Research Participant
Key Study Information & Informed Consent Form

Title of Study: **RECOVER-Adult Cohort Cycle 2: A Long-Term Follow Up Study of Post-Acute Sequelae of SARS-CoV-2 Infection in Adults**
s25-01662

Principal Investigator: Name of the Principal Investigator

Key Study Information

You are invited to take part in a research study. Joining the study is your choice. This form begins with a summary of key information about the research study. The key information is designed to help you quickly understand the important details about the study and decide whether or not you want to participate. After the key information section, you will find the full research informed consent form, which provides more detailed explanations about the study. We've kept this part of the form focused and concise to make it easier for you to review and understand.

Purpose of the Research Study

This study will look at how COVID-19 affects memory and thinking, heart and lung health, and conditions like chronic fatigue and dizziness. By learning about these problems, doctors may improve health care for people with COVID-19 in the future. We are asking you to take part because you were already in the RECOVER study for adults. This study follows people from RECOVER for a longer time.

Length of the Study and Study Activities

You will be in the study for about 2 years. We will ask you to do the following study activities:

- **Home surveys (3 sets total):** You will do surveys at home that ask about your health.
- **In person visits and surveys (2 total):** In the in-person visits, you will take tests of your sense of smell, strength, walking, heart, lungs and thinking. You will also have blood drawn for biospecimen banking. These two visits will be about 18 months apart. If you prefer, the surveys for these two visits can be done at home before your visit. Each visit is expected to last about 3-5 hours.

Possible Risks and Benefits

The consent form lists all the risks and benefits. The main risks are loss of privacy, worsening symptoms during or after the visit, mild discomfort from blood draws, and feeling tired during walking, standing, or thinking tests. These risks are similar to challenges you might face in daily life. You may stop at any time. You may not benefit personally from being in this study, but the information gathered may help researchers and doctors understand COVID-19 and improve care for future patients.

Alternatives to Participation

You don't have to join this study. If you choose not to join, you will still receive regular health care. You can stop being part of the study at any time.

Questions

If you have any questions or concerns about the study, contact *[insert study contact name, phone number and/or email address].*

Informed Consent Form

Title of Study:	**RECOVER-Adult Cohort Cycle 2: A Long-Term Follow Up Study of Post-Acute Sequelae of SARS-CoV-2 Infection in Adults** **i25-01662**
Site Study Leader:	Name of the Principal Investigator Department of Principal Investigator Applicable Medical Center Address Phone Numbers
Study Leaders:	**Stuart Katz, MD MS** NYU Grossman School of Medicine Leon H. Charney Division of Cardiology 530 First Avenue, Skirball 9R New York, NY 10016 **Leora Horwitz, MD, MHS** NYU Grossman School of Medicine Department of Population Health 227 E 30th St, #633 New York, NY 10016
For questions or concerns about the study, please call:	Name of the Site Principal Investigator Department of Principal Investigator Applicable Medical Center Address Phone Numbers
Emergency Contact:	Insert Emergency Contact Insert Phone Number/Pager, etc.

1. About volunteering for this research study

You are being invited to take part in a continuation of the RECOVER research study for adults. Joining the study is your choice. You can decide whether or not you want to participate. Before you decide, it's important to understand:

- What the study is about,
- What you will do, and
- The possible risks and benefits

You may want to talk about this study and this form with your family, friends, or doctor. If you have any questions about the study or about this form, please ask us. If you decide to take part in this study, you must sign this form. We will give you a signed copy to keep.

2. Why are we doing this study?

This study is a continuation of the first RECOVER (Researching COVID to Enhance Recovery) Adult study and continues to be funded by the National Institutes of Health (NIH) National Heart Lung and

Blood Institute (NHLBI). In the first study, researchers enrolled over 14,000 adults across the U.S. to learn about Long COVID and its symptoms. That study gave us important information about what Long COVID looks like and how common it is.

Now, in this second study, we want to follow some of those same people for about two more years to see how their health changes over time. We will use the samples and information collected from you in this study to learn more about problems with thinking and memory, heart and lung health, and conditions like chronic fatigue and autonomic dysfunction. Information collected from you in the first study will be linked to the information collected in this study. By doing this, we hope to understand why some people get better and others do not, and whether new health problems appear later. This will help doctors find better ways to prevent and treat Long COVID in the future.

This study will compare people with these symptoms to those who don't have them. It will include people who had COVID-19 and those who never did.

We're asking you to take part in this study because you were already part of the RECOVER study for adults.

