



Participant Name: _____ Date: _____

Title of Study: VA CoronavirUs Research and Efficacy Studies-1 (VA CURES-1)

Principal Investigator: _____ VA Facility: _____

Principal Investigators for Multisite Study: Edward Janoff, MD and Sheldon Brown, MD

KEY SUMMARY INFORMATION ABOUT THIS STUDY

You are being invited to take part in a research study that is being funded by the Department of Veteran Affairs Clinical Science Research and Development (CSR&D). Before you decide to take part in the study, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive. Taking part in this study is completely voluntary.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

A novel coronavirus infection can result in a disease called COVID-19. Current treatments are very limited. This study looks at one possible treatment for COVID-19. In this study, hospitalized Veterans with COVID-19 will either get convalescent plasma containing antibodies to the virus from people who have recovered from COVID-19 (plasma) or a salt and water solution (saline). The treatment will be given through a tube going into a vein in the arm (infusion). Neither the Veteran nor the doctor will know what treatment has been given. Convalescent plasma is not an FDA-approved treatment for COVID-19. This study will help researchers understand if this treatment is effective in treating COVID-19.

If you complete all the visits, you will be in the study up to 35 days. There will be five tests for the virus in the 35 days, most likely via a nasal swab. In addition, there will also be up to 6 blood draws. If you get well enough to leave the hospital, you will need to come back for up to two follow-up visits (Days 15 and 29 after completing treatment). There will be one telephone follow-up visit (Day 22 after completing treatment). You may exit the study at any time.

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WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

- You want to be a part of finding effective treatment for COVID-19.
- You hope this research will help fellow veterans and others.
- You want to contribute to science.
- You think this treatment could work.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

- You might not want to take a chance of receiving the saline solution instead of the plasma.
- There is no guarantee that this treatment can help you.
- You might be unsure about possible side effects.
- You might not want to have 5 tests for the virus.

DO YOU HAVE TO TAKE PART IN THE STUDY?

Your participation in this study is completely voluntary. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is {Principal Investigator, Local Site Investigator as applicable} at the [insert name of VA facility]. If you have questions, or concerns about this study or you want to withdraw from the study his/her contact information is: {PI or LSI contact information as applicable}.

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BACKGROUND AND PURPOSE OF STUDY

As of the end of December 2020, more than 18 million people in the US have tested positive for the coronavirus (SARS-Coronavirus-2), and more than 325,000 have died. There is no cure for this virus at this time, and very few medications have been proven helpful. The coronavirus leads to a disease called COVID-19.

This study looks at one possible treatment option for COVID-19, which is plasma from people who have recovered from the coronavirus (convalescent plasma). For other viral disease, treatment with the convalescent plasma appears safe and has been widely used, but the evidence for benefit in those diseases remains unclear. There is little information on how well it works to treat COVID-19, even though many people have received it as compassionate treatment. Beginning convalescent plasma therapy early in hospitalization for other viral infections has shown some benefit but has not been well studied. Convalescent plasma is not an FDA-approved treatment for COVID-19. The goal of this study is to see if convalescent plasma is a useful treatment for COVID-19. We will find out if the plasma will help the body fight the virus. Our hope is that it will decrease the severity of respiratory and systemic infection in the body and lead to fewer deaths.

HOW LONG WILL I BE IN THE STUDY?

This study is taking place at approximately 25 VA Medical Centers located across the US. Around 2000 Veterans will be screened and 1500 enrolled during the duration of the study. Your involvement will last up to 35 days. The entire study, from the date the first person enters until the last participant is seen, is expected to last about 20 months.

