

CONSENT FORM FOR THE DONATION OF CONVALESCENT WHOLE BLOOD OR PLASMA TO TREAT COVID-19

1. General information about COVID-19 and convalescent whole blood or plasma for COVID-19 treatment.

COVID-19 is the infectious disease caused by the most recently discovered coronavirus. Currently, there is no known medicine or treatment that can prevent or cure COVID-19. However, individuals who have completely recovered from COVID-19 may have certain antibodies in their plasma (the liquid part of their blood), known as “convalescent plasma,” that can be used to treat individuals with serious or life-threatening COVID-19 infections. The Food and Drug Administration (FDA) has recently approved the transfusion of convalescent plasma as an investigational treatment for COVID-19 infections. This is currently the only antibody treatment available for COVID-19 patients.

Because you have fully recovered from COVID-19, we believe that patients who are currently ill with COVID-19 may improve faster if they received some of your blood or plasma. However, because this is an experimental treatment, we do not know this for sure and it is possible that a patient with COVID-19 may not recover, even after receiving blood from a person who has recovered from COVID-19. Convalescent plasma has been used in treatments of other diseases including polio, measles, SARS, and Ebola.

2. What are the eligibility requirements to donate convalescent whole blood or plasma for COVID-19 treatment?

In order to donate convalescent whole blood or plasma for COVID-19 we may first ask you to allow us to review your medical records from the health facility which treated you for COVID-19, to assess if you can safely donate blood or plasma.

You must also meet the following eligibility criteria:

- **A prior diagnosis of COVID-19** as documented by:
 - A diagnostic test (e.g. nasopharyngeal swab) taken at the time of illness, or;
 - A positive serological test for SARS-CoV-2 antibodies after recovery, if prior diagnostic testing was not performed at the time COVID-19 was suspected.
- **Complete resolution of your COVID-19 systems** as evidenced by:
 - Complete resolution of symptoms at least 28 days prior to donation; or
 - Complete resolution of symptoms at least 14 days prior to donation, AND negative results for COVID-19 either from one or more nasopharyngeal swab specimens or molecular diagnostic test from blood; or
 - Symptom free less than 14 days AND negative test results on different days.

3. What will happen if you agree to donate blood?

Testing your blood

If you agree to donate some blood or plasma for the treatment of COVID-19, we will ask you to come to the blood donation center and we will first take a small amount of your blood (about 10 mL) from a vein in your arm using a single use sterile syringe and needle and do some tests that will tell us the type of blood that you have and also whether your blood can be used for treatment of COVID-19. Even though you are volunteering to provide your blood, there may be various reasons why we may not be able to accept your blood donation. If, however, you are suitable to donate, we will arrange a suitable time for the donation.

Collection and storage of blood or plasma units

For the donation, we will ask you to come to the blood donation facility. We encourage you to eat a salty snack or meal the day before donation and drink 8 to 16 ounces of fluid 10 to 30 minutes before donating. Water or sports drinks are great choices. The nurse/doctor will then ask you to lie on a couch or a clinic bed. The inner area of one of your elbows will be cleaned with an antiseptic solution before a trained health worker inserts a sterile needle, connected to a blood bag, into your vein. The volume of blood taken will be about 350-450mL. It usually takes only about 10 minutes to donate a unit of blood.

If you are donating the plasma on a special machine, a trained health worker will put a small needle into a vein in your arm, through a sterile single use needle, after making that part of the arm numb. A small tube will be connected to a machine that will collect the liquid part of the blood into a separate bag, and return the red part of your blood back to your body. To stop the blood from clotting, a liquid, known as an anticoagulant, will be automatically mixed with the blood as it is pumped from the body into the machine. The trained health worker will collect about half a litre (e.g. small mineral water bottle) of plasma. This procedure will take about 45-60 minutes.

You will be given light refreshments after the procedure. After resting for about 15-30 minutes, you will be able to return to your normal activities, although you should avoid strenuous activities for the rest of the day. You should drink plenty of fluids over the next 24 hours. Your body will replace the lost fluid within about 36 hours.

After your donation

The blood that has been collected will be stored in a refrigerator with an identification number. If plasma has been collected or separated from your whole blood donation, it will also be stored in a refrigerator or freezer. It will not have your name on it. The remaining red cells may or may not be used. When there is a patient who is likely to benefit from the use of blood or plasma donated by you, it will be taken out from the stock, brought to room temperature, and then given to the patient through a vein. We will keep a close watch on the patient and record everything, so that we learn from the experience and know more about its use in the treatment of COVID-19.

4. Possible risks and discomforts

Taking blood from your arm may sometimes cause bruising, mild pain or discomfort and in very rare circumstances, infection. We will take all preventive measures to minimize these risks. Some

people may feel light-headed or little giddy, especially while donating plasma. This lasts for only a few minutes and quickly subsides.

5. Confidentiality

Any information that you provide and all test results will be treated confidentially. The medical staff who test your blood have the responsibility to inform you of all the blood test results, and to advise you on any treatment they think you will require.

6. Will I know who receives my blood?

A patient who is currently ill with COVID-19 may receive your blood. It may also be possible that people who are at high risk of contracting COVID-19 may receive your blood. It is difficult to predict who exactly will receive the blood that you donate. The person must have a compatible blood type to yours. Your name will not be on the blood or plasma you have donated, it will just be identified with a unique donation number. No one will know whose blood is being given to the patient. And you will not know who receives it either. But be assured that it will be used for a patient who requires it and all information about you and your donation will remain confidential.

7. Will the person who receives the blood know who has provided it?

No. No one, including the person who receives your blood, will know who has provided the blood. This is so that your privacy can be protected.

Be assured that the blood or plasma that we collect will be treated with respect.

8. Expenses and payments

There will be no charges to you for any cost related to this donation. There will be no payment for you to participate in this donation either.

9. Participation and withdrawal from donation

You are free to decide whether or not to donate blood or plasma. If you do not meet the donor suitability criteria, you will be immediately informed by the doctor in charge, [*insert applicable information for healthcare professional in charge*].

Once your blood and/or plasma has been collected, you can request that it is withdrawn at any time prior to it being transfused to a patient by informing the attending doctor.

You cannot request that your blood or plasma donation should not be used for transfusion once it has been given to a patient. Your decision to request the discard of your blood or plasma, if it has not been transfused, will not affect your future care.

10. Who to contact if you have any questions

If you have any questions, feel free to contact us at cmspresident@cmsdocs.org or call (877) CMS-DOCS (267-3627).

Your signature documents your permission for the donation.

Signature

Full name (please print)

Date