UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title: A randomized controlled adaptive study comparing COVID-19 convalescent plasma to non-immune plasma to limit coronavirus-associated complications in hospitalized patients.

Research Project Investigators:	Annie Luetkemeyer, M.D. Professor of Medicine UCSF, 1001 Potrero Ave, Room 418B, Box 0874 San Francisco, CA. Phone: 415-476-4082 ext 130 e-mail: annie.luetkemeyer@ucsf.edu	Sarah Doernberg, M.D., MAS Associate Professor of Medicine UCSF, 505 Parnassus Rm 0654, Box 0654 San Francisco, CA. Phone: 415-353-2626 Email: Sarah.Doernberg@ucsf.edu
	Priscilla Hsue Professor of Medicine UCSF, 1001 Potrero Avenue 5G20 San Francisco, CA. Phone: 628-206-8257 Email: Priscilla.Hsue@ucsf.edu	Peter Chin-Hong, M.D. Professor of Medicine UCSF, 513 Parnassus, MSB, 410E San Francisco, CA. Phone: 415 502 9585 Email: Peter.Chin-Hong@ucsf.edu

Study Coordinators:	Kelvin Moore, Sohee Park, Victor Arechiga, and Pierre Cedric-Crouch

This form is for use in a research study that may involve subjects who may or may not have the capacity to consent to take part in the study. When the subject cannot legally consent to take part, pronouns "you" and "your" should be read as referring to the subject rather than the person (legally authorized representative) who is signing this form for the subject. In cases where the subject's representative gives consent, the subject should be informed about the study to the extent possible given his/her understanding. During the course of the study, if the subject regains the capacity to consent, informed consent will be obtained from the subject and the subject offered the ability to leave the study if desired.

This is a clinical research study. Your study doctor(s), Annie Luetkemeyer, MD and/or Priscilla Hsue, M.D. at UCSF ZSFG Division of HIV, ID & Global Medicine and/or Sarah Doernberg, M.D. and/or Peter Chin-Hong, M.D. at the University of California San Francisco (UCSF) will explain the study to you.

STUDY SUMMARY

Introduction: We are asking you to consider taking part in a research study being done by Annie Luetkemeyer, Priscilla Hsue, Sarah Doernberg and Peter Chin-Hong at UCSF.
This consent form describes a clinical research study and is designed to help you decide if you would like to be a part of the 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 could be used as medicines. In a study, the study treatments are 'experimental,' which means they have not been proven to work. That is why studies are needed to find out if new therapies are safe and work in people. This section provides the information we believe is most helpful and important to you in making your decision about participating in this study. More information that may help you decide can be found in other sections of the document.

The first part of this consent form gives you a summary of this study. We will give you more details about the study later in this form. The study team will also explain the study to you and answer any questions you have.

What you should know about this study:

- You are being asked to join this clinical research study because you are currently hospitalized with an illness known as COVID-19 caused by the new coronavirus, SARS CoV-2.

- Read this consent form carefully or have someone you trust read it to you. Take as much time as you need to understand the study.

- Ask the study team to explain any words or information that you do not understand.

- You are a volunteer and you do not have to join this study. Your other option is to continue receiving any other care you have already been receiving. If you join the study, you can change your mind later. You can decide not to take part, or you can quit at any time. There will be no penalty or loss of benefits if you decide not to join or to quit the study.

- During the study, we will tell you if we learn any new information that might affect whether you wish to continue to be in the study.

- You should not volunteer for another study that gives volunteers a new study drug for COVID-19 for at least 15 days after you start receiving the study drug on Day 1. If you want to be in another study for COVID-19, you should talk to a member of the study team first.

Purpose of the study: You have been diagnosed with disease caused by the SARS-CoV-2 also known as coronavirus disease 2019 (COVID-19). SARS-CoV-2 is transmitted in a manner similar to other respiratory virus and has been associated with cough, fever, and shortness of breath, and in more severe cases, failure of the ability to breath, or even death. There are currently no proven treatment options for coronavirus disease (COVID-19) and the related

pneumonia, caused by Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) beyond supportive care.

