Convalescent Plasma to Limit Coronavirus Associated Complications: A Randomized, Double-Blind, Controlled, Phase 2 Study Comparing the Efficacy and Safety of Human Coronavirus Immune Plasma (HCIP) vs. Control (SARS-CoV-2 non-immune) Plasma Among Outpatients with Symptomatic COVID-19.

NCT 04373460

Informed Consent Form
July 21, 2021 final IRB approval date

Participant ID _

RESEARCH SUBJECT CONSENT FORM

Plasma Recipient Consent

Title of Project: Convalescent Plasma to Limit Coronavirus Associated Complications: A Randomized, Double-Blind, Controlled Phase 2 Study Comparing the Efficacy and Safety Human Coronavirus Immune Plasma (HCIP) vs. control (SARS-CoV-2 non-immune plasma) Among Outpatients with Symptomatic COVID-19

JHM IRB Application No.: IRB00247590

Sponsor/Supporter/Funded By: Bloomberg Philanthropies, DoD, NIH and the State of Maryland Overall Study

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See "Study Site Information" page(s) near the end of this consent form for your local study team contacts.

You are being invited to take part in a research study. This study is a multi-site study, meaning it will take place at several different locations. Because this is a multi-site study this informed consent form includes two parts. The first part of this document includes information that applies to all study sites. The second part of the consent form includes information specific to the study site where you are being asked to enroll.

In this consent form "you" generally refers to the research subject. If you are being asked as the legally authorized representative, parent, or guardian to permit the subject to take part in the research, "you" in the rest of this form generally means the research subject.

This consent form describes the research study and helps you decide if you want to participate. It provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights and responsibilities as a research participant.

You should read and understand the information in this document including the procedures, risks and potential benefits.

If you have questions about anything in this form, you should ask the research team for more information before you agree to participate.

You may also wish to talk to your family or friends about your participation in this study.

Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

Participation in this study is voluntary. Even if you decide to join now, you can change your mind later.

Research Summary (Key Information):

This study is being done at multiple sites across the United States. Before making your decision, both the site-specific information and general study information will be reviewed with you.

We invite you to take part in a research study called "Convalescent Plasma to limit Coronavirus." We are working to identify a possible investigational drug to reduce complications of SARS-CoV-2, also known as "Coronavirus disease" or "COVID-19". The FDA has given us permission to test an investigational blood plasma product called "Anti-SARS-CoV-2 Convalescent Plasma" ("Convalescent Plasma") in this study. This product is made from blood plasma taken from people who have recovered from SARS-CoV-2. Blood plasma is the yellow, clear part of blood that remains after you remove the blood cells.

We are asking you to join this study because you are an adult who has been diagnosed with COVID-19 and have symptoms of the virus.

This study will randomly assign (like flipping a coin) one group of participants to receive an intravenous (in a vein in your arm) transfusion of the convalescent plasma. The other group will be given an intravenous transfusion of a standard blood plasma product taken from people who did not have COVID-19. Doctors will not know which participant has received which blood plasma product. The convalescent plasma from people who have recovered from SARS-CoV-2 has antibodies to fight against the virus. We want to see if giving this plasma to individuals who test positive for the virus may reduce their symptoms and help minimize complications from the illness. About 1344 people will join this study.

The study will involve collecting blood and nasal swabs at up to 5 different study visits including screening (Day (-1)) and/or plasma infusion (Day 0) visit, and day 14, 28, and 90 after the plasma infusion. A total of approximately 5 tablespoons of blood and 4 nasal swabs will be collected.

For all participants, there are standard risks of transfusion that you should consider. In addition, there is a risk that Convalescent Plasma may worsen the infection, or the inflammation associated with the infection. Another potential risk is that your natural immune response to infection could be lessened by receiving the antibody-containing plasma, making it more likely that you could be re-infected.

Taking part in this study is entirely voluntary. We urge you discuss any questions about this study with our staff members. Talk to your family and friends about it and take your time to make your decision. If you decide to participate, you must sign this form to show that you want to take part.

Section 1. PURPOSE OF THE RESEARCH

This research is being done to develop a possible new therapy to treat coronavirus disease (COVID- 19).

