PASS IT ON
PASSIVE IMMUNITY TRIAL FOR OUR NATION

Institutional Review Board
Informed Consent Document for Research
MASTER CONSENT

Study Title: **Passive Immunity Trial for Our Nation (PassItOn)**
Version Date: November 4, 2020

Part 1 of 2: MASTER CONSENT

Name of participant:_____Age: _____

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 consent form includes two parts. Part 1 of this consent form is the Master Consent and includes information that applies to all study sites. Part 2 of the consent form is the Study Site Information and includes information specific to the study site where you are being asked to enroll. Both parts together are the legal consent form and must be provided to you.

Key Information:
The first section of this document contains some key points that the research team thought you would find important. The study is described in more detail after this section. If you do not understand something, please ask someone.

Key information about this study:
You are being asked to take part in this research study because you tested positive for the SARS Coronavirus 2 (SARS-CoV-2), which leads to Coronavirus Disease 2019 (COVID-19). Currently COVID-19 is infecting people across the US. This study will enroll about 1000 people at up to 51 sites in the US.

COVID-19 illnesses have ranged from very mild (including some with no reported symptoms) to severe, including illness resulting in death. While information so far suggests that most COVID-19 illness is mild, more serious illness can occur in any person with COVID-19 and lead to hospitalization. Older people and people of all ages with severe chronic medical conditions like heart disease, lung disease and diabetes, for example, seem to be at higher risk of being hospitalized for COVID-19.

The purpose of this study is to collect information needed to understand if a potential treatment, convalescent plasma, might help patients who are sick with COVID-19 recover faster.

If you agree to be in the study, you will be in the study for about 29-36 days. You will either receive a 1 unit (about 1 ¼ cups) of convalescent plasma or fluids with multivitamins. We do not know if the convalescent plasma will make COVID-19 better or worse or have no effect.

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The United States Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the use of COVID-19 convalescent plasma to treat hospitalized patients with COVID-19. The FDA notes there is not enough evidence to show that COVID-19 convalescent plasma should be a new standard of care for the treatment of patients with COVID-19. The emergency use authorization is not intended to replace randomized clinical trials and enrollment of patients into ongoing randomized clinical trials is critically important to fully understand the safety and efficacy of COVID-19 convalescent plasma.

Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

This study is randomized, blinded, and placebo-controlled, which means that you will either receive convalescent donor plasma or placebo. A placebo is made to look like the convalescent plasma but does not have any convalescent plasma in it. Researchers use a placebo to see if the study plasma works better or is safer than not taking any active study plasma. Randomized means that no one can choose who receives the study plasma and who receives the placebo. It is up to chance. You have a one in two chance of receiving convalescent donor plasma or placebo. The Placebo for this study is Lactated Ringer's with multivitamins. Lactated Ringer's is a water, salts and minerals solution. Blinded means that you, the study doctor and the study team will not know which infusion you receive.

Convalescent plasma is the liquid part of blood that is collected from patients who have recovered from COVID-19. COVID-19 patients develop antibodies in the blood against the virus.

Antibodies are proteins that might help fight the infection. Convalescent plasma is being investigated for the treatment of COVID-19 because there is some information that suggests it might help some patients recover from COVID-19.

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study.

Side effects and risks that you can expect if you take part in this study:
Are there any risks to me?
A risk of taking part in this study is the possibility of a loss of confidentiality or privacy. Loss of privacy means having your personal information shared with someone who is not on the study team and was not supposed to see or know about your information. The study team plans to protect your privacy.

Blood Draw
Pain, redness, soreness, bruising, or infection may occur at the needle stick site. Rarely, some people faint. The study doctor may put some cream (called EMLA) on your skin to numb the area so you will not feel the needle stick as much. The numbing cream may make your skin, or the area have a change in skin color, but this is rare.

Risks of transfusion of plasma and/or blood:
Common risks of plasma transfusions may include one or more of the following:

- Fever (high body temperature)
- Rash (change in the color and texture of skin that usually causes an outbreak of red patches or bumps on the skin)
- Hives (swollen, pale red bumps or plaques (wheals) on the skin that appear suddenly)
- Headache (pain in the head)

Other more serious risks are rare and may include the following:

- Serious allergic reactions including anaphylaxis that may affect your ability to breathe or swallow, increase your heart rate, cause back pain, dark urine, chills, itching and rash
- Bacterial infections (an infection caused by bacteria)
- Viral infections [an infection caused by virus like Hepatitis B, Hepatitis C, West Nile Virus, Zika, and human immunodeficiency virus (HIV)]
- Hemolytic transfusion reaction (destruction of red blood cells)
- Transfusion-related acute lung injury (TRALI) symptoms including dyspnea (shortness of breath), hypotension (low blood pressure) and fever (high body temperature)
- Deep vein thrombosis (blood clots in a vein, possible pain, swelling, and/or redness)
- Pulmonary emboli (blood clot in the lung)
- Transfusion-associated circulatory overload (TACO) (risk of volume overload that could cause pulmonary edema)
- Hypothermia (low body temperature)

- Metabolic complications (group of risk factors that raises your risk for heart disease and other health problems, such as diabetes and stroke)

There is a possible risk of the plasma worsening your disease. Another potential risk is that the treatment plasma may make it more difficult for your infection fighting (immune system) to fight new infections. Based on available information and the use of convalescent plasma in other diseases like influenza and SARS, these risks are minimal risks to no risks.