People who recover from COVID-19 do so, at least in part, because their blood contains substances called antibodies, which are capable of fighting the virus that causes the illness. It turns out that for some other diseases caused by respiratory viruses, giving people the liquid portion of blood containing SARS-CoV-2 antibodies, called convalescent plasma, obtained from those who have recovered from the virus, leads to more rapid improvement of the disease. We want to test safety and efficacy of convalescent plasma to determine if it prevents subjects from severe progression of disease requiring increasing amounts of oxygen or possible need for a breathing machine (mechanical ventilation).

Study Procedures:

If you agree to join this study, we will first do some tests to make sure it is safe for you to join. This includes testing your blood for your blood type to make sure you can receive plasma that is compatible. Only hospitalized adults 18 years old and older and who test positive for COVID-19 can join this study. For female subjects, a pregnancy test (urine or serum) will be done.

If you qualify for this study and decide to join, you will get 1 infusion of convalescent plasma or plasma from a blood donor who did not have COVID-19 infection while you are hospitalized. Study staff will check in with you on Days 1, 2, 5, 8, 15, 29, 120 to ask you about your symptoms while you remain in the hospital. As long as you are hospitalized, visits will take place in the hospital. If you are already discharged from the hospital, you will be seen or contacted by phone by a study staff member for the study visits. Study evaluations will include a blood collection on Days 1, 2, 5, 8, 15, 29, 120 and a swab of the back of the nose at days 3, 7, 14 It is possible that the visits on Days 2, 5, 8, 15, 29, 120 will need to take place by telephone, in which case blood and nasal specimens will not be collected . We will use the blood for research and safety tests. Your total amount of time on this study will be about 120 days. You will be not compensated for taking part in the study.

Possible Risks: There are risks to taking part in a research study. Blood and plasma have been used for many other conditions, and in general are very safe. Some of the most likely risks of participation in this study include:

- **Randomization risks:** You will be assigned to a study treatment program by chance, and the study treatment you receive may prove to be less effective or to have more side effects than the other study treatment(s) or other available treatments.

- **Blood drawing (venipuncture) risks:** Drawing blood may cause temporary discomfort from the needle stick, bruising, infection, and fainting.

- **Back of the nose (nasopharyngeal): swab risks:** Risks include gagging and discomfort during collection a little during the test, and you may have a minor nosebleed afterwards.

- **Placebo risks:** If you are in the group that receives the control treatment, in this case plasma from someone who does not have antibodies to SARS-CoV-2, your condition will go without the active (study) treatment for course of your disease.

There are also rare but serious risks of participation, which are related to the risks of receiving a plasma infusion.

If you are assigned to the convalescent plasma arm:

- Although the risk of contracting COVID-19 infection from receiving a plasma infusion has not been formally tested yet, we believe that it would be very low because the donor has fully recovered from the infection.

In either study arm:

- Transfusion of plasma carries the risk of adverse reactions such as allergic reactions, transfusion-associated circulatory overload or lung damage with profound breathing difficulty and has the possibility of transmission of infections including HIV and Hepatitis B and C. The risk of these infections is very low, as plasma is screened for infections and is matched to your blood type to reduce the risk of a bad reaction.

Possible Benefits: You may benefit from participating in the study, but this cannot be guaranteed. We do not know if convalescent plasma will be an effective treatment for COVID-19, and you might not experience any benefit. If you are in the group that receives **convalescent plasma** and it proves to treat your condition more effectively with fewer side effects than standard therapy and non-immune plasma, you may benefit from participating in the study, but this cannot be guaranteed. However, we believe that this study treatment might be effective in improving the likelihood of you recovering from the disease, getting better sooner or having less severe disease.