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WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

- You will be evaluated during your hospitalization to see if you can be included in this study. We will perform a physical exam and collect your medical history, as well as personal information from your medical records. Most of this information will be collected based on the care you are receiving as a patient in the hospital.
- Following the exam, if you can be included in the study, you will receive two units of either plasma or saline through a tube going into a vein in your arm (infusion) within 36 hours of study entry. Each infusion should last approximately 1-2 hours. The two infusions should happen within 12 hours of each other.
- The study will use compatible blood type plasma.
- You will have an equal chance of getting either the plasma or the saline. In this study of 50% of participants will receive the plasma, and 50% of participants will receive the saline.
- The selection of your treatment will be made at random, similar to flipping a coin. There is no way for you or the study staff to choose the treatment you will receive. Neither you nor your doctor will know which treatment you receive.
- You will continue to receive all treatments that your medical team considers best for your care.
- We will monitor your progress daily while you are in the hospital and for about 29 days after you received your treatment. We will record your vital signs, check for any adverse reactions, monitor your symptom status and record certain medications you are taking while being treated for COVID-19. If you are discharged from the hospital, we will continue to monitor you through the 29 days, with up to one phone call and two return visits to the hospital during that time.
- During the study we will collect up to 6 blood samples and 5 respiratory samples from you.

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The collected blood and respiratory samples will be coded (labeled with an ID number not your name) and securely stored. Samples obtained for this study will be stored for up to 20 years and will be used to answer future research questions about COVID-19. You will not be told about research results related to the blood and respiratory samples. You will not be re-contacted regarding your blood and respiratory samples after your participation in this study.

Table 1. Blood and Respiratory Specimen Collection During the Study

Day	1	2	4	7	15	29
Blood for safety tests (1 Tablespoon)	X	X	X	X	X	X
Respiratory specimens for diagnosis/viral clearance	X		X	X	X	X
Blood for current and unspecified research (2 Tablespoons)	X	X	X	X	X	X
Blood Volume Collected						
Total blood volume	3 Tablespoons	3 Tablespoons	3 Tablespoons	3 Tablespoons	3 Tablespoons	3 Tablespoons
Total blood volume over all study days	Up to 18 Tablespoons					

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WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

There is always a chance that any procedure can cause discomfort or harm. The procedures in this study are no different. The blood draws, infusions and nasal swabs can be uncomfortable. If you are discharged from the hospital during the 29-day study period, you will be asked to come back for up to two in-person follow-up visits, even if you are not feeling well yet.

Whether you receive the plasma or saline, there is a chance that your COVID-19 symptoms will not improve and may become worse. You also may experience a rare or unexpected risk or side effect that is not yet known to us.

Vaccines are currently available for COVID-19. The Center for Disease Control (“CDC”) recommends that vaccines for COVID-19 can be given 90 days after COVID-19 infection or receipt of convalescent plasma. Since you are infected with COVID-19, participation in the VA CURES-1 study will have little impact on the recommendation or timing for vaccination after COVID-19 infection.

Do not take part in other research while you are a participant in this study without first getting approval from the study doctor. Limiting your participation to this study may help to protect you from injury or discomfort caused by duplicating procedures or potential drug interactions. Also, participating in more than one trial may invalidate the results of both. Your study team will let you know if the other trials you are interested in are allowed.

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Risks or Discomforts from Plasma Infusion

Plasma is routinely given for other medical conditions such as excess bleeding after surgery. The trial will provide compatible blood type plasma. Serious side effects from plasma transfusion are very uncommon. Serious side effects that have occurred include:

- Excess retention of fluid which can lead to excess water in the lung – pulmonary edema.
- A rare acute lung injury.
- Allergic and other immune reactions may occur, but are rare even when the donor and recipient have different blood types. This can result in anemia, fever, rash including hives, or a decrease in platelets with increased risk of excessive bleeding.
- There is a theoretical possibility that receiving plasma rich in antibody to the virus that causes COVID-19 may prevent your body from making its own protective antibody response and decrease your resistance to a future infection if you are re-exposed.
- All intravenous treatment has a low risk of bacterial infection and there is the possibility of transmission of other infectious diseases despite the rigorous screening that all blood products undergo.

Part of the reason for this study is to determine if the benefit of plasma outweighs the risk of these rare, but potentially, serious side effects.

Risks or Discomforts from Saline Infusion

If given saline, as with any infusion, you may experience mild pain, tenderness, swelling, redness, itching and bruising at the site where the infusion occurred.

Risks from Blood Draw

As with any blood draw, you may experience mild pain at the site of the blood draw, possible bruising, redness and swelling, bleeding at the site, and in rare cases, infection at the site of the blood draw.

