Non-motor Features of Parkinson's Disease

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STUDY INFORMATION:

Study Title: Non-Motor Features and Mechanisms of Parkinson's Disease

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

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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 study is to better understand sleep disruption in individuals with Parkinson's disease and to evaluate possible benefits of light therapy on sleep, as well as mood and cognition. Since light is a known regulator of the sleep/wake cycle (circadian rhythm), light therapy may help to re-set and normalize this cycle to improve sleep. Because movement during sleep increases when sleep is disrupted, we will use measurements of movement in sleep to determine the degree of sleep disruption. To obtain these measurements, participants will wear a study watch (called Actiwatch), and movement patterns will be analyzed after the watch is returned. The charting of movement using the Actiwatch is called "actigraphy". Study participants may agree to actigraphy only or may also agree to participate in the light therapy trial.

If you choose to take part in actigraphy only, you will be asked to:

- Wear the Actiwatch for one week

If you choose to take part in the optional light therapy trial, you will also be asked to:

- Sit near a light source for 2 hours per day in the morning for either 4 or 8 weeks. The light source will be your choice of: floor lamps, light goggles, or natural outdoor light.

- Wear the Actiwatch for an additional week at the end of the trial
- Have a neurological exam and answer questionnaires at the beginning and end of the trial in person or by secure video conference (except if this information was already obtained for one of the time points through another study at MSBI)
- Collect a night time urine sample at the beginning and end of the trial to measure melatonin levels
- Have a morning blood draw at the beginning and end of the trial to measure protein levels.
- There is no cost to you and no payment for participating in the study.
- You blood sample may be stored indefinitely for research purposes

If you choose to take part, the main risk to you is the risk of blood draw.

You may benefit from taking part in this research. Some potential benefits are: the light therapy may improve your sleep, mood or cognition and you will be helping to increase knowledge about Parkinson's disease and its treatments.

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 have Parkinson's Disease and are participating in the Genetics of Movement Disorders study at Mount Sinai.

Your participation in this research study is expected to last one week if you only participate in actigraphy and either four or eight weeks if you participate in the light intervention.

There are 50 people expected to take part in this research study at Mount Sinai Beth Israel.

Funds for conducting this research are provided by New York State through The Empire Clinical Investigator Program.

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

DESCRIPTION OF WHAT'S INVOLVED:

If you agree to participate in this research study, here is what may be involved:
A) Actiwatch: You will be asked to wear a device called an "Actiwatch" on your wrist to measure your movement throughout the day and night. This will be worn for a week prior to light therapy and a week at the end of light therapy. If you chose not to do the light therapy, you will wear the Actiwatch for one week only.

B) Lights or light goggles (optional): You will be asked to sit under a light source or wear light goggles for two hours each morning for up to 8 weeks. A coordinator may come to your home to install some floor and/or table lamps for this purpose.

B) Questionnaires: You will be asked questions about your medical history in person or by Zoom (approximately 30 minutes). This will occur twice if you agree to the light intervention (before and after the intervention), and once if you do not.

B) Exam: You will receive a brief (approximately 15 minutes) neurological examination in person or by Zoom. This will occur twice if you agree to the light intervention, and once if you do not. If you have had a recent exam through participation in our other research this can be substituted.

C) Videotape (optional): Part of your examination will be videotaped. This may be done in person or through a HIPAA approved video platform. The purpose of the videotape recording is for scientific review by other physicians and research staff.

L) Urine sample (optional): You may be asked whether you are willing to contribute a urine sample.

D) Blood sample(s) (optional): You may be asked to submit approximately 2-3 tablespoons of blood. This blood will be used to analyze protein levels associated with circadian rhythms. You will not share in any financial benefits of these uses and findings. The blood will be obtained by venipuncture, requiring the insertion of a needle into a vein in the forearm. This may be associated with transient sudden pain which will then disappear and may be followed by a black and blue mark

The examination and blood draw will take place either at Mount Sinai Union Square or in your home or the examination may take place by HIPAA compliant Zoom call. The study visit will be coordinated and conducted by a study coordinator and/or a study physician.

The following procedures are optional parts of the study: light therapy, urine sample, blood sample, videotape, video call. The history, exam, and wearing the Actiwatch are necessary for

inclusion in the study. Please indicate below whether you are willing to participate in any of the optional part of the study.

