STUDY INFORMATION:

Study Title: Expanded Access to Convalescent Plasma for the Treatment of Patients with COVID-19

Mount Sinai Treating Physician-Investigator: Nicole Bouvier, MD

Mailing Address: One Gustave L. Levy Place, Box 1124, New York, NY 10029

Phone: (212) 241-1956

Please read this information carefully. It tells you important things about this program for use of the investigational product, Convalescent Plasma, for patients with COVID-19. A member of the clinical staff will talk to you about taking part in this program. If you have questions at any time, please ask us.

Feel free to discuss the program with your family, friends, and healthcare provider before you make your decision. *NOTE:* If you are a family member or legally authorized representative (LAR) signing this consent form for someone else, "you" in the consent form refers to the patient with COVID-19.

If you decide to take part in this program, you will sign this consent form to show that you want to take part. We will give you a copy of this form to keep. A copy of this form will be put in your medical record.

Why are you being asked to take part in this program?

You have been diagnosed with disease caused by the SARS-CoV-2 also known as coronavirus disease 2019 (COVID-19). SARS-CoV-2 is transmitted in a manner similar to influenza and other respiratory virus and has been associated with cough, fever, and shortness of breath, and in more severe cases, failure of the ability to breathe, or even death. Currently, we don't have any approved medicines or vaccines to treat or prevent COVID-19.

People who recover from COVID-19 do so, at least in part, because their blood contains substances called antibodies, which are capable of fighting the virus that causes the illness. It turns out that for some other diseases caused by respiratory viruses, giving people the liquid portion of blood, called plasma, obtained from those who have recovered from the virus, leads to more rapid improvement of the disease. We think that patients with COVID-19 may improve faster if they receive plasma from those who have recovered from COVID-19, because it may have the ability to fight the virus that causes COVID-19.

We are asking you to consider receiving plasma from someone who has recovered from COVID-19. Their plasma will have substances that could improve your chances of recovery.

We do not know if this treatment will or will not help you, and we don't know if it will have any harmful effects either. This is one of the only treatments that we have at present, but you need to know that it has not yet been proven to work. Because we do not have other better treatment options at present, if you are willing, we would like to try this treatment out, and learn from the testing.

What will happen to you while you are in this program?

You will be given plasma, the liquid portion of the blood, from a person who has recovered from COVID-19 that is compatible with your blood type. It will be given into one of your veins, using a sterile single use needle, and will be given over the course of about one to two hours. About 200 mL of plasma will be given in an initial infusion. Additional infusions of plasma may occur throughout your hospital stay if the treating physician determines that additional treatments are clinically justified.

Because this therapy has not yet been tested, and you want to try this new therapy, we would like to learn as much as possible about its effects. We will therefore record some information about your response to the treatment, such as how long you needed to stay in the hospital or needed help with breathing.

What are the possible risks or discomforts from being in this program?

Blood and plasma have been used for many other conditions, and in general are very safe. Although the risk of contracting COVID-19 infection from receiving the treatment has not been formally tested yet, we believe that it would be very low because the donor has fully recovered from the infection. Transfusion also carries the risk of adverse reactions such as allergic reactions, transfusion-associated circulatory overload or lung damage with profound breathing difficulty, and transmission of infections including HIV and Hepatitis B and C; although the risk of these infections is very low, as only screened and compatible blood is used for transfusion. The risks to pregnancy are unknown. You may have other side effects that are not known at this time and may include serious injury or pain, disability or death. There is also a chance that confidentiality of your private information could be lost; however, procedures are in place to minimize this risk.

Can I change my mind after I say "Yes"?

Taking part in this program is voluntary. You can change your mind at any time. If you wish to stop the treatment, just tell your doctor. Your decision will not stop you from getting the usual care that all patients receive at this center.

What are the possible benefits from being in this program?

We do not know if convalescent plasma will be an effective treatment for COVID-19, and you might not experience any benefit. However, we believe that this treatment might be effective in improving the likelihood of you recovering from the disease.

Do you have other choices?

You can choose to get this treatment or not. Your choice will not affect the care that you are receiving at this center. We will always do our best to take care of you. If you agree to this treatment, you will also be helping us learn whether the treatment works and how it works to help other patients, though you can withdraw at any time.

