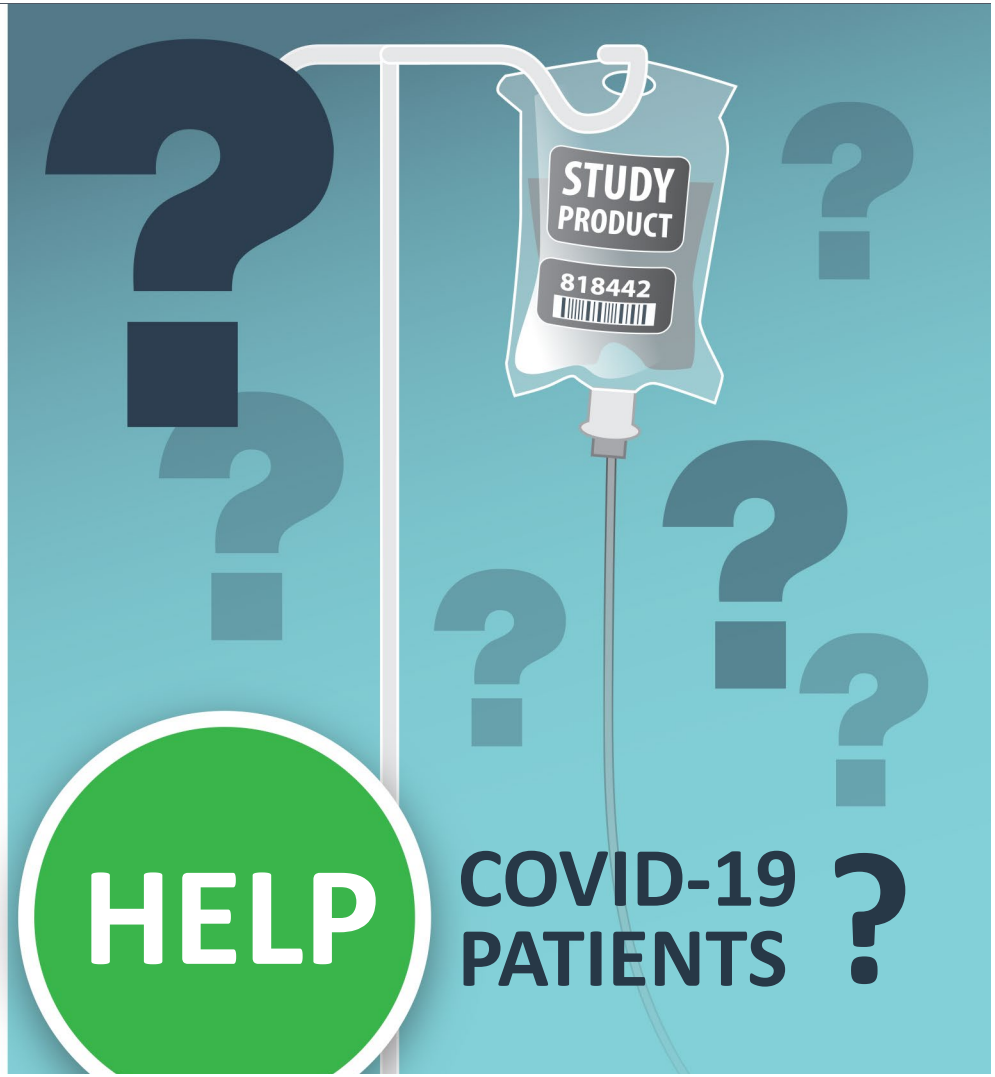
What you should know about this study

- You may be eligible if you have COVID-19 illness, your symptoms started within the past 7 days and your doctors plan to discharge you home from the emergency department.
- Please read the information about this study carefully. Take as much time as you need. You can also talk to your family and friends about the study. Ask the study team to explain any words or information that you do not understand.
- You are a volunteer. If you join the study, you can change your mind later. You can decide not to take part, or you can leave the study at any time.
- There will be no punishment or loss of benefits if you decide not to join or to leave the study. The medical care you are getting now will not change.

What is a clinical research study?

A clinical research study helps doctors test new ways to treat a disease. One way to do this is by studying new treatments, to see if they work to treat the disease. In a study, the treatments are “experimental,” which means they have not been proven to work. That is why studies are needed to find out if new treatments are safe and work in people.



What is this study about?

We are looking for new treatments for COVID-19. We are studying convalescent plasma to learn whether it can prevent people with milder COVID-19 illness from getting much sicker with COVID-19 and having fewer bad effects from the disease.

This study is taking place in several hospitals across the country. We expect to enroll about 600 people.

