Larkin Community Hospital

Informed Consent- Human Subject Research

(THIS IS A CLINICAL RESEARCH STUDY, WHICH INCLUDES ONLY PATIENTS WHO VOLUNTARILY AGREE TO PARTICIPATE; YOU MAY WITHDRAW AT ANY TIME WITHOUT ANY CONSEQUENCES)

Study Title:

Measurement of IL-6 and Secondary Inflammatory Markers Before and After Therapeutic Plasma Exchange (TPE) in Hospitalized Patients with COVID-19

Principal Investigator:

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Sub-Investigator

For questions/concerns about your research rights, contact:
Institutional Review Board or IRB

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Research Sites:

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Larkin Community Hospitals
Multi-Specialty Clinic
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NOTE: This consent may contain words or phrases that you do not understand. Please ask the study doctor or the study staff to explain any terms or information you do not clearly understand. You may take home an unsigned copy of this consent form to think about or discuss it with your family or friends before making your decision. Please take your time to make your decision. Know that your information will not be used or distributed for future research studies, even if identifiers are removed.

Introduction:

You are being asked to participate in this study because you are experiencing symptoms due to SARS-CoV-2, better known as COVID-19. The goal of this clinical trial is to determine whether or not therapeutic plasma exchange (TPE) can lower your levels of IL-6, among other markers of inflammation. These markers of inflammation are what doctors use to determine your prognosis. Inflammatory substances show the doctors how your body is responding to the infection and it helps them to make a decision as to how serious your case is and how aggressive the treatment plan should be.

If TPE is able to decrease the levels of inflammation in patients diagnosed with COVID-19, then we believe it will help to reduce the symptoms that you experience. TPE is a process that involves taking a sample of your blood and sending it through a filtering machine. This filtering is what removes the toxins and inflammatory substances from the blood thereby decreasing inflammation levels. The blood is then returned to you and you will be watched carefully for any signs of bad reaction. Please read this form in its entirety so that you know all of the information available to you about participating in this trial.

The staff is available at all times to answer questions that you may have about the trial if you choose to participate. They will explain every part of the procedure in great detail on a level that you are comfortable with until you are fully understanding of the benefits, risks, and procedure. Please, do not hesitate to ask a member of the staff if there is anything that you are unsure of in this consent form.

Why is this study being done?

There is evidence supporting that TPE can reduce the levels of inflammatory substances in your blood. COVID-19 raises the levels of inflammation in the body which leads to the worsening of symptoms. As inflammation increases, the destruction of healthy lung tissue is increased, this is why we believe a treatment aimed at lowering inflammation in the body could prove to be helpful to patients. Knowing this information, we believe that TPE is a valuable treatment option for COVID-19 and could reduce your time spent in the hospital or increase your chances of survival. We hope that this will shorten your duration of symptoms, your time of infectivity, and increase your overall quality of life while infected with COVID-19.

NOTE: This informed consent document is to allow us authorization to record, report, and follow-up with you regarding this specific study only. This informed consent document will not act as consent to any procedures or surgeries

What will I be doing if I agree to be in the study?

If you wish to enroll in the study, and the Principal Investigator provides approval for your enrollment, then you will be enrolled in the trial. A computer program will randomly select from participants and place them in one of the two study groups. Neither the investigator nor you can choose which group you will be in. You will have an equal chance of being placed in either of the two groups. Based on the protocol, you will either be placed into group 1 where you will receive only the Standard of Care (SOC) for COVID-19, or group 2 where you will receive TPE as well as the SOC. After receiving the study treatment, you will be monitored for 15 minutes. You will be examined by the doctors periodically and bloodwork will be drawn to check your

inflammatory markers. Participation in the trial will also include submitting to Nasopharyngeal swab testing (like the swab test taken from your nose that led to your first being diagnosed with COVID-19) for COVID-19 during the study.

What are the dangers to me?

Side effects from TPE are rare but may include allergic reactions, rashes, bleeding, infections, electrolyte disturbances, air embolism (a bubble of air in your blood stream), reduced ability of your body to form blood clots, and reductions in the levels of your body's immunoglobulins which are used to fight infection. Problems may also arise at the site of access where your blood will be drawn from and returned to you. Additionally, it is possible that during the treatment your blood may be cleared of a prescription drug that you are taking, but you will be monitored of this.

