Title: Extended Home-use Trial of a Novel Device to Reduce Chronic Neuropathic Pain
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STUDY INFORMATION:

Study Title: Extended home-use trial of a novel device to reduce chronic pain

Study site(s): Icahn School of Medicine at Mount Sinai, Mount Sinai Hospital

Lead Researcher (Principal Investigator): David Putrino, PT, Ph. D

Physical Address: Mount Sinai Hospital; Abilities Research Center (ARC) 5 E 98th St, Sub-basement, room 18

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Phone: 212-824-8369

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 assess the effectiveness of a new wearable device at relieving chronic pain. The device is called the Sana Pain Reliever (Sana PR – pictured below). The Sana PR is a mask with ear buds that will display light in front of your eyes. The device runs for 16 minutes at a time. The device is not FDA approved.

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

- Follow study directions for the entire 14-week duration of the study.
- Attend all four video calls or study visits to the Abilities Research Center at Mount Sinai.
- *Complete the procedures outlined in Description of What's Involved section*

If you choose to take part, the main risks to you are associated with photosensitivity to the flashing lights, which can include headaches, dizziness, and nausea.

This study is not designed to benefit you personally; however, future benefits may include a reduction in your chronic pain.

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 experience long-lasting pain.

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

There are 180 people expected to take part in this research study at Mount Sinai.

Funds for conducting this research study are provided by Sana Health Inc.

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:

This study will be an at home trial with the Sana Pain Reliever device (Sana PR). For this trial, you will be loaned the device and a tablet, with the application that controls the device and has electronic forms of the questionnaires, for 8 weeks. You will be instructed on how to use the device and application, and you will also be given all equipment necessary to charge the Sana PR headset and tablet device. The study will include four video calls or study visits to the Abilities Research Center located at: 5 E 98th St., Sub-basement room #18, New York, NY, 10029. The following outlines what is involved at each stage of the study:

Study Devices

The mask and computer tablet will be loaned to you for the duration of the study. If you will complete the study visits over video call the devices will be mailed to you ahead of the first call. The tablet will come with a video calling software (Zoom) installed for completing these study video calls. You will then mail the devices back to us using a provided shipping label. If you will complete the study visits in person the devices will be given to you at these study visits, and you will return the devices to us at later study visits (described below). Both devices will be activated and deactivated remotely at the start and end of the study.

Clinical Assessment 1 (Start of Study)

During this video call/visit, you will complete a short screening to make sure this study is a good fit for you based on your type of pain. You will be asked to complete several questionnaires about your pain, sleep quality and your quality of life. You will also be asked to report demographic information, a medical history of your pain (including techniques you use to try to help relieve the pain) and your current medications (both prescribed and over-the-counter). You will be loaned the study tablet at this visit and taught how to use it. This visit will last approximately 90 minutes.

At Home Symptom Monitoring (Weeks 1–2)

For the two weeks between Clinical Assessment 1 and Clinical Assessment 2, you will use this tablet once a day immediately prior to going to sleep and answer a few questions in the application about your quality of sleep from the night before, pain levels and the medication you used that day. Reach out to the research team at (212) 824-8369 if you have any questions or issues with the tablet or application. During this time, your level of compliance to the protocol will be monitored. Your eligibility to continue participating in the next at home portion of this study with the Sana PR device is dependent on your ability to comply with what is being asked of you to complete during this At Home Symptom Monitoring period.

Clinical Assessment 2 (End of Week 2)

During this video call/visit, you will be asked to complete several questionnaires about your pain, sleep quality and your quality of life. You will also be asked to report any changes in your current medications (both prescribed and over-the-counter) and techniques you use to manage your pain from the first initial assessment. Then you will be randomized into one of two study groups that will test two different settings of the Sana PR device. The study group you will be assigned to will be chosen by chance, like flipping a coin. You will have an equal chance of being given each study group. Neither you nor the study researcher will choose or know which study treatment you are getting. This information could be obtained in an emergency, however. You will then be taught how to use the Sana PR device, and will then complete your first session using the device. *The video call/visit will last approximately 90 minutes. A member of the research team will call you 48 hours later to check to see if you have had any negative symptoms as a consequence of participating in this study that result in immediate and/or long-term negative health outcomes from using the device or participating in this study. The researcher will also check for difficulties using the devices and answer any questions you may have.*

At Home Use of Device (Weeks 3-10)

You will control the Sana PR device with the same application on the tablet that you used in the first two weeks of the study. Over this time, you will use the Sana PR device whenever you are in pain. Before and after each use, the application will ask you to rank how much pain you are feeling. Before your first daily use of the device, you will also be asked to rank your quality of sleep from the evening prior. In addition to using the device during the day, you will also use the device each night immediately prior to or accompanying to falling asleep. Each night, prior to using the device, the application will ask you to rank your pain and will ask which of your reported medications you took that day. Additionally, every other week the application will ask you to complete a few questionnaires about your pain, quality of sleep and quality of life. You will be notified via text message on your mobile device and by a notification on the tablet about these questionnaires. Reach out to the research team at (212) 824-8369 to report any negative symptoms or experiences from using the device or if you have any questions or issues with the Sana PR device, tablet or application. During this time, your level of compliance to the protocol will be monitored. The research team will reach out to you via telephone or email if the level of your compliance drops to make sure you have not stopped using the device due to a negative health outcome from using the device.

