Appendix A

PATIENT CONSENT AND PRIVACY AUTHORIZATION FORM

Patient Number: _____

Clinician / physician: _____

Please read this information carefully. It tells you important things about the use of this investigational product, Convalescent Plasma, for patients with COVID-19. A member of the clinical staff will talk to you about taking part in this program. If you have questions at any time, please ask us.

Feel free to discuss the program with your family, friends, and healthcare provider before you make your decision. NOTE: If you are a family member or legally authorized representative signing this consent form for someone else, "you" in the consent form refers to the patient with COVID-19.

If you decide to take part in this program, you will sign this consent form to show that you want to take part. We will give you a copy of this form to keep. A copy of this form will be put in your medical record

You can contact …	**At …**
Principal Clinician/Physician:	Phone: Institution Name and Address:

Why are you being asked to take part in this program?
You have been diagnosed with disease caused by the SARS-CoV-2 also known as coronavirus disease 2019 (COVID-19). SARS-CoV-2 is transmitted in a manner similar to influenza and other respiratory viruses and has been associated with cough, fever, and shortness of breath, and in more severe cases, failure of the ability to breath, or even death. Currently, we don't have any approved medicines or vaccines to treat or prevent COVID-19.

People who recover from COVID-19 do so, at least in part, because their blood contains substances called antibodies, which are capable of fighting the virus that causes the illness. It turns out that for some other diseases caused by respiratory viruses, giving people the liquid portion of blood, called plasma, obtained from those who have recovered from the virus, leads to more rapid improvement of the disease. We think that patients with COVID-19 may improve

faster if they receive plasma from those who have recovered from COVID-19, because it may have the ability to fight the virus that causes COVID-19.

We are asking you to consider receiving plasma from someone who has recovered from COVID-19. Their plasma will have substances that could improve your chances of recovery.

We do not know if this treatment will or will not help you, and we don't know if it will have any harmful effects either, but this is one of the only treatments that we have at present, but you need to know that it has not yet been proven to work. Because we do not have any other treatment option at present, if you are willing, we would like to try this treatment out, and learn from the testing.

What will happen to you while you are in this program?
You will be given plasma, the liquid portion of the blood, from a person who has recovered from COVID-19 that is compatible with your blood type. It will be given into one of your veins, using a sterile single use needle, and will be given over the course of about one to two hours. About 200-500 mL of plasma will be given in this infusion.

Because this therapy has not yet been tested, and you want to try this new therapy, we would like to learn as much as possible about its effects. We will therefore record some information about your response to the treatment, such as how long you needed to stay in the hospital or needed help with breathing.

What are the possible risks or discomforts from being in this program?
Blood and plasma have been used for many other conditions, and in general are very safe. Although the risk of contracting COVID-19 infection from receiving the treatment has not been formally tested yet, we believe that it would be very low because the donor has fully recovered from the infection. Transfusion also carries the risk of adverse reactions such as allergic reactions, transfusion-associated circulatory overload or lung damage with profound breathing difficulty, and transmission of infections including HIV and Hepatitis B and C; although the risk of these infections is very low, as only screened and compatible blood is used for transfusion.

Can I change my mind after I say "Yes"?
Taking part in this program is voluntary. You can change your mind at any time. If you wish to stop the treatment, just tell your doctor. Your decision will not stop you from getting the usual care that all patients receive at this center.

What are the possible benefits from being in this program? We do not know if convalescent plasma will be an effective treatment for COVID-19, and you might not experience any benefit. However, we believe that this treatment might be effective in improving the likelihood of you recovering from the disease.

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

What tests or procedures will you need to pay for if you take part in this program?
You will not need to pay for the convalescent plasma. However, you and/or your insurance will need to pay for all other tests and procedures that you would have as part of your clinical care, including co-payments and deductibles. You will have to pay for any costs not covered by your insurance.

How will your privacy and the confidentiality of your information be protected?
An authorized medical institute will use medical information collected or created as part of your medical care, such as medical records and test results that identify you by name or in another way that they request from your physicians and other health care providers. Your medical information will also be shared with appropriate regulatory authorities. Additionally, all the information or data collected about you to help understand if the therapy is effective will be kept confidential and only be used by the recipients listed here to better understand COVID-19 and its potential treatment(s) and for regulatory oversight of this program.

By signing this form, you give permission to your medical provider to disclose your medical information as described in this form. This permission lasts until the end of the program. Recipients of your medical information may not be subject to federal privacy laws, and your medical information may no longer be protected by federal privacy laws after disclosure. You may take back this permission at any time by telling your doctor. No new medical information will be collected from you after you take back your permission, but any medical information that was already collected will continue to be used and shared as needed for the scientific integrity of the program.

Your signature documents permission for you (or the patient) to take part in this program.

Name of Patient: _____

Signature (Patient or Authorized Representative): _____

Date & Time: _____

Person Obtaining Consent

I have explained the program to the patient/authorized representative and have answered all questions about this program to the best of my ability.

Name: _____

Date & Time: _____

Signature: _____

Appendix B

Donor Records			
Date of donation		Place of donation	
Registration number		plasma unit number	
Name		Age	
Gender	M/F	History of pregnancy /abortion (F)	Yes/ No
Date of discharge from COVID-19 treatment center		Onsets severity at time of illness	
Temperature & Pulse		Weight	
BP		Hemoglobin/Hct	
ABO/Rh blood group		SARS-CoV-2 Neutralizing antibody titer	
SARS-CoV-2 RNA results #1		Tests done on	
SARS-CoV-2 RNA results #2		Tests done on	
HIV test result		Marker tested	
HBV test result		Marker tested	
HCV test result		Marker tested	
Syphilis test result		Marker tested	
Any other infection(s)		Marker (s) tested	
Volume of plasma collected		Date of donation	
C.P bag Serial number		C.P expiry date	
Name of staff collecting blood			

Signature: _____

Appendix C

Patient Plasma Transfusion Records			
Date of transfusion		Place of transfusion	
Name		Registration number	
Date of onsets beginning and onsets severity		Age	
Gender	M/F	Patient's ABO/Rh group	
Number of plasma unit transfused		ABO and RhD group of unit transfused	
Time of starting transfusion		Time of completing transfusion	
Patient vital signs			
Pre transfusion medications			
Transfusion reaction	yes/no	Type of reaction	
Volume transfused		Serial number of transfused bag	
Name of staff performing clinical transfusion			

Signature: _____

Appendix D

Patient monitoring form									
Name:					Date of admission:				
Parameters	**Before Plasma Therapy**	**After Plasma Therapy**							
		Day 1	**Day 2**	**Day 4**	**Day 6**	**Day 8**	**Day 10**	**Day 12**	**Day 14**
Viral load									
Temperature & Pulse									
PAO_2/FIO_2									
CBC									
LFT									
RFT									
CRP									
Chest image									
Pneumonia									
ARDS									

Comments:

_____

_____

_____

Signature: _____