What tests or procedures will you need to pay for if you take part in this program?

You will not need to pay for the convalescent plasma. However, you and/or your insurance will need to pay for all other tests and procedures that you would have as part of your clinical care, including co-payments and deductibles. You will have to pay for any costs not covered by your insurance.

What if you are injured during this program?

If you are injured or made sick from taking part in this investigational treatment program, medical care will be provided. 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 study doctor for more information.

Who can I contact if I have questions?

If you have any questions, concerns, or complaints at any time about this investigational treatment program, or you think the treatment program has hurt you, please contact:

- Nicole Bouvier, MD, Mount Sinai Treating Physician-Investigator
  - Phone number: (212) 241-1956
- Michael Joyner, MD, Mayo Clinic Principal Clinician/Physician
  - Phone number: (507) 225-7197
  - Institution name and address:
    Mayo Clinic Hospital, St. Mary's Campus
    4-184 Joseph
    1216 Second Street SW
    Rochester, MN 55905

If you have questions about the study, you may also contact the Convalescent Plasma Expanded Access Program Hotline at Mount Sinai at 516-231-4320.

If you experience an emergency during your participation in this treatment program, contact 911 or go to the emergency room.

This investigational treatment program has been reviewed and approved by the Mayo Clinic Institutional Review Board (IRB). Mount Sinai IRB will assist in the local oversight of the program.

You may reach an IRB representative for any of the following reasons at the phone numbers listed below:

- Your questions, concerns, or complaints are not being answered by the Treating Physician-Investigator.
- You cannot reach the Treating Physician-Investigator.
- You are not comfortable talking to the Treating Physician-Investigator.
- You have questions about your rights as a subject of this treatment program.
- You want to get information or provide input about this treatment program.
- **Program for Protection of Human Subjects at The Icahn School of Medicine at Mount Sinai**

- Phone number (212) 824-8200

- **Mayo Clinic Institutional Review Board**
  - Phone number: (507) 266-4000
  - Toll-free number: (866) 273-4681

How will your privacy and the confidentiality of your information be protected?

The Mayo Clinic and Dr. Joyner will use medical information collected or created as part of your medical care, such as medical records and test results that identify you by name or in another way that they request from your physicians and other health care providers. Your medical information will also be shared with appropriate regulatory authorities, including the U.S. Food and Drug Administration (FDA). The Mount Sinai and Mayo IRBs, responsible for overseeing research on human subjects and investigational treatment protocols, and the Food and Drug Administration will be granted direct access to your medical records for verification of the treatment procedures and data, if necessary. FDA is authorized to remove information with identifiers if necessary to complete their task. By signing this document you are authorizing this access. Additionally, all the information or data collected about you to help understand if the therapy is effective will be kept confidential and only be used by the recipients listed here to better understand COVID-19 and its potential treatment(s) and for regulatory oversight of this program. If the treatment team uncovers abuse, neglect, or reportable diseases, this information may be disclosed to appropriate authorities.

By signing this form, you give permission to your medical provider to disclose your medical information as described in this form. This permission lasts until the end of the program. Recipients of your medical information may not be subject to federal privacy laws, and your medical information may no longer be protected by federal privacy laws after disclosure. You may take back this permission at any time by telling your doctor. No new medical information will be collected from you after you take back your permission, but any medical information that was already collected will continue to be used and shared as needed for the scientific integrity of the program.

If as part of this treatment program 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 Treating Physician-Investigator. If that is the case, the information in the following section concerns you.

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.

SIGNATURE BLOCK FOR ADULT PATIENT:

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 Patient

_____ _____ _____
Printed Name of Patient Date Time

SIGNATURE BLOCK FOR ADULT UNABLE TO CONSENT:

Your signature below documents your permission for the Patient named below to take part in this program and to the use and disclosure of the patient's protected health information. A signed and dated copy will be given to you.

_____
Printed Name of Patient

_____ _____ _____ _____
Signature of Authorized Representative | Printed Name of Authorized Representative | Date | Time

PERSON EXPLAINING PROGRAM AND OBTAINING CONSENT:

I have explained the program to the patient/authorized representative and have answered all questions about this program to the best of my ability.

_____
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 patient (or their LAR), and that consent was freely given by the patient (or their LAR).

----------FOR IRB USE ONLY----------

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