Please make your doctor away of any medications you are currently taking. If any of these occur, the majority can be managed symptomatically. If you experience symptoms that are concerning to you, please tell the investigator, staff, or study physician immediately. If you experience any severe symptoms, immediately contact a member of the healthcare team or investigative team and seek emergency medical care.

How many people will take part in the study?

The trial will consist of 10 participants living in the Greater Miami Metropolitan Area who are severely ill with COVID-19.

Are there any benefits to me for taking part in this research study?

As of the date that this study began, there is no proven benefit of TPE and therefore we cannot guarantee that there will be any benefit to you directly, but if you are enrolled in the group that receives TPE, then we hypothesize that this may provide you with a shortened duration of symptoms due to COVID-19 illness. The severity may be less compared to patients who have not received TPE. Regular follow up for all groups may enable early detection of worsening COVID-19 symptoms, leading to earlier initiation of treatment for the illness. Patients may be followed up for the duration of their symptoms. Still, the treatment will be terminated if adverse effects such as allergies to the therapy, including but not limited to a rash, or worsening of oxygen saturation and/or admission to ICU are evident.

How long will I be in the study?

You will be enrolled in this study for a total of 60 days, you choose to withdraw or are removed from the trial, you are discharged, or death occurs, whichever occurs first.

Can I stop being in the study?

Yes. Taking part in this study is voluntary. You can withdraw from the study at any time and for any reason. Your decision would not stop you from getting the usual care if you were to become sick. Inform the investigator if you decide to withdraw from the trial. Also, the study

doctor may remove you from it at any time if he/she believes it is to protect your safety, or if the research is stopped.

What side effects or risks can I expect from being in the study?

The risks and side effects of TPE are transfusion-related events, including, but not limited to serious, life threatening allergic reactions that can result in difficulty breathing, rashes, drop in blood pressure and passing out or a temporary blackout. It can cause fevers, chills, and an accumulation of fluid in the heart and lungs that makes it difficult to breathe and can cause swelling in the extremities. Destruction of the red blood cells, blockage of blood vessels by bubbles of air, bleeding problems, accidental removal of prescription drugs from the blood, and transfusion-related acute lung injury which is an allergic reaction within 6 hours that can lead to difficulty in breathing and may even require you to have a tube inserted into your lungs to help you breathe with the assistance of a machine are all additional possible outcomes. There is a risk of an infection caused by the blood that we return to you.

Abnormal laboratory values may also result, including low calcium which may result in abnormal heart rhythm, muscle spasms, tingling in the fingers, low red blood cells which can lead to a feeling of tiredness and pale skin color, low potassium which can lead to weakness, constipation, and cramping, low sodium which can lead to feeling tired/confused and seizures, low chloride which can lead to thirst, weakness, fatigue, vomiting, and diarrhea, and low levels of platelets, the cells your body uses to form clots and stop bleeding. Further severe effects include a fall in blood pressure which may result in not enough blood reaching the brain which in turn may result in loss of consciousness, difficulty breathing, and affect the heart rate. There is also the possibility that the procedure may cause abnormal heartbeat which may require intensive treatment including applying electric shock to correct the abnormal rhythm.

You will be provided with contacts that you can call in case you experience any symptom that is alarming to you.

What other choices do I have if I do not take part in this study?

The standard of care for COVID-19 is given to all patients, regardless of their participation in this trial. Currently, there is no vaccine or accepted treatment available for COVID-19. If you choose not to take part in the study, this will not affect the care you would receive if you were to seek attention at this hospital for any illness hereafter.

What are the costs of taking part in this study?

The hospital will incur any cost explicitly associated with this clinical trial. You will remain responsible for covering the costs associated with hospitalization and treatment in the event of requiring medical attention or hospital admission for COVID-19.

Will I Be Paid for Participating in This Study?

You will not receive payment for participating in this study.

What happens if I am injured because I took part in this study?

There are no funds designated to compensate subjects for injury. The center for this trial is fully equipped to treat your medical needs that may arise during the trial. The Principal Investigator will provide further information, in the event of an injury related to the trial, to the best of his ability.

What are my rights if I take part in this study?

You will have all of your rights as a patient in the state of Florida. You have the right to withdraw from the study at any time. If you withdraw or fall sick, then you can discuss treatment plans with your physician about your medical case.

Voluntary Participation?

Taking part in this study is voluntary. Your decision to participate or not participate will not stop you from getting the standard of care that all patients receive at this hospital. Tell the investigative team immediately if you are considering withdrawing or decide to withdraw from the trial.