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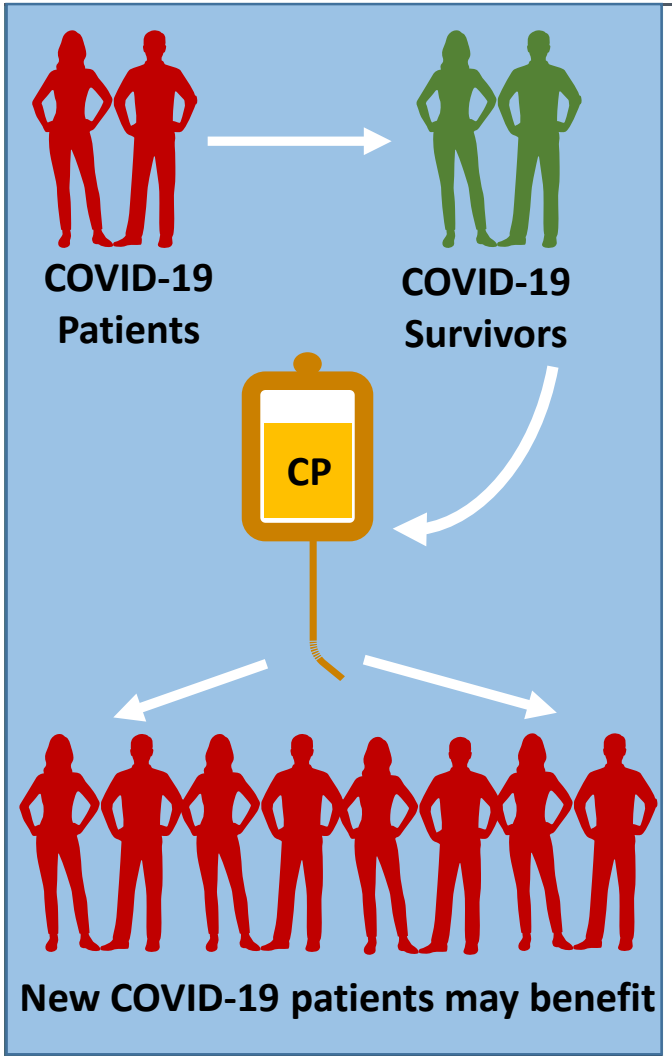