Your Other Options: You do not have to participate in this study. You can choose to get this study treatment or not. Your choice will not affect the care that you are receiving at this center. We will always do our best to take care of you. If you agree to this study treatment, you will also be helping us learn whether the study treatment works and how it works to help other people, though you can withdraw at any time.

Following is a more complete description of this study. Please read this description carefully. You can ask any questions you want to help you decide whether to join the study. If you join this study, we will give you a signed copy of this form to keep for future reference.

DETAILED STUDY INFORMATION

This part of the consent form gives you more detailed information about what the study involves.

Research studies include only people who choose to take part. Please take your time to make your decision about participating. You may discuss your decision with your family and friends and with your health care team. If you have any questions, you may ask your study doctor.

You are being asked to take part in this study because you have you are currently hospitalized with an illness known as COVID-19 caused by the new coronavirus, SARS CoV-2.

Why is this study being done?

The purpose of this study is to understand if convalescent plasma may help to reduce the risk of serious respiratory complications associated with COVID-19 infection and to understand the safety of this study treatment.

What intervention is being studied?

This is a randomized blinded, placebo-controlled trial will assess the efficacy and safety of anti-SARS-CoV-2 convalescent plasma in hospitalized subjects with acute respiratory symptoms up to 14 days after the onset of initial symptoms. The convalescent plasma, matched to your blood type, is given as an infusion, which means that it is given through a plastic tube attached to a needle that is put into a vein in the arm.

To find out if convalescent plasma (the study intervention) works, we need to compare it to getting something that does not have the drug in it, something called a placebo. The placebo, control human plasma, looks like the study drug but does not have the SARS-CoV-2 antibodies in it, as will come from people who have not had COVID-19 infection. Using a placebo is common in research studies. The placebo is also given as an infusion. Half of the people enrolled will received convalescent plasma, the other half will receive non-immune plasma.

Will you get the convalescent plasma or non-immune plasma?

There are 2 study groups. If you join the study, you will be randomly put into one of two groups. This is decided by chance. Out of every 2 people on this study, 1 will get the study drug and 1 will get placebo. You will have a 50:50 chance of getting the study intervention, convalescent plasma. You and the study doctors will not know what group you are in or if you are getting the convalescent plasma or the non-immune plasma. To ensure the safe administration of the blood product and appropriate ordering of the right study treatment, some members of your care team may know which kind of plasma you are getting, convalescent vs. placebo. They will not tell you what you have been assigned to. When the study is over, we learn if the convalescent plasma (the study drug) is safe and if it was successful in treating people with COVID-19.

This study is sponsored by UCSF. The study doctors have no financial or proprietary interests in this study.

How many people will take part in this study?

About 50 people will take part in this study

What will happen if I take part in this research study?

If you agree to join this study, **before you begin the main part of the study** you will have a test showing you tested positive for COVID-19 and answer questions about your symptoms. These exams, tests or procedures are part of regular hospital care and will be done even if you do not join the study.
If you have had some of these tests done recently, they may not need to be repeated. This will be up to your study doctor. **During the main part of the study, we will** first do some tests to make sure it is safe for you to join. This includes basic blood tests, including:

- Blood Tests:
    - Blood tests of your white cells, red cells, and platelets (complete blood cell count)
    - Blood clotting tests (PT, PTT)
    - Measurements of inflammation (d-dimer, , , ferritin, CRP)
    - Kidney and liver function tests
    - Blood typing
- Swab of the back of the nose to test for a SARS-CoV-2 virus
- Chest imaging (CT or Chest x-ray): obtained as part of standard care
- For female subjects of childbearing age, a pregnancy test (urine or serum) will be performed.

You will be **"randomized"** into one of the study groups described below. Randomization means that you are put into a group by chance. A computer program will place you in one of the groups. Neither you nor your study doctor can choose the group you will be in. You will have an equal chance of being placed in either group.

If you qualify for this study and decide to join, you will be placed in 1 of 2 groups.