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WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

You may not get any medical benefit from taking part in this research study. However, there is a possibility that your COVID-19 symptoms will improve. Even if you experience no direct benefit from participation yourself, the information we gather from you may help researchers determine if the plasma treatment can reduce the symptoms of COVID-19. Taking part in this study will inform future treatment of this very serious illness.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT WANT TO JOIN THIS STUDY?

Your participation in this study is completely voluntary. If you decide that you do not want to take part in this study, you can still receive best supportive care (BSC) for your COVID-19 symptoms. Convalescent plasma can be given outside the study under an Emergency Use Authorization (EUA) and this would need to be arranged through your current health care providers.

A recent study using convalescent plasma with high levels of antibodies against COVID-19 has shown that the patients who received the plasma had less severe COVID-19 symptoms, possibly indicating that plasma with high levels of antibodies may reduce the severity of COVID-19 symptoms.

WHAT ARE THE COSTS TO ME IF I TAKE PART IN THIS STUDY?

You will not be charged for any treatments or procedures that are part of this study. If you usually pay co-payments for other VA care and medications, you will still pay these co-payments for VA care that is not part of this study.

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WILL I BE COMPENSATED FOR MY TIME AND PARTICIPATION?

After you are discharged from the hospital, you will be offered 0.50 cents/mile for travel to and from your follow-up study visits (up to 100 miles roundtrip per follow-up visit). In addition, you will also be offered \$50 per each outpatient research follow-up visit (total of 2 in-person visits and 1 telephone visit), with a maximum payout of \$300.00 during study treatment and enrollment. Payments involved for being a part of this research study will count as income and may affect your income taxes.

Table 2: Study Compensation

Visit	Reimbursement
Follow-Up (Day 15): In-person	\$50.00
Follow-Up (Day 22): Telephone	\$50.00
Follow-Up (Day 29): In-person	\$50.00
Mileage (\$0.50/mile for up to 100 miles Roundtrip/Visit)	Up to \$50.00/Visit
Maximum Total	\$300.00

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

A new public health law under the Public Readiness and Emergency Preparedness Act (PREP Act) was issued by the Department of Health and Human Services on March 10, 2020. This law limits your ability to sue if you are in a COVID-19 research study. If this study uses a drug, device or vaccine designed to treat, diagnose, cure or prevent COVID-19, you cannot sue the manufacturers, the study sponsor, healthcare providers or other professionals involved in the study for injury or harm (i.e., getting hurt) unless the injury or harm was on purpose. You may be compensated for injury or harm through a Department of Health and Human Services program called the Countermeasures Injury Compensation Program (CICP). For more information about this program, please contact the Health Resources and Services Administration’s CICP by phone at 855-266-2427 or online at <https://www.hrsa.gov/cicp/about/index.html>.

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VA will provide necessary medical treatment should you be injured by being in this study. You will be treated for the injury at no cost to you. This care may be provided by the local VAMC or arrangements may be made for contracted care at another facility. In case of research related injury resulting from this study, you should contact your study team. If you have questions about medical treatment for any study related injuries, you can call the operator at this VA Medical Center and ask for medical administration.

You still have the right to hold VA responsible for negligence that is not related to a COVID-19 research study.

WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?

You will be notified of any new information about the safety of the plasma treatment if it becomes available during your participation. You might be asked to sign an updated informed consent form containing any new safety information. You may withdraw from the study at any time. If you do so, your study doctor will arrange for your medical care to continue.

BLOOD AND RESPIRATORY SAMPLE BANKING

Blood and respiratory samples will be collected for this study. Once obtained they will be coded (labeled with an ID number, not your name) and securely shipped to the Cooperative Studies Program Albuquerque Central Biorepository in Albuquerque, NM for storage and analysis. The researchers at the Cooperative Studies Program Albuquerque Central Biorepository will not have access to the link file that connects your name and code number. They will not be able to link your sample back to your identity. Samples obtained for this study will be stored for up to 20 years in a sample repository and will be used to answer current and future research questions about COVID-19. You will not be contacted by anyone from this repository or anyone who is using the samples in this repository for research purposes. The research results related to the blood and respiratory samples will not be conveyed to you or your medical provider after your participation in this study. You will not be re-contacted regarding your blood and respiratory samples after this project is completed.