COVID-19 is the infection caused by a virus (a type of germ) called Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2). This is a new virus that that in 2020 has caused a global pandemic. There are currently no proven options for treatment or prevention of this infection. Most people infected with this virus have mild symptoms including fever, cough, and shortness of breath. Some people get very sick from this virus, requiring hospitalization and some need the use of a breathing machine (ventilator). These people tend to be older and have chronic medical problems, but younger people can have more serious infections too.

People who become infected with a virus such as SARS-CoV-2 usually develop an immune response and produce antibodies against the virus. Antibodies are natural proteins made by the body's immune system that attack viruses and other germs. These antibodies are found in plasma, which is the yellow, clear part of the blood. There have been other studies using plasma to treat other types of viruses that showed some positive results. Human plasma containing antibodies to the SARS-CoV-2 virus is a potential option for prevention and treatment of COVID-19. This type of treatment, known as passive antibody therapy, could be rapidly available when there are sufficient numbers of people who have recovered from infection and can donate antibody-containing plasma.

This study is designed to test whether administration of plasma containing antibodies to people infected with the SARS-CoV-2 virus is able to prevent disease progression or lessen the severity of disease. We have collected plasma from people who have high levels of these antibodies because they have recovered from COVID-19. We will transfuse this high-antibody plasma into one group of infected people, and transfuse the other group of people with regular plasma that does not contain high levels of antibodies to COVID-19. We want to see if the COVID-19 antibody-containing plasma helps prevent the progression of infection or lessens the severity of current symptoms.

While there are no FDA approved therapies for outpatient COVID-19, monoclonal antibody infusion therapy has been effective in preventing hospitalization when given early in the first week of illness. Emergency use authorization has been granted by the FDA for monoclonal outpatient use. If you are eligible for monoclonal therapy, you should consult with your provider about its availability. Standard clinical practice involves supporting patients, who are severely ill requiring hospitalization, with supplemental oxygen and other standard care as needed. Patients involved in this study will have no changes in management from standard care other than the administration of 1 unit of either COVID-19 antibody-containing convalescent plasma or standard (control) plasma without antibodies to SARS-CoV-2.

Are there any investigational drugs/devices/procedures?

The use of Anti-SARS-CoV-2 Convalescent Plasma in this research study is investigational. The word "investigational" means that Anti-SARS-CoV-2 Convalescent Plasma is not approved for marketing by the Food and Drug Administration (FDA). The FDA is allowing the use of Anti-SARS-CoV-2 Convalescent Plasma in this study.

All plasma was collected from donors who recovered from COVID-19 and had high levels of antibody against the SARS-CoV-2. Some of the donors may have been compensated for the time they spent donating the plasma. All donor plasma was also tested to determine the amount of antibodies it has against the SARS-CoV-2. All plasma has also been tested for infectious diseases that can be transmitted in blood, including HIV, hepatitis viruses, and syphilis. The plasma used in the control group of the study had identical collection and processing procedures but was collected from community blood donors rather than individuals who have recovered from COVID-19. The plasma used in this study has been tested in similar ways and meets the same standards as plasma used in any hospital blood bank.

Who can join this study?

To participate in this study, you must be 18 years of age or older. Participants who are laboratory confirmed COVID-19 positive AND have developed symptoms of COVID-19 are eligible.

People who will not be allowed to participate in this study include:

- Individuals with psychiatric or cognitive illness or recreational drug/alcohol use that in the opinion of the principal investigator, would affect subject safety and/or compliance;
- Are/had receiving any treatment drug for COVID-19 within 14 days prior to screening evaluation (including monoclonal antibodies, off label, compassionate use or trial-related therapeutics). Steroid treatment at any time does not affect study eligibility
- If clinically indicated, administration of monoclonal antibodies can follow study plasma treatment and does not affect study enrollment.
- Those with a history of severe transfusion-associated allergic reaction.

How many people will be in this study?

There will be about 1344 volunteers enrolled in this study.

Section 2. PROCEDURES

If you agree to be in this study, we will ask you to do the following things:

Screening Procedures

At the screening visit to see if you are eligible for the study where we will:

- Review and sign this consent form;
- Ask you about your health and any medicines you are taking;
- Do a physical exam;
- For females, we will do a pregnancy test;
- If you have not had a recent test of your blood type, we will check that by taking about

1 teaspoon of blood;
- Ask you about any symptoms that could be due to COVID-19;
- Do a repeat throat and nasal swab for the SARS-CoV-2 virus; and
- Do additional standard baseline blood tests as well as blood tests for the SARS-CoV-2 virus by taking about 3 teaspoons of blood.

