Convalescent plasma in the Treatment of COVID 19

Principal Investigator: Latha Dulipsingh, MD

NCT04343261

Recipient Consent

Version 3

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Trinity Health Of New England

INFORMED CONSENT FOR INVESTIGATIONAL PROTOCOLS AT TRINITY HEALTH OF NEW ENGLAND

STUDY TITLE: *CONVALESCENT PLASMA IN THE TREATMENT OF COVID 19 (PATIENT)*

PRINCIPAL INVESTIGATOR: LATHA DULIPSINGH, M.D.

CO-INVESTIGATOR: DANYAL IBRAHIM, M.D.

This is a clinical trial (a type of research study). This research study includes only patients who choose to take part. This consent form explains the research study and your part in the study. Please read it carefully and take as much time as you need. Please take your time to make your decision. Your participation is voluntary.

You are being asked to take part in this study because you have *coronavirus 2(SARS-CoV-2)/COVID-19*.

The epidemic of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)/COVID-19 originated in Wuhan, China in Dec 2019 and has rapidly spread worldwide. On March 11th 2020, WHO declared this a pandemic, and as of March 30th, 739,929 people in 190 countries have been affected with a total of 34,800 deaths. As of March 30th, 2020, the United States has reported 143,055 positive cases and 2,513 deaths.

Currently there are no approved treatment options for COVID-19 and there are trials underway for antiviral medications (drugs that fight viruses). There is evidence that plasma from individuals who have recovered from certain viral infections contain antibodies. This plasma has been used to treat patients who are currently infected with that virus. A very recent publication showed a case series of five (5) critically ill patients with COVID-19 and Acute Respiratory Distress Syndrome (ARDS) who were treated with convalescent plasma containing neutralizing antibody and detected an improvement in the patients' clinical status.

The purpose of this study is to use blood from individuals who have recovered from a COVID-19 infection and use it as a treatment for those who are currently sick with a severe or life-threatening COVID-19 infection.

Once you or legally authorized representative have decided to participate in the study, you will be given 2 consecutive transfusions of 200 ml (less than a cup) of a donor's plasma. You will be in the study for the rest of your hospital stay.

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There are risks to the study drug that are described later in this consent form. Some of the risks may include injection site irritation and transfusion related reactions.

There may not be a direct benefit to you for your participation in this study, however, your participation may help others in the future who are diagnosed with *COVID-19*.

You or legally authorized representative may choose not to participate in this study and you will receive the current standard of care for the treatment of *COVID-19*.

If you or legally authorized representative are interested in learning more about this study, please continue reading the information below.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to find out what effects (good and bad) plasma from patients recovered from COVID-19 infection has on you and your infection. This research is being done because there is no Food and Drug Administration (FDA) approved treatment for the COVID-19 infection at this time.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY

An estimated 45 people will take part in this study at Trinity Health Of New England sites (Saint Francis Hospital and Medical Center, Saint Mary's Hospital, Mercy Hospital, Mount Sinai Hospital and Johnson Memorial Hospital).

WHAT IS INVOLVED IN THE STUDY?

If you take part in this study, you will have the following tests and procedures:

- **You will receive intravenous transfusion of the donor plasma. Plasma consists of the non- cellular portion of blood that is separated and frozen after collection, You will receive 200 ml of the plasma twice over 60 minutes to 180 minutes. You would receive a total of 400 ml of the plasma within 2-4 hours**

- **You will have labs tested as part of your standard of care, but in addition we will check your blood to evaluate your viral load and if you have formed antibodies to the virus on days 0, 3, 5 and 7.**

Procedures that are part of your regular care will be done even if you do not join the study

- **Daily blood tests and diagnostic tests**

HOW LONG WILL I BE IN THE STUDY?

You will be in the study for the duration of your hospital stay. The researcher may decide to take you off this study if your clinical condition is determined not suitable.

You can stop participating at any time. However, any information collected prior to your decision to stop participation maybe used as part of the study. You may request to have any blood products collected

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as part of the study destroyed, if they have not been already used as part of the study. If you decide to stop participating in the study, we encourage you to talk to the researcher and your regular doctor first.

WHAT ARE THE RISKS OF THE STUDY?

While on the study, you are at risk for these side effects. You should discuss these with the researcher and/or your regular doctor. There also may be other side effects that we cannot predict. Other drugs will be given to make side effects less serious and uncomfortable. Many side effects go away shortly after the intravenous injections are stopped, but in some cases side effects can be serious or long-lasting or permanent.