3. How long will I be in the study? How many other people will be in the study?

The study will last for about four years, but you will do activities for about two years. During those two years, you will do study activities every six months. About 5,205 people across the United States will take part in this study.

4. What will I be asked to do in the study?

During the study, you will answer survey questions every six months and will have two in-person visits: one at the start of the study, and one 18 months after enrollment.

If you later find that you are not well enough to do a particular test or visit, then you should alert your study site. Site staff may be able to work with you to find a solution.

Remote Surveys

You will complete surveys every six months. These surveys will be like those you have already done in the first study, and will ask about your health, symptoms, daily activities, COVID vaccines, new diseases, and how your condition affects your quality of life. Each set of surveys will take 1-2 hours to complete. You can stop at any time to take a break. The research team will also look at national health records and your medical records to find out about your health and about any tests you have had outside the research study. Your medical records may be included in the study to help the team fully understand your condition or medical history.

In-Person Assessments

During each in-person visit (once at baseline, and once at 18 months), you will complete several health assessments. These are routine, minimal-risk tests that help us understand health, memory, and physical capabilities. Each in-person visit is expected to take 3-5 hours. Below is a table that explains what you will do, when it will happen, and why. You will also complete surveys at the baseline and 18-month visits. If you prefer, the surveys for these two visits can be done at home before or after your in-person visit. The in-person visit includes time for breaks.

Table 1: Procedures performed at in-person visits			
Procedure	**When**	**Why is this done?**	**Will I get these results back?**

Vital signs (heart rate, blood pressure, breathing rate, oxygen levels), height, weight, waist circumference	Baseline and 18 months	To check general health	Yes
30-second sit-to-stand test	Baseline and 18 months	To measure leg strength and risk of falling	Yes
6-minute walk test	Baseline and 18 months	To assess fitness and endurance	Yes
10-minute active stand test	Baseline and 18 months	To monitor blood pressure, heart rate and symptoms while standing	Yes
University of Pennsylvania Smell Identification Test (UPSIT)	Baseline and 18 months	To check your sense of smell	Yes
Electrocardiogram	Baseline and 18 months	To check your heart function	Yes
Cognitive tests	Baseline and 18 months	To measure attention, memory, problem-solving and language skills	No

We cannot give you the results of the cognitive (thinking) tests because in this study they are used for research purposes and only include some of the tests used in a full clinical cognitive exam. They do not represent a full picture of your thinking. Giving you results from just a subset of tests could be confusing. For this reason, we will not share these results with you.

In-Person Biospecimen Collection

We will collect up to about 4.8 tablespoons (71 mL) of blood during each in-person visit, for a total of about 9.6 tablespoons over the course of the study. Your samples will be stored at the RECOVER Research Biorepository at Mayo Clinic, MN.

Communicating with the Research Team

[**By text**

If you agree, the research team can contact you by text message to:

- Remind you about visits,
- Provide survey links, and
- Share study information.

Important points about texts:

- Text messages are not private and can be intercepted, so they come with some privacy risks.
- Fees related to text messages (such as charges from your cell carrier) are your responsibility.
- Texts will typically be sent during normal business hours unless a visit is scheduled outside these hours.
- Texting should not be used for emergencies: call 911 or visit a hospital for urgent medical needs.

You can tell the study team at any time if you want to stop getting text messages. Please make sure to keep the research team updated if your mobile/cell phone number changes during the study.

At the end of this form, we will ask you to provide your initials to show whether you agree or do not agree to receive text messages from the research team.]

By email
We may contact you by email to remind you about visits, provide survey links, share study information, or provide results. When we send email messages that include information about your health, like test results, we will help keep your personal information confidential by "encrypting" the message. You may have to create a username and password and log onto a website to see the information. Please make sure to keep the research team updated if your email address changes during the study.

Contact for Future Research Studies
The study team may contact you in the future to ask if you'd like to join other research studies related to COVID-19 or other health conditions. You can decide at that time if you want to participate in those studies.

At the end of this form, we will ask you to provide your initials to show whether you agree or do not agree to be contacted for future research.

Biospecimen and Data Storage for Future Research

As a main study activity, this study collects data (information collected from study procedures and survey responses) and blood (biospecimen sample collection) to be stored and shared for future research use. The stored data and samples will be used for future research related to COVID-19 and other health conditions. You do not have to agree to do all the procedures in the study or store samples for future research, but if you do not, you will not be able to join this study.

