Convalescent Plasma Transfusion Informed Consent Information

Updated November 2, 2020

The purpose of this document is to provide written information regarding the risks, benefits and alternatives of transfusion of Convalescent Plasma (kon-vuh-LES-unt PLAZ-muh). This information supplements the information you learn from your doctor. It is important that you fully understand this information, so please read this document thoroughly. If you have any questions regarding this therapeutic procedure, ask your doctor prior to signing the consent form.

Information about the Treatment

Reason for treatment (diagnosis, condition, or indication) and brief description
- You have been diagnosed with COVID-19, a disease caused by the new coronavirus SARS-CoV-2. Convalescent Plasma therapy uses blood donated from people who've recovered from COVID-19 to help others recover. Convalescent Plasma is the liquid part of blood collected from patients who have recovered from COVID-19. Blood donated by people who've recovered from COVID-19 has antibodies to the virus that causes it. The donated blood is processed to remove blood cells, leaving behind liquid (plasma) and antibodies. This plasma with antibodies can be given to people with COVID-19 to boost their ability to fight the virus. The U.S. Food and Drug Administration (FDA) authorized Convalescent Plasma therapy for people with COVID-19, but the therapy is considered investigational. The FDA is allowing its use under the emergency use authorization (EUA) during the pandemic because few options currently exist to treat COVID-19. You are receiving a non-emergency use authorization (EUA) compliant unit of plasma that was manufactured under the prior Emergency Access Protocol (EAP). The unit you are getting still has antibodies but there are requirements related to labeling from FDA that blood collection agencies are working on but not yet in place.
- You will receive the Convalescent Plasma through a needle inserted into your arm or hand. A central line may be used if you have one (used to give medicine, intravenous fluid, blood over a long period of time). Your doctor will decide on the right amount and type of Convalescent Plasma based on your medical condition and diagnosis. Receiving Convalescent Plasma can take approximately one to two hours depending on your specific condition and diagnosis.

Potential benefits of the treatment
- Convalescent plasma therapy may help people recover from COVID-19. It may lessen the severity or shorten the length of the disease.
- Recent research studies provide some encouraging, but not guaranteed, benefits to Convalescent Plasma therapy.
Risks and side effects of the treatment

- The use of Convalescent Plasma is investigational, which means more experience is needed before the FDA has enough information to approve it as safe and effective.
- Convalescent Plasma therapy has some potential risks, such as:
  - Allergic reactions
  - Lung damage and difficulty breathing
  - Infections such as HIV and hepatitis B and C
    - The risk of such infections is low. Donated Convalescent Plasma, as is true for all other blood products, are tested for safety to assure as much as possible it does not carry any infectious agents.
  - Some people may have mild complications or none at all. Other people may have severe or life-threatening complications.
  - Risk to pregnancy or nursing mothers is unknown.
  - 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.

Alternatives

- There may be other options besides getting a Convalescent Plasma transfusion. Other options include but not limited to:
  - Discussing with your doctor the possibility of participating in a research study that is looking at other investigational treatments; OR
  - The choice to refuse any treatment.
Informed Consent or Refuse to Receive Convalescent Plasma Products

By signing this form, I certify that I understand the risks, benefits, and alternatives to receiving a transfusion of Convalescent Plasma products. I have had a chance to ask questions, and my questions have been answered to my satisfaction. I understand that I can refuse or stop treatment at any time without harming my access to receive health care services when I need them. I understand that I may ask for, and be provided with, an interpreter.

☐ PROVIDER has informed me about convalescent plasma, and I am in receipt of the FACT sheet from the manufacturer.

Please check one box, then sign and date below:

☐ I GIVE MY INFORMED CONSENT to receiving the transfusion services described above.

☐ I REFUSE to receive the transfusion services described above.

A copy of the signed form will be maintained in your medical record.

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<th>Parent Legal Representative Name</th>
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Relationship of the person’s legal representative (parent/conservator/guardian)

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Interpreter ID Number