

Addendum to standard institutional Blood Transfusion Consent for (insert study number and title and to be printed on institutional letter head)

Instructions: This document must be signed in addition to the institutions standard blood transfusion consent and the consent for study protocol.

Purpose

This consent is to inform you of the additional minimal risk associated with receiving plasma collected from donors who have recovered from COVID-19 infection (Convalescent COVID-19 plasma).

Donor qualification for investigational plasma

Donors of Convalescent COVID-19 plasma have met all standard blood donor criteria and have been tested by approved tests for the virus that causes COVID-19 infection; and have been found to be negative for detectable virus and to have significant immunity to the virus.

Additional risk not described in accompanying consent for blood transfusion

There is a rare chance that, despite our best testing, there may be virus in the plasma that we did not find. We have minimized this risk by waiting at least 14 days after the donor has had their last symptoms and performing repeat testing and confirming that the test result is negative for the virus before collecting the plasma. Even in sickest patients, only 1% had virus detected in their blood.

Although there is no proven risk, there are two additional possible concerns when receiving Convalescent COVID-19 plasma. The first is that this plasma may slow down the rate at which your body clears the virus because it may change your natural immune response to the virus. The second concern is that there is a remote chance that there are substances in your blood that may interact with the study plasma and make you sicker.

I have read and understand the information on this page. I have asked my questions and am satisfied with the answers.

I consent to receiving Convalescent COVID-19 plasma.

Sign here:

Patient or representative signature

Date/Time

Relationship of representative of patient

Date/Time

Witness of signature

Date//Time

Investigator signature

Date/Time