Your study data will be shared through RECOVER and NIH-designated repositories to support scientific research. Data will be transmitted to secure platforms such as NHLBI BioData Catalyst (BDC).The storage, management, and future access to your data is overseen by the NIH through its NHLBI, which funds this study. Your data may be made accessible in the following ways:

- Protected Data: Identifiable data, stored in a private repository only accessible to approved researchers in the RECOVER Network, following strict policies and procedures, with access recommended by the RECOVER leadership and a designated committee.
- De-identified Data: De-identified data (name and personal details removed), stored in a repository accessible only by request. Request may be made by members of the public and other researchers.
- Exploratory Data: Fully anonymized data available for public use. This data is fully anonymized and access to this data does not require any special permissions.

Your biospecimens will be safely stored at the RECOVER PASC Biorepository (PBC) at Mayo Clinic in Rochester, Minnesota. Once the study is completed, any leftover de-identified biospecimens may then be made available to researchers both within and outside of the RECOVER Network. This process is overseen by the PBC leadership and follows strict policies.

We will work to protect your privacy and keep your information confidential, as required by law. This includes using security measures to limit who can access your information. Your data and samples will be coded to protect your identity before they are shared with researchers outside of the RECOVER Network. This means your name and personal information will be removed from your data and samples and replaced with a code so researchers cannot easily link this information to you. During the study, the

site study staff and the study's Data Resource Core (DRC), will have access to a special linking code that connects your participant ID to your personal information.

The storage, management, and future access to your de-identified biospecimens is overseen by the PBC. Only researchers who seek approval to use your samples for future research may be granted approval by the RECOVER ancillary studies committee and the biospecimen availability committee. This committee follows strict procedures when granting approval to use your data and samples for future research. The researchers must agree to follow strict procedures in conducting their research.

Additional safeguards to protect your information are further described in Sections 14 and 15 of this form.

If you change your mind about storing your samples, you can withdraw your samples from the Biorepository by contacting the Site Study Leader named at the top of this form. To do this, you must send a written notice (by letter or email) to the Site Study Leader. In your message, please clearly state that you want your data removed from future research and that any unused samples should be destroyed.

Identifiers will be removed from your data and specimens no later than five years after completion of the study. After such removal, no one will have access to the linking code, and you will not be able to ask us to destroy your data and specimens, because it won't be linked to you anymore. After your name and other personal details are removed from your data and samples, and we can no longer link them back to you, the de-identified data and specimens may be used for future research or shared with other researchers, and we will not request additional informed consent from you to use these de-identified data and specimens.

Optional Future Genetic (Genomic) Research

This study does not perform genomic or DNA testing on your samples.

In the future, researchers may want to study genes and DNA to better understand how people's bodies work, why some people get certain illnesses and why others do not. This type of research may study how genes are related to health conditions, symptoms, or responses to certain treatments. Future research may also perform a whole genome analysis on your DNA sample. Usually, researchers study just a few areas of your genetic code that are linked to a disease or condition. In whole genome studies, all or most of your genes are analyzed and used by researchers to study links to many diseases or conditions. Sharing your stored data and samples for this type of research is optional and you do not need to take part in this optional research to join the main study. Your care and relationship with the study team will not change based on your choice.

If you choose to join this optional future research, no extra blood will be taken. Researchers will use the samples already collected during the main study. No additional samples are required to participate in the optional research.

You will not personally benefit from allowing your samples to be used in future genetic research. However, what researchers learn may help improve understanding of diseases and improve care for patients in the future.

Risks of future genetic research

Risks for genetic research involve privacy, not physical harm. Before your data and samples are shared for research, they will be de-identified so that information that directly identifies you is removed. Even with these protections, there is a small risk that confidentiality could be breached. If this occurred and the information were misused, it could possibly cause emotional, social, or financial harm, such as stigma or discrimination. Future genetic research may find health-related information that was not expected, including information that could be relevant to family members. Any future genetic research is separate from this main study. The current study researchers and study staff will not have access to data from future genetic studies, and you will not receive individual results or other information from such future research.

You can choose whether to allow your samples and data to be used for future genetic research and choosing yes or no will not affect your ability to join this study. If you do not consent to this optional research, the DRC will appropriately mark your samples and data so that they are not selected for studies that involve genetic analysis or whole genome sequencing.

At the end of this form, we will ask you to provide your initials to show whether you agree or do not agree to allow your data and samples to be used for future genetic research.

5. What are the possible risks or discomforts?

Being in this study may cause some minimal risks or discomforts similar to those you experience in everyday life. If you usually have worsening symptoms after physical or mental effort, you may find that your symptoms get worse during or after study visits too.