Procedures Before Study Drug

From the screening visit tests, we will be able to determine if you qualify for this study and if we have plasma that matches your blood type. Once we determine that you qualify for this study, you will be assigned randomly (like flipping a coin) to receive either plasma containing high levels of antibody against the SARS-CoV-2 virus or standard control plasma (SARS-CoV-2 non-immune plasma) that does not contain antibodies to the virus. All participants will also receive routine care.

While we prepare the plasma, we will collect some baseline information about your symptoms you have, vital signs (temperature, pulse, respiration rate, and blood pressure), and some other clinical information (such as whether you require any supplemental oxygen and whether you are in the ICU). We will also need to collect about 6 tablespoons of blood from you. We will swab the back of your throat to look for the SARS-CoV-2 virus. We will then administer the study plasma in a vein through a catheter (thin tube) (see below) and draw blood after the transfusion to determine antibody levels.

Study Plasma Administration

All participants will receive standard treatment and recommendations following COVID-19 exposure and these recommendations are up to your doctor. Any person requiring hospitalization will receive standard care. In addition, we will give you study plasma. In both groups, the plasma will be given through an IV catheter (tube) placed in a vein. You will receive one dose of the study plasma on Day 0 of the study. The transfusion will take about 1 hour.

All of the plasma was collected from donors. Some of the donors may have been compensated for the time they spent donating the plasma. Plasma containing high levels of antibody against the virus was collected from people who have recovered from COVID-19. All donors have met FDA requirements for plasma donors indicating that they have recovered from the infection. All plasma was tested to determine the amount of antibodies it has against the SARS-CoV-2 virus. All of the plasma has also been tested for the infectious diseases that can be transmitted in blood, including HIV, hepatitis viruses, and syphilis. The plasma used in the control group of the study had identical collection and processing procedures but was collected from community blood donors rather than individuals who have recovered from COVID-19. The plasma used in this study has been tested in similar ways and meets the same standards as plasma used in any hospital blood bank.

Procedures After Study Drug Administration

On 1, 3, 5, 7, and 10 days after you received your study plasma (either the convalescent plasma or the standard control plasma), we will evaluate you by telephone call. You will be given a thermometer for daily fever measurements. Where available a pulse oximeter may also be given. You will be given a daily diary to keep track of your symptoms. You will need to return to the clinic after screening for visits on day 14, 28, and 90. The visits may be in the hospital or clinic. Each visit will take approximately one hour. During these visits we will ask questions about your symptoms, collect

clinical information, check your vital signs, and perform a brief physical exam. We will collect about 6 tablespoons of blood for safety and research reasons. We will also swab the back of your throat on days 14 and 28.

If you are in the hospital and do not participate in scheduled follow-up visits, we will try to reach you there. If we cannot reach you or you are unable to answer questions yourself, we may contact your health care providers or emergency contacts to ask about your health.

Section 3. TIME DURATON OF THE PROCEDURES AND STUDY

You will be in this study for 90 days.

Section 4. DISCOMFORTS AND RISKS

Blood Products

Informed consent is only required for administration of whole blood, one of its 4 main parts: red blood cells, platelets, plasma, white blood cells and cryoprecipitate. This information is given to help you make a decision about the use of blood products (e.g. plasma) in this study.

Plasma given to both groups in this study will be processed in the same way that all blood banks process blood and plasma for standard transfusions. Donors are screened before they give blood. All donated blood is carefully tested for infections. This includes testing for viruses such as HIV, Hepatitis B & C, West Nile and Zika. All of these steps make it less likely the blood/blood product could make you sick. Nevertheless, no guarantees can be made about the quality of supplied blood.

