Form Version Date: May 12, 2020

STUDY INFORMATION:

Study Title: Impact of COVID-19 on individuals with Spinal Cord Injury

Principal Investigator (Head Researcher): Thomas Bryce, MD

Physical Address: Klingenstein Clinical Center (KCC), 1450 Madison Ave, New York, NY 10029-6574
Mailing Address: One Gustave L Levy Place Box 1240, New York, NY 10029

Phone: 332-215-2940**;** 332-215-2939; 332-215-2959

SUMMARY OF THIS RESEARCH STUDY:

In medicine there are many unanswered questions. A research study is when scientists try to answer a question about something that we don't know enough about. Participation in a research study may or may not directly help you or others. Participation is entirely voluntary. It is completely up to you whether or not you take part. You can also change your mind at any time and it will not affect your ability to get medical care within the Mount Sinai Health System.

Most of the world has been affected by the 2019 novel coronavirus disease (COVID-19) pandemic, which is caused by the severe-acute respiratory syndrome (SARS-CoV-2) virus. Much is not known about how COVID-19 has affected the lives of persons with spinal cord injury (SCI).

The purpose of this research study is to determine how COVID-19 has affected persons with SCI whether they personally had COVID-19 or not. It will look at how COVID-19 affects a person's health both physically and mentally as well as how it affects the services they need. This knowledge gained from this study will help us to meet the needs of the SCI community as it relates to the COVID-19 pandemic and similar future pandemics.

If you choose to participate, you will be asked to provide information by means of a phone interview or online survey about the impact that COVID-19 has had on your life including your health status and any services you may receive. You will be compensated for your participation after the survey has been completed. You may also be contacted in the future with further follow-up questions such as those related to antibody testing for COVID-19.

Because this study involves collection of confidential information, there exists the potential risk for loss of private information; this risk always exists, but there are procedures in place to minimize the risk.

Participating in this research will not benefit you directly.

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

PARTICIPATION IN THIS RESEARCH STUDY:

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

You may qualify to take part in this research study because you are an individual with a spinal cord injury of any cause.

Funds for conducting this research are provided by the Christopher Reeve Paralysis Foundation and the Craig H Neilsen Foundation.

LENGTH OF TIME AND NUMBER OF PEOPLE EXPECTED TO PARTICIPATE:

Your participation in this research study is expected to last at least 1 year.
The number of people expected to take part in this research study is approximately 2000 individuals throughout the tristate area.

DESCRIPTION OF WHAT'S INVOLVED:

If you agree to participate in this research study, the following information describes what may be involved:

- Information about you, your spinal cord injury, and your health will be collected by the research team.
- You will participate in a phone or online survey in which you will answer questions regarding your health history, social history, services you receive for spinal cord injury-related care, and wheelchair maintenance and breakdowns, if applicable, prior to and after the COVID-19 pandemic as well as how all of the above have been affected by the pandemic.
- You also agree to allow us to review your medical charts and other hospital records so that we may describe your medical status and the kinds of medical, nursing, and rehabilitation treatments and services you have received.
- You also agree to allow us to contact the Social Security Administration so that we can determine how you have been affected economically by the pandemic.
- You also agree to allow us to contact others who may know how to reach you (such as friends or family members) if we cannot reach you at your last known address or phone number should we need to get in contact with you again at a future date for additional surveys as part of your participation in this study.

- You also allow us to contact you in the future to ask whether you are interested in participating in other research on spinal cord injury that Rehabilitation Medicine staff members may be developing and for which you may be a suitable subject.

USE OF YOUR DATA AND/OR SPECIMENS:

In the future, your identifiable information may be removed from the private information that is collected as part of this research. After this removal, the information could be used for future research studies or shared with other research teams for future research studies. You will not be informed of the details of specific research that is done with your medical information. That means that a research project might be done that you would not consent to if provided with the details of that research project. Future research would be related to spinal cord injury and/or the effects of the COVID-19 pandemic.

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: completing the interview and allowing us to review your records as described above.

COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

If you agree to take part in this research study, we will pay you $50 by means of a gift card for your time and effort through email or through the mail.

Tax law may require the Mount Sinai Finance Department to report the amount of payment you receive from Mount Sinai to the Internal Revenue Service (IRS) or other agencies, as applicable. Generally, this reporting would take place if you receive payments that equal $600 or more from Mount Sinai in a calendar year. You would be responsible for the payment of any tax that may be due.

POSSIBLE BENEFITS:

It is important to know that you may not get any benefit from taking part in this research. Others may not benefit either. However, possible benefits to others include: information from the interview and medical chart reviews that may be useful to health care providers, organizations that provide support and advocacy for persons with spinal cord injury, and governmental agencies. This information may help guide future interventions both medical and supportive during future pandemics and other large-scale emergency situations. The information may also help guide advocacy for persons with spinal cord

injury with regards to governmental services. In addition, some of the information gathered may be used to develop other spinal cord injury and COVID-19-related research studies.

REASONABLY FORESEEABLE RISKS AND DISCOMFORTS:

Because this study involves collection of confidential information, there exists the potential risk for loss of private information; this risk always exists, but there are procedures in place to minimize the risk. There exists the potential risk of a breach in data resulting in access to information such as the type of medical insurance you have or medical or economic assistance you may receive, but this risk will be minimized.

OTHER POSSIBLE OPTIONS TO CONSIDER:

You may decide not to take part in this research study without any penalty. The choice is totally up to you.