Possible loss of privacy or confidentiality

When we share your data and study samples, there is a very small chance that someone who shouldn't access them may see them. We will work hard to protect your privacy by keeping your surveys, data and samples in a secure environment that only authorized people can access. In addition, researchers using your information and study samples must agree not to try to find out who you are. However, there is still a slight chance that they may be able to find out who you are, which might affect areas like your finances, insurance, job or reputation.

Group risks

We won't share your name with researchers, but we may provide basic information like your race, ethnic group, or sex. This helps researchers learn how health problems affect different groups or people, which may improve care. However, sharing this information could also lead to harmful stereotypes or discrimination against certain groups.

Survey risks

The surveys you fill out are considered low risk. However, some questions may upset or frustrate you. Surveys might feel tiring or mentally challenging, too. You can take breaks at any time and return to the surveys later. Depending on how you answer some survey questions, we may contact you to check on your health or refer you to medical care.

Basic physical examinations

There are no specific risks related to measuring vital signs (like your heart rate and blood pressure), height, weight and waist circumference, or testing your ability to get up from a chair or your sense of smell.

Active stand and 6-minute walk test risks

You may get tired, lightheaded, short of breath or dizzy during these tests. You could also have palpitations (a feeling that your heart is racing).

Electrocardiogram (ECG) risks

The ECG test records your heart's electrical activity and is harmless. However, there may be minor discomforts, such as redness or itching from the sticky pads placed on your chest, or irritation from shaving if it's needed before attaching the pads.

Cognitive test risks

Thinking and memory tests may feel frustrating or stressful. To reduce stress, trained staff will guide you through the testing, and you can stop or take breaks if needed.

Blood draw risks

Having blood drawn is safe but can cause minor short-term effects, including: feeling lightheaded, faint or dizzy; or having bruising, redness or pain at the needle site. Rarely, people may pass out, sometimes causing injury, or get an infection at the needle site. Only trained professionals will perform the blood draw to minimize these risks. If you have experienced any of these side effects while having blood drawn, please inform the study staff.

Risk of incidental findings

Physical tests or the ECG may reveal health conditions that require medical attention. If this happens, the study team will contact you and let you know if further testing is recommended.

6. Can I be in the study if I am pregnant or breastfeeding?

Yes, you can be in the study if you are pregnant or breastfeeding. This is a long-term follow-up study with no drugs or experimental treatments involved. If you become pregnant, the study team will ask you to provide information about the outcome of your pregnancy and the health of your baby.

7. What if new information becomes available?

During this study, we may find information that could be important to you. This includes information that might cause you to change your mind about being in the study. We will let you know as soon as possible if this information is available to us.

At some places, your main doctor, and other people who care for you and who can look at your health records will be able to see this information. Also, the surveys and tests done as part of this study will be looked at by an expert who may find something that is not normal. If something that could affect your health is found, someone from the study team will talk to you in person or by phone about this new information.

Some tests may be done on your stored samples in a research laboratory. A research laboratory does tests where the results are just used for research. The results may not be reliable for use in your health care, or we may not know what the results mean for your health. Research laboratory tests may be done while you are in the study, or in the future after the study is finished. The law does not let us give you results of tests done in research laboratories because they are not meant for patient care.

8. What are the possible good things (benefits) from being part of the study?

You may not receive direct benefit from being in this study. However, what we learn could help researchers understand COVID-19 better and improve care for people in the future.

9. What other choices do I have if I do not join the study?

Joining the study is entirely up to you. Whether you choose to participate or not, your current medical care and benefits will not be affected.

10. Will I be paid for being in this study?

You will be paid for finishing each study visit as follows:

- [enter payment amount] for each in-person visit and completed survey (2 visits total)
- [enter payment amount] for each remote survey visit completed (3 total)

If you leave the study or are withdrawn before finishing, you will still be paid for the visits and surveys that you did.

We will pay you back for reasonable travel costs related to study visits, as long as receipts are provided. If you must travel from outside the local area, the study team will discuss additional reimbursement for air travel, hotels, and meals.

Because payments for participating are required to be reported to the IRS if they are more than $2,000 in one year, you will need to give the study staff either your Social Security number or your Alien Registration number. You will also be asked to fill out a form called the IRS W-9. If you do not have either of these numbers or are not willing to complete the W-9, you may be in the study but will not receive any payment.