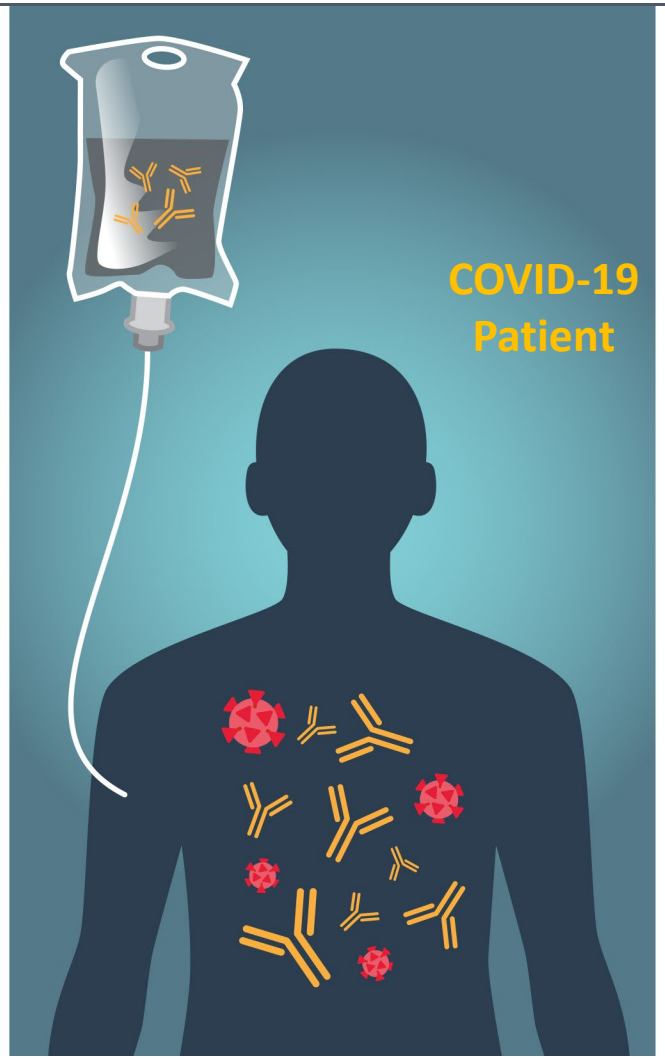

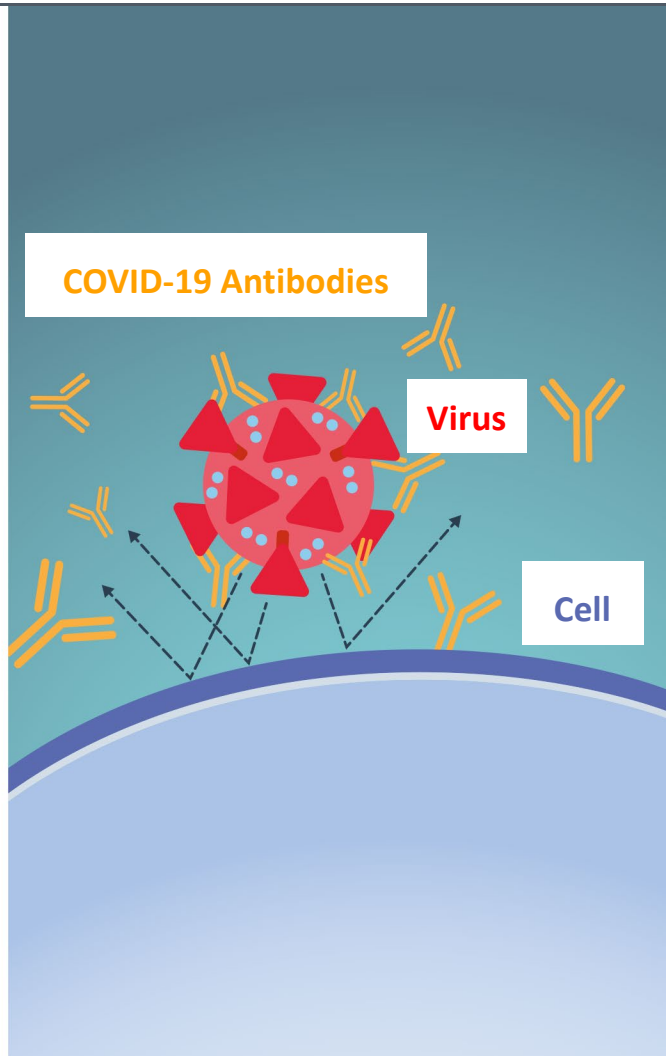

What drug is being studied?

We are studying a COVID-19 Convalescent Plasma (CP). We think it may work to help the body fight COVID-19. When germs, like the SARS-CoV-2 virus that causes COVID-19, enter your body, your immune system makes antibodies to fight them. CP is made from blood taken from persons who have recovered from COVID-19. Plasma is the clear yellow fluid part of blood and it contains antibodies that can fight the SARS-CoV-2 virus.

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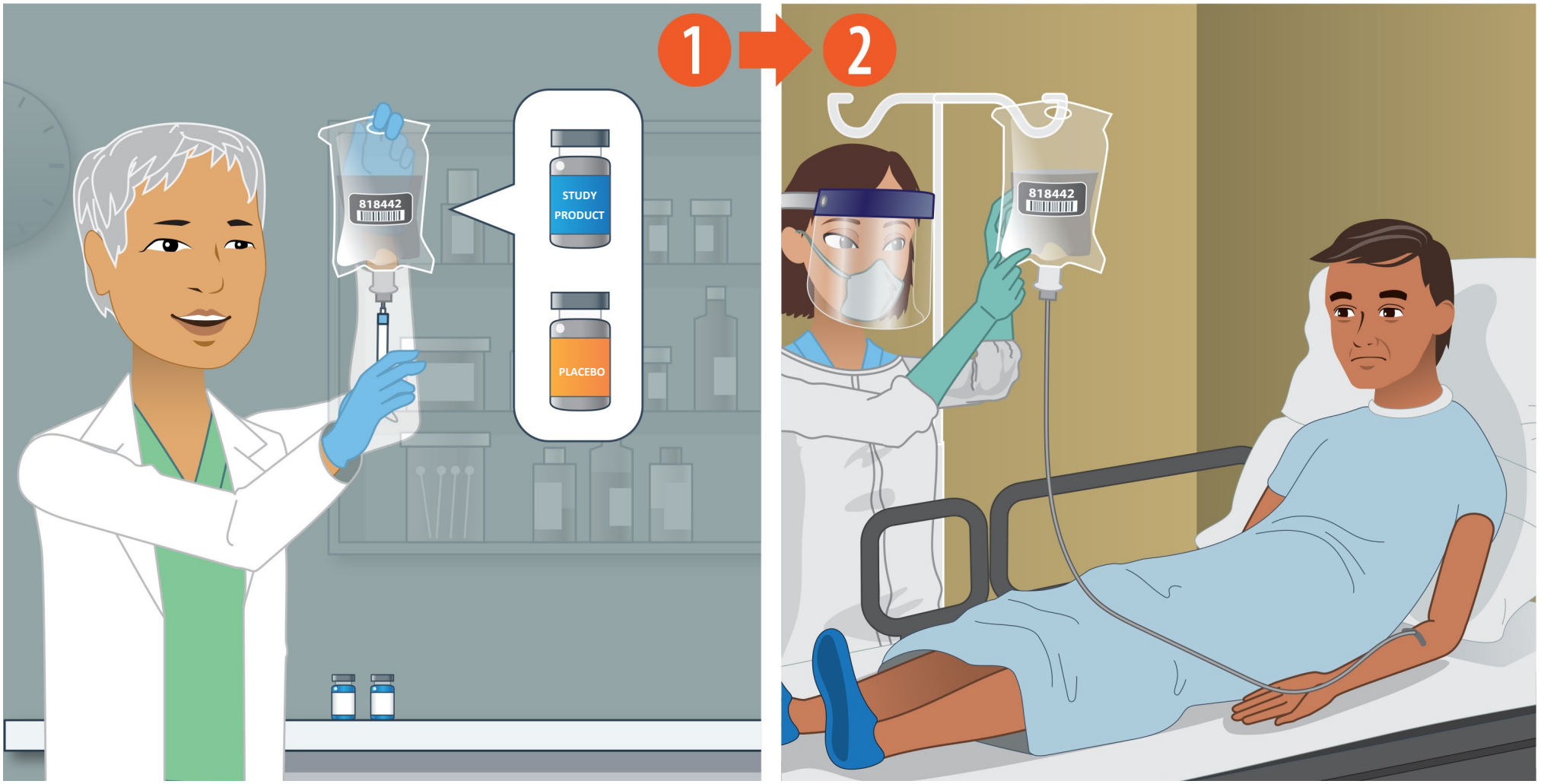
Does everyone in the study receive convalescent plasma?

