Northwestern Medicine®

PATIENT LABEL

CONSENT FOR INVESTIGATIONAL COVID-19 CONVALESCENT PLASMA TRANSFUSION

COVID-19 convalescent plasma is the liquid portion of blood collected from persons who have recovered from COVID-19. It may contain substances called antibodies which are capable of fighting the virus that causes COVID-19.

I understand that the COVID-19 convalescent plasma transfusion discussed in this consent is an investigational treatment for COVID-19. This investigational treatment has not been approved by the US Food and Drug Administration (FDA). The investigational COVID-19 convalescent plasma was collected by a registered blood establishment. The investigational COVID-19 convalescent plasma is being offered under a temporary exception provided by the FDA in its Guidance on Investigational COVID-19 Convalescent Plasma dated September 2, 2020. I also understand that, currently, only the drug remdesivir is FDA approved for treatment of COVID-19 in hospitalized patients.

I authorize Dr. _____ at Northwestern Medicine, and his/her staff/assistants to administer investigational COVID-19 convalescent plasma to me, based on their judgement of the potential benefit given my individual needs. The alternatives and risks of investigational COVID-19 convalescent plasma, and the alternatives and risks of not receiving investigational COVID-19 convalescent plasma, have been explained to me.

A **possible benefit** of receiving investigational COVID-19 convalescent plasma is that you may improve more quickly from your COVID-19 disease. However, there is limited data to determine if investigational COVID-19 convalescent plasma will be an effective treatment for COVID-19, and I understand that I might not experience any benefit from receiving investigational COVID-19 convalescent plasma.

Possible side effects include risks generally associated with transfusions, including 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 blood is used for transfusion. The risk of contracting COVID-19 infection from receiving investigational COVID-19 convalescent plasma has not been formally tested yet, but is thought to be very low because the plasma donor has fully recovered from the infection. You may have other side effects that are not known at this time and may include serious injury or pain, disability, or death. It is your choice to accept treatment with COVID-19 convalescent plasma or stop it at any time.

I have read and understand the above and my questions have been answered. I consent to receiving a transfusion of investigational COVID-19 convalescent plasma.

Time _____ ☐ am ☐ pm Date ____/____/_____

Patient Signature (Patient or Authorized Representative) _____

Time _____ ☐ am ☐ pm Date ____/____/_____

Physician Signature _____