Most risks associated with plasma therapy are those that occur regardless of the type of antibodies in the plasma. The risks of receiving plasma are similar to the risks with any blood products as described in the following table:

Table 1: Expected Adverse Events (general blood plasma transfusion):

Standard risks of human plasma	Steps to reduce risk
Transfusion Reaction: (< 5 in 100 people) • Fever and/or chills/rigors • Itching and hives • Passive hemolysis (breakdown of red blood cells) • Low blood pressure, bronchospasm, (wheezing), difficulty breathing, and organ injury are more serious but also much less common. These are called. transfusion related acute lung injury (TRALI)	• Transfusion according to standard blood banking procedures and practices • Standard monitoring during- and shortly after transfusion, • Ready access to medications to treat transfusion reactions if needed (for example, antihistamines, acetaminophen, corticosteroids, epinephrine) • Standard ,measures to reduce TRALI include limiting certain people from donating (such as women who have had many pregnancies)

Transfusion associated circulatory overload (TACO): (less than 1 in 1000 people) • Pulmonary edema (excess fluid in the lung) can develop in individuals with underlying heart or kidney disease	• Risk is limited by transfusing only minimum volume necessary • Attention to fluid volumes in patients with severe heart or kidney disease predisposing to TACO
Infection: (less than 1 in 1000) • Bacteria, Viruses, Parasites, Prions	• Screening of donors and testing of all blood products per standard blood banking procedures

Most risks associated with plasma therapy are those that occur regardless of the type of antibodies in the plasma. The risks of receiving plasma are similar to the risks with any blood products as described above. Fevers, rashes, hives, or headaches occasionally happen with plasma infusions. More rare side effects may include serious allergic reactions including anaphylaxis, which can be life threatening.

Infections (e.g. Hepatitis B, hepatitis C, HIV, Zika, and West Nile) may also rarely occur as described above even though we screen for these diseases. These risks are minimized by the careful screening and matching processes that you will undergo.

A type of lung injury has been seen with some transfusions. This transfusion-related acute lung injury (TRALI) has been shown to be related to antibodies against your cells that come from other people's plasma. The risk of TRALI is reported as 1 out of 5000 transfusions. If this happens it could make it hard to breathe, or you may have to be put on a breathing machine. There is also the risk that the proteins in the plasma will cause blood clots to form. These blood clots could go to your heart or lung making it difficult to breathe.

The plasma volume is roughly 250 mL (1 cup). There is a risk that if you cannot tolerate this amount of volume it may become harder to breathe or put a strain on your heart. People that are known to have conditions that would not tolerate this volume of blood are excluded from the study. However, this condition could still occur.

By signing this consent form and agreeing to participate in this study, you acknowledge that you will be given blood products, specifically 1 unit of plasma. By signing this consent form and agreeing to participate in this study you also acknowledge that you understand how and why blood/blood products will be administered, as well as the benefits and potential risks. These risks include fever, allergic reactions, transmission of infectious disease, fluid overload, acute lung injury and death. You acknowledge that you understand that risks exist despite testing of donor blood and precautions taken during administration.

Anti-SARS-CoV-2 Convalescent Plasma

Specific risks of the investigational Anti-SARS-CoV-2 Convalescent Plasma include the general risks of human blood product administration as described above. There is a risk that plasma containing antibodies to the SARS-CoV-2 virus may lead to antibody-mediated enhancement of infection (ADE). This could make either the infection, or the inflammation associated with the infection, worse. Another potential risk is that the natural immune response to infection could be lessened by the administration of antibody-containing plasma, which could lead to participants being susceptible to re-infection.

The following table outlines potential risks specific to SARS-CoV-2 Convalescent Plasma:

Table 2: Potential Adverse Events Specific to SARS-CoV-2 Convalescent Plasma

Risks specific to SARS-CoV-2 convalescent plasma	Steps to reduce risk
Transmission of SARS-CoV-2 • It is not expected that SARS-CoV-2 is readily transmissible by transfusion since other respiratory viruses (e.g., influenza, SARS, MERS) are not considered transfusion transmissible.	• To further reduce this theoretic risk, blood donors must have waited 14 days after resolution of symptoms and have tested negative for COVID-19 using sensitive molecular assays.
Antibody-mediated disease enhancement (ADE) • Theoretic risk that antibodies to a virus may enhance disease severity of a similar, distinct virus	• There is awareness of this theoretical risk; there will be close monitoring of all adverse events; such will include vigilance for ADE
Limited immune response and lack of protective immunity • Antibody-containing plasma may decrease the natural humoral response to SARS-CoV-2 infection, leading to the lack of lasting immunity	• Measure antibody levels against SARS-CoV-2 several months after transfusion in individuals who develop disease • Vaccinate individuals who do not have persistent antibody after infection, if and when a vaccine becomes available

Blood Draws

Taking blood may cause discomfort, bleeding, or bruising where the needle enters the body. In rare cases, it may result in fainting. There is a small risk of infection.

