The UNIVERSITY OF CHICAGO
The Division of the Biological Sciences • The University of Chicago Medical Center

CONSENT/AUTHORIZATION FOR PARTICIPATION IN A RESEARCH PROTOCOL

Protocol Number: IRB20-0523 Name of Subject: _____
Medical History Number: _____

STUDY TITLE: Pilot Study for Use of Convalescent Plasma Collected from Patients Recovered from COVID-19 Disease for Transfusion as an Empiric Treatment during the 2020 Pandemic at the University of Chicago Medical Center

Consent form for recipient subjects receiving convalescent plasma

Doctors Directing Research: _Maria Lucia Madariaga, MD, Chancey Christensen, MD, Madan Kumar DO, Micah Prochaska MD, Stephen Schrantz MD

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Telephone Number: 773-702-5227

KEY INFORMATION

We are asking you to choose whether or not to volunteer for a research study looking at use of plasma in those with severe COVID-19 infections. In doing this, we are using part of the blood of people who have recovered from COVID-19. The purpose of this section is to give you key information to help you decide whether to participate. We have included detailed information after this section. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is above.

Throughout this form, the term "you" will refer to you or to the person for whom you are providing consent as a surrogate decision maker, as applicable.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

You have been diagnosed with COVID-19. SARS-CoV-2 coronavirus disease, also called COVID-19, is a disease transmitted through close contact with respiratory droplets or other bodily fluids of infected people. Some of the symptoms of the disease include cough, fever, diarrhea, difficulty breathing. The disease is severe in 20% of patients affected and can cause life-threatening problems and death. We are currently in a world-wide pandemic with a rapidly increasing number of cases in the United States.

To date, no treatments have been proven to be better than others or better than simply supporting patients through their illness with medical care. Only a few primary prevention measures have been established focusing on avoiding direct contact with the body fluids of people infected with the virus..

We are asking you if you/your family member would consider receiving plasma from someone who has recovered from COVID-19. Plasma is part of blood. People who recover from COVID-19 do so because their blood may contain substances called antibodies which are capable of fighting COVID-19. It is unknown if patients with COVID-19 might improve faster if they received the plasma (the liquid part of blood) from those who have recovered from COVID-19. There is no definitive evidence to know if this is the case. We are testing to see whether we can develop a process in which we identify plasma donors who have recovered from COVID-19, collect their plasma, and safely give it to patients who are sick with severe or life-threatening COVID-19.

By doing this study, we hope to learn how to deliver convalescent plasma in a feasible way. Your participation in this research will last about 3 months. The FDA has agreed that this research can proceed with what are called "individual emergency investigational new drug applications" and we will contact the FDA to receive this designation prior to any plasma being given.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

By doing this study we hope that we can learn more about how and if plasma can be used to help patients who are sick with COVID-19 infections. For a complete description of benefits, refer to the Detailed Consent information provided further below.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

Plasma has been used for many other conditions, and in general is safe. Although the risk of contracting COVID-19 infection from receiving the treatment has not been tested yet, we believe that it would be low as the donor has been screened for active infection with the COVID-19 virus and because the donor has identified as fully recovered from the infection. Transfusion also carries the risk of adverse reactions such as allergic reactions and transmission of infections including HIV and Hepatitis B and C, though these risks are low as only screened and compatible blood is used for transfusion. For a complete description of risks, refer to the Detailed Consent information provided below.

You can choose to get be in this research study 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 being in this study, you will also be helping us learn about how to carry out this investigational therapy and if and/or how it works to help other patients, though you can withdraw at any time. For a complete description of alternate treatment/procedures, refer to the Detailed Consent information below.

DO YOU HAVE TO TAKE PART IN THE STUDY?

Taking part in this study is voluntary. If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

You may choose not to participate at any time during the study. You will not lose any services, benefits or rights you would normally have if you choose to leave the study. The University of Chicago/University of Chicago Medical Center will not condition (withhold or refuse) treating you on whether you sign this

Authorization or revoke your authorization at a later time. If you do not sign this form, you will not receive the research-related intervention(s).

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is Maria Lucia Madariaga, MD of the University of Chicago. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is: mlmadariaga@uchicago.edu or 773-270-2004.

If you have a research related injury, you should immediately contact Maria Lucia Madariaga MD, 773-270-2004.

For questions about your rights as a research subject, please contact the University of Chicago BSD IRB at 773-702-6505.

