Convalescent Plasma to Stem Coronavirus: A Randomized Controlled Double Blinded Phase 2 Study Comparing the Efficacy and Safety of Human Coronavirus Immune Plasma (HCIP) vs. Control (SARS-CoV-2 non-immune plasma) among Adults Exposed to COVID-19

NCT 04323800

Master Informed Consent Form

Combined with Johns Hopkins University Site Specific Consent Information

Master Consent Version: January 13, 2021
Site Specific Consent Version: November 23, 2020

Participant ID _____

RESEARCH SUBJECT CONSENT FORM

Plasma Recipient Consent

Project Title:	Convalescent Plasma to Stem Coronavirus: A Randomized Controlled Double Blinded Phase 2 Study Comparing the Efficacy and Safety of Human Coronavirus Immune Plasma (HCIP) vs. control (SARS-CoV-2 non-immune plasma) among Adults Exposed to COVID-19
JHM IRB Application No.:	IRB00245634
Sponsor/Supporter/Funded By:	Bloomberg Foundation, Department of Defense (DoD), NIH, and the State of Maryland
Overall Study Principal Investigator:	Shmuel Shoham, MD Johns Hopkins University, School of Medicine 1830 E. Monument St., Baltimore, MD 21287 Email: sshoham1@jhmi.edu Phone: (410) 614-6431 24 Hour Phone: 202-215-6760

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.

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.

This research is being done to develop a possible new therapy for prevention and treatment of coronavirus disease (COVID-19).We would like to study whether human plasma containing antibodies to the SARS-CoV-2 virus could be an option for prevention and treatment of COVID-19. This type of treatment, known as passive antibody therapy, could be a way of rapidly treating patients 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 giving plasma containing antibodies to the SARS-CoV-2 virus will prevent illness or lessen the severity of illness in people who are at high risk of developing COVID-19 after getting exposed to someone who is infected. We have collected plasma from people who have high levels of these antibodies after they have recovered from COVID-19. We will study two groups of people who have had recent exposure to a person with COVID-19. One group with receive high-antibody plasma through a vein while the other group (called the control group) will receive regular plasma through a vein. We want to see if the antibody-containing plasma helps prevent COVID-19 illness or lessens its severity.

Participants being asked to join this study must have had high risk exposure to a person with COVID-19 within 96 hours of enrollment, and not have active COVID-19 infection. Procedures include a screening visit where you will be asked to sign this consent form, review medications and symptoms, physical exam, pregnancy test (for females), blood draw, and nasal swab.

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 control plasma that does not contain antibodies to the virus.

In both groups, the plasma will be given through an IV catheter (tube) placed in a vein. You will receive 1 dose of the study plasma on Day 0 of the study.

After you receive the study drug, we will evaluate you on Days 1, 3, 7, 14, 28, 60 and 90. You will be in this study for a total of 90 days.

Risks of participating in this research may include: transfusion reaction: (less than 5%): infection: (less than 0.1%) or impact on future administration: (less than 5%). More details about these risks and steps being taken to minimize or mange them are detailed later in this form.

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.

Participation in this study may prevent you from participating in other clinical trials.

Section 1. PURPOSE OF THE RESEARCH

This research is being done to develop a possible new therapy for prevention and treatment of 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 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 usually produce antibodies against the virus. Such antibodies are natural proteins made by the body's immune system that bind up the virus to lessen the harm they would cause. These antibodies are found in plasma, which is the yellow, clear part of the blood. If the plasma containing antibodies are donated by a patient who has recovered from infection and is given to another patient early in their infection, it may be possible to prevent or reduce the amount of illness they get. There have been other studies using plasma to treat other types of viruses that showed some favorable results. We would like to study whether human plasma containing antibodies to the SARS-CoV-2 virus could be an option for prevention and treatment of COVID-19. This type of treatment, known as passive antibody therapy, could be a way of rapidly treating patients when there are sufficient numbers of people who have recovered from infection and can donate antibody-containing plasma. In contrast to vaccines, which begin to provide protection weeks after vaccination, antibody-containing plasma would provide its protective benefits immediately. Additionally, passive antibody therapy is the only way to provide immunity for some patients with weak immune systems who are not able to benefit from vaccines.