Throat and Nasopharyngeal Swabs

Generally, this procedure is well tolerated. It may cause discomfort, though we try to minimize discomfort as best we can. Occasionally, a throat swab can cause you to cough or gag, and rarely vomit.

Interviews or questionnaires

You may get tired or bored when we are asking you questions or you are completing questionnaires. You do not have to answer any question you do not want to answer.

Special Concerns

If you decide to participate in this study, you will not be able to donate blood for at least one year from the day you received the plasma. If you are male or a non-pregnant female, your doctor may ask you to wait at least 5-6 months before receiving a live attenuated (weakened) influenza vaccine, the measles, rubella, mumps vaccine, or the varicella (Chickenpox) vaccine. This is because the plasma you receive in this study may temporarily interfere with the body's ability to mount a good immune response to those vaccines as desired.

Currently, there are no data on the safety and efficacy of SARS-COV-2 vaccination in persons who recently have COVID-19, received monoclonal antibodies or convalescent plasma as a part of COVID-19 treatment. Per current CDC recommendations, persons with documented acute SARS-CoV-2 infection in the preceding 90 days should delay vaccination until near the end of this period, though if the patient desires and can receive vaccine, this will be allowed.

Based on the estimated half-life of antibody therapies as well as evidence suggesting that reinfection is uncommon in the 90 days after initial infection, vaccination should be deferred for at least 90 days after receipt of monoclonal antibodies or convalescent plasma, as a precautionary measure until additional information becomes available, to avoid interference of the antibody treatment with vaccine-induced immune responses.

Are there risks related to pregnancy?

All females will have a pregnancy test done prior to enrollment. All participants must be willing to practice an effective contraceptive method or remain abstinent during the study period. If you are pregnant or become pregnant, there may be additional risks that are currently unforeseeable. Plasma is sometimes used during pregnancy, so we do not anticipate any additional risk with this plasma, but we do not know for certain. You may want to consult with your obstetrician about your vaccine status and receiving plasma. There is a risk that the plasma could cause premature labor, complications after the child is born, or miscarriage. It is unknown whether this research may hurt an embryo or fetus.

Identifiable private information

There is the risk that information about you may become known to people outside this study.

Unknown risk

There may be side effects and discomforts that are not yet known.

Section 5. POTENTIAL BENEFITS

You may or may not benefit from being in this study. We do not know if you will benefit from receiving the investigational plasma product or the control plasma.

If you take part in this study, you may help others in the future. If this study product is effective, it could be rapidly available when there are sufficient numbers of people who have recovered from infection and can donate antibody-containing plasma.

Section 6. ALTERNATIVES

You do not have to join this study. While there are no FDA approved therapies for outpatient COVID-19, monoclonal antibody infusion therapy has been effective in preventing hospitalization when given early in the first week of illness. Emergency use authorization has been granted by the FDA for monoclonal outpatient use. If you are eligible for monoclonal therapy, you should consult with your provider about its availability.

Section 7. STATEMENT OF CONFIDENTIALITY

A description of this clinical trial will be 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 the website at any time for NCT04373460.

7.1 Privacy and Confidentiality Measures

To maintain confidentiality, the Study Investigator will be responsible for keeping records in a locked area and results of tests coded to prevent association with participants' names. Data entered into computerized files will be accessible only by authorized personnel directly involved with the study and will be coded. Participants' research records will be available to representatives of the FDA, DoD the NIH, the manufacturer of the study product, investigators at the site involved with the study, and the reviewing IRB. The results of the research study may be published, but subjects' names or identifiers will not be revealed. Records will remain confidential.

Section 8. CERTIFICATE OF CONFIDENTIALITY

Your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

Section 9. COMPENSATION FOR INJURY

Every effort to prevent injury as a result of your participation will be taken. It is possible, however, that you could develop complications or injuries as a result of participating in this research study. In the event of injury resulting from this research, medical treatment is available but will be provided at the usual charge. See more information in the site-specific information section of this informed consent for information pertaining to your study site.