Not everyone in the study will receive convalescent plasma (CP). Half the people in the study will receive a placebo. The placebo is a liquid that looks like CP but does not have antibodies in it. To find out if the study helps people get better sooner and is safe, we compare it to placebo. The placebo and the study drug are given as an infusion through a plastic tube in your arm.



Will you get convalescent plasma or placebo?

If you join the study, you will be randomly be put into either the placebo group or CP group. This is decided by chance. Out of every 2 people on this study, 1 will get CP and 1 will get placebo. You will not know whether you are receiving CP or the placebo. Your doctors may know but we have asked them not to tell you. We will also appreciate it if you don't try to find out. This will allow us to objectively compare how well those who receive CP do, compared to those who receive placebo.

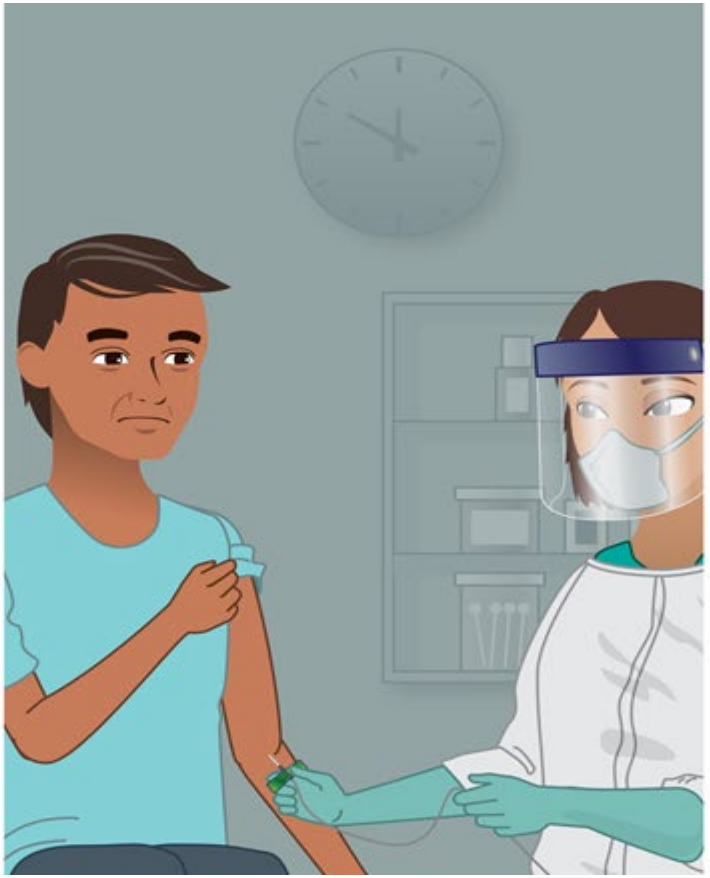
What happens if you agree to be in this study?

If you sign the consent form, it means that you agree to be in the study. You do not have to be in the study. If you do choose to join the study, you can change your mind at any time and leave the study. After you sign the consent, we will ask you questions about your medical history and when you became ill. We will also check your blood type and collect an additional sample of blood for future analysis.

What does the study involve?