Please track all payments made to you for your participation in any research for this calendar year. You must let us know immediately if/when the total research payments from any research studies are $2,000 or more (not including travel reimbursements) in one calendar year.

Information and samples you provide might be used to develop new tests or drugs, or other things that may be sold to make money. While these discoveries could lead to patents or licenses, there are no plans to share profits or pay you if that happens.

11. Will I have to pay for anything?

There is no cost to you for being in this study. All study visits, procedures, and tests that are part of the research are provided at no cost to you. However, if you need medical care during the study that isn't part of the research, you or your health insurance may be billed. If your insurance does not cover these costs or you do not have insurance, these costs will be your responsibility.

12. What happens if I am injured from being in the study?

For medical emergencies, call 911. If you think you have been hurt because of being part of this research study, tell the Site Study Leader as soon as you can. The Site Study Leader's name and phone number are listed in this consent form.

If you are hurt because of being part of this research, we will put you in contact with a doctor to give you treatment if you want. We may ask your insurance company or someone else, if appropriate, to pay for the costs of the treatment due to your being hurt, but you may also need to pay for some of this cost.

There are no plans for the study site or NYU Langone Health or NYU Grossman School of Medicine to pay you or give you anything else for being hurt. You do not give up the rights you have under the law by signing this form.

13. When is the study over? Can I leave the study before it ends?

The study will last for 4 years, but your participation will only last about 2 years. The study might be stopped early, or you could be removed if:

- The researchers in charge of the study feel it is important to remove you for your health or safety;
- You don't follow study instructions;
- The group funding the study, the main researchers in charge, or people monitoring the safety of the study decide to stop the study; or
- Enough information about Long COVID is known that the study is not needed.

You are free to leave the study at any time for any reason. You may also withdraw your consent for future contact and decide not to allow your samples to be used in the future. Leaving the study early will not affect your care, how your health care is paid for, or what kind of health insurance you can get.

14. How will you protect my confidentiality (privacy)?

Your medical information is protected health information, or "PHI", and is protected by federal and state laws, such as the Health Insurance Portability and Accountability Act, or HIPAA. This includes information in your research record as well as information in your medical record at [study site]. In compliance with [study site] policies and procedures and with HIPAA, only those individuals with a job purpose can access this information.

Medical information created by this research study may become part of your medical record. We may include your research information in your medical record for several reasons, including for the billing of services provided in connection with the study, to securely document any medical services you receive, and so that other members of the [study site] community who may treat you have access to important information about your health.

You have a right to access information in your medical record. In some cases, when necessary to protect the integrity of the research, you will not be allowed to see or copy certain information relating to the study while the study is in progress, but you will have the right to see and copy the information once the study is over in accordance with [study site] policies and applicable law.

Certificate of Confidentiality

To help us further protect your confidentiality, this research is covered by a Certificate of Confidentiality from the NIH. The NIH has issued a Certificate of Confidentiality for this research. This adds special protection for the research information (data, documents, or biospecimens) that may identify you.

Research information protected by this Certificate of Confidentiality cannot be disclosed to anyone else who is not connected with the research, without your consent. With this Certificate of Confidentiality, the researchers may not disclose or use research information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, without your consent. However, disclosure, without your consent, is still necessary if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases).

The Certificate of Confidentiality cannot be used to refuse a request for information from appropriate government agencies responsible for project oversight.

The Certificate of Confidentiality does not prevent you from releasing information about yourself and your involvement in this research, including for your medical treatment. Federal regulations may also allow for the use or sharing of information for other scientific research.

By agreeing to be in this research and signing below, you are giving your consent to share research information with others at [study site]. This means that your research information, including test results, may be included in your [study site] electronic medical record.

If you are a student or employee of [study site], note that your research information may be accessible to supervisors or others not directly involved in the research as needed for your medical treatment.

15. HIPAA Authorization

As noted in the Confidentiality section above, federal law requires us, and our affiliated researchers, health care providers, and physician network to protect the privacy of information that identifies you and relates to your past, present, and future physical and mental health conditions. We are asking for your permission (authorization) to use and share your health information with others in connection with this study, for purposes of this research, including conducting and overseeing the study.

Your treatment outside of this study, payment for your health care, and your health care benefits will not be affected even if you do not authorize the use and disclosure of your information for this study.

What information may be used or shared with others in connection with this study?

All information in your research record for this study may be used and shared with those individuals listed in this section. Additionally, information in your medical record that the research team believes may be important to the study may be accessed by those listed here. This includes, for example, results from your physical examinations, laboratory tests, procedures, questionnaires, and diaries.