You will not lose any legal rights by signing this form.

A new public health order, called the Public Readiness and Emergency Preparedness Declaration (PREP), was issued by the federal government on March 10, 2020. This order limits your legal rights to sue if you are harmed while participating in a COVID-19 clinical study that uses certain drugs to treat COVID 19. This includes the Anti-SARS-CoV-2 Convalescent Plasma used in this study. Subjects using Anti-SARS-CoV-2 Convalescent Plasma in this study will have limits on their right to sue the manufacturers, the study sponsor, healthcare providers and others for significant injuries and adverse reactions that result from this study. The federal government has created a fund that people harmed in these kind of studies can apply to if they are seriously injured called the Countermeasures Injury Compensation program. More information on this program is available from the federal government.

Section 10. RESEARCH FUNDING

The institution and investigators are receiving funding from the Department of Defense, the National Institutes of Health, the State of Maryland, and/or private/public donations.

Section 11. BIOLOGICAL SPECIMENS

The blood and viral swabs collected from you during this study are important to science. You will not own the blood, viral swabs and data after you give it to the study. You will not receive any financial benefit from any product or idea created by the investigators using the data or materials collected from you.

With appropriate protections for privacy, study investigators may share your biospecimens and information with other researchers, but without identifiers associating them with you. Your biospecimens may be used for commercial profit. You will not share in this potential commercial profit. We will share clinically relevant results with you if you option for disclosure.

Section 12. VOLUNTARY PARTICIPATION

Taking part in this research study is voluntary. You do not have to participate in this research. If you choose to take part, you have the right to stop at any time. If you decide not to participate or if you decide to stop taking part in the research at a later date, there will be no penalty or loss of benefits to which you are otherwise entitled.

Your investigator may take you out of the research study without your permission. Some possible reasons for this are:

- Staying in the study would be harmful.
- You need treatment not allowed in the study.
- You fail to follow instructions or are not able to attend required study visits.
- You become pregnant.
- The study is cancelled.
- There may be other reasons to take you out of the study that we do not know at this time.

If you will be participating in another clinical trial while in this research, you should discuss the procedures and/or treatments with your physician or the investigators. This precaution is intended to protect you from possible side effects from interactions of research drugs, treatments, or testing.

During the course of the research you will be provided with any significant new finding s that may affect your willingness to continue participating in this research.

Section 13. CONTACT INFORMATION FOR QUESTIONS OR CONCERNS

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, contact your Site Principal Investigator or research team. The Site Principal Investigator's contact inf01mation is containe d in section "Site Specific Consent Inf01mation" page(s) towards the end of this consent f01m.

This study has been reviewed by an fustitutional Review Board (IRB), a group of people that reviews human research studies. The IRB can help you if you have questions about your rights as a research pa1t icipant or if you have other questions, concerns or complaints about this research study.

For this study, Johns Hopkins has agreed to se1ve as the single IRB (sIRB) providing oversight for all sites. You may contact the Johns Hopkins IRB at 410-502-2092 or jhmeirb@jhmi.edu with your questions or concerns.

OPTIONAL COMPONENTS

Request to collect and store at Johns Hopkins biospecimens for future research

Your samples/data may help researchers at Johns Hopkins and other institutions learn about, prevent, or treat COVID-19. As pa1t oft his research study, we would like to as k you to let us store your blood for future research. This research could include other diseases. The stored blood might be used for whole genome sequencing and you will have an option to decide and still be pa1t of the study. The research may involve research tools such as whole or part human gene sequencing. Gene sequencing of your DNA provides researchers with the code to your genetic material.

We would like to look at human genes which affect COVID-19 and to share pa1ts of the blood with outside researchers or companie s interested in COVID-19 tests.

Will you allow us to store, share, and use the biospecimens we collect for this study for use in future research including genetic research, COVID-19 or other infectious diseases research?

Y ES D _____
Signature of Participant

N oD _____
Signature of Participant

Future Contact

We would like your permission for our research team to contact you in the future to provide you results of this study and to offer you opportunities for future research. Please note that your decision below does not prevent other researchers at the research institution from contacting you about other research.

Will you allow us to contact you in the future?

YEsO _____ _____
Signature of Pa1ticipant Date

NoD _____ _____
Signature of Participant Date