DETAILED CONSENT

WHAT IS INVOLVED IN THE STUDY?

About 110 people will take part in this study at the University of Chicago. This would include 100 potential donors of the plasma and up to 10 individuals like yourself who are sick from infection with COVID-19.

If you choose to participate the study staff will review the consent with you. As able, you will be emailed a copy of the consent to review. If email is not available then the study staff will don appropriate personal protective equipment and obtain your consent according to infection control guidelines. If the consent needs to be obtained from the health care proxy or power of attorney then the initial contact and consent will be obtained by the treating attending or study staff with permission of the treating attending over the phone and using other measures as needed to get your proxy's written consent (which can be an electronic consent).

Before receiving plasma transfusion, your medical record will be assessed for inclusion criteria (that is, to determine if you meet the requirements to enter the study) and medical history will be obtained. About 2 teaspoons of blood will be drawn for research at some point for study in the laboratory.

On the day of plasma administration, you will be given the liquid portion collected from the blood (plasma) of a person who has recovered from COVID-19. It will be given into one of your/their veins, using a sterile single use needle, and will be given over the course of about four hours. About 300 mL of plasma will be given over 4 hours. You will be monitored closely with vital signs and symptoms.

We will draw about 2 teaspoons blood for research on days 1, 3, 7, and 14 after plasma administration. As able, and depending on how you do medically, we will follow up with you over the phone to ask about symptoms and medical history at day 28, 60 and 90.

In the future, identifiers associated with your data and/or specimens could be removed from the data and specimens. The de-identified data and specimens could then be used for future research by our research

team or other researchers without notifying you or asking your permission for this use.

The results from this study will not be shared with you.

Dr. Maria Lucia Madariaga may decide to take you off of the study without your consent if:

- You are unable to meet the requirements of the study or your medical condition changes;
- New information becomes available that indicates that participation in this study is not in your best interest; or
- If the study is stopped

WHAT ARE THE RISKS OF THE STUDY?

Less likely

There are risks associated with any transfusion of plasma including:

- transmission of transfusion transmitted viruses (e.g. HIV, HBV, HCV, etc.),
- allergic transfusion reactions,
- severe, potentially life-threatening reaction to transfusion, in severe cases this can produce what is called anaphylaxis and is a severe allergic reaction which causes hives and difficulty breathing and come even (but rarely) be **life threatening**,
- fevers related to transfusion
- transfusion related acute lung injury (TRALI),
- and transfusion associated cardiac overload (TACO).

We will take precautions to minimize risks.

Less likely but serious

There is a theoretical possibility that plasma therapy may make COVID-19 disease worse and even that there could still be virus in the donor's plasma.

Risk of blood draw includes pain, bruising at the point where blood is taken, redness and swelling of the vein and infection, and rare risk of fainting.

There may be other risks that could arise which are not reasonably foreseeable. If new information becomes available which could influence your willingness to continue, this new information will be discussed with you.

ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?

We cannot promise that you will benefit from participating in this study. However, we do hope and expect that your participation in this study will help us learn more about COVID-19 infections and about how to treat them.

WHAT OTHER OPTIONS ARE THERE?

Instead of being in this study, you may choose not to participate or you may choose to participate in other clinical trials that may be available that aim to study other investigational treatments for COVID-19 disease. If you choose not to participate, you will received standard treatments for your disease based on your doctors' decisions of what is best for you and after talking with you and/or your family.

WHAT ARE THE COSTS?

Clinical services provided during a clinical research study are either research-related or considered part of the usual medical care for patients with your disease or condition. Tests, procedures, and activities that are ordered by your medical care team to monitor your disease or condition (whether you are participating in a clinical trial or not) are described as 'usual medical care'. 'Research-related' is the term used to describe any tests, procedures, or activities that you are being asked to undergo only because of your participation in this clinical trial.

All of the tests, procedures, and activities you will undergo as part of your participation in this clinical research study are considered research-related. You will not be responsible for the costs of tests or services that are being performed solely for the purposes of this study. However, this does not include visits or care received at the University of Chicago Medicine (or affiliate sites) that is not related to your participation in this clinical research study. You or your insurance will be financially responsible for the costs of your usual, ongoing medical care. Financial responsibilities from routine care may include deductibles and co-payments and this care will be subject to all the same requirements and restrictions of your insurance

If you have questions about whether specific clinical services are research related or part of your usual medical care, please speak to your physician or research contact person.