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WHO COULD PROFIT FROM THE STUDY RESULTS?

Specimens may not be used for commercial profit.

DOES THIS STUDY INVOLVE GENETIC RESEARCH?

The study does not involve genetic research.

DO I HAVE TO TAKE PART IN THE STUDY?

Participation in this study is voluntary. If you decide not to take part in this study, there will be no penalty or loss of benefits to which you are otherwise entitled. You will receive the same care that you would have otherwise received.

By signing this consent, you are agreeing to begin full participation. This means staying in contact with the research team, receiving the study product, and completing the required tests.

You have the right to change your mind about taking part in this study, at any time. Please contact the research team if you decide not to fully participate in the study. At that time, the team might ask you to consider limited participation.

Limited participation options will be:

1. For you to withdraw study treatment but allow us to continue monitoring you through scheduled visits and calls, follow-up specimen collection, and review of medical records.

OR

2. For you to allow the research team to continue looking at your medical records, but we will not contact you.

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You also have the right to decide to completely withdraw from the study. Whatever you decide, the research team will document your decision in your medical record.

If you completely withdraw from the study, the study doctor may continue to review the data already collected from you, but will not collect further information. Specimens collected for this research study cannot be withdrawn once they have been obtained.

If you leave the study early, you will not lose any benefits to which you are entitled. Your decision will not affect the relationship you have with your doctor or other staff. Your decision will not affect any of the usual care that you receive.

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION

There are certain times when the study doctor may have to remove you from the study. If at any time the study doctor believes participating is no longer in your best interest, s/he has the right to remove you from this study.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

If you take part in this study, researchers will need to collect private information about you. Information about you will be handled as confidentially as possible. Your name, initials, or other identifying information will not be given out without your permission, unless we are required to do so by law. Information will be stored on computers that are protected with passwords, and in locked file cabinets that are only accessible by the research team. If you choose to provide contact information for a person who might help the study team to contact you, that information will be protected in a similar way.

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The information collected for this study will be kept confidential. We will include information about your study participation in your medical record. There are times when we might have to show your records to other people. For example, someone from the Food and Drug Administration, the Office of Human Research Protections, the Government Accountability Office, the Office of the Inspector General, the VA Office of Research Oversight, the VA Central IRB, our local Research and Development Committee, and other study monitors may look at or copy portions of records that identify you.

The key connecting names and code numbers will be kept in a separate locked filing cabinet or on separate secure computer drive. Destruction of all research records pertaining to this study will be in accordance with the Department of Veterans Affairs record retention schedule.

The data from the study may be published; however, you will not be identified. Your information will be combined with information from other people taking part in the study. Any presentations or papers from this study will not identify you personally.

We will access your medical record in the course of the study to identify referrals for treatments, actual treatments and other healthcare information that helps us to understand the overall impact the study treatments are having. We will enter notes in your medical record indicating your participation in this study. We may talk with your VA clinicians if something comes up that we think they could help with. You will be informed of which type of transfusion you received at the end of the study trial.

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By signing this document, you authorize the Veterans Health Administration (VHA) to permit (insert name of Site Investigator) and his/her research team to use and disclose the following information about you, and to contact and discuss your research activities with your VA clinicians to mutually address any clinical needs:

- Information about you that is created during the research study includes:
 - The number of times you have used VA services;
 - The results of diagnostic exams that become part of the study records; and
 - Information collected as part of interviews you have with the study staff and questionnaires you fill out during the study.
- Information in your medical record that is needed for this research study might include:
 - The results of past physical exams;
 - Lists of medications you are currently taking;
 - Diagnostic procedures; and
 - Medical status.

Other researchers may use information about you from this study and other sources, together with your medical records, to do more related research. The purpose is to learn more about related health conditions. The information may be used during or after this study. We will only share your information with other researchers if their research is approved by a committee that protects the rights and safety of patients in research, and if you, as the participant, give us permission.