If you are in group 1 you will get one infusion of convalescent plasma on the day 0 you are randomized into the study or as soon a feasible from enrollment while you are hospitalized.

If you are in group 2 you will get one infusion of non-immune plasma (placebo) on the day 0 you are randomized into the study or as soon as feasible from enrollment while you are hospitalized.

Regardless of which group you are in, you will have the following evaluations:

Study staff will check in with you or your care team or call you by phone on Days 1, 2, 5, 8, 15, 29, 120 to ask you about your COVID-19 related symptoms while you remain in the hospital, check your vital signs and how much oxygen you are on, and review your current medications. As long as you are hospitalized, visits will take place in the hospital. If you are already discharged from the hospital, you will be contacted by a study staff member for the study visits and if feasible, will be asked to come in person for day 29 and day 120. This visit will be at San Francisco General Hospital in the outpatient research center in building 80, 4th floor, 995 Potrero Avenue

Tests to be conducted:

Day	1	2	5	8	15	29	120
Compete blood count		x	x	x	x	x	x
Kidney and liver function tests		x	x	x	x		
Clotting and inflammation measurements (PT, PTT, D-dimer, hsCRP, ferritin)	x	x	x	x	x	x	x
SARS-CoV-2 viral test (nasal swab with or without oral swab)	x	x	x	x	x		
Blood for future testing including SARS-CoV-2 Antibody	x		x	x	x	x	x

Blood stored for future testing will be evaluated for predictors of response to COVID treatment and to look at the response to plasma infusion. If you decide you no longer want this blood stored for future testing, you may contact the study doctors and ask that this blood be destroyed. If the blood has already been tested it will not be possible to be destroyed. If you do not want your blood drawn for future possible studies, you may choose not to participate in the study

During the study, you will be able to receive standard of care treatment for COVID-19 disease, including remdesivir if this medication is available. When you are finished receiving convalescent plasma or control non-immune human plasma (placebo**)** you will continue the standard of care for COVID-19. Your participation in this study limits you from participating in other COVID-19 clinical trials for up to 14-days if you are eligible. After 14 days in the event that you remain severely ill, and in consultation with the study doctors, additional experimental treatment or enrollment in clinical trials, if you are eligible, will be permitted. If you need non-standard of care treatment before 14 days after infusion of plasma, this will be discussed on a case by case basis with your care team and the study doctors.

Study location: All study procedures will be done at Zuckerberg General Hospital or at University of California San Francisco (UCSF).

How long will I be in the study?

You will be asked to take **convalescent plasma or non-immune human plasma (placebo) for one infusion.** We would like to keep track of your medical condition for 120 days. Keeping in touch with you and checking on your condition every year helps us look at safety and efficacy of this trial.

Can I stop being in the study?

Yes. You can decide to stop at any time. Tell the study doctor if you are thinking about stopping or decide to stop. He or she will tell you how to stop your participation safely.
It is important to tell the study doctor if you are thinking about stopping so any risks from your participation in this trial can be evaluated by your study doctor. The study doctor may stop you from taking part in this study at any time if he/she believes it is in your best interest, if you do not follow the study rules, or if the study is stopped.

What side effects or risks can I expect from being in the study?

You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. However, study doctors don't know all the side effects that may happen. Side effects may be mild or very serious. Your study team may give you medicines to help lessen side effects. Many side effects go away soon after you stop taking the convalescent plasma or non-immune human plasma (placebo). In some cases, side effects can be serious, long lasting, or may never go away. There also is a risk of death.

You should talk to your study doctor about any side effects you experience while taking part in the study.

Risks and side effects related to this trial include those which are:

Likely

- **Randomization risks:** You will be assigned to a study treatment program by chance, and the study treatment you receive may prove to be less effective or to have more side effects than the other study treatment(s) or other available treatments.

- **Blood drawing (venipuncture) risks**: Drawing blood may cause temporary discomfort from the needle stick, bruising, infection, and fainting.