WHAT HAPPENS IF I HAVE AN INJURY?

If you suffer an unanticipated injury as a direct result of this research and require emergency medical treatment, the University of Chicago Medical Center will provide such treatment at the University of Chicago Medical Center at no cost to you. You must notify Dr. Maria Lucia Madariaga as promptly as possible after your injury in order to receive this care. An injury is "unanticipated" if it is not one of the known effects of a study drug, medical device or procedure, and is not the result of your disease or condition. The costs of any non-emergency care for such an injury will be billed to you or your insurance in the ordinary manner. If you think that you have suffered a research related injury, you must let Dr. Maria Lucia Madariaga know right away.

WILL I BE PAID FOR MY PARTICIPATION?

You will not be paid to participate.

WHAT ABOUT CONFIDENTIALITY?

There is a risk of potential loss of confidentiality. To minimize this risk, study records that identify you will be kept confidential. The data will be stored in a password-protected database on a secure server at the University of Chicago. Only study staff will have access to the data. The results from tests and/or procedures performed as part of this study may become part of your medical record. Any research

information in your medical record will be kept indefinitely.

During this study, Dr. Maria Lucia Madariaga and her research team will collect protected health information (PHI) about you for the purposes of this research. The research team includes the individuals listed on this consent form and other personnel involved in this study at the University of Chicago. Protected Health Information (PHI) consists of any health information that is collected about you, which could include your medical history and new information collected as a result of this study. Some of this information will come from your medical record. The information to be used on this study includes your name, medical record number, contact information (phone number, email number, address), social security number, and dates (including date of birth, dates of medical procedures and tests, and dates of clinic visits). We will use these identifiers to check on your health status, collect safety data, and for long term follow-up up to day 90 after transfusion.

Your records may be reviewed by federal agencies whose responsibility is to protect human subjects in research including the Food and Drug Administration (FDA) and Office of Human Research Protections (OHRP). Representatives of the University of Chicago, including the Institutional Review Board (a committee that oversees the research) and the Office of Clinical Research may also view the records of the research. If your research record is reviewed by any of these groups, they may also need to review your entire medical record.

Once information is shared outside the University of Chicago, please note that your identifiable health information may be shared with someone else. The same laws that the University of Chicago must obey may not protect your health information.

During your participation in this study, you will have access to your medical record. Dr. Maria Lucia Madariaga is not required to release to you research information that is not part of your medical record.

This consent form will be kept by the research team for at least six years. The study results will be kept in your research record and be used by the research team until completion of this study.

At the time of study completion, either the research information not already in your medical record will be destroyed or information identifying you will be removed from study results.

Data from this study may be used in medical publications or presentations. Your name and any other identifying information will be removed before this data is used. If we wish to use identifying information in publications, we will ask for your approval at that time. We may also share de-identified data with collaborators or others for research purposes.

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

We are collecting your tissue and/or blood as part of this study. We may use your samples for other research studies, including genetic testing, without contacting you, including sharing your samples with others for research purposes here and outside University of Chicago. It is possible that these samples may be shared with a for profit company for research.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

If you choose to no longer be in the study and you do not want any of your future health information to be used, you must inform Dr. Maria Lucia Madariaga in writing at the address on the first page. Dr. Maria Lucia Madariaga may still use your information that was collected prior to your written notice.

We will tell you about significant new information that may affect your willingness to stay in this study.

You will be given a signed copy of this document. Your authorization to use and disclose your health information does not have an expiration date

CONSENT

SUBJECT

The research project and the procedures associated with it have been explained to me. The experimental procedures have been identified and no guarantee has been given about the possible results. I will receive a signed copy of this consent form for my records.

I agree to participate in this study. My participation is voluntary and I do not have to sign this form if I do not want to be part of this research study.

Signature of Subject: _____

Date: _____ Time: _____ AM/PM (Circle)

PERSON OBTAINING CONSENT

I have explained to _____the nature and purpose of the study and the risks involved. I have answered and will answer all questions to the best of my ability. I will give a signed copy of the consent form to the subject.

