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Are you participating in any other research studies? \_\_\_\_\_ Yes \_\_\_\_\_No

SUMMARY

* Voluntary Consent: Taking part in this research study is voluntary and you may withdraw your participation at any time.
* Purpose of Research: To learn if blood plasma collected from people who have recovered from coronavirus disease (COVID-19) can be used to successfully treat people currently infected with the virus.
* Risks: Transfusions pose a very low risk of adverse reactions including allergic reactions, lung damage, and transmission of infections including HIV and Hepatitis B and C, although rare, due to modern screening procedures.
* Benefits: It is possible but not guaranteed that treatment may decrease the risk of disease progression.

**PURPOSE OF RESEARCH**

You are invited to participate in a research study that is looking at the benefits of convalescent plasma for the treatment of COVID-19. Convalescent plasma is the liquid part of blood that is collected from donors who have recovered from the novel coronavirus disease, COVID-19. We hope that antibodies in the convalescent plasma will help recipients to recover from infection more quickly. You were selected as a possible participant in this study because you have tested positive for COVID-19 and needed to be seen by a physician, but you do not need to be hospitalized.

If you decide to terminate your participation in this study, you should notify Dr. Kevin Schulman at (650) 724-0543.

This research study is looking for 206 participants who are positive for COVID-19 and need clinical evaluation but who do not require hospitalization. Stanford University expects to enroll up to 206 research study participants.

**VOLUNTARY PARTICIPATION**

Your participation in this study is entirely voluntary. Your decision not to participate will not have any negative effect on you or your medical care. You can decide to participate now, but withdraw your consent later and stop being in the study without any loss of benefits or medical care to which you are entitled.

**DURATION OF STUDY INVOLVEMENT**

This research study is expected to take up to two years. Your involvement in the study would be for approximately 15 days including 1-2 days for screening and treatment and the remaining time for daily check-ins that take up to 15 minutes per day.

**PROCEDURES**

If you choose to participate, the Protocol Director and his research study staff will perform some tests and evaluations to see if you meet all the requirements for participation and collect some additional information. These include collecting your demographic information and medical history, vital signs (such as rate of breathing, blood pressure, heart rate, temperature), and laboratory tests that may include any or all of the following:

* COVID-19 testing on nasopharyngeal, throat, and/or tracheal aspirate or broncho alveolar lavage (samples from your upper respiratory system)
* Serological testing (measures the amount of virus in your blood)
* Routine blood draws, and an additional blood sample collection (we will review this later in this form)
* Blood typing (to ensure your blood type is compatible with the plasma you receive)
* Urine or serum pregnancy test for females of childbearing potential

You will also be asked to complete a questionnaire.

If you meet all the requirements for participation, you will be randomized at a ratio of 1:1 to receive either convalescent plasma (plasma with the COVID-19 antibodies) or normal plasma (plasma without the COVID-19 antibodies). 1:1 randomization is much like a coin toss, where you have equal chances to be selected for either option.

Study plasma administration: Based on the randomization, you will be given one to two units of normal donor or convalescent plasma that is compatible with your blood type. It will be given into one of your veins, using a sterile single use needle, and will be given over the course of about one to two hours. About 200-500 mL of plasma (exact amount will be determined by your weight) will be given in this infusion. We will check your vital signs at several timepoints before, during, and after you receive the plasma infusion.

Once your treating physician determines you are free to leave, you will be discharged to go home.

In addition to the above procedures, a member of the study team will contact you by phone every day for the 15 days immediately following treatment. They will ask you some questions concerning your health, symptoms and how you are feeling, and whether you required care in urgent care, the emergency department, or required hospitalization. The study team may look at your medical records to determine whether you received further medical care during the 15 day study period.

Your specimens may be sent outside of Stanford for analysis if outside investigators have relevant assays or expertise not available to Stanford study investigators.

Any of your specimens which are used in research may result in new products, tests or discoveries. In some instances, these may have potential commercial value and may be developed and owned by the Investigators, Stanford University and/or others. However, donors of specimens do not retain any property rights to the materials. Therefore, you would not share in any financial benefits from these products, tests or discoveries.

