HAWAIʻI PACIFIC HEALTH | KAPIʻOLANI PALI MOMI STRAUB WILCOX

EXPANDED ACCESS PROGRAM
PATIENT CONSENT AND PRIVACY AUTHORIZATION FORM

Title of Study:	Expanded Access to Convalescent Plasma for the Treatment of Patients with COVID-19
Study #:	20-003312
Research Medical Director:	Wade Kyono, MD
24-hour Contact Numbers:	Kapiʻolani Medical Center: 808-983-6000 Pali Momi Medical Center: 808-486-6000 Straub Medical Center: 808-522-4000 Wilcox Medical Center: 808-245-1100

This form contains information about the program you are being asked to participate in for an investigational treatment for patients with COVID-19. ***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 are signing this consent form on behalf of someone else, please indicate your relationship to the patient.

_____

Your medical records will be reviewed if you decide to participate in this study. Your medical records may contain information about AIDS or HIV infection, venereal disease, treatment for alcohol and/or drug abuse, or mental health or psychiatric services and the research team may have access to that information.

If you no longer want to allow access to your medical information you must put your request in writing and provide it to your doctor.

No financial compensation or coverage will be routinely provided by the program or doctor. If you require treatment for any injury or illness related to procedures required by the program, or if you suffer side effects while in the program, you should contact your doctor, who will provide any necessary medical care and advice. The cost of this medical care and advice will be billed to you or your medical insurance in the usual manner.

By signing this consent form, you will not give up any legal rights.

You have the right to refuse to sign this consent and authorization form. However, by refusing to sign, you cannot participate in this program and you may not receive program-related treatment.

You will receive a signed copy of this form.

MAYO CLINIC

Approval Date: May 20, 2020 **Not to be used after: March 31, 2021**

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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, 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