These risks can be further reduced by our standard screening for blood transfusions, monitoring of your vital signs and clinical status, and routine patient care techniques that are standard for all hospitalized patients.

The study plasma will follow FDA guidance for donor screening and testing of plasma products.

Possible Risks of Lactated Ringer's with multivitamin:
The risks of receiving Lactated Ringer's with multivitamins are very low but could include

- heart failure due to fluid overload which could cause difficulty breathing
- allergic reaction to multivitamins

All study participants will be closely monitored for any potential reactions by study and clinical personnel. If convalescent plasma is helpful in treating COVID-19 and you are in the placebo group, you will not receive the benefits of convalescent plasma for COVID-19 treatment.

Risks to Women Who Are or May Become Pregnant
The effect of convalescent plasma on an embryo or fetus (developing baby still in the womb), or on a breastfeeding infant, is unknown. However, convalescent plasma has been used in treating patients with Ebola virus disease and COVID-19 in China. While there is limited information, there are no reports of immediate adverse effects with convalescent plasma use in pregnancy. Intravenous immunoglobulin (IVIG), which is a product made up of antibodies that can be given through a vein, has been safely used in pregnancy. You can take part in this study if you are pregnant or trying to become pregnant.

Risks that are not known:
Because this treatment is investigational, meaning non-FDA approved, there may be risks that we do not know about at this time.

Good effects that might result from this study:
Are there possible benefits to me?
You may benefit from taking part in this study through survival, faster recovery time, or decreased need for intensive care and/or oxygen therapy.

There are benefits to science and humankind that might result from this study. It is also possible the convalescent plasma will not have a beneficial effect. If this is the case, the information from your response to the study will help the researchers and may help people with COVID-19 in the future.

New Findings
If we learn any significant new findings during the study that might influence your decision to participate, we will contact you and explain them.

Procedures to be followed:
Procedures:

Screening, consent and baseline
We will review your medical record and collect information about you during screening and throughout your taking part in this study. This will include your COVID-19 symptoms (fever, cough, and shortness of breath), We will confirm that you have a positive COVID-19 test. We will draw about 6 ml (about 1 ¼ teaspoons) of blood for COVID-19 titers and to learn your blood type.

Day 1 (the day you are enrolled)
You will receive about 200-399 mls (about 1 ¼ cups) of plasma that works with your blood type or placebo. The plasma will be provided. You will either receive an infusion of convalescent plasma or placebo.

The infusion will be given through your IV line (a needle in your vein) and will take between 1 to 3 hours. Before, during and after the infusion we will monitor your vital signs (heart rate, blood pressure, breathing and temperature) and for any reactions to the infusion.

Day 2-8 (or for as long as you are in the hospital up until day 8)
On each of these days while you are in the hospital, we will review your vital signs as well as monitor for fevers, cough, shortness of breath, and lab tests that are part of standard of care treatment. On Day 2 only we will draw 7.5 ml (about 1 ½ teaspoons) of blood for COVID-19 titers and to check your health.

Days 8, 15, 29 (these assessments will be done by telephone if you have been discharged from the hospital).
On these days, we will check on your health status.

Reasons why the study doctor may take you out of this study:
The study doctor may stop you from taking part in this study at any time:
1. if it is in your best interest,
2. if you don't follow the study procedures,
3. if the study is stopped.

What will happen if you decide to stop being in this study?
If you decide to stop being part of the study, you should tell your study doctor. Deciding to not be part of the study will not change your regular medical care in any way.

If you leave this research study early, or are withdrawn from the study, no more information about you will be collected; however, information already collected about you in the study may continue to be used.

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

Privacy:
Any samples and information about you may be made available to others to use for research. To protect your privacy, we will not release your name. You will not receive any benefit as a result of the tests done on your samples. These tests may help us, or other researchers learn more about the causes, risks, treatments, or how to prevent this and other health problems.

Study Results:
If you leave this research study early, or are withdrawn from the study, no more information about you will be collected; however, information already collected about you in the study may continue to be used.

The results of the study group will be published but you will not be individually identified.

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STUDY SITE INFORMATION

Study Title: Passive Immunity Trial for Our Nation (PassItOn)
Version Date: August 25, 2020

Part 2 of 2: STUDY SITE INFORMATION

Site Name:	Vanderbilt University Medical Center
Site Principal Investigator:	Todd W. Rice, M.D., M.Sc.
Site Principal Investigator Contact:	615-322-3412
Site Study Coordinator *(if applicable)*:	Alesia Pruitt, BS
Site Study Coordinator Contact *(if applicable)*:	615-343-8010

This part of the consent form includes information about the site that is asking you to participate in this study and is specific to participation at your site only. Before making your decision, both the site-specific information and the general study information should be reviewed with you. Your medical record will contain a note saying you are in a research study and may contain some research information about you. Anyone you authorize to receive your medical record will also get this information.