The information and biospecimens collected in this study could be used for future research studies or distributed to another investigator for future research studies after removing identifiable private information about you. We will not obtain additional informed consent from you or your legally authorized representative for this purpose.

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A description of this clinical trial is available on <http://www.ClinicalTrials.gov> as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

If you have any questions, complaints, or concerns about the research or related matters, please contact (insert Local Site Investigator here) at _____, or (insert Site Coordinator or other study personnel here) at _____.

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the VA Central Institutional Review Board (IRB) toll free at 1-877-254-3130. The VA Central IRB oversees the safety of human participants in this study. You may contact them with questions, complaints or concerns about the study; or if you would like to obtain more information, or to offer input.

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BLOOD USE FOR FUTURE RESEARCH

Blood samples will be obtained in this study for future research. The samples will be stored for up to twenty years and will be used to answer future research questions about COVID-19. Participation in the unspecified use of your blood is strictly voluntary. Please initial below if you do not want to participate in the unspecified usage of your blood. This will not change the amount of blood that is drawn.

Participant:

_____ My initials indicate you may NOT use my blood samples for future unspecified research purposes.

Legally Authorized Representative:

_____ As the legally authorized representative of the participant, I will initial to indicate that you may NOT use the Participant's blood samples for future unspecified research purposes.

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FUTURE USE OF DATA

The information collected about you during the course of the study will be stored in a research database maintained by the VA Palo Alto Cooperative Studies Program Coordinating Center until destroyed according to VA regulations. The database will be shared per VA policy and applicable Federal requirements among the researchers involved in this project and others in the future who have a VA-approved agreement to use the study data.

Your personal information that discloses your personal identity will not be released without your permission unless required by law. Your personal information will always be kept separate from the research database. Please indicate with your initials below whether we have your permission to use your identifiers for future COVID-19 research.

Participant:

_____ YES. My initials indicate you may use my identifiers for future COVID-19 research.

_____ NO. My initials indicate you may not use my identifiers for future COVID-19 research.

Legally Authorized Representative:

_____ YES. As the legally authorized representative of the participant, my initials indicate that you may use the Participant's identifiers for future COVID-19 research.

_____ NO. As the legally authorized representative of the participant, my initials indicate that you may not use the Participant's identifiers for future COVID-19 research.

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FUTURE RE-CONTACT

In the future, we may have additional studies about COVID-19. Please indicate with your initials below whether we have your permission to contact you in the future about additional COVID-19 research. This will not enroll you in a future study; it just gives us permission to contact you to inform you of the COVID-19 studies available.

Participant:

_____ YES. My initials indicate you may contact me about future COVID-19 studies.

_____ NO. My initials indicate I decline to be contacted about future COVID-19 studies.

Legally Authroized Representative:

_____ YES. As the legally authorized representative of the participant, my initials indicate that you may contact the participant about future COVID-19 studies.

_____ NO. As the legally authorized representative of the participant, my initials indicate that you may not contact the participant about future COVID-19 studies.

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AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

A member of the study team has explained this research study to you, including its procedures, the possible risks or discomforts, and the potential benefits you may experience. We have explained the other treatment options that are available to you without entering into this study and that this study is voluntary. We have also provided you the chance to ask questions and obtain answers.

Your signature below indicates that you have read this informed consent form, or it has been read to you and that you voluntarily consent to participate in this study. You will receive a copy of this consent form after you sign it.

I agree to participate in this research study as has been explained in this document.		
_____ Participant's Name	_____ Participant's Signature	_____ Date

The participant is unable to give informed consent. I, as the legally authorized representative of the participant, give consent for their participation in this study.		
_____ Name of Legally Authorized Representative	_____ Signature of Legally Authorized Representative	_____ Date

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Indicate below your authority to act as the participant’s legally authorized representative to both sign this informed consent document on the participant’s behalf and to authorize access, collection, and use of the participant’s protected health information in this research project under the HIPAA Privacy Law:

Spouse

Parent

Adult Child (18 years of age or over) for his or her parent

Adult Sibling (18 years of age or over)

Grandparent

Adult Grandchild

Guardian appointed to make medical decisions for individuals who are incapacitated

Other per local or state law

Specify: _____

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LSI Verification Date: NA