- **Placebo risks**: If you are in the group that receives non-immune plasma (placebo), you will not receive convalescent plasma as part of the study

Less Likely

- **Nasal swab**: local discomfort, vomiting, coughing, nosebleed.

Rare but serious

- Although the risk of contracting COVID-19 infection from receiving the study treatment has not been formally tested yet, we believe that it would be very low because the donor has fully recovered from the infection.
- Transfusion of plasma carries the risk of adverse reactions such as allergic reactions, transfusion-associated circulatory overload or lung damage with profound breathing difficulty and has the possibility of 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.

- There is a rare risk that convalescent plasma could make your COVID worse, not better. This has not been seen in the over 5,000 COVID patients who have received convalescent plasma in the US.

Unknown Risks: The experimental study treatments may have side effects that no one knows about yet. The researchers will let you know if they learn anything that might make you change your mind about participating in the study.

Privacy Risks: You will be emailed a PDF copy of this signed and dated consent form. There may be risks of loss of privacy and confidentiality if the PDF copy of this consent form is viewed and/or stored on a personal electronic device (PED), especially if that PED is shared with other users or is lost, hacked, or subject to a search warrant or subpoena. Also, the PDF copy of the consent may not be able to be permanently removed from a PED.

Risks in pregnant or breastfeeding women: Blood products can be administered safely during pregnancy and breastfeeding, which will not exclude you from participation in this study. Transfusion of blood products, including plasma, have the rare risk of transfusion reaction, fluid overload and bloodborne infection described above, all of which could potentially affect an unborn child. We do not have information on the use of convalescent plasma for COVID-19 during pregnancy and breastfeeding. It is not known if pregnancy will specifically affect plasma safety or effectiveness. If you are pregnant and choose to participate in this study, the study team will collect information on the outcome of your pregnancy.

Are there benefits to taking part in the study?

If you are in the group that receives convalescent plasma and it proves to treat your condition more effectively with fewer side effects than standard therapy and non-immune plasma, you may benefit from participating in the study, but this cannot be guaranteed.

What other choices do I have if I do not take part in this study?

- You can choose to get this study treatment or not. Your choice will not affect the care that you are receiving at this center. We will always do our best to take care of you. If you agree to this study treatment, you will also be helping us learn whether the study treatment works and how it works to help other people, though you can withdraw at any time. Convalescent plasma can be obtained outside of this study in some circumstances, but is typically reserved for people who are severely ill and in the intensive care unit, or who have serious underlying problems with their immune system.

How will my specimens and information be used?

Researchers will use your specimens and information to conduct this study. We may pool data from this study with other similar research studies to better answer the question about how well convalescent plasma works in COVID-19. Any data shared from this study will not contain your name or personal information. Once the study is done using your specimens and information, we may share them with other researchers so they can use them for other studies in the future. We will not share your name or any other personal information that would let the researchers know

who you are. We will not ask you for additional permission to share this de-identified information.

How will information about me be kept confidential?

Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total privacy. Some information from your medical records will be collected and used for this study. If you do not have a UCSF medical record, one will be created for you. Your signed and dated consent form and some of your research tests will be added to your UCSF medical record.

Therefore, people involved with your future care and insurance may become aware of your participation and of any information added to your medical record as a result of your participation. Study tests that are performed by research labs, and information gathered directly from you by the researchers will be part of your research records but will not be added to your medical record. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Authorized representatives from the following organizations may review your research data for the purpose of monitoring or managing the conduct of this study:

- Representatives of the Sponsor, UCSF
- Representatives from Vitalant and the American Red Cross, which will provide the plasma for study treatment
- Representatives of the Food and Drug Administration (FDA)
- Advarra IRB
- Representatives from the iCONA collaboration, which is conducting a data pooling effort of similar randomized controlled trials evaluating CCP in hospitalized COVID patients.

Are there any costs to me for taking part in this study?