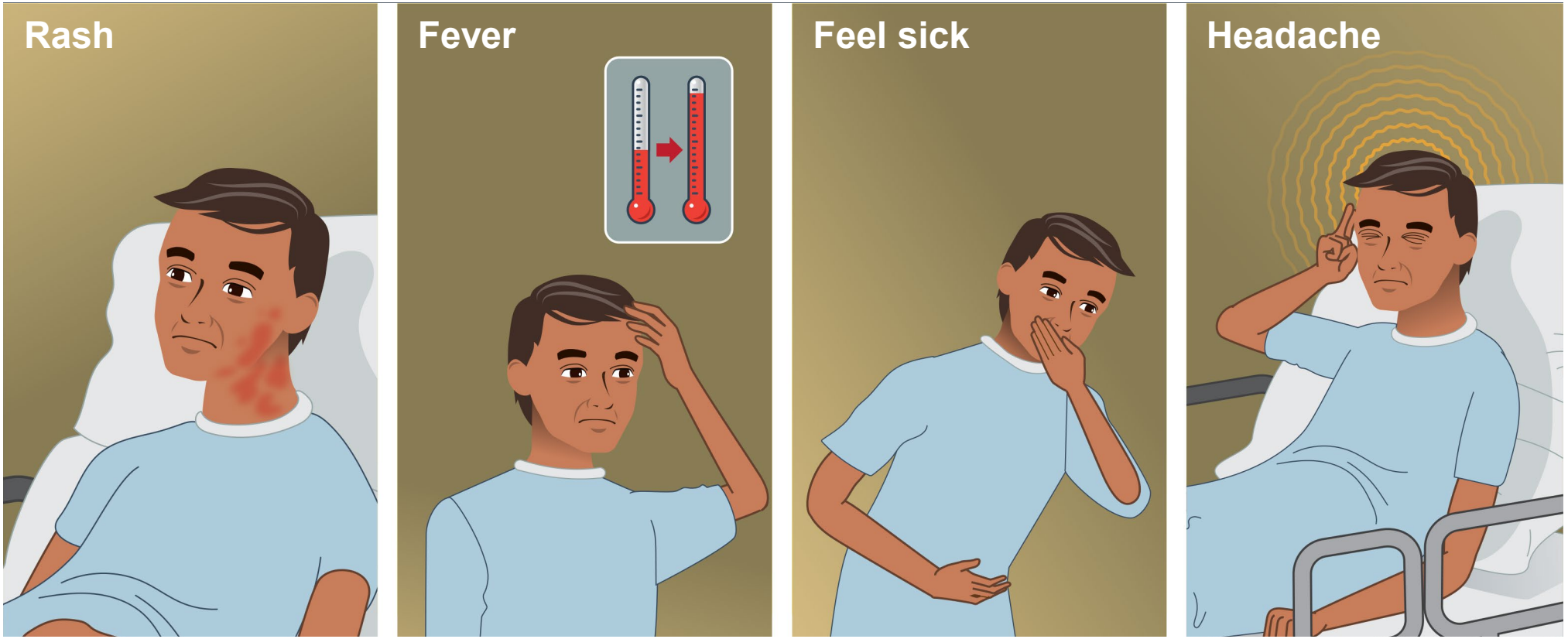
If you join the study, you will get one infusion of either the CP or the placebo at the beginning of the study. The infusion will take about 30 minutes. We will watch you closely for side effects during and for about 1 hour after the infusion. We will also collect another sample of blood to examine how well your immune system responds to the study treatment.

Any other medications or treatments you will be given will be what you would usually receive in this hospital for your condition.



What else will happen on this study?

You will be in the study for 30 days. Before you are discharged from the emergency department, we will collect your contact information so we can reach you. During the first 2 weeks following discharge, we will call you every other day to see how you are doing. You can also tell us how you are doing by completing an online survey (we will send you the link). We will also ask you to come back to the hospital at **15** and **30** days after you enter the study. During these visits, we will ask you questions about how you are feeling and collect blood samples to examine how your immune system is responding to the study treatment. If you are admitted to a hospital during the study period, we will collect information from your medical records to better understand why you were hospitalized. We will also review your medical records to see whether you have visited an emergency department or urgent care during the study period.



What could be the side effects from convalescent plasma?

There may be side effects from convalescent plasma (CP). These side-effects are uncommon. In a study of 5,000 patients with COVID-19 who were given CP, only 2 of those patients had complications that were due to CP, and none of those complications resulted in death.

Uncommon (1-5% chance) reactions to CP that usually are not dangerous are: Fever, Chills, Itching, Rash or hives, Headache, Bruising

Rare (less than a 1% chance) but more serious reactions to CP are: Kidney problems, Trouble breathing, Worsening of heart failure, allergic and other immune system reactions.

Very rare (less than 1 in 1,000,000) but possibly life threatening risks to CP are: Getting an infectious disease like hepatitis or HIV/AIDS or a bacterial infection, Blood clots, Lung injury, Death. These complications were not seen in a recent study of 5000 patients who received CP.