Women of Childbearing Potential

If you are a woman who is able to become pregnant, it is expected that you will use an effective method of birth control to prevent exposing a fetus to a potentially dangerous agent with unknown risk. If you are pregnant or currently breast feeding, you may not participate in this study. You understand that if you are pregnant, if you become pregnant, or if you are breast-feeding during this study, you or your child may be exposed to an unknown risk.

To confirm to the extent medically possible that you are not pregnant, you agree

to have a pregnancy test done before beginning this research study.

You must agree to avoid sexual intercourse or use a birth control method judged to be effective by the investigator and which will not interfere with the proposed investigation. You must accept the risk that pregnancy could still result despite the responsible use of reliable method of birth control. You agree to notify the investigator as soon as possible of any failure of proper use of your birth control method, or if you become pregnant, either of which may result in your being withdrawn from the study.

Future Use of Private Information and/or Specimens

Research using private information and/or specimens is an important way to try to understand human disease. You are being given this information because the investigators want to save private information and/or specimens for future research.

Your specimens will be coded with an assigned number and stored at Stanford for 5 years. They will not contain any personal information that could identify you.

Identifiers might be removed from identifiable private information and/or identifiable specimens and, after such removal, the information and/or specimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you.

Genetic Testing and Future Research

As part of the analysis on your specimens, the investigators may do genetic testing. Genetic research is research that studies genes, including gene characteristics and gene versions that are transmitted by parents to children. Genetic research may include looking at information, such as personal appearance and biochemistry, gene sequences, genetic landmarks, individual and family medical histories, reactions to medications and responses to treatment. Genetic research raises certain questions about informing you of any results. Possible risks of knowing results include: anxiety; other psychological distress; and the possibility of insurance and job discrimination. A possible risk of not knowing includes being unaware of the need for treatment. These risks can change depending on the results of the research and whether there is a treatment or cure for a particular disease.

Sometimes patients have been required to furnish information from genetic testing for health insurance, life insurance, and/or a job. A Federal law, the Genetic Information Nondiscrimination Act of 2008 (GINA), generally makes it illegal for health insurance companies, group health plans, and employers with 15 or more employees to discriminate against you based on your genetic information.

The results of the study of your specimens from this project will be used for research purposes only, and you will not be told the results of the tests.

This research might include whole genome sequencing.

**PARTICIPANT RESPONSIBILITIES**

As a participant, your responsibilities include:

* Follow the instructions of the Protocol Director and study staff.
* Keep your study appointments. If it is necessary to miss an appointment, please contact the Protocol Director or research study staff to reschedule as soon as you know you will miss the appointment.
* Tell the Protocol Director or research study staff about any side effects, doctor visits, or hospitalizations that you may have.
* Tell the Protocol Director or research staff if you believe you might be pregnant.
* Complete your questionnaires as instructed.
* Ask questions as you think of them.
* Tell the Protocol Director or research staff if you change your mind about staying in the study.

**WITHDRAWAL FROM STUDY**

If you first agree to participate and then you change your mind, you are free to withdraw your consent and discontinue your participation at any time. Your decision will not affect your ability to receive medical care for your disease and you will not lose any benefits to which you would otherwise be entitled.

If you decide to withdraw your consent to participate in this study, you should notify Dr. Schulman at (650) 724-0543.

The consequences of withdrawing from the study are not predictable and could be either positive or negative. If you withdraw before receiving the plasma treatment, you will not receive any potential benefit from virus-fighting antibodies that are in the convalescent plasma, should you be randomly assigned to that treatment group and not the placebo group. Alternatively, not receiving plasma means you will not be exposed to potential adverse reactions that are rare but can occur with blood product transfusions.

The Protocol Director may also withdraw you from the study without your consent for one or more of the following reasons:

* + Failure to follow the instructions of the Protocol Director and study staff.
  + The Protocol Director decides that continuing your participation could be harmful to you.
  + Pregnancy
  + You need treatment in the hospital or treatment not allowed in the study.
  + The study is cancelled.
  + Other administrative reasons.
  + Unanticipated circumstances.