Signature of Person Obtaining Consent: _____

Date: _____ Time: _____ AM/PM (Circle)

INVESTIGATOR/PHYSICIAN:

Signature of Investigator/Physician _____

Date: _____ Time: _____ AM/PM (Circle)

PROXY/SURROGATE CONSENT:

The subject on whose behalf I consent has no legally authorized representative or that person is unavailable despite efforts to contact him/her. I believe my proxy decision on behalf of the subject conforms as closely as possible to what the subject would have done or intended under the circumstances. This decision takes into account what I believe are the subjects' personal, philosophical, religious and/or moral beliefs and ethical values relative to the purpose of life, sickness, medical procedures, suffering and death. As soon as is possible, the subject will be made aware of his/her involvement in this research protocol. These issues have been discussed by the doctors directing this research and myself.

Signature of Individual Providing Surrogate consent: _____

Relationship to Subject: _____

Date: _____ Time: _____ AM/PM (Circle)

The University of Chicago Hospitals

HEALTH CARE SURROGATE ACT
CERTIFICATION
CONCERNING RESEARCH

1. To the best of my knowledge, the patient/subject (name) _____ does not have a Durable Power of Attorney for Health Care, a Living Will, or Declaration for Mental Health Treatment that applies to the patient's condition and the decision to participate in this research.
   After personally examining the patient named above, I have determined to a reasonable degree of medical certainty that the patient lacks decisional capacity to make decisions about this research. The cause, nature and duration of the lack of decisional capacity is summarized as follows:
   _____
   _____
   _____

2. If possible, the patient has been informed and has not objected to the above determinations, the identity of the surrogate decision maker, and the decision made by the surrogate. The proposed research and the factors to be considered by the surrogate decision maker have been discussed with the surrogate and he/she has demonstrated understanding and willingness to make the decision in accordance with such factors. The decision of the surrogate is reflected in the attached surrogate consent form.

Attending Physician: _____ _____
Date

I concur in the determination that the patient named above lacks decisional capacity.

Concurring Physician*: _____ _____

*(*MUST be a physician not involved in this project)* Date

Surrogate Decision Maker: Name
Address
Telephone (___)
(___)
Relationship to Patient/Subject

I have witnessed the discussion between the attending physician and surrogate decision maker and the decision expressed by the surrogate on behalf of the patient named above.

_____ _____

Witness Date

See Reverse Side for definitions under Illinois Health Care Surrogate Act and factors to be considered by the surrogate.
This form should be placed in the subject's medical record and a copy attached to the research consent form, or if no written consent form is required, kept with the subject's research records.

DEFINITIONS:

"Decisional Capacity" means the ability to understand and appreciate the nature and consequences of a decision regarding research and the ability to reach and communicate an informed decision in the matter as determined by the attending physician.

"Surrogate Decision Maker" means an adult individual or individuals who (i) have decisional capacity, (ii) are available upon reasonable inquiry; (iii) are willing to make medical treatment decisions on behalf of a patient who lacks decisional capacity, and (iv) are identified by the attending physician in accordance with the provisions of this Act in the following order of priority: (1) the patient's guardian of the person; (2) the patient's spouse; (3) any adult son or daughter of the patient; (4) either parent of the patient; any adult brother or sister of the patient; (6) any adult grandchild of the patient; (7) a close friend of the patient; (8) the patient's guardian of the estate.

"Close Friend" means any person 18 years of age or older who has exhibited special care and concern for the patient and who presents an affidavit to the attending physician stating that he or she (i) is a close friend of the patient, (ii) is willing and able to become involved in the patients health care, and (iii) has maintained such regular contact with the patient as to be familiar with the patient's activities, health, and religious and moral beliefs. The affidavit must also state facts and circumstances that demonstrate that familiarity.

FACTORS TO BE CONSIDERED BY SURROGATE DECISION MAKER:

The surrogate shall make a decision for an adult patient conforming as closely as possible to what the patient would have done or intended under the circumstances, taking into account evidence that includes, but is not limited to, the patient's personal, philosophical, religious and moral beliefs and ethical values relative to the purpose of life, sickness, medical procedures, suffering, and death. An unrevoked advance directive, such as a Living Will, Durable Power of Attorney for Health Care, or Declaration for Mental Health Treatment that is no longer valid due to a technical deficiency or is not applicable to the patient's condition may be used as evidence of a patient's wishes.

If the adult patient's wishes are unknown and remain unknown after reasonable efforts to discern them, or if the patient is a minor, the decision shall be made on the basis of the patient's best interests as determined by the surrogate. In determining the patient's best interests, the surrogate shall weigh the benefits to the patient of initiation or continuing the research against the burdens and risks of the research and shall take into account any other information, including the view of family and friends, that the surrogate believes the patient would have considered if able to act for herself or himself.

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