Follow-Up 1 (End of Week 10)

During this video call/visit, you will be asked to complete several questionnaires about your pain, sleep quality, your quality of life and how you felt the device impacted you, if in any way. You will also be asked to report any changes in your current medications (both prescribed and over-the-counter) and any changes in the techniques you use to manage your pain. . You will also be asked to report your thoughts on the device and if you would use it in your daily life. Additionally, you will be asked to report any *negative symptoms or experiences from using the device*. This video call/visit will last approximately 90 minutes.

At Home Symptom Monitoring (Weeks 11–14)

For the four weeks between Follow-Up 1 and Follow-Up 2, you will use the study tablet once a day immediately prior to going to sleep, and answer a few questions in the application about your quality of sleep from the night before, pain levels and the medication you used that day. Reach out to the research team at (212) 824-8369 to report any negative symptoms or experiences from using the device or if you have any questions or issues with the tablet or application.

Follow-Up 2 (End of Study)

During this video/call visit, you will be asked to complete several questionnaires about your pain, sleep quality, your quality of life and how the device impacted you, if in any way. You will also be asked to report any changes in your current medications (both prescribed and over-the-counter) and any changes in the techniques you use to manage your pain. You will also be asked to report your thoughts on the device and if you would use the device in your daily life. Additionally, you will be asked to report *any negative symptoms or experiences from using the device*. This video call/visit will last approximately 90 minutes.

Because this project involves the use of 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.

Randomization

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 device you get. It will be by chance, like flipping a coin. You will have an equal chance of being given each study device. Neither you nor the Lead Researcher or your own doctor will know which study device you are getting. If there is an emergency, they can get this information.

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 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.
   II. 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_____

(6) Do you give permission to have portions of your data and/or samples deposited in large public databases (repositories) for use in research with the limits you may have chosen above? Please read the paragraphs below which explains repositories, then initial your choice:

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.

Whether or not you have allowed us to share your data and/or samples, the researchers at Mount Sinai will keep data and/or samples collected about you during this research study to use in future research studies consistent with the wishes you expressed above.

YOUR RESPONSIBILITIES IF YOU TAKE PART IN THIS RESEARCH:

If you decide to take part in this research study, you will be responsible for the following things:

- You must report any changes in medications and any changes to your current strategies for dealing with your pain within 28 days of beginning this study or for the duration of this study.
- Reporting all *negative symptoms or experiences from using the device.*

- Contacting the research team immediately if there are technical difficulties with the device.
- *Completing the procedures outline in Description of What's Involved section.*
- *Returning the mask and tablet devices loaned to you for this study*

COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

If you agree to take part in this study, you will be paid a maximal total of $150 for your time and effort.

This amount will be pro-rated: you will receive $25 for each of the two baseline assessments, and $50 for each of the two follow-up assessments, which amounts to $150. This will be paid to you in the form of a check following your final assessment. *Checks require some time to be prepared and will be given to you as available. Payment is dependent on you returning both the Sana PR and tablet devices.*

It can take up to 6 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.

POSSIBLE BENEFITS:

This study is not designed to benefit you personally. However, possible future benefits to others include a possible reduction in the amount of chronic pain that you typically experience.

POSSIBLE RISKS AND DISCOMFORTS:

- Risk of loss of private information; this risk always exists, but there are procedures in place to minimize the risk.
- Standard risks associated photosensitivity: nausea, headache, dizziness
- In addition to these risks, because this is an investigational device that is not FDA approved, there are risks that may not be known and the severity of these risks may not be known. The unknown risks might be minor or might be major (death).
- The investigational device in this study may or may not provide relief of chronic pain. It is important to understand that even if the device makes you feel better, you will still have to return it at the end of this study. However, this device is available commercially, so you are able to purchase it after completion of this study if you choose.

OTHER OPTIONS TO CONSIDER:

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

Instead of being in this research study, you may choose one or more of the many currently available treatments for chronic pain. These choices include:

- Pharmaceuticals such as antidepressants, anticonvulsants, local anesthetics, and opioids.
- Physical techniques such as cognitive behavioral therapy, relaxation/mindfulness, physical therapy, chiropractic therapy, TENS, and thermal applications.
- Surgical options such as Botox nerve blocks, trigger point injections, and epidural steroid injections.