**POSSIBLE RISKS,DISCOMFORTS, AND INCONVENIENCES**

Blood and plasma have been used for many other conditions, and in general are very safe. Transfusion does carry the risk of adverse reactions such as allergic reactions, transfusion-associated circulatory overload or lung damage with profound breathing difficulty, and transmission of infections including HIV and Hepatitis B and C, although the risk of these infections is very low, as only screened and compatible blood is used for transfusion.

This study also includes the following risks:

* Phlebotomy (blood draw): local discomfort, bruising, hematoma, bleeding, and fainting
* Oropharyngeal and throat swab: local discomfort and vomiting

Treatment may also involve risks which are currently unforeseeable. You should talk with the Protocol Director if you have any questions.

**POTENTIAL BENEFITS**

The benefits to being in this study are unknown, however, it is anticipated that treatment will decrease the risk of disease progression and possibly avoid admission to the ICU where aggressive respiratory support includes mechanical ventilation and other extreme measures.

We cannot and do not guarantee or promise that you will receive any benefits from this study.

**ALTERNATIVES**

The alternative to being in this study is routine standard of care.

**PARTICIPANT’S RIGHTS**

You should not feel obligated to agree to participate. Your questions should be answered clearly and to your satisfaction. If you decide not to participate, tell the Protocol Director.

You will be told of any important new information that is learned during the course of this research study, which might affect your condition or your willingness to continue participation in this study.

**ClinicalTrials.gov**

A description of this clinical trial will be available on [*http://www.ClinicalTrials.gov*](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.

**CONFIDENTIALITY**

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed except as authorized by you or as required by law**.** However, there is always some risk that even de-identified information might be re-identified.

Patient information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

The purpose of this research study is to obtain information on the safety and effectiveness of COVID-19 convalescent plasma; the results will be provided to the Food and Drug Administration and other federal and regulatory agencies as required.

**Authorization To Use Your Health Information For Research Purposes**

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

**What is the purpose of this research study and how will my health information be utilized in the study?**

The purpose of this study is to determine if COVID-19 convalescent plasma (plasma collected from a recovering patient) can be used to successfully treat a different patient in the early stages of coronavirus disease. Study results will be published within the scientific community and possibly elsewhere, but personal health information will not be disclosed. Information from this study will be submitted to the FDA.

**Do I have to sign this authorization form?**

You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study, including receiving any research-related treatment. Signing the form is not a condition for receiving any medical care outside the study.

**If I sign, can I revoke it or withdraw from the research later?**

If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you must write to:

Dr. Kevin Schulman

John A. and Cynthia Fry Gunn Building, Room 326

366 Galvez Street

Stanford, CA 94305

**What Personal Information Will Be Obtained, Used or Disclosed?**

Your health information related to this study, may be used or disclosed in connection with this research study, including, but not limited to, name, address, phone number, electronic mail address, date of birth, dates associated with hospitalization, doctor appointments, and clinic visits, medical record number, medical history including symptoms, treatment, date-of-onset and other information related to your COVID-19 infection, blood tests including COVID-19 viral titers, nucleic acid tests to detect the virus in your samples, ABO compatibility tests (blood typing) and routine laboratory tests to monitor safety.

**Who May Use or Disclose the Information?**

The following parties are authorized to use and/or disclose your health information in connection with this research study:

* The Protocol Director, Dr. Kevin Schulman
* The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
* Research Staff

**Who May Receive or Use the Information?**

The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

* The Office for Human Research Protections in the U.S. Department of Health and Human Services
* The Food and Drug Administration
* Data Safety Monitoring Board

Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

**When will my authorization expire?**

Your authorization for the use and/or disclosure of your health information will end on January 1, 2070, or when the research project ends, whichever is earlier.

**Will access to my medical record be limited during the study?**

To maintain the integrity of this research study, you may not have access to any health information developed as part of this study until it is completed. At that point, you would have access to such health information if it was used to make a medical or billing decision about you (e.g., if included in your official medical record).

