PATIENT CONSENT FOR TREATMENT WITH INVESTIGATIONAL COVID-19 CONVALESCENT PLASMA AND PRIVACY AUTHORIZATION FORM

Consent for the transfusion of investigational COVID-19 convalescent plasma for treatment of patients with COVID-19

Please read this information carefully. It tells you important things about the use of investigational COVID-19 convalescent plasma as a treatment for patients with COVID-19. A member of the clinical staff will talk to you about the risks and benefits of receiving a transfusion with investigational COVID-19 convalescent plasma, as well as about any other available options. If you have questions at any time, please ask your clinical team.

Feel free to discuss investigational COVID-19 convalescent plasma with your family, friends and healthcare provider before you make decisions about treatment. If you decide to say yes to receiving investigational COVID-19 convalescent plasma, please sign this consent form to indicate that you want this investigational treatment.

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.

What is COVID-19?

Coronavirus disease 2019 is also called COVID-19. COVID-19 is caused by the SARS-CoV-2 virus. SARS-CoV-2 is transmitted in a manner similar to influenza and other respiratory viruses.

What is investigational COVID-19 Convalescent Plasma?

Plasma is the liquid portion of the blood. After an infection, a person’s plasma has infection-fighting antibodies; this is called convalescent plasma. The use of convalescent plasma as a treatment for some infectious diseases dates to the late 1800s, and has been shown to lead to more rapid improvement in some patients.

People who recover from COVID-19 do so, at least in part, because their blood develops antibodies, which are capable of fighting the virus that causes the illness. Plasma with antibodies to the SARS-CoV-2 virus donated after a person recovers is called COVID-19 convalescent plasma. The donor of investigational COVID-19 convalescent plasma must be completely recovered from COVID-19 and must be evaluated on the day of donation and found to be healthy. The donor must meet all applicable safety criteria before donation and undergoes the same infectious disease testing required of all blood donors, including testing for HIV, Hepatitis B, Hepatitis C and other diseases. This is considered investigational because COVID-19 convalescent plasma is still being studied and is not licensed by FDA.

Do patients need investigational COVID-19 convalescent plasma?

You have been diagnosed with COVID-19, caused by the SARS-CoV-2 virus which can lead to cough, fever, shortness of breath and, in more severe cases, failure of the ability to breath, or even death. Currently, there are no FDA-approved medicines or vaccines to treat or prevent COVID-19.

You are being asked to consider treatment with investigational COVID-19 convalescent plasma from someone who has recovered from COVID-19 because their plasma will have antibodies capable of fighting the virus, which could improve your likelihood of recovery. Investigational COVID-19 convalescent plasma is not licensed by FDA because there is not enough evidence to show it is effective in the treatment of COVID-19. There is no certainty that this investigational treatment will or will not help you; the risk for potential side effects is not well known either. Investigational COVID-19 convalescent plasma is one of the only treatments available for patients with COVID-19 at present and is approved by FDA for investigational use.

What will happen during the transfusion?
You will be given investigational COVID-19 convalescent plasma that is compatible with your blood type. It will be administered via 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.

What are the possible risks or discomforts from transfusion with Investigational Convalescent Plasma?
Blood and plasma transfusions are used as treatments for many other conditions, and have been proven to be generally safe, with some of the most common risks explained below. One risk is contracting the COVID-19 infection from receiving the treatment. This risk has not been formally tested yet, although evidence indicates the risk would be very low because the donor must be fully recovered from the infection and healthy on the day of donation. The risk is also believed to be low because there have been no reports of the virus being transmitted by plasma transfusion during this pandemic.

Transfusion 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 compatible blood that meets all safety criteria 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"?
Treatment with investigational COVID-19 convalescent plasma 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 this transfusion?
We do not know if investigational convalescent plasma will be an effective treatment for COVID-19 because it is still being studied. You might not experience any benefit. However, experts believe that this treatment might be effective in improving your chances of recovering from this disease.

Do I have other choices?
Currently, there are no drugs or other therapeutics approved by the FDA to prevent or treat COVID-19 infection. Like investigational COVID-19 convalescent plasma, FDA may allow for the use of other investigational medicines to treat people in the hospital with COVID-19. You can choose to get this treatment or not. Your choice will not affect the care that you are receiving at this center. Your healthcare providers will do their best to take care of you.

By signing this form, you acknowledge that you understand the risks and benefits of receiving investigational COVID-19 convalescent plasma.

Your signature documents permission for you (or the patient) to receive investigational COVID-19 convalescent plasma.

Printed Name of Patient

_____

Signature (Patient or Authorized Representative):

_____

Date: _____/_____/ _____ Time: _____ AM/PM

Person Obtaining Consent
I have explained the investigational treatment to the patient/authorized representative and have answered all questions about this investigational treatment to the best of my ability.

Printed Name_____

Signature _____ _____

Date: _____/_____/ _____ Time: _____ AM/PM

NOTE: This Sample Form is provided by AABB for illustrative purposes only and is not intended for use "as is." Please consult with your institution's legal counsel to ensure compliance with applicable laws, regulations, and internal policies.