This study is designed to test whether giving plasma containing antibodies to patients infected with the SARS-CoV-2 virus will prevent illness or lessen the severity of illness in people who are at high risk of developing COVID-19 after getting exposed to someone who is infected. We have collected plasma from people who have high levels of these antibodies because they have recovered from COVID-19. We will study two groups of people who have had recent exposure to a person with COVID-19. One group with receive high-antibody plasma through a vein while the other group (called the control group) will receive regular plasma through a vein. We want to see if the antibody-containing plasma helps prevent COVID-19 illness or lessens its severity.

There is no proven therapy for treatment or prevention of COVID-19. Standard clinical practice involves hospitalizing severely ill patients and providing them oxygen and other standard care as well as a ventilator, if needed. Patients involved in this study will receive standard care as needed in addition to the infusion of either antibody-containing plasma or control (SARS-CoV-2 non-immune plasma).

Are there any investigational drugs/devices/procedures?
The use of Anti-SARS-CoV-2 Convalescent Plasma in this research study is an investigational drug. 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.

Who can join this study?
To participate in this study, you must be 18 years of age or older. Participants must have had high risk exposure, as defined by the Center for Disease Control and Prevention (CDC), to a person with COVID-19 within 96 hours of enrollment, and not have active COVID-19 infection.

People who will not be allowed to participate in this study include:
- Individuals with conditions that in the opinion of the principal investigator, would affect subject safety and/or compliance
- Individuals with symptoms consistent with COVID-19 infection at time of screening or before dosing, or anyone with laboratory evidence of COVID-19 infection at time of screening.
- Those with a history of severe transfusion-associated allergic reaction

How many people will be in this study?
There will be about 500 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 we will:
- ask you to review and sign this consent form.
- ask you about your health and any medicines you are taking.
- take your vital signs
- do a pregnancy test for females.
- will check your blood type by taking about 1 teaspoon of blood, if you have not had a recent test.
- ask you about any symptoms that could be due to COVID-19.
- do a throat or nasal swab for the SARS-CoV-2 virus.
- do additional standard 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, we will be able to decide 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 control plasma that does not contain antibodies to the virus. All participants will also receive routine care.

Day 0
While we prepare the plasma, we will collect some baseline information about what symptoms you have, your vital signs (temperature, pulse, respiration rate, and blood pressure), ask you about your health and any medicines you are taking, and perform a physical exam.

If you do not have any symptoms of COVID-19, we will give you the study plasma in a vein through a catheter (see below).

Study Drug Administration (Transfusion):
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 1 dose of the study plasma on Day 0 of the study.

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 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, Day 1-90:
After you receive the study drug, we will evaluate you on Days 1, 3, 7, 14, 28, 60 and 90. If you become sick and are admitted to the hospital, please inform us so that we can visit you there. Otherwise, we will need to have you to return to the clinic for the visits on Day 1, 7, 14, 28, and 90. The Day 3, and Day 60 visits will be completed over the phone. Each visit should take up to 1 hour. At each of these time points, we will, ask questions about your symptoms and collect some clinical information. If your visits are in-person, we will also check your vital signs. On Days 1, 7, 14, and 90 we will collect about 6 tablespoons of blood for safety tests and other research tests. We will also swab the back of your throat on Days 1, 7, 14, and 28.

If you are in the hospital, discharged from the hospital, or do not participate in scheduled follow-up visits, we will try to reach you by phone. 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
Participation in this study may prevent you from participating in other clinical trials.

Blood Products

This information is given to help you make a decision about the use of plasma, which is a blood product used in this study.

Blood is safer now than ever before. Donors are screened before they give blood. All donated blood is carefully tested for infections. This includes Supplier 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.

Risks of Administration Vary, but Include:	**Steps Taken to Reduce the Risk May Include:**
Transfusion Reaction: (less than in 100 people) • Fever, itching and hives are the most common mild symptoms • Low blood pressure, difficulty breathing, and organ injury are more serious but also much less common	Before being given, • Donated plasma is matched with your blood type and tested for antibodies, and • You may be given medicine to reduce side effects • You will be monitored for any symptoms and the administration will be stopped if necessary
Infection: (less than 1 in 1000) • Bacteria • Viruses • Parasites • Prions	Donors are screened prior to being allowed to give blood and all donated blood is carefully tested by suppliers before being sent to the hospital
Impact on Future Administration: (less than 5 in 100) Your body may react to the blood/blood product and develop antibodies that may make it more difficult to match donated blood, complicate future pregnancies or make future administration less effective	• Suppliers remove white blood cells from plasma to decrease the risk of this happening • Before being given, plasma is matched with your blood type

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 would 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.