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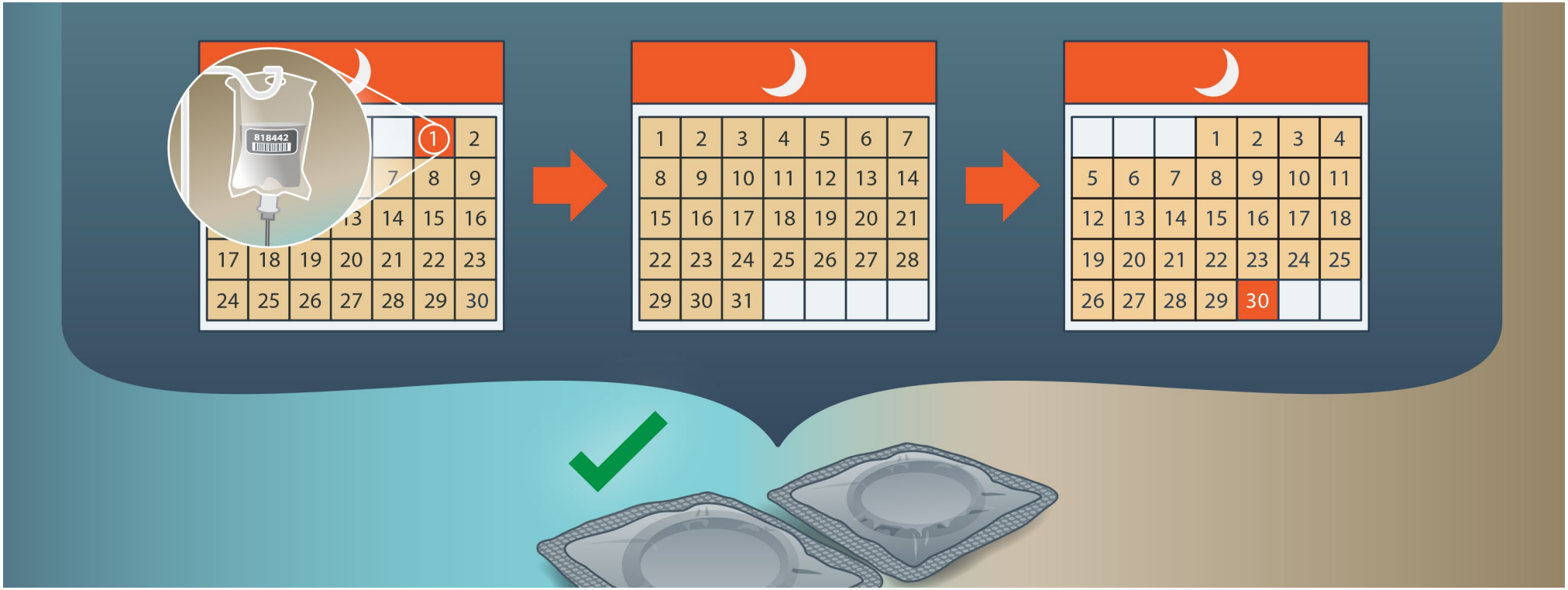
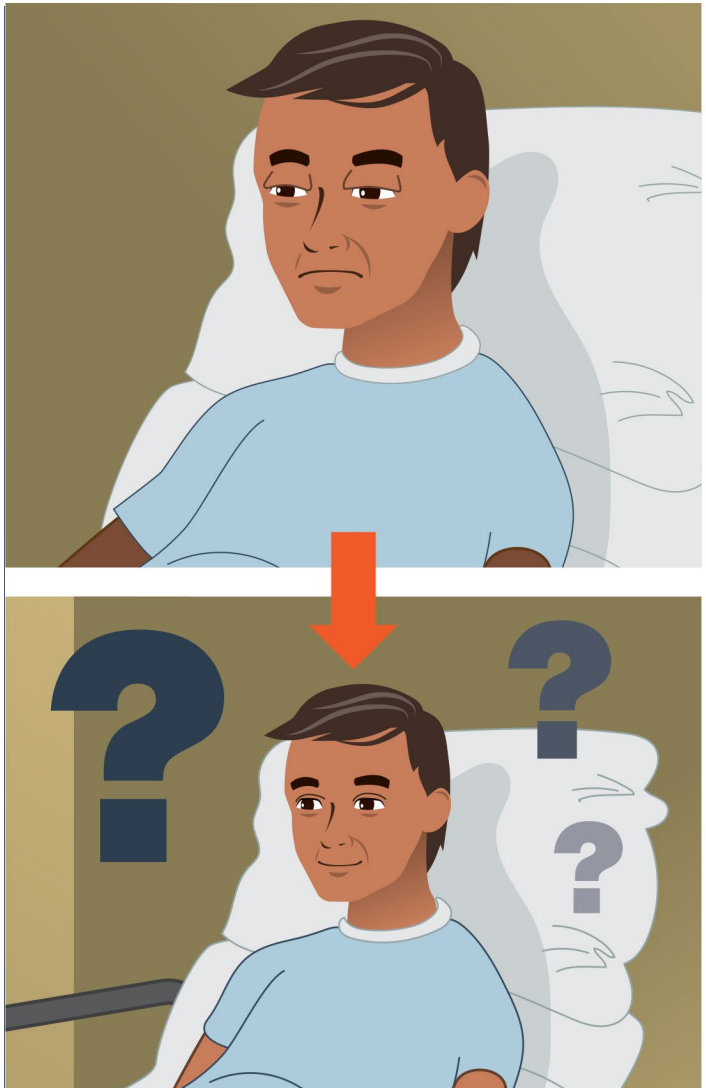
Are there any other risks related to this study?

The needle used to draw blood or place an IV line can hurt. You may get a bruise where the needle went in. Sometimes drawing blood causes people to feel lightheaded or even to faint. There is a very small risk of getting an infection where the needle went into the vein. This could be treated with antibiotics.



