EXPERIMENTAL SUBJECTS BILL OF RIGHTS

You have been asked to participate as a subject in an experimental procedure. Before you decide whether you want to participate in the experimental procedure, you have a right to:

(a) Be informed of the nature and purpose of the experiment;

(b) Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;

(c) Be given a description of any discomforts and risks reasonably to be expected from your participation in the experiment;

(d) Be given an explanation of any benefits reasonably to be expected from your participation in the experiment;

(e) Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to you, and their relative risks and benefits;

(f) Be informed of the avenues of medical treatment, if any, available to you after the experimental procedure if complications arise;

(g) Be given an opportunity to ask any questions concerning the medical experiment or the procedures involved;

(h) Be instructed that consent to participate in the experimental procedure may be withdrawn at any time and that you may discontinue participation in the medical experiment without prejudice;

(i) Be given a copy of this form and the signed and dated written consent form;

and

(j) Be given the opportunity to decide to consent or not to consent to the medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on your decision.

SIGNATURE OF PARTICIPANT OR LEGALLY AUTHORIZED REPRESENTATIVE	**PRINTED NAME**	**DATE**

Cover Sheet for "Expanded Access to Convalescent Plasma for the Treatment of Patients with COVID-19"

Local Principal Investigator: John Stephan, Sharp HealthCare

Treating Physician: _____
Phone number:_____

Local Institutional Review Board (IRB): Sharp HealthCare IRB
7930 Frost Street, Suite 300
San Diego, CA 92123
(858) 939-7195 or (858) 939-7161

If you get sick or hurt in this study, please tell your treating physician right away. You will receive immediate treatment if an injury results because of your participation in this study. If you are injured as a result of this study, you or your insurance will be responsible for the costs associated with your care.

By signing this consent, you have not waived any of your legal rights.

Sharp HealthCare will not provide any compensation to you in the event you sustain a research related injury while participating in this study. You or your insurer will be billed for any additional costs. The hospital staff can provide more information.

Authorization to Use your Protected Health Information (PHI)

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

Protected Health Information: PHI is any personal health information through which you can be identified. We are asking for your permission to use your PHI in this research study. The information we may use includes your name, date of birth, medical history, medical record number, information about your hospitalization, and test results.

Who will access, use, or disclose your PHI?

- Your Treating Physician and the Staff at Sharp HealthCare
- The Local Principal Investigator, John Stephan
- Sharp HealthCare Research Staff

Who will see your PHI?

Representatives of:

- The Mayo Clinic and researchers working on the study
- Health care providers or vendors who provide services to you in connection with this study
- Sharp HealthCare Institutional Review Board
- The Mayo Clinic Institutional Review Board
- US Food and Drug Administration (FDA)

How long will we use and share your information, and what will it be used for?

The information noted above will be used to collect data that is specific to this study. The information will be kept until December 31, 2035. The use and sharing will only be for the purposes described in the Informed Consent Form and this Protected Heath Information Authorization Form.

After disclosure by the research staff, your information leaves the control of Sharp HealthCare. That means that your Protected Health Information may be shared with other entities and may no longer be protected by the privacy laws and regulations that protect such information normally.

You may change your mind and revoke (take back) this authorization at any time.

If you decide not to share your PHI anymore:
You must write to the local principal investigator and tell him that you no longer want to share your information. Write to the local principal investigator at:

John Stephan, Sharp HealthCare
7930 Frost Street, Suite 300
San Diego, CA 92123

You will still get the same medical care that you have always had from Sharp HealthCare.

The research team can continue to use any of the PHI that they already have.

If you revoke this authorization, no one at Sharp HealthCare or the researchers will be able to further use or disclose your protected health information from this study, except to the extent that they have already relied on this information to conduct the study.

Your revocation will terminate your eligibility to continue participating in the study, but will not otherwise affect the care that you may receive in the future from Sharp HealthCare or the participating providers.

Do you have the right to see and receive a copy of your research information?
You can see your research information if it is also being used for your health care. You might not be able to review or receive your records related to the study until the study has been completed.

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Authorization:

If you agree to share your PHI, you must sign this form below. If you do not sign this form, you will not be able to participate in the research study. You will be given an electronic copy of this form. You may request a printed copy of this signed form to be mailed to your home address.

SIGNATURE OF PARTICIPANT PRINTED NAME DATE

OR

SIGNATURE OF PARTICIPANT'S LEGALLY AUTHORIZED REPRESENTATIVE (IF APPLICABLE) PRINTED NAME DATE

AUTHORITY OF LEGALLY AUTHORIZED REPRESENTATIVE OR RELATIONSHIP TO PARTICIPANT

December 31, 2035
EXPIRATION DATE

MAYO CLINIC

Approval Date: June 26, 2020 **Not to be used after: March 31, 2021**

EXPANDED ACCESS PROGRAM
PATIENT CONSENT AND PRIVACY AUTHORIZATION FORM

Title: Expanded Access to Convalescent Plasma for the Treatment of Patients with COVID-19
IRB#: 20-003312 **Clinical Staff:** Michael Joyner, M.D.

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.

You can contact …	**At …**	**If you have questions about …**
Principal Clinician/Physician: Michael Joyner, M.D.	**Phone:** (507) 255-7197 **Institution Name and Address:** Mayo Clinic Hospital, Saint Marys Campus 4-184 Joseph 1216 Second Street SW Rochester, Minnesota 55905	▪ Tests and procedures ▪ Injuries or emergencies ▪ Any concerns or complaints ▪ Withdrawing from the program ▪ Materials you receive ▪ Appointments
Mayo Clinic Institutional Review Board (IRB)	**Phone:** (507) 266-4000 **Toll-Free:** (866) 273-4681	▪ Rights of a program participant ▪ Any program-related concerns or complaints ▪ Use of your Protected Health Information

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 breath, 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. Approximately 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, cardiac (heart) rhythm irregularities, blood clotting, 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.

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). 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.

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.

Your signature documents permission for you (or the patient) to take part in this program.

_____
Printed Name of Patient

_____ / / : AM/PM
Signature (Patient or Authorized Representative) Date Time

Person 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.

_____ / / : AM/PM
Printed Name Date Time

_____
Signature