Who may use and share information in connection with this study?

The following individuals may use, share, or get your information for this research study:

- The research team, including the Site Study Leader and other people helping with the study or who are in charge of watching over the study at [study site];
- The researchers at NYU Grossman School of Medicine, who are in charge of helping with and watching over the study at all the places across the country where the study is happening;
- Non-research staff who need this information to do their jobs (such as for treatment, payment (billing), or health care operations);
- Researchers within the RECOVER network: The researchers at Massachusetts General Hospital, who are in charge of storing the information for this study; the researchers at Mayo Clinic who are in charge of the research biorepository; researchers, reading centers and laboratories doing specialized tests or analyses for RECOVER; researchers funded to do research on RECOVER data; and researchers at other RECOVER study centers;
- The group that funded the study: NIH NHLBI;
- The ethical review board (also called institutional review board or IRB) that oversees the research and the research quality improvement programs;
- The group that is watching over the safety of patients and families in the study (called the observational study safety monitoring board). The NIH decides who will be in this group;
- People working with repositories such as RECOVER Data Gateway (RDG) and PASC Biorepository at Mayo Clinic, people working with NIH-designated data repositories such as the National Center for Biotechnology Information, the database of Genotypes and Phenotypes (dbGAP), NHLBI BioData Catalyst (BDC), and BDC-PIC-SURE;
- A company hired to oversee the quality of the RECOVER research information (Biomedical Research Alliance of New York);

- People or groups that we hire to do work for the study, such as data storage companies, insurers, and lawyers;
- Governmental agencies in charge of watching over or overseeing the research (for example, the US Department of Health and Human Services);
- Health care providers, including your doctors and others who care for you related to this study, and laboratories or other people who are looking at your health information as part of this study;
- Other places that are involved in this research; and
- Researchers not affiliated with RECOVER, only upon request and approval following established policies and procedures.

Your information may be re-disclosed (shared) or used for other reasons if the person who gets your information is not required by law to protect the privacy of the information.

What if I do not want to give permission to use and share my information for this study?

Signing this form is voluntary. You do not have to give us permission to use and share your information, but if you do not, you will not be able to participate in this study.

Can I change my mind and withdraw permission to use or share my information?

Yes, you may withdraw or take back your permission to use and share your health information at any time for this research study. If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. To withdraw your permission, you must send a written notice to the principal investigator for the study noted at the top of this form. If you withdraw your permission, you will not be able to stay in this study.

How long may my information, data and samples be used or shared?

Your permission to use or share your personal health information for this study will never expire unless you withdraw it.

16. The Institutional Review Board (IRB) and how it protects you

The IRB reviews all human research studies – including this study. The IRB follows Federal Government rules and guidelines designed to protect the rights and welfare of the people taking part in research studies. The IRB also reviews research to make sure the risks for all studies are as small as possible. The NYU Langone Health IRB Office number is 212-263-4110. The NYU Langone Health IRB is made up of doctors, nurses, non-scientists, and people from the community.

17. Who can I call with questions, or if I'm concerned about my rights as a research participant?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research participant, you should speak with the Site Study Leader listed in this consent form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the NYU Institutional Review Board (IRB) at (212) 263-4110.

A description of this clinical study will be available on http://www.ClinicalTrials.gov. 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.

18. Consent

Please initial next to your choice for each optional study activity below:

Communicating by Text

_____ Yes, I agree to receive texts from the research team.
Initial here

_____ No, I do not agree to receive texts from the research team.
Initial here

Contact for Future Research Studies

_____ Yes, I agree to be contacted for future research studies.
Initial here

_____ No, I do not agree to be contacted for future research studies.
Initial here

Future Genetic Research

_____ Yes, I agree to allow my data and samples to be used for future genetic research.
Initial here

_____ No, I do not agree to allow my data and samples to be used for future genetic research.
Initial here

By signing below, I confirm that I understand the study information provided to me and I agree to participate in this study.

Name of Participant (Print)	Signature of Participant	Date

Name of Person Obtaining Consent (Print)	Signature of Person Obtaining Consent	Date

Witness to Consent Process for Non-English-Speaking participants (using a translated consent form OR "Short Form" in participant's Spoken Language)

Statement of Witness

As someone who understands both English and the language spoken by the participant, I represent that the English version of the consent form was presented orally to the participant in the participant's own language, and that the participant was given the opportunity to ask questions.

Name of Witness (Print)	Signature of Witness	Date