Potential risks and benefits of these alternatives include:

- Pharmaceuticals can have adverse side effects and, in some cases, there is a risk of addiction.
- Surgical options are invasive and carry general risks associated with minor surgical procedures such as infection or risk of nerve damage.
- These alternatives may result in pain relief

The study staff are unable to prescribe any of the above alternative treatment options in any circumstance. You should consult your personal physicians if you would like to consider any of these options.

Your participation in the study does not preclude you from using these alternate options, however, should you wish to commence a new treatment modality we ask that you do inform us of your intentions to change your pain management as promptly as possible.

IN CASE OF INJURY DURING THIS RESEARCH STUDY

If you are injured or made sick from taking part in this study, you will get medical care. The group funding this research study will pay you for any reasonable and necessary medical expenses to diagnose and treat research-related injury or illness. This does not prevent you from seeking payment for injury related to malpractice or negligence. You can contact the Lead Researcher for more information.

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 study, please contact the Lead Researcher or the research staff. AT that. Point, the research team will ask that you return the equipment that was loaned to you back to the research team.

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 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.

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 212-824-8369.

If there is an emergency, 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 device 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/fax numbers, dates directly related to the individual (birth, date of diagnosis), e-mail/internet protocol (IP) addresses or web universal resource locators (URL's), social security number, medical records number.

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.)
- completing the tests, procedures, questionnaires and interviews explained in the description section of this consent.

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

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

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

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

- The commercial sponsor and/or their representative (who will use the results for submissions to the Food and Drug Administration): Sana Health Inc
- A Data Safety Monitoring Board or other committee that will monitor the study on an ongoing basis for safety.
- The United States Food and Drug Administration
- The United States Department of Health and Human Services and the Office of Human Research Protection.

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

For how long will Mount Sinai be able to use or disclose your PHI?
Your authorization for use of your PHI for this specific study does not expire.

Will you be able to access your records?
During your participation in this study, you will have access to your medical record and any study information that is part of that record. The research team is not required to release research information to you that is not part of your medical record.

Do you need to give the researchers permission to obtain, use or share your PHI?
NO! If you decide not to let the research team obtain, use or share your PHI, you should not sign this form, and you will not be allowed to volunteer in the research study. If you do not sign, it will not affect your treatment, payment, or enrollment in any health plans or affect your eligibility for benefits.

Can you change your mind?
If you decide to stop being in the study, please contact the Lead Researcher or the research staff. The research team may ask you whether they can continue to collect information from your medical record. You will also have to decide if you wish to limit the continued use of the information collected during the study. Under US privacy laws you may also withdraw your permission for the researchers to use and share any of your protected information for research, but you must do so in writing to the Lead Researcher at the address on the first page.

Even if you withdraw your permission, the Lead Researcher may still use the information that was already collected, but only to complete this research study. Your health information may still be used

or shared after you withdraw your authorization if you have an adverse event (a bad effect) from taking part in the research study.

If you have not already received it, you will also be given The Hospital's Notice of Privacy Practices that contains more information about how The Hospital uses and discloses your PHI.

It is important for you to understand that once information is disclosed to others outside Mount Sinai, the information may be re-disclosed and will no longer be covered by the federal privacy protection regulations. However, where possible, Mount Sinai has entered into agreements with those who will receive your information to continue to protect your confidentiality.

If researchers are reviewing your medical records or asking questions about your medical history or conditions, it is possible that they may learn information related to your HIV status. If that is the case, the following information concerns you. If researchers are not reviewing your medical records or asking questions about your medical history or conditions, then you may ignore the following section.

Notice Concerning HIV-Related Information

If you are authorizing the release of HIV-related information, you should be aware that the recipient(s) is (are) prohibited from re-disclosing any HIV-related information without your authorization unless permitted to do so under federal or state law. You also have a right to request a list of people who may receive or use your HIV-related information without authorization. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the New York State Division of Human Rights at (888) 392-3644 or the New York City Commission on Human Rights at (212) 416-0197. These agencies are responsible for protecting your rights.

How the Institutional Review Board (IRB) can help you:

This research has been reviewed and approved by an Institutional Review Board (IRB). You may reach a representative of the Mount Sinai Program for Protection of Human Subjects at telephone number (212) 824-8200 during regular work hours (Monday-Friday, 9am-5pm, excluding holidays) for any of the reasons listed below. This office will direct your call to the right person within the Mount Sinai Health System:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You are not comfortable talking to the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

ADULT PARTICIPANT:

Your signature below documents your permission to take part in this research study and to the use and disclosure of your protected health information. A signed and dated copy will be given to you.

Signature of Participant	Printed Name of Participant	Date	Time

PERSON EXPLAINING STUDY AND OBTAINING CONSENT:

Signature of Consent Delegate	Printed Name of Consent Delegate	Date	Time

WITNESS SECTION:

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

Signature of Witness	Printed Name of Witness	Date	Time