IN CASE OF INJURY DURING THIS RESEARCH STUDY:

If you believe that you have suffered an injury related to this research as a participant in this study, you should contact the Principal Investigator.

ENDING PARTICIPATION IN THE RESEARCH STUDY:

You may stop taking part in this research study at any time without any penalty. This will not affect your ability to receive medical care at any of the Mount Sinai Health System hospitals or to receive any benefits to which you are otherwise entitled.

If you decide to stop being in the research study, please contact the Principal Investigator or the research staff.

You may also withdraw your permission for the use and disclosure of any of your protected information for research, but you must do so in writing to the Principal Investigator at the address on the first page. Even if you withdraw your permission, the Principal Investigator for the research study 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 participating in the research study.

Withdrawal without your consent: The study doctor, the sponsor or the institution 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 study team have not been followed, the

investigator believes it is in your best interest, or for any other reason. If specimens or data 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 Principal Investigator at the following phone numbers: 332-215-2940**;** 332-215-2939; 332-215-2959.

This research has been reviewed and approved by an Institutional Review Board. You may reach a representative of the Program for Protection of Human Subjects at the Icahn School of Medicine at Mount Sinai at telephone number (212) 824-8200 during standard work hours 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 subject.
- You want to get information or provide input about this research.

DISCLOSURE OF FINANCIAL INTERESTS:

Sometimes, physicians/researchers receive payments for consulting or similar work performed for industry. Effective September 2014 Mount Sinai reviews only payments to an individual totaling more than $5,000 a year per entity when determining potential conflicts of interest. If you have questions regarding industry relationships, we encourage you to talk your physician/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 you take part in this research project it will be necessary for the research team and others to use and share some of your private protected health information. Consistent with the federal Health Insurance Portability and Accountability Act (HIPAA), we are asking your permission to receive, use and share that information.

<u>What protected health information is collected and used in this study, and might also be shared with others?</u>

As part of this research project, the research team at the hospital(s) involved in the research will collect your name, address, telephone number, e-mail address, social security number, sex, information on recent hospital visits or admissions, medical record number, health plan account number, date of injury,

and dates of birth and death. The researchers will also collect contact information (name, address, phone number, email) of alternate contacts who may know how to reach you (emergency contacts, next of kin, other friends or family).

The researchers will also get information from your medical record from your private doctor, Emergency Department visits, or any other visit you have made to a Mount Sinai Health System clinician.

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 interviews, covering: your functioning, well-being, activities, health problems, health and rehabilitation services received, equipment used, work status, and earnings
- reviewing results of your physical examinations that generally also include blood pressure readings, heart rate, breathing rate and temperature
- completing the questionnaires and interviews explained in the description section of this consent
- Sharing your protected health information with the Social Security Administration and the U.S. Department of Labor.

Why is your protected health information being used?

Your personal contact information is important to be able to contact you during the study. Your health information and the results of any tests and procedures being collected as part of this research study will be used for the purpose of this study as explained earlier in this consent form. The results of this study could be published or presented at scientific meetings, lectures, or other events, but would not include any information that would let others know who you are, unless you give separate permission to do so. Your personal information including your full name, date of birth, and social security number will be shared with the Social Security Administration and the U.S. Department of Labor in order to determine how income and benefits have been affected by COVID-19 pandemic.

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. If the research team uncovers abuse, neglect, or reportable diseases, this information may be disclosed to appropriate authorities.

Who, outside Mount Sinai, might receive your protected health information?

As part of the study, the Principal Investigator, study team and others in the Mount Sinai workforce may disclose your protected health information, 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 Principal Investigator):

- The Social Security Administration and the U.S. Department of Labor.
- The United States Department of Health and Human Services and the Office of Human Research Protection.

In all disclosures outside of Mount Sinai except as noted above, 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 Principal Investigator 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 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, the Office of Human Subjects Protection (OHRP) of the Department of Health and Human Services 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. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

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

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

Do you need to give us permission to obtain, use or share your health information?
NO! If you decide not to let us obtain, use or share your health information 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?
You may withdraw your permission for the use and disclosure of any of your protected information for research, but you must do so in writing to the Principal Investigator at the address on the first page. Even if you withdraw your permission, the Principal Investigator for the research study may still use your protected information that was already collected if that information is necessary to complete the study. Your health information may still be used or shared after you withdraw your authorization if you should have an adverse event (a bad effect) from being in the study. If you withdraw your permission to use your protected health information for research that means you will also be withdrawn from the research study, but standard medical care and any other benefits to which you are entitled will not be

affected. You can also tell us you want to withdraw from the research study at any time without canceling the Authorization to use your data.

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 protected health information.

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, even if your information will no longer be protected by federal regulations, where possible, Mount Sinai has entered into agreements with those who will receive your information to continue to protect your confidentiality.

If as part of this research project your medical records are being reviewed, or a medical history is being taken, it is possible that HIV-related information may be revealed to the researchers. If that is the case, the following information concerns you. If this research does not involve any review of medical records or questions about your medical history or conditions, then the following section may be ignored.

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.

ADULT PARTICIPANT:

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

_____	_____	_____	_____
Signature of subject	Printed Name of Subject	Date	Time

PERSON EXPLAINING STUDY AND OBTAINING CONSENT:

_____	_____	_____	_____
Signature of consent delegate	Printed Name of consent delegate	Date	Time

WITNESS SECTION:

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

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

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