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 for you 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 in your leg veins. 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 cup 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. If individuals in this study develop COVID-19 after enrollment, 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 being susceptible to re-infection.

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 as good of an 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 received convalescent plasma for SARS-CoV-2 prophylaxis. Based on the estimated half-life of antibodies, vaccination is recommended to be deferred for at least 90 days after receiving convalescent plasma, to avoid interference of the antibody treatment with vaccine-induced immune responses.

By participating in this study, there is a 50% chance of receiving convalescent plasma. If an opportunity to receive a SARS-CoV-2 vaccine arises for you, please contact us to discuss options.

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 and from receiving the plasma therapy. Prior studies have suggested benefits for antibody-containing plasma in preventing or treating other diseases. It is possible that receiving plasma with high levels of antibody against the SARS-CoV-2 virus will decrease the risk of developing COVID-19. If you do develop COVID-19, it is possible that the antibody-containing plasma will make the infection less severe or help you to improve faster.

If you take part in this study, you may help others in the future. If this therapy is successful, it could be rapidly available when there are sufficient numbers of people who have recovered from infection and can donate antibody-containing plasma. In the case of a pandemic due to a virus with no known treatments or vaccines, this type of therapy may be the first available preventive or treatment option. Additionally, giving antibody therapy is the only way to provide immunity for some immunocompromised patients who do not benefit from vaccines.

Section 6. STATEMENT OF CONFIDENTIALITY

A description of this clinical trial will be available on http:///www.ClinicalTrials.gov, as required by U.S. law. The number is NCT04323800. 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 the Web site at any time.

6.1 Privacy and Confidentiality Measures

To maintain confidentiality, the Principal 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' records will be available to the FDA, Department of Defense (DoD), the National Institutes of Health (NIH), the manufacturer of the study product and their representatives,

investigators at the site involved with the study, and the IRB. The results of the research study may be published, but participants' names or identifiers will not be revealed. Records will remain confidential.

Section 7. 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 8. 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.

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 9. RESEARCH FUNDING

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

Section 10. 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 11. 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 findings that may affect your willingness to continue participating in this research.

Section 12. 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 information is contained in section "Site Specific Consent Information" page(s) towards the end of this consent form.

This study has been reviewed by an Institutional 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 participant or if you have other questions, concerns or complaints about this research study.

For this study, Johns Hopkins has agreed to serve 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 biospecimens for future research

Your samples/data may help researchers at Johns Hopkins and other institutions learn about, prevent, or treat COVID-19. As part of this research study, we would like to ask 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 part 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 parts of the blood with outside researchers or companies interested in COVID-19 tests.

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

YES ☐ _____
Signature of Participant

NO ☐ _____
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?

YES ☐ _____ _____
Signature of Participant Date

NO ☐ _____ _____
Signature of Participant Date

SITE SPECIFIC CONSENT INFORMATION

Site Name: Johns Hopkins University

Study Title: Convalescent Plasma to Stem Coronavirus: A Randomized Controlled Double Blinded Phase 2 Study Comparing the Efficacy and Safety of Human Coronavirus Immune Plasma (HCIP) vs. control (SARS-CoV-2 non-immune plasma) among Adults Exposed to COVID-19 **Plasma Recipient Consent**

JHM IRB Application Number: IRB00245634

Site Principal Investigator: Shmuel Shoham, MD

Site Principal Investigator Contact Information:

Johns Hopkins University, School of Medicine
1830 E. Monument St., Baltimore, MD 21287
Email: sshoham1@jhmi.edu
Phone: (410) 614-6431
24 Hour Phone (202) 215-6760

Emergency Contact: _____

Introduction:

This study is being done at multiple sites. This part of the consent form includes information about your site and is specific to participation at your site only. Before making your decision, both the site-specific information and general study information will be reviewed with you. You will have the opportunity to discuss any questions, including questions about this portion of the consent document, with your site's study team.

Site-Specific Study Procedures & Associated Risks:

A medical record may be created as a result of your participation in this study. Your consent form and some of your test results would be included in this record. Therefore, your other doctors may become aware of your participation.

Costs to Study Participants:

You will receive a separate Insurance and Research Participant Financial Responsibility Information Sheet (Sheet).

This Sheet will give you the following information:

- The procedures, tests, drugs or devices that are part of this research and that will be paid for by the study (no cost to you).
- The procedures, tests, drugs or devices that will be billed to you and/or your health insurer. If you have health insurance, you will be responsible for any co-pays or deductibles not covered by your insurance.

