, or if it is found that contacting you is not practical (for example, because you have moved), your data and/or samples may still be used. The Institutional Review Board (IRB) will be asked for permission to use the data and/or samples linked to your identity. The IRB can give permission for researchers to use and share identifiable health information without contacting you, but only if it determines that sharing the data and/or samples will not be more than minimal risk to you or your privacy. The IRB is a committee of doctors and scientists and nonscientists, including people not associated with this hospital or medical school, whose job it is to protect people who participate in research.

(5) Do you give permission to have your data and/or samples given **to other researchers,** including those at Mount Sinai, other medical or scientific institutions and for-profit companies, for use in research within the limits you have chosen above?

Please initial your choice: Yes_____No_____

YOUR RESPONSIBILITIES IF YOU TAKE PART IN THIS RESEARCH:

If you decide to take part in this research study you will be responsible for attending all study visits, wearing the PRO-Diary watch as requested, & notify the research team of any changes to medications.

COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

Being in this research study will not lead to extra costs to you. If you are a CFS patient or sedentary healthy control, you will be reimbursed $350 at the conclusion of the study- $100 for intake, $125 for BVA/CPET Day 1 and $125 for BVA/CPET Day 2. Active healthy controls, will be reimbursed $225 at the conclusion of the study- $100 for intake and $125 for CPET. In addition, up to $25 for local travel and $350 for air/train travel costs; receipts will be necessary to recover travel expenses, and all payments will be made to you in 4-6 weeks by a check which will be mailed to you. There is a potential for incidental findings that may lead to the need for additional medical care, which may result in extra costs.

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 reporting would take place if you receive payments that equal $600 or more from Mount Sinai in a calendar year. You would be responsible for the payment of any tax that may be due.

POSSIBLE BENEFITS:

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 others include furthering the knowledge of Post-exertional malaise and potentially help develop treatment options for CFS patients. The results of the 2-day exercise protocol have been used to support a patient's complaint of being severely ill; copies of the test results will be provided to you if you wish.

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REASONABLY FORESEEABLE RISKS AND DISCOMFORTS:

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.

PRO-Diary. The only risk of the PRO-Diary is that it may alert you to provide symptom severity data at an inopportune time.

Maximal Exercise Testing. As a CFS patient, the major risk of the 2-CPET procedures is that you may develop post-exertional malaise. Risks for exercise testing in all subjects include arrhythmia, chest pain, heart attack, syncope, cardiac arrest, hypotension, dizziness. We have done several hundred CPET studies in CFS without any of these problems. In normal subjects the risks related to exercise testing are extremely rare. The risk of an adverse event occurring is minimized by having physician monitoring during testing. There are no risks associated with respiratory gas analysis during exercise.

Measurement of Cardiac output: There are no side effects associated with biorelactance measurements.

Measurement of total blood volume *(CFS patients only):* This research study includes exposure to radiation during the blood volume analysis. This radiation exposure is for research purposes, and is in addition to any radiation needed for your medical care. Radiation can damage the genetic material (DNA) in cells. At low doses, cells usually can repair this damage. Risk from radiation is believed to be related to the total lifetime exposure. For each research study we calculate an "effective dose" to estimate the effects or harm of the radiation on your organs. This quantity will help predict the effect of radiation on tissue. You should think about your own history of radiation exposure for tests (like x-rays or CT scans) in deciding about the radiation usage in this study. If you have questions about the total amount of radiation exposure you will be receiving, you should ask your doctor.

To put your estimated effective dose in perspective, the radiation that you will get for this research study will be less than the average person in the United States receives each year from natural sources (sun, outer space, air, food, & soil) and medical procedures. Based on these calculations, the risk from the radiation exposure in this study is very small.

Blood draw & Intravenous Infusion ***(CFS patients only).*** Although rare, there are risks of bleeding, bruising and infection associated with the blood draw and placement of an intravenous line.

Fluid Replacement ***(CFS patients only).*** There is risk of shortness of breath in patients receiving intravenous infusion of saline but in patients with normal cardiac and renal function as is the case with patients, like you, this should not occur.

Breach of confidential medical information is always possible, and efforts will be made to minimize this as all data will be coded and kept within password protected computer files on the Mount Sinai data storage network, which meets all required HIPPA requirements.

OTHER POSSIBLE OPTIONS TO CONSIDER:

You may decide not to take part in this research study. If you decide not to take part, this will not affect the clinical care you receive at Mount Sinai. The choice is totally up to you.

IN CASE OF INJURY DURING THIS RESEARCH STUDY:

If you are injured or made sick from taking part in this research study, you will get medical care. Generally, it will be billed to you or your insurance. You will be responsible for all treatment costs not covered by your insurance, including deductibles, copayments, and coinsurance. This does not prevent you from seeking payment for injury related to malpractice or negligence. You can contact the Lead Researcher for more information.

ENDING PARTICIPATION IN THE RESEARCH STUDY:

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

If you decide to stop being in the research study, please contact the Lead Researcher or the research staff. If you stop being in the research study, already collected information may not be removed from the research study database and will continue to be used to complete the research analysis. You may be asked whether the study doctor can collect information from your routine medical care. If you agree, this data will be handled the same as research data.

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 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 Investigator at phone number 212-241-9886.

If there is an emergency, please call 212-241-9886 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.

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.

During the study the researchers will gather information by:

- Taking a medical history (includes current and past medications or therapies, illnesses, conditions or symptoms, family medical history, allergies, etc.)
- doing a physical examination that generally also includes blood pressure reading, heart rate, breathing rate and temperature
- Completing the tests, procedures, questionnaires and interviews explained in the description section of this consent.
- reviewing mental health records
- reviewing psychotherapy notes

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).
- Outside laboratory who will be performing laboratory analysis for all the research centers involved in this project: University of Wisconsin-Madison
- The sponsoring government agency and/or their representative who need to confirm the accuracy of the results submitted to the government or the use of government funds: National Institute of Health (NIH)
- A Data Safety Monitoring Board or other committee that will monitor the study on an ongoing basis for safety.

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

For how long will Mount Sinai be able to use or disclose your protected health information?
Your authorization for use of your protected health information 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 us permission to obtain, use or share your health information?

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.

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Effective Date: 4/28/2025
End Date:2/24/2026

The research staff will not share any of your research information or biospecimens with anyone who is not a member of the research team, including any family members or friends, other than to those identified above. However, you should know that if we learn that you or someone else is threatened with serious harm, such as a child or an elderly person being abused, the investigators 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 and to the use and disclosure of your protected health information. A signed and dated copy will be given to you.

Signature of subject	Printed Name of Subject	Date	Time

PERSON EXPLAINING STUDY AND OBTAINING CONSENT:

Signature of consent delegate	Printed Name of consent delegate	Date	Time

WITNESS SECTION:

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

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

Signature of Witness	Printed Name of Witness	Date	Time