Two types of procedures will be done during this study. Some are part of your standard medical care and others are only for research. You or your insurer will be billed for the standard medical care. You will be responsible for your co-pays, deductibles, and any other charges that your insurer will not pay. There is a possibility that your insurer may not cover all standard medical care costs if you are receiving medical services out of network. Any procedures done only for research will not be charged to you or your insurer. The sponsor will provide the convalescent plasma or non-immune plasma and administration at no cost to you.

Will I be paid for taking part in this study?

You will be paid $40.00 for each in-person visit to the research site that occurs after you are discharged from the hospital. You will not be paid for phone visits or visits that occur while you are hospitalized. This would occur on days 29 and day 120, and would be a maximum of $80.00. You will not be paid for phone visits or visits that occur while you are hospitalized.

What happens if I am injured because I took part in this study?

It is important that you tell your study doctor in person or my calling him/her, Dr. Annie Luetkemeyer Annie Luetkemeyer, MD [415.476-4082 ext 130] and /or Priscilla Hsue, M.D. [628-206-8257] at UCSF ZSFG Division of HIV, ID & Global Medicine and/or Sarah Doernberg, M.D [415-353-2626] and/or Peter Chin-Hong, M.D. [415-502-9585] at University of California San Francisco.

Treatment and Compensation for Injury: If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. The costs of the treatment may be billed to you or your insurer just like any other medical costs, or covered by the University of California depending on a number of factors. The University and the study sponsor do not normally provide any other form of compensation for injury.
For further information about this, you may call the office of the Institutional Review Board at 415- 476-1814.

To pay medical expenses, the sponsor will need to know some information about you like your name, date of birth, and Medicare Beneficiary Identifier (MBI). This is because the sponsor has to check to see if you receive Medicare and if you do, report the payment it makes to Medicare.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

If you are an employee or relative of an employee of this research center, you are under no obligation to participate in this study. You/your family member may withdraw from the study at any time and for any reason, and neither you/your family member's decision to participate in the study, nor any decision on your/their part to withdraw, will have any effect on your/your family member's performance appraisal or employment at this clinical research center. You/your family member may refuse to participate or you/your family member may withdraw from the study at any time without penalty or anyone blaming you.

If you are an employee or relative of an employee of this research center, you are under no obligation to participate in this study. You/your family member may withdraw from the study at

any time and for any reason, and neither you/your family member's decision to participate in the study, nor any decision on your/their part to withdraw, will have any effect on your/your family member's performance appraisal or employment at this clinical research center. You/your family member may refuse to participate or you/your family member may withdraw from the study at any time without penalty or anyone blaming you.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

Whom to contact about this study

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the study doctor at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, contact:

- By mail:
  Study Subject Adviser
  Advarra IRB
  6940 Columbia Gateway Drive, Suite 110
  Columbia, MD 21046
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00043570.

If you wish to ask questions about the study or your rights as a research subject to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the office of the Institutional Review Board at 415-476-1814

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

CONSENT

You have been given copies of this consent form and the Experimental Subject's Bill of Rights to keep.

You will be asked to sign and date a separate form authorizing access, use, creation, or disclosure of health information about you (HIPAA)

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to participate or to withdraw at any point in this study without penalty or loss of benefits to which you are otherwise entitled.

If you wish to participate in this study, you should sign and date below.

Date	Subject's Signature for Consent
Date	Person Obtaining Consent

AND/OR:

Date	Legally Authorized Representative
Date	Person Obtaining Consent

Attestation Statement

I confirm that the research study was thoroughly explained to the subject. I reviewed the consent form with the subject and answered the subject's questions. The subject appeared to have understood the information and was able to answer the following questions correctly:

1. What is the purpose of this study?
2. If you decide to be in the study, what will you be asked to do?
3. What is the possible benefit of participating in this study?
4. What are the possible risks of participating in this study?
5. If you decide not to participate in this study, what options do you have?
6. Will participating in this study cost you anything? If so, what will you have to pay for?
7. Do you have to be in this study?
8. If you decide to be in the study, can you leave the study when you want to?