Payment for Study Participation:

Participants will receive compensation according to the following schedule, (payable through Venmo) and a parking voucher. To process the payment we will need to know your name, address, and social security number. We will provide you with information on how to set up a Venmo account.

$ 50 for the screening visit
$ 150 for the transfusion visit
$ 75 day 1 follow up visit
$ 75 day 7 follow up visit
$ 75 day 14 follow up visit
$ 75 day 28 follow up visit
$ 75 day 90 follow up visit
TOTAL possible $575

You may be required to provide your social security number to be paid for taking part in this study. Federal tax law requires that you report your research payments when you file your taxes. If your total payments from Johns Hopkins exceed $600 per year, Johns Hopkins will report these payments to the Internal Revenue Service and you will receive a 1099-MISC form from us.

Compensation for Research-Related Injury:

Johns Hopkins does not have a program to pay you if you are hurt or have other bad results from being in the study. However, medical care at Johns Hopkins is open to you as it is to all sick or injured people.

The costs for any treatment or hospital care you receive as the result of a study-related injury that are not covered by a health insurer will be billed to you.

By signing this form you will not give up any rights you have to seek compensation for injury.

Site IRB Contact Information:

This study has been reviewed by an Institutional 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 participant or if you have other questions, concerns or complaints about this research study. You may contact the IRB at 410-502-2092 or jhmeirb@jhmi.edu

Additional information about your local site:

Communicable diseases:
The law requires us to report positive tests to the health department. This reporting will include information that identifies you (for example name, date of birth, home address, phone number, etc.) as required by Maryland law. The health department may use this information to contact you for further follow up and/or to help conduct health surveillance activities aimed at preventing or controlling diseases.

What happens to data and biospecimens that are collected in the study?
Johns Hopkins and our research partners work to advance science and public health. The data and biospecimens we collect from you are important to this effort.

Biospecimens may include any of the following: blood, tissue, saliva, urine, bone marrow, cells, etc. Most biospecimens contain DNA, which is the genetic code for each person.

If you join this study, you will not own the data and/or biospecimens collected from you as part of this research study. If researchers use them to create a new product or idea, including those that may have commercial value, you will not benefit financially from these efforts.

What testing or procedures may be done with your biospecimens?
Your biospecimens may be used for a variety of research purposes. The specific testing that will be part of this study includes standard blood tests along with blood tests for the SARS-CoV-2 virus. We will also collect nasopharyngeal and throat swabs to test for the SARS-CoV-2 virus.

How will your data and/or biospecimens be shared now and in the future?
Sharing data and/or biospecimens is part of research and may increase what we can learn from this study.

Often, data/biospecimen sharing is required as a condition of funding or for publishing study results. It also is needed to allow other researchers to validate study findings and to come up with new ideas.

Your data and/or biospecimens may be shared:
- directly with research collaborators, other researchers, sponsors, government agencies, publishers of papers and other research partners
- through government or other databases/repositories

Data/biospecimen sharing could change over time, and may continue after the study ends.

We will do our best to protect and maintain your data/biospecimens in a safe way. Generally, if we share your data/biospecimens without identifiers (such as your name, address, date of birth) further review and approval by an IRB is not needed. However, when we share data/biospecimens, we limit the uses of the information and whether these data/biospecimens can be shared with another research team. If data/biospecimens are shared with identifiers, further IRB review and approval may be needed and the IRB will determine whether additional consent is required.

Johns Hopkins researchers may also use the biospecimens collected in this study for future research purposes, which may include gene sequencing and genetic testing. Each cell contains your complete DNA. Gene sequencing of your DNA provides researchers with the code to your genetic material. This future research may be unrelated to the current study and may include outside collaborators.

Because science constantly advances, we do not yet know what future testing may include. If biospecimens are tested/used in ways not described above, further IRB review and approval may be needed and the IRB will determine whether additional consent is required.

If you are not comfortable with the use of your data/biospecimens in future research, you may not want to participate in this study.

How will your privacy be maintained and how will the confidentiality of your data be protected?

HIPAA Authorization for Disclosure of Protected Health Information

What information is being collected, used, or shared?
To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Johns Hopkins Medicine and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?
The people who may request, receive or use your private health information include the researchers and their staff. Additionally, we may share your information with other people at Johns Hopkins, for example if needed for your clinical care or study oversight. To improve coordination of your research and clinical care, some information about the study you join will be included in your electronic medical record.