What do you need to know about pregnancy and breastfeeding during the study?

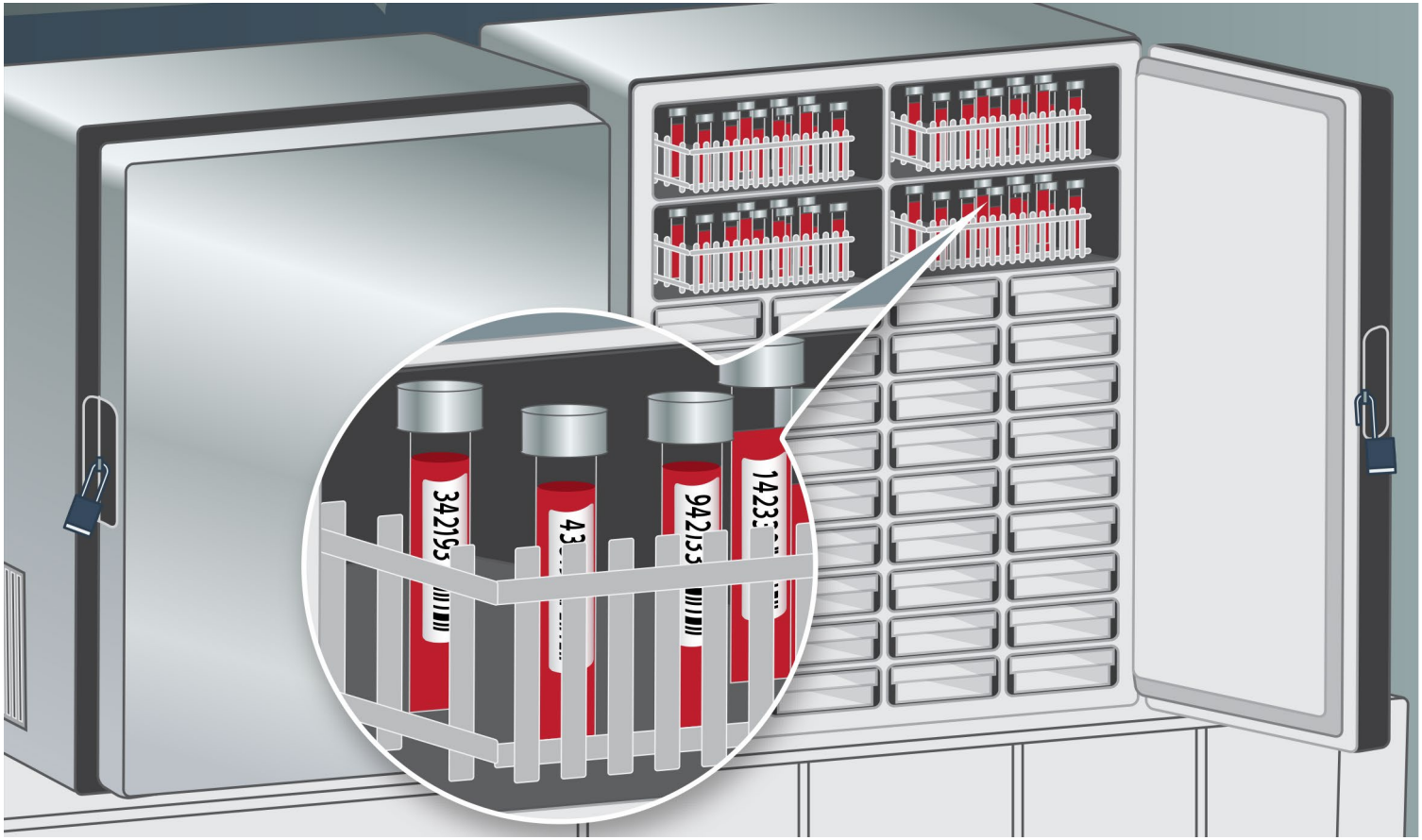
You can join this study even if you are pregnant or breastfeeding. There are no data to suggest that convalescent plasma poses any increased risk to pregnant participants or to breast feeding mothers or their children.



Are there benefits of being this study?

If you get convalescent plasma (CP) it may prevent you from developing severe COVID-19 illness, but we do not know that. CP may not be helpful, or it may have harmful side effects (see slide 10). It is important to remember that half of the people in this study will get placebo and will not get CP. If you get placebo, it will not help you.