Risks and side effects related to the intravenous injection we are studying include:

Side effects from intravenous injection include:

- skin irritation
- pain
- swelling
- bleeding and/or bruising

Serious risks include:

- Transfusion related acute lung injury this is when you may develop shortness of breath due to fluid accumulation in the lungs
- Transfusion associated circulatory overload this can occur due to an overload of your blood volume especially in those with pre existing heart disease.
- Allergic/anaphylactic reactions

Other less common risks include:

- Transmission of infections
- Febrile non-hemolytic transfusion reactions (increase of temperature during or after transfusion)
- Red Blood Cell (RBC) allo-immunization (your immune's response to the blood transfusion)
- Hemolytic transfusion reactions (reaction occurring after a blood transfusion)

Social risks: There is a chance that people outside of the research team may learn of your study participation.

For more information about risks and side effects, ask the researcher or contact Principal Investigator, Latha Dulipsingh, M.D. at 860-714-4402.

During the research study, you will be notified of newly discovered side effects which may affect your health or willingness to participate. You maybe be asked to sign a new consent form that shows that you have been informed of new information relating to this research study.

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WHAT SAFEGUARDS WILL BE USED?

All private medical health records, tests and results will be kept with research staff in a locked office and locked cabinet for privacy and confidentiality protection. We also de-identify any personal identifiers from the records and all electronic data will be saved in password protected and encrypted hard drives.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may or may not be direct medical benefit to you. We hope the information learned from this study will benefit other patients diagnosed with *COVID-19* in the future.

During the research study, you will be notified of newly discovered significant findings. You maybe asked to sign a new consent form that shows that you have been informed of new information relating to this research study.

WHAT OTHER OPTIONS ARE THERE?

Instead of being in this study, you have the option to be treated using the current standard of care treatment. Please talk to your regular doctor about these and other options.

WHAT ABOUT CONFIDENTIALITY?

Your confidentiality will be guarded to the greatest extent possible.

Trinity Health Of New England conforms to the Health Insurance Portability and Accountability Act (HIPAA). Your medical records will be maintained in accordance with state and federal laws. Efforts will be made to keep your personal information private. We cannot guarantee absolute confidentiality. Private identifiable information about you may be used or disclosed for purposes of this research study project as stated in the study's agreement form.

You have the right to get access your medical records. You may request that your medical record be given to your personal physician. Please refer to the Trinity Health Of New England's Notice of Privacy Practice for more information on how medical information about you may be used or disclosed. Please refer to the Trinity Health Of New England Notice of Privacy Practice for more information on how medical information about you may be used or disclosed.

WHAT ARE THE COSTS?

Taking part in this study may lead to added costs to you or your insurance company, and any costs not covered by your insurance will be your responsibility.

Trinity Health Of New England sites may not be financially responsible for costs associated with this study. Please ask about any expected added costs or insurance problems.

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In the case of injury or illness resulting from this study, emergency medical treatment is available but will be provided at the usual charge. If you sustain injuries from your participation in this research study, you may not be compensated by Trinity Health Of New England. You or your insurance company will be charged for continuing medical care and/or hospitalization.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled.

We will tell you about new information that may affect your health, welfare or willingness to stay in this study.

If you change your mind after signing this consent, you have the right to revoke your consent, in writing, at any time.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions, concerns or a research-related injury, please contact the Principal Investigator, Latha Dulipsingh, M.D. at 860-714-4402.

For questions about your rights as a research participant, use of protected health information, research related concerns or complaints, please contact the Trinity Health Of New England Institutional Review Board (which is a group of people who review the research to protect your rights) at 860-714-4068. You may also write to:

Institutional Review Board
Trinity Health Of New England
260 Ashley Street, 3rd floor
Hartford, CT 06105

You may also contact the Institutional Review Board to obtain information or offer input with an informed individual unaffiliated with this specific research protocol or in case you are not able to reach the research team, or wish to talk to someone not on the research team.

WHERE CAN I GET MORE INFORMATION?

You may call Latha Dulipsingh, M.D. at 860-714-4402 for additional information.

You will get a copy of this form.

If information has arisen that is clinically important to you, it is the responsibility of the Principal Investigator to share this information with you and check if it affects your willingness to participate in the research.

DISCLOSURE OF BENEFITS TO INVESTIGATORS INVOLVED IN THE STUDY

There is no direct benefit to the investigators for participating in this study.

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SIGNATURES

By signing this form I acknowledge that I have read or have had read to me this informed consent document and have been given the opportunity to ask questions and have them answered. I voluntarily agree and consent to take part in this study as described in this document.