_____	_____
Printed Name of Person Conducting the Informed Consent Discussion	Position
_____	_____
Signature of Person Conducting the Informed Consent Discussion	Date

IRB# 20-30794

University of California San Francisco (UCSF Health)
Permission to Use Personal Health Information for Research

Study Title (or IRB Approval Number if study title may breach subject's privacy): **A randomized controlled adaptive study comparing COVID-19 convalescent plasma to non-immune plasma to limit coronavirus-associated complications in hospitalized patients**

Principal Investigator Name: **Annie Luetkemeyer, MD**

Sponsor/Funding Agency (if funded): **University of California, San Francisco**

A. What is the purpose of this form?

State and federal privacy laws protect the use and release of your health information. Under these laws, the University of California or your health care provider cannot release your health information for research purposes unless you give your permission. Your information will be released to the research team which includes the researchers, people hired by the University or the sponsor to do the research and people with authority to oversee the research. If you decide to give your permission and to participate in the study, you must sign this form as well as the Consent Form. This form describes the different ways that **UCSF Health** can share your information with the researcher, research team, sponsor and people with oversight responsibility. The research team will use and protect your information as described in the attached Consent Form. However, once your health information is released by **UCSF Health** it may not be protected by the privacy laws and might be shared with others. If you have questions, ask a member of the research team.

B. What Personal Health Information will be released?

If you give your permission and sign this form, you are allowing **UCSF Health** to release the following medical records containing your Personal Health Information. Your Personal Health Information includes health information in your medical records, financial records and other information that can identify you.

☒ Entire Medical Record	☐ Lab & Pathology Reports	☐ Emergency Dept. Records
☐ Ambulatory Clinic	☐ Dental Records	☐ Financial records
☐ Progress Notes	☐ Operative Reports	☐ Imaging Reports
☐ Other Test Reports	☐ Discharge Summary	☐ History & Physical Exams
☐ Other (describe):	☐ Consultation	☐ Psychological Tests

_____

C. Do I have to give my permission for certain specific uses?

Yes.

☒ The research team will also be collecting information from your medical record that is marked by the check box. The following information will only be released if you give your specific permission by putting your initials on the line(s).

☒ I agree to the release of information pertaining to drug and alcohol abuse, diagnosis or treatment. _____(initials)
☒ I agree to the release of HIV/AIDS testing information._____ (initials)
☒ I agree to the release of genetic testing information._____ (initials)
☒ I agree to the release of information pertaining to mental health diagnosis or treatment._____ (initials)

D. Who will disclose and/or receive my Personal Health Information?

Your Personal Health Information may be shared with these people for the following purposes:

1. To the research team for the research described in the attached Consent Form;
2. To others at UC with authority to oversee the research
3. To others who are required by law to review the quality and safety of the research, including: U.S. government agencies, such as the Food and Drug Administration or the Office of Human Research Protections, the research sponsor or the sponsor's representatives including but not limited to the contract research organization (CRO), or government agencies in other countries.

E. How will my Personal Health Information be shared for the research?

If you agree to be in this study, the research team may share your Personal Health Information in the following ways:

1. To perform the research
2. Share it with researchers in the U.S. or other countries;
3. Use it to improve the design of future studies;
4. Share it with business partners of the sponsor; or
5. File applications with U.S. or foreign government agencies to get approval for new drugs or health care products.

F. Am I required to sign this document?

No, you are not required to sign this document. You will receive the same clinical care if you do not sign this document. However, if you do not sign the document, you will not be able to participate in this research study.

G. Optional research activity

☒ There are no optional research activities.

☐ The research I am agreeing to participate in has additional optional research activity such as the creation of a database, a tissue repository or other activities, as explained to me in the informed consent process, I understand I can choose to agree to have my information shared for those activities or not.