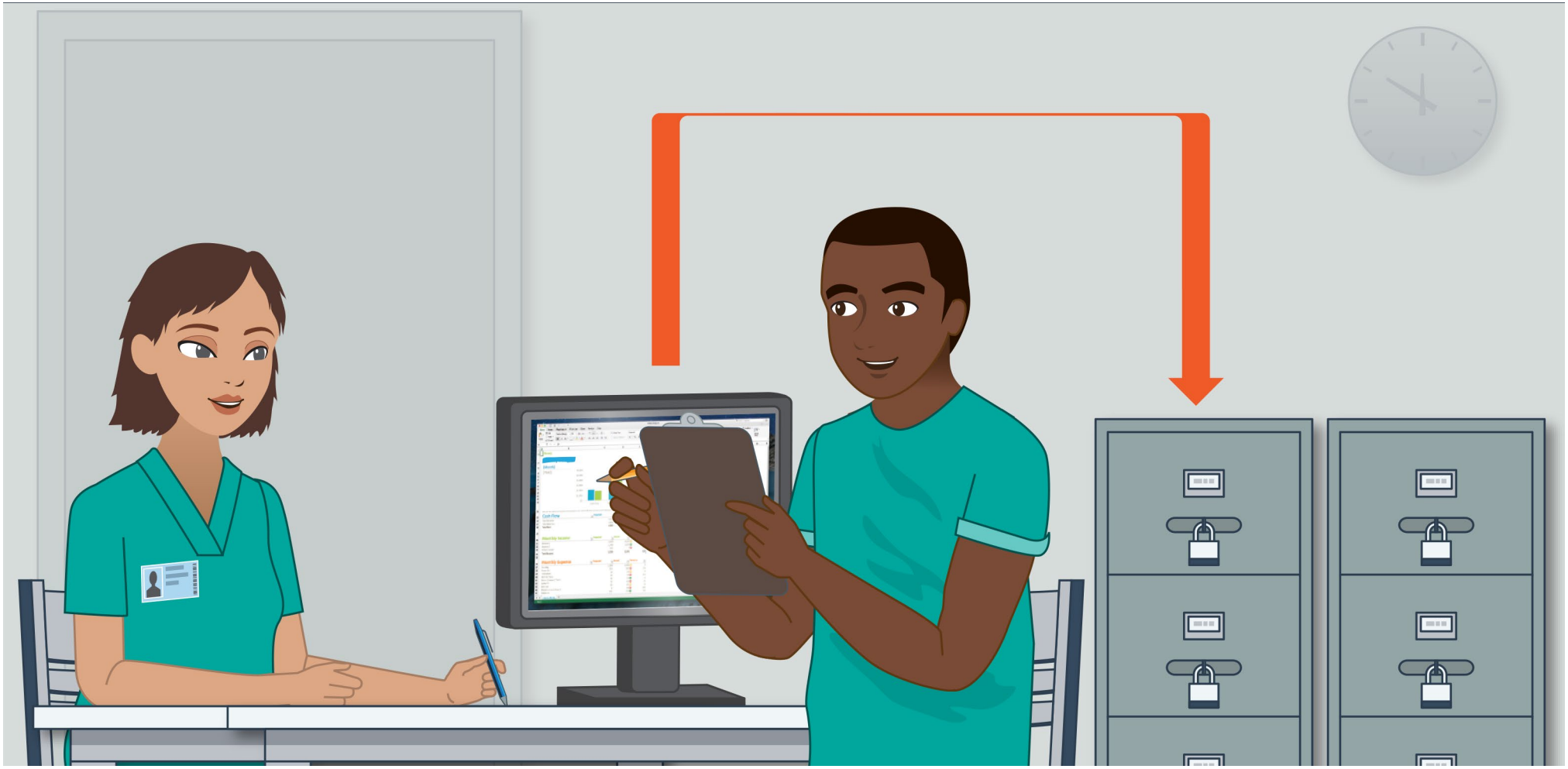
By being in this study, you will help doctors learn more about how to treat COVID-19 in people who are well enough to be managed from home. If CP is shown to be safe and effective there may be a large health impact with many lives saved.



What will happen to your samples and personal information?

Your information will be sent to the University of Pittsburgh for analysis and storage. Your samples and data will be marked with a code and not with your name and they will be stored for a very long time for future research about COVID-19.

You and your doctor will not get results from any of these tests. We will not sell your samples. We may share your coded samples and data with COVID-19 researchers, without any information that could identify you. If you change your mind and decide you do not want us to store your samples or data, please let us know.



How will your privacy be protected?

We will take every reasonable step to keep your information private and to keep anyone from misusing it. However, we cannot guarantee that nobody will get it. The following people may see your medical and research information: the ethics committees that are responsible for protecting the rights of participants in research studies; the sponsor, the group paying for the research (US National Institutes of Health, The Biomedical Advanced Research and Development Authority (BARDA)), other study research staff and study monitors; the regulatory agencies from the US (Food and Drug Association).All of these people are committed to protecting your privacy. The rights you have regarding your samples and data are described in the consent document.

What else should you know about study participation?

- We will ask you who to contact if we are not able to reach you after you leave the hospital, so we can find out how you are doing.
- We will give you the study treatment at no cost. We will pay for all lab work and other tests that are part of this study. You, your insurance company, or some other third-party payer must pay for all non-study medicines and hospital costs.
- If you are hurt because of this study, you or your insurance will have to pay for any needed treatment. The study cannot pay you or pay for any care for study-related injuries or for your illness.
- A description of this clinical trial is be available at www.ClinicalTrials.gov.