Site specific procedures and risks:
Consent to Transfuse Plasma
I have been told that I may receive blood or blood products. I understand what a blood transfusion is, how it is done, why it is done, and the risks involved. The benefits of getting blood or blood products include but are not limited to:

- delivery of oxygen to important organs
- treatment of bleeding
- reduced risk of bleeding.

The risks include but are not limited to:

- fever, chills, allergic reactions, and problems with extra fluid in the blood
- less often, major reactions
- rarely, exposure to infections such as hepatitis B, hepatitis C, and HIV.

I understand these risks exist even though donors and blood are carefully screened and tested. Alternatives to transfusion have been explained to me, as well as the risks and consequences of not having a transfusion. My questions have been answered.

I have read and understand this information and

❑ **Consent to receive blood products. [This consent is valid for 1 inpatient admission or for 1 year for outpatient treatment.]**

Payments for your time spent taking part in this study or expenses:
If you complete Day 15 and Day 29 you will receive a check for $25 for each of those two time points for taking part in this study.

Costs to you if you take part in this study:
If you agree to take part in this research study, you and/or your insurance will not have to pay for the tests and treatments that are being done only for research. However, you are still responsible for paying for the usual care you would normally receive for the treatment of your illness. This includes treatments and tests you would need even if you were not in this study. These costs will be billed to you and/or your insurance.

You have the right to ask what it may cost you to take part in this study. If you would like assistance, financial counseling is available through the Vanderbilt Financial Assistance Program. The study staff can help you contact this program. You have the right to contact your insurance company to discuss the costs of your routine care (non-research) further before choosing to be in the study. You may choose not to be in this study if your insurance does not pay for your routine care (non-research) costs and your doctor will discuss other treatment plans with you.

Payment in case you are injured because of this research study:
If it is determined by Vanderbilt and the Investigator that an injury occurred as a direct result of the tests that are done for research, then you and/or your insurance will not have to pay for the cost of immediate medical care provided **at Vanderbilt** to treat the injury.

There are no plans for Vanderbilt to pay for any injury caused by the usual care you would normally receive for treating your illness or the costs of any additional care. There are no plans for Vanderbilt to give you money for the injury.

Who to call for any questions or in case you are injured:
If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact Todd Rice, M.D. at 615-322-3412.

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the

Vanderbilt University Medical Center Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Confidentiality:
Vanderbilt University Medical Center may share your information and/or samples, without identifiers, to others or use it for other research projects not listed in this form. The sponsor, Vanderbilt University Medical Center, Dr. Rice and his staff will comply with any and all laws regarding the privacy of such information. There are no plans to pay you for the use or transfer of this de-identified information.

You will not be identified by name in any published reports about this study or in any other scientific publication or presentation.

There is a risk that if people outside the study get your health data, they could misuse it for purposes other than those outlined in this consent. The study team has strict privacy and confidentiality protection procedures in place to prevent this from occurring so the chance of this happening to you is extremely small.

This study may have some support from the National Institutes of Health (NIH). If so, 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.

Authorization to Use/Disclose 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 Vanderbilt University Medical Center 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 Vanderbilt, for example if needed for your clinical care or study oversight. By signing this form, you give permission to the research team to share your information with others outside of Vanderbilt University Medical Center. This may include study safety monitors, government agencies, data managers and other agents and contractors used by the study team. 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.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

<u>STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY</u>
I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

PARTICIPANT:

Date _____ Signature of patient/volunteer _____

Printed Name of patient/volunteer _____

Consent obtained by:

Date _____ Signature _____

Printed Name and Title _____

WITNESS/INTERPRETER (if required):

Date _____ Witness/Interpreter Signature _____

Printed Witness/Interpreter Name _____

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I,_____ [name of decision-maker/surrogate], am the _____ [state relationship to participant] of _____ [state participant's name]. I have read the informed consent document, or it has been explained to me. I have had the opportunity to ask any questions and all of my questions have been answered. I have been informed that an investigational treatment may be administered to _____ _____ [participant's name]. I believe receiving such treatment would be in the interests of_____[participant's name] and is consistent with what he/she would have decided had he/she been able to do so.

Your decision to allow your family member/friend to participate in this research study is voluntary. You may choose not to allow his/her participation and he/she will receive alternative treatments without affecting his/her healthcare/services or other rights. You are also free to withdraw him/her from this study at any time. In the event new information becomes available that may affect the risks or benefits associated with this research study or your willingness to allow continued participation in this research study, you will be notified so that you can make an informed decision whether or not to continue your family member/friend's participation in this study.

Your family member/friend will periodically be re-evaluated for the capacity to give consent. If he/she is found to be capable, continued participation in this study would only occur with his/her consent.

_____	___/___/___
Signature of Health Care Decision-Maker/Surrogate	Date
_____	___/___/___
Signature of Witness	Date
_____	___/___/___
Name and Signature of person obtaining consent	Date