RUTGERS
New Jersey Medical School

Department of Medicine
Rutgers New Jersey Medical School
Rutgers, The State University of New Jersey
185 South Orange Avenue
Newark, NJ 07103

CONSENT FOR THE EXPANDED ACCESS USE OF COVID-19 CONVALESCENT PLASMA

TITLE OF STUDY: **Investigational COVID-19 Convalescent Plasma Transfusion into Severely or Life-Threateningly Ill COVID-19 Patients**

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STUDY SUMMARY: This consent form is part of an informed consent process for a research study and it will provide information that will help you decide whether you want to take part in this study. It is your choice to take part or not.

The **purpose of the research** is to: provide compassionate use of investigational product COVID-19 convalescent plasma (CCP) from recovered COVID-19 patients to patients currently ill with severe or life-threatening COVID-19. If you take part in the research, you will receive the investigational CCP. Your time in the study will consist of CCP transfusions during your hospital stay as well as follow-up phone calls 30 and 90 days after your first transfusion.

Possible harms or burdens of taking part in the study may be that COVID-19 infection may not improve and could even worsen if the subjects receive CCP. Taking part in the study may not directly benefit patients receiving CCP though information obtained may help future patients with this disease.

An alternative to taking part in the research study is to not take part in it.

When To Use This Form

This consent form is designed to provide you with information regarding the use of COVID-19 convalescent plasma (plasma collected from recovered COVID-19 patients) that will be used in the compassionate treatment with the use of the medical investigational product COVID-19 convalescent plasma for your current condition. Please take your time reviewing this information before you consent to its use. If you have questions at any time, you should feel free to ask them and should expect to be given answers that you completely understand.

Background

Currently an investigational treatment being explored for COVID-19 involves the use of convalescent plasma collected from recovered COVID-19 patients. It is possible that convalescent plasma that contains antibodies (proteins that can neutralize virus) to SARS-CoV-2 (the virus that causes COVID-19) might be effective against the infection.

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One possible explanation for the efficacy of convalescent plasma therapy is that the antibodies from convalescent plasma might suppress the virus presence in the blood (viremia).

Purpose
You have been diagnosed with a COVID-19 infection. There are currently no approved drugs/biologics that are effective for this infection. Use of convalescent plasma has been studied in outbreaks of other respiratory infections. Although promising, convalescent plasma has not been shown to be effective in every disease studied.

COVID-19 convalescent plasma (plasma collected from recovered COVID-19 patients) is an experimental treatment that has only been used in a small number of patients with COVID-19 to date.

Description of Procedures
You will be receiving COVID-19 convalescent plasma as an intravenous (into your vein) infusion. Your doctor will make decisions regarding the dose and duration of the compassionate treatment with the use of the medical investigational product COVID-19 convalescent plasma you will receive.

Benefits
The possible benefit of this compassionate treatment with the use of the medical investigational product COVID-19 convalescent plasma is that it may help to treat your COVID-19 infection. The information obtained about you may help future patients with this disease and will add knowledge about this disease. However, if compassionate treatment with the use of the medical investigational product COVID-19 convalescent plasma does not work, you may not benefit.

Risks
It is possible that your infection may not improve and could even worsen if you receive COVID-19 convalescent plasma. There are currently no data on risks and/or discomforts associated with the use of this treatment. No information on reproductive risks or harm is currently available. There is a possibility that COVID-19 convalescent plasma can be harmful to your baby if you are pregnant or nursing while receiving this compassionate treatment with the use of the medical investigational product COVID-19 convalescent plasma.

Alternatives
Your participation in this compassionate treatment with the use of the medical investigational product COVID-19 convalescent plasma treatment is voluntary. If you choose not to participate, your option is to continue to receive routine care from your doctor. You do not have to take part to be treated for your condition.

Follow-up / Participation
Duration of participation currently is not defined; it can be up to 14 days from receiving first dose of COVID-19 convalescent plasma.

Injuries
Patients seeking compassionate treatment with the use of the medical investigational product COVID-19 convalescent plasma will be exposed to certain risks of personal injury in addition to those associated with standard forms of therapy, which is included above in the “Risks” section. It is possible that during the course of this compassionate treatment with the use of the medical investigational product COVID-19 convalescent plasma, new adverse effects of COVID-19 convalescent plasma that result in personal injury may be discovered. The University will make appropriate referrals for medical and/or dental treatment for patients who sustain personal injuries or illnesses as a direct consequence of the compassionate treatment with the use of the medical investigational product COVID-19 convalescent plasma. The patient's health insurance carrier or other third-party payer will be billed for the cost of this compassionate treatment with the use of the medical investigational product COVID-19 convalescent

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plasma; provided that the University shall not submit to federally funded programs, e.g., Medicare, Medicaid or CHAMPUS, for reimbursement first if submission to such programs is prohibited by law. No financial compensation will be provided by the University and no other type of assistance is available from the University.