By signing this form, you give permission to the research team to share your information with others outside of Johns Hopkins. This may include the sponsor of the study DoD and its agents or contractors, outside providers, study safety monitors, government agencies like FDA, other sites in the study, data managers and other agents and contractors used by the study team. The Department of Defense (DoD) and the U.S. Army Medical Research and Materiel Command (USAMRMC) will have access to records for audit purposes.

We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?
You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your information be used or shared?
Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?
You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

How will your information be protected?
Subject confidentiality is strictly held in trust by the participating investigators, their staff, and the sponsors and their agents. No information concerning the study or the data will be released to any unauthorized third party without prior written approval of the sponsor. The results of the research study may be published, but subjects' names or identifiers will not be revealed. Records will remain confidential. To maintain confidentiality, the PI will be responsible for keeping records in a locked area and results of tests coded to prevent association with subjects' names. Data entered into computerized files will be accessible only by authorized personnel directly involved with the study and will be coded. Subjects' records will be available to the FDA, the NIH, the manufacturer of the study product and their representatives, investigators at the site involved with the study, and the IRB.

Signature Lines:

Your signature on this form means that you have reviewed the information in this form, you have had a chance to ask questions, and you agree to join the study. You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

_____

Signature of Participant (Print Name) Date/Time

_____

Signature of Person Obtaining Consent (Print Name) Date/Time

_____

Signature of Legally Authorized Representative (LAR) (Print Name) Date/Time
FOR ADULTS NOT CAPABLE of GIVING CONSENT

_____

Relationship of LAR to Participant Date/Time
(Indicate why the LAR is authorized to act as a surrogate health care decision-maker under state or applicable local law)

_____

Signature of Interpreter/Witness to Consent Procedures (Print Name) Date/Time
(Required for studies enrolling non-English speakers using the short form process or otherwise as determined required by the IRB)

I have received the separate Insurance and Research Participant Financial Responsibility Information Sheet.

_____

Signature of Participant, LAR or Parent/Guardian (Print Name) Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR AND A COPY MUST BE GIVEN TO THE PARTICIPANT. IF APPROPRIATE FOR THIS STUDY, A SCANNED COPY OF THE SIGNED CONSENT FORM SHOULD BE UPLOADED TO THE PARTICIPANT'S EPIC/EMR RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).

DOCUMENTATION OF PHYSICIAN/MID-LEVEL PROVIDER CONSENT

My signature below indicates that I have discussed the risks, benefits, and alternatives, answered any questions, and believe the participant is able to make an informed choice to join the study.

_____

Signature of Physician/Mid-Level Provider (Print Name) Date/Time

_____

Signature of Participant (Print Name) Date/Time

_____

Signature of Legally Authorized Representative (LAR) (Print Name) Date/Time
FOR ADULTS NOT CAPABLE of GIVING CONSENT

_____

Relationship of LAR to Participant Date/Time
(Indicate why the LAR is authorized to act as a surrogate health care decision-maker under state or applicable local law)

_____

_____

Signature of Interpreter/Witness to Consent Procedures (Print Name) Date/Time
(Required for studies enrolling non-English speakers using the short form process or otherwise as determined required by the IRB)

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR AND A COPY MUST BE GIVEN TO THE PARTICIPANT. IF APPROPRIATE FOR THIS STUDY, A SCANNED COPY OF THE SIGNED CONSENT FORM SHOULD BE UPLOADED TO THE PARTICIPANT'S EPIC/EMR RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).

COVID-19 WITNESS/INTERPRETER SIGNATURE AND ATTESTATION PAGE

A signed consent document (original or copy) from the participant or their legally authorized representative (LAR) was not able to be obtained by the study team due to COVID-19 transmission concerns.

My signature below indicates that I can confirm that the following took place:

- I was present for the consent process for this study which took place remotely (either over the phone or electronically)
- The research participant/LAR was given the information in the consent document and had the chance to ask questions
- The research participant/LAR agreed to participate in the study and confirmed that he/she has signed the informed consent document (if presented with a paper document)/clicked "agree to participate" (if presented with electronic consent)

Signature of Interpreter/Witness to Consent Procedures (Print Name) Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR AND A COPY MUST BE GIVEN TO THE PARTICIPANT. IF APPROPRIATE FOR THIS STUDY, A SCANNED COPY OF THE SIGNED CONSENT FORM SHOULD BE UPLOADED TO THE PARTICIPANT'S EPIC/EMR RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).