A. Light Therapy:

❑ Yes, I agree to the light therapy trial. (Please initial)_____
❑ No, I do not agree to the light therapy trial. (Please initial)_____

B. Urine sample:

❑ Yes, I agree to give a urine sample. (Please initial)_____
❑ No, I do not agree to give a urine sample. (Please initial)_____

C. Blood sample(s):

❑ Yes, I agree to the blood samples. (Please initial)_____
❑ No, I do not agree to the blood samples. (Please initial)_____

D. Video call:

❑ Yes, I agree to a pre-scheduled **HIPAA compliant video call**. (Please initial)_____
❑ No, I do not agree to a HIPAA compliant video call. (Please initial)_____

E. Videotape:

❑ Yes, I agree to be **videotaped**. (Please initial)_____
❑ No, I do not agree to be videotaped. (Please initial)_____

If you agree to the videotape, the videotape will be kept indefinitely for scientific review by the Mount Sinai study team. It will not be shared outside the study team unless you give permission to do so on this form (see “use of your data and/or specimens” section).

There will be no specific results available while you are participating in this study except under circumstances where research findings would affect your health or the health of a family member.

If you desire genetic counseling or diagnostic evaluation, you may ask the investigators for a referral, or you may make a separate appointment with one of the investigators in this study for this purpose.

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:

Information generated by this research can only be linked to you by way of a code, which is controlled by the principal investigator, Dr. Rachel Saunders-Pullman.

Your coded sample may be used for research purposes unrelated to the study for which it was collected. You will not be informed of the details of specific research that is done with your medical information and bio-specimens. That means that a research project might be done that you would not consent to if provided with the details of that research project.

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. If in the future you wish to withdraw your data and/or samples from the repository you may ask the investigator to do so. They are described in more detail in the Risks section.

As stated above, the research subject's videotape will be kept indefinitely by the study team to enable scientific review of his/her symptoms in the future. It will not be shared with others unless you give permission to do so below. It will not be published without your specific separate consent to do so. If you change your mind about allowing us to keep your videotape in the future, you should contact the principal investigator or her team, so that stored files, including backups, will be permanently deleted.

Please state your preference below:

1. Use of videotape within Mount Sinai:

❑ Yes, I agree to have the videotape used for training purposes within the Mount Sinai System. I understand that if the videotape is used for this purpose, the videotape will not be altered, and my face will be visible. (Please initial)_____
❑ No, I do not agree to have the videotape used for training purposes within the Mount Sinai System. (Please initial)_____

2. Use of videotape outside of Mount Sinai:

❑ Yes, I agree to have the videotape used for training and scientific conferences outside the Mount Sinai System. I understand that if the videotape is used for this purpose, the researchers will edit the videotape to obscure or limit views of my face and identifiable features that are not relevant to teaching, but that this may not always be possible. (Please initial)_____
❑ No, I do not agree to have the videotape used for training purposes outside the Mount Sinai System. (Please initial)_____

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: answering questions about your medical and family history, giving a urine and blood or saliva sample, having a neurological exam, and completing any other parts of the study that you agreed to.

COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

You will not be paid for taking part in this study. Being in this study will not cost you anything extra. If you are examined at Mount Sinai Beth Israel we will pay for your parking expenses, with a maximum reimbursement of $40. If you seek a referral to one of the physicians or genetic counselors in this study for evaluation or genetic counseling, you will be responsible for the charges.

This study is being done by the researchers for academic purposes only, and no financial gains are anticipated. However, it is possible that products may someday be developed with the help of your data and/or samples, and there are no plans to share any profits from such products with you.

Reimbursement for research related expenses:

After you have completed a visit you will need to submit all study related receipts to the study coordinator. *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 you or others include providing important information about sleep disruption in Parkinson's disease. If you participate in light therapy possible benefits may be improved sleep, mood, or cognition.

POSSIBLE RISKS AND DISCOMFORTS:

Actiwatch - There is no anticipated risk to wearing the Actiwatch.

Light therapy - There is no anticipated risk to light therapy.

Psychological: You may experience anxiety as a result of your participation in this study. If you desire, you may ask the investigator for a referral or make an appointment with one of the investigators to address this.