_____

Name/Signature of Participant (Print Name) Date

_____

Signature of Legally Authorized Representative (Print Name) Date
(If applicable)

_____

Signature of Person Obtaining Consent (Print Name) Date

_____

Signature of Witness to the consent process (Print Name) Date

****Note**, if you are signing as the legally authorized representative of the participant, please indicate your relationship to the participant here (this should demonstrate your authority to consent to health care for the participant):_____

If a verbal consent is obtained from legally authorized representative, please indicate the name and relationship of the person giving consent.

Please indicate your relationship to the participant here (this should demonstrate your authority to consent to health care for the participant):_____

_____

Signature of Person Obtaining Consent (Print Name) Date

_____

Signature of witness to the consent process (Print Name) Date

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Research Authorization for Use/Disclosure of Protected Health Information

Participant Name: _____

In connection with my participation in the research study described below at Trinity Health Of New England, I, the undersigned participant, understand that private identifiable health information about me will be obtained, used and disclosed for purposes of the research project. Accordingly, I hereby authorize the use or disclosure of my health information, including, if applicable, protected drug and/or alcohol abuse, confidential HIV-related and psychiatric information ("Protected Health Information") in the manner described herein, for purposes related to my participation in the following research study (the "Research Study"): ***Convalescent plasma in the treatment of COVID 19***

Such purposes shall include all activities related to the conduct of the research study, as well as activities that ensure that my rights as a participant in a research study are being protected and that the research is being conducted properly.

I. Information Covered by Authorization.

The Protected Health Information that may be used or disclosed in connection with this authorization includes the following: *[check all applicable items]*

- X Existing medical records or information accessed by researchers as part of Research Study;
- X Information from interviews and questionnaires conducted as part of Research Study, including medical history;
- X All data obtained during any study procedure;
- X All medical records or reports created in connection with Research Study; such as any radiology reports, lab results, psychological test results, consultation reports, results of physical examinations, summary notes and treatment records;
- ☐ Other *[describe]:*

II. Authorized Uses/Disclosures.

Information about your participation in this research study may be included in your medical record, which is used throughout Trinity Health Of New England sites. Doctors outside of Trinity Health Of New England sites may not have access to this information. This form authorizes the following persons or entities to obtain, use or disclose my Protected Health Information in connection with the Research Study:

- The Principal Investigator, Latha Dulipsingh, M.D.
- The Co-Investigator, Danyal Ibrahim, M.D.
- Any research or Trinity Health Of New England staff working under the principal investigator's or any co-investigator's direct supervision

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The Protected Health Information may be disclosed to the following *[check applicable items]:*

- X Trinity Health Of New England Research Department staff or Institutional Review Board Members;
- X Any government agency overseeing this research at Trinity Health Of New England site for which authorization would be required by law;
- X The research sponsor, Trinity Health Of New England
- X My physician, Dr. Latha Dulipsingh, for purposes of providing information about my health to my regular physician;
- X Other researchers for data comparison purposes, provided data used for this purpose is stripped of personally identifying information;
- ☐ Other *[identify by name or category]:*

III. General Provisions.

I understand that by signing this authorization I agree to the use and disclosure of my protected Health Information as described above. I understand that I am not required to sign this authorization, but if I do not sign this authorization I may not participate in the Research Study. My decision not to sign this authorization will not affect my ability to obtain future treatment from a Trinity Health Of New England site or any health care provider named in this authorization, except for any research-related treatment.

I understand that I am entitled to a copy of this authorization form. I agree that a copy of this authorization will be as valid as the original. I understand that I may revoke this authorization at any time by notifying Latha Dulipsingh in writing, but if I do it won't have any effect on actions taken prior to receipt of the revocation. If I revoke this authorization I understand that once revoked, Trinity Health Of New England sites and the investigators named above may continue to use or disclose my Protected Health Information as necessary to maintain the integrity and reliability of the Research Study. I will send any notice of my desire to revoke this authorization to:

Latha Dulipsingh, M.D.
Diabetes and Endocrinology Center
1075 Asylum Avenue, Hartford, CT 06105

This Authorization does not have an expiration date.

I understand that under applicable law recipients of my Protected Health Information may not be subject to the federal privacy laws. Consequently, information disclosed under this authorization may be subject to further disclosure by the recipient and may no longer be protected by the federal privacy regulations. Such information, however, may continue to be protected for recipients that are subject to the federal privacy regulations or other state or federal confidentiality laws or contractual confidentiality obligations.

I understand that I may obtain a copy of the Trinity Health Of New England Privacy Notice for a description of the Hospital's privacy practices for protected health information, and that I have a right to review such Notice's before signing this authorization.

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_____ _____

Participant Signature (or authorized representative) Date

Print Name: _____

**Note, if you are signing as the legally authorized representative of the participant, please indicate your relationship to the participant here (this should demonstrate your authority to consent to health care for the participant):

_____

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