I agree to allow my information to be disclosed for the additional optional research activities explained in the informed consent process._____(initials)

H. Does my permission expire?

This permission to release your Personal Health Information expires when the research ends and all required study monitoring is over.

I. Can I cancel my permission?

You can cancel your permission at any time. You can do this in two ways. You can write to the researcher or you can ask someone on the research team to give you a form to fill out to cancel your permission. If you cancel your permission, you may no longer be in the research study. You may want to ask someone on the research team if canceling will affect your medical treatment. If you cancel, information that was already collected and disclosed about you may continue to be used for limited purposes. Also, if the law requires it, the sponsor and government agencies may continue to look at your medical records to review the quality or safety of the study.

J. Signature

Subject

If you agree to the use and release of your Personal Health Information, please print your name and sign below. You will be given a signed copy of this form.

_____
Subject's Name (print)--*required*

_____ _____
Subject's Signature Date

Parent or Legally Authorized Representative

If you agree to the use and release of the above named subject's Personal Health Information, please print your name and sign below.

Parent or Legally Authorized Representative's Name (print)	Relationship to the Subject
Parent or Legally Authorized Representative's Signature	Date

Witness

If this form is being read to the subject because s/he cannot read the form, a witness must be present and is required to print his/her name and sign here:

Witness' Name (print)

Witness' Signature

Date

Instructions for Researchers: This version clarifies Instructions for Researchers Item 3b. There are no other changes to the document. Do not make any changes to this form other than the following items:

The IRB **will not** be confirming the accuracy of the information you complete on this form. The researchers are responsible for accurately completing the HIPAA Research Authorization as follows:

1. Page 1, Item B: Mark all sources of PHI that will be released
2. Page 2, Item C:
    a. Check the first box if any of the 4 categories of sensitive information will be collected
    b. Then, check the box ***only*** for each specific type of information that will be collected for this study
    c. Obtain the participant's initials ***only*** *for the specific types of information*
3. Page 3, Item G:
    a. Check one of the boxes indicating if there are optional research activities or not
    b. Obtain the participant's initial *only if the study involves optional research activity, and the participant agrees to the optional research activity.*
4. Page 3, Item J: Obtain the participant's name, signature, and date; *complete subsequent signature lines* ***if applicable***
5. Provide the subject with a signed copy of the form

Note: The Word document of this form allows you to check the boxes electronically. You can make a 'master version' of this form for this study with all pertinent boxes checked.

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO

EXPERIMENTAL SUBJECT'S

BILL OF RIGHTS

The rights below are the rights of every person who is asked to be in a research study. As an experimental subject I have the following rights:

1) To be told what the study is trying to find out,
2) To be told what will happen to me and whether any of the procedures, drugs, or devices is different from what would be used in standard practice,
3) To be told about the frequent and/or important risks, side effects, or discomforts of the things that will happen to me for research purposes,
4) To be told if I can expect any benefit from participating, and, if so, what the benefit might be,
5) To be told of the other choices I have and how they may be better or worse than being in the study,
6) To be allowed to ask any questions concerning the study both before agreeing to be involved and during the course of the study,
7) To be told what sort of medical treatment is available if any complications arise,
8) To refuse to participate at all or to change my mind about participation after the study is started. This decision will not affect my right to receive the care I would receive if I were not in the study,
9) To receive a copy of the signed and dated consent form,
10) To be free of pressure when considering whether I wish to agree to be in the study.

If I have other questions I should ask the researcher or the research assistant. In addition, I may contact the Institutional Review Board, which is concerned with protection of volunteers in research projects. I may reach the committee office by calling: (415) 476-1814 from 8:00 AM to 5:00 PM, Monday to Friday, or by writing to the UCSF Human Research Protection Program, Box 0962, 3333 California St., Ste. 315, San Francisco, CA 94143.

Call 476-1814 for information on translations.