Blood sample: Persons submitting blood samples may experience transient pain and there may be a black and blue mark at the site at which blood is drawn.

Urine samples: There are no known risks associated with stool or urine collection.

Group Risks - Although we will not give researchers your name, we will give them basic information such as your race, ethnic group, and sex. 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 even promote discrimination.

Privacy Risks - Risk of loss of private information; this risk always exists, but there are procedures in place to minimize the risk.

Your name and other information that could directly identify you (such as address, date of birth or social security number) will never be placed into a scientific database. However, because your genetic information is unique to you, there is a small chance that someone could trace it back to you. The risk of this happening is very small, but may grow in the future. Since the database includes genetic information, a break in security may also pose a potential risk to blood relatives as well as yourself. For example, it could be used to make it harder for you (or a relative) to get or keep a job or insurance. If your private information was misused it is possible you would also experience other harms, such as stress, anxiety, stigmatization, or embarrassment from revealing information about your family relationships, ethnic heritage, or health conditions.

Insurance Risks – There is a Federal law called the Genetic Information Nondiscrimination Act (GINA). This law makes it illegal for health insurance companies, group health plans, and most employers of over 15 people to discriminate against you based on your genetic information. However, it does not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

OTHER OPTIONS TO CONSIDER:

You may decide not to take part in this research study. You may also agree to only part of the study; for example you may decline light therapy and/or being videotaped. 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 study, you will get medical care. Generally, this care will be billed to you or your insurance in the ordinary manner and you will be responsible for all treatment costs not covered by your insurance, including deductibles, co-payments and coinsurance. This does not prevent you from seeking payment for injury related to malpractice or negligence. Contact the investigator for more information.

ENDING PARTICIPATION IN THE RESEARCH STUDY:

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

If you decide to stop being in the study, please contact the Lead Researcher or the research staff. You 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 it may not be possible to remove already collected data and samples from databases and analyses, as they may have already been used in a publication or shared anonymously with study collaborators.

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.

You may be asked whether the investigator can collect information from your routine medical care. If you agree, this data will be handled the same as research data.

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 888-228-1688 (toll free), or 212-844-6053.

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

DISCLOSURE OF FINANCIAL INTERESTS:

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

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 protected health information is collected and used in this study, and might also be shared with others?

As part of this research project, the research team at the hospital(s) involved in the research will collect your name, address, telephone/fax numbers, e-mail, date of birth, other dates if applicable (eg. date of medical visit/procedure, date of death), social security number (for reimbursement/payment), medical records number, photographic images.

The researchers will also get information from your medical record, particularly records from your neurologist(s) or neurosurgeon(s) if applicable.

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 genetic tests

The following additional information applies as follows:

- Study participants do not get any genetic results from this study.

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 to treat you in collaboration with others in the Mount Sinai Health System.

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 School's Program for the Protection of Human Subjects is responsible for overseeing research on human subjects, 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.*

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

<u>Who, outside Mount Sinai, might receive your PHI?</u>
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 sponsoring agency and/or their representatives who need to confirm the accuracy of the results or the use of funds: New York State (Empire clinical research award)
- The United States Department of Health and Human Services (DHHS) and the Office of Human Research Protection (OHRP) (the government organization that is responsible for protecting human research participants).
- The United States Food and Drug Administration.

The following individuals may receive your coded data and/or samples, but not data that identifies you.

Laurie Ozelius, PhD at Massachusetts General Hospital, Neil Risch, PhD at UCSF, Ilir Agalliu, MD, PhD and Dr. Cuiling Wang, MD, Albert Einstein College of Medicine.

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

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

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

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

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

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

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

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

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

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

Notice Concerning HIV-Related Information

If you are authorizing the release of HIV-related information, you should be aware that the recipient(s) is (are) prohibited from re-disclosing any HIV-related information without your authorization unless permitted to do so under federal or state law. You also have a right to request a list of people who may receive or use your HIV-related information without authorization. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the New York State Division of Human Rights at (888) 392-3644 or the New York City Commission on Human Rights at (212) 306-5070. These agencies are responsible for protecting your rights.

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	Date	Time

_____
Printed Name of Subject

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 subject, and that consent was freely given by the subject.

_____	_____	_____	_____
Signature of Witness	Printed Name of Witness	Date	Time