Costs to Participants
You will not be required to pay any money for the cost of the compassionate treatment with the use of the medical investigational product COVID-19 convalescent plasma.

Confidentiality
All efforts will be made to keep your personal information confidential, but total confidentiality cannot be guaranteed.

This compassionate treatment with the use of the medical investigational product COVID-19 convalescent plasma treatment may only be performed by collecting and using your medical information. Data protection laws give you the right to control the use of your personal information. Therefore, by signing this form you specifically authorize your information to be checked, transferred and processed as follows:

The authorized representatives of the Ethics Committee/Investigational Review Board and regulatory authorities' inspectors may review your medical information by direct access to your medical records. Compassionate treatment with the use of the medical investigational product COVID-19 convalescent plasma data may be transferred to other countries for processing, including countries not covered by the data protection legislation

Authorized representatives from Rutgers may generate publications based on your case as it may add value to the medical community. If the results of this study are published, you will not be identified by name.

Those persons or organizations that receive your information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, if permitted by the laws governing them.

Voluntary Participation
In agreeing to take part in this expanded access use project, you acknowledge that participation in this project is voluntary and can be withdrawn at any time. You may choose not to participate or you may change your mind at any time.

If you do not want to participate in the project or decide to stop participating, your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

You may also withdraw your consent for the use of data already collected about you, but you must do this in writing to:

Marc Klapholz, MD, MBA, FACC, FAHA
Professor and Chair, Department of Medicine
Rutgers New Jersey Medical School
Chief of Medicine Service, University Hospital
185 South Orange Avenue, MSB I-609C,
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Questions / Rights

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If you have any questions about taking part in this project or if you feel you may have suffered an injury related to your participation in this project, you can call the study doctor:

Marc Klapholz, MD, MBA, FACC, FAHA
Professor and Chair, Department of Medicine
Phone: (973) 972- 4595

If you have any questions about your rights regarding the expanded access use of COVID-19 convalescent plasma, you can contact Rutgers IRB Director Carlotta Rodriguez at 973-972-3608.

PARTICIPANT ACKNOWLEDGEMENT

By signing this form, I give my consent and acknowledge that I have been informed of the purpose of compassionate treatment with the use of the medical investigational product COVID-19 convalescent plasma, possible benefits, risks, and complications that might come from receiving COVID-19 convalescent plasma and the alternatives. I understand that COVID-19 convalescent plasma treatment has only been approved by the FDA under compassionate use with no proven benefits at this time. I understand the risks that I am taking and I have had the opportunity to ask questions, all of which have been answered to my satisfaction. I have read the consent form, received answers to my questions, fully understand the consent form and authorize my receipt of COVID-19 convalescent plasma. By my signature below, I acknowledge that I have read each section of this consent form carefully and have had all my questions answered. I acknowledge that I have been given a copy of my signed consent form to keep for my records.

Participant's Name (Printed):_____

Participant's Signature:_____ Date:_____

Signature of Investigator/Individual Obtaining Consent

To the best of my ability, I have explained and discussed the full contents of the project including all of the information contained in this consent form. All questions of the participant have been accurately answered.

Name of Investigator/Person Obtaining Consent (Printed):_____

Signature:_____ Date: _____

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If participant does not have the capacity to consent and protocol is approved for inclusion								
x								
Signature of Legally Authorized Representative (LAR) or Next of Kin							Date	
x								
Printed name of Legally Authorized Representative (LAR) or Next of Kin								
If Next of Kin, please mark ONE relationship from list below (in descending order of priority):								
	Spouse		Adult Child		Custodial Parent		Adult Sibling		Adult relative (related by blood or adoption)

Investigator (or authorized designee) Obtaining Consent (printed name)

Investigator (or authorized designee) Obtaining Consent Signature

Today's date

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AGREEMENT TO PARTICIPATE

Surrogate Proxy Consent

The purpose and procedures for this Study have been described to me verbally and in writing. My questions about this Study have been answered and I have been provided with information about who to contact with additional questions.

As Surrogate, I freely give my consent to allow _____ (printed name of subject) to take part in this Study and authorize that his/her health information as described above, be collected/disclosed in this Study. I understand that by signing this form I am agreeing for the individual named above to take part in research. I understand that I will receive a copy of this form to take with me.

Name of Surrogate
(Print): _____

Signature: _____ Date: _____

Signature of Investigator/Individual Obtaining Consent

To the best of my ability, I have explained and discussed the full contents of the study including all of the information contained in this consent form. All questions of the research subject and those of his/her parent or legally authorized representative have been accurately answered.

Investigator/Person Name (Print): _____

Signature: _____
_____ Date: _____

Signature of Proxy Consent Process Witness

I have observed the proxy consent process which included a description of the purposes and procedures of this Study and an opportunity for questions and answers about this Study. I attest that I am not the subject, his/her guardian or authorized representative, or a researcher on this study and can attest that the requirements for informed consent to the medical research have been satisfied.

Name of Witness (Print):
_____

Signature: _____ Date: _____