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Signature of Adult Participant Date

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Print Name of Adult Participant

**FINANCIAL CONSIDERATIONS**

Payment/Reimbursement

You will not be paid to participate in this research study.

Costs

If you participate in this study, the study will pay for those services, supplies, procedures, and care associated with the study that are not a part of your routine medical care. However, there may be additional costs to you. These include basic expenses like transportation and the personal time it will take to come to the study visits. You and/or your health insurance must pay for services, supplies, procedures, and care that are required during this study for routine medical care. **You will also be responsible for any co-payments and/or deductibles as required by your insurance.** Participation in this study is not a substitute for health insurance.

**COMPENSATION for Research-Related Injury**

All forms of medical diagnosis and treatment – whether routine or experimental – involve some risk of injury. In spite of all precautions, you might develop medical complications from participating in this study. If such complications arise, the Protocol Director and the research study staff will assist you in obtaining appropriate medical treatment. In the event that you have an injury or illness that is directly caused by your participation in this study, reimbursement for all related costs of care first will be sought from your insurer, managed care plan, or other benefits program. **You will be responsible for any associated co-payments or deductibles as required by your insurance.**

If costs of care related to such an injury are not covered by your insurer, managed care plan or other benefits program, you may be responsible for these costs. If you are unable to pay for such costs, the Protocol Director will assist you in applying for supplemental benefits and explain how to apply for patient financial assistance from the hospital.

You do not waive any liability rights for personal injury by signing this form.

**CONTACT INFORMATION**

Questions, Concerns, or Complaints: If you have any questions, concerns or complaints about thisresearch study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Protocol Director, Dr. Kevin Schulman. You should also contact him at any time if you feel you have been hurt by being a part of this study.

Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at (650)-723-5244 or toll free at 1-866-680-2906.  You can also write to the Stanford IRB, Stanford University, 1705 El Camino Real, Palo Alto, CA 94306.

Appointment Contact: If you need to change your appointment, please contact Lori Panu at (650) 724-1703.

**EXPERIMENTAL SUBJECT’S BILL OF RIGHTS**

As a research participant you have the following rights. These rights include but are not limited to the participant's right to:

* be informed of the nature and purpose of the experiment;
* be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
* be given a description of any attendant discomforts and risks reasonably to be expected;
* be given an explanation of any benefits to the subject reasonably to be expected, if applicable;
* be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;
* be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;
* be given an opportunity to ask questions concerning the experiment or the procedures involved;
* be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;
* be given a copy of the signed and dated consent form; and
* be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

May we contact you about future studies that may be of interest to you?

\_\_\_\_ Yes \_\_\_\_ No

Signing your name means you agree to be in this study and that you will receive a copy of this signed and dated consent form.

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Signature of Adult Participant Date

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Print Name of Adult Participant

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_

Signature of Legally Authorized Representative (LAR) Date

(e.g., family member, guardian or conservator)

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Print Name of LAR

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

LAR’s Authority to Act for Participant

(e.g., family member, guardian or conservator)

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Signature of Person Obtaining Consent Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Print Name of Person Obtaining Consent

The following witness line is to be signed only if the consent is provided as a summary form and accompanied by a short form foreign language consent.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_                \_\_\_\_\_\_\_\_\_\_\_\_

Signature of Witness                                                        Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Print Name of Witness

*(e.g., staff, translator/interpreter, family member)*

* *Translated short form must be signed and dated by both the participant (or their LAR) AND the witness.*
* *The English consent form (referred to as the "Summary Form" in the regulations):*
  + *Must be signed by the witness AND the Person Obtaining Consent (POC).*
  + *The non-English speaking participant/LAR does not sign the English consent.*
  + *The non-English speaking participant/LAR should not sign the HIPAA participant line*
  + *If the participant or the LAR is non-English speaking, the Person Obtaining Consent (POC) must ensure that 1) the LAR's Description of Authority is completed and 2) that any questions or options presented by the consent form are documented and initialed by the POC on the Summary Form, per the participant's wishes, as they are understood during the consent process.*