NOTE: Accepting you as a participant in this study is a voluntary decision on our end as well. The Principal Investigator has the right to terminate your participation without your consent and without providing you with specific reasons.

What is the purpose of Authorization (Permission) to Use or Disclose (Release) Identifiable Health Information?

The purpose of the Authorization (Permission) to Use or Disclose (Release) Identifiable Health Information is to use data gathered from this trial to determine if TPE was a beneficial treatment or not. This information may be shared in a public but anonymous manner to help educate and inform other healthcare providers and investigators on the current development of preventative and therapeutic options for COVID-19. No personally identifiable information will be released. All study participants will be assigned a study ID that cannot be traced back to your personal information.

What personal health information is collected and used in this study and might also be shared (disclosed)?

The researchers may copy and use the portions of your medical record that they will need for their research. The results of all medical tests performed as part of the study, physical examination results, and information that you provide to members of the study team. This includes images and results of any imaging study such as x-rays, MRI, or CT scan. Other information that will be used and/or released may consist of the following:

- the history and diagnosis of your disease;
- specific information about the treatments you received, including previous treatment(s) you may have had;
- information about other medical conditions that may affect your treatment;

- information on side effects (adverse events) you may experience;
- how these side effects were treated;
- long-term information about your general health and the status of your disease;
- data that may be related to the tissue that may be collected from you; and
- numbers or codes that will identify you, such as your social security number and medical record number.

You may request a blank copy of the study data forms from the study doctor or his research staff to learn what information will be shared.

Will my information be kept private?

You have a right to keep information about your health private. The research team will work to remove details that could be used to identify you before sharing any information about your health. The collected study data may be published to share knowledge gained about your treatment with others. Despite precautions, there is a small chance that this data could be linked back to you.

NOTE: Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- Larkin Community Hospital and its related employees
- Office of Human Research Protections (OHRP)
- Larkin Community Hospital Institutional Review Board (IRB)
- Health insurers and payers
- Department of Health and Human Resources (DHHS) agencies

How long will my authorization (permission) remain in effect?

Your authorization will remain in effect until three years after the completion of the study or until you choose to revoke your authorization. After three years, the research team will destroy any information about your records. Your medical records will continue to be stored as per state guidelines.

NOTE: Once you give us permission to use and release your protected health information collected for this research study, the consent you granted does not end unless you withdraw yourself as a study subject from the research study.

May I withdraw or cancel my authorization or permission?

You can withdraw your authorization or consent to participate in this trial at any time and without any penalty. To remove your permission, please contact the Principal Investigator(s) listed below. They will make sure that your request to withdraw from the study is completed quickly.

You may cancel your permission to allow your protected health information to be used or released at any time by sending a written notice to the Principal Investigator. If you withdraw your

authorization, your participation in this research study will end effective the date you withdraw your permission. The study staff will not collect any new health information about you after your withdrawal notification is received. However, your protected health information collected before the receipt of your withdrawal notification will remain part of the research study information. If you sign this form and enter the research study, but later change your mind and withdraw your permission, you will be removed from the research study at that time.

To withdraw your permission, please contact the person below. He will make sure your written request to revoke your authorization is processed correctly.

Principal Investigator and/or Designee

Michael Talalaev, D.O.

What are my rights regarding access to my personal health information?

You will retain your rights to your personal health information as a patient. This includes the right to know about your results, your disease, and treatment if any.

NOTE: While the research study is going on, you will not have access to your information while it is being collected. After the study is over, you will have the right to see and obtain a copy of the medical information collected from you during this study, for as long as the information is kept by the study staff and other groups, subject to federal privacy regulations.

Who can answer my questions about the study?

Michael Talalaev, D.O.
Address: 7031 SW 62nd Avenue, South Miami, FL, 33143
Telephone: 305-284-7608
Email: michael.talalaev@gmail.com

Primary Care Physician/Specialist Notification Option

Please indicate below whether you would like us to notify your primary care physician or your specialist of your participation in this study.
(Check only one box.)

- Yes, I want the study doctor to inform my primary care physician/specialist of my participation in this study.

- No, I do not want the study doctor to inform my primary care physician/specialist of my participation in this study.
- I do not have a primary care physician/specialist
- The study doctor is my primary care physician/specialist

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You will get a copy of this form. If you want more information about this study, ask your study doctor, Principal Investigator.

Signature

I have been given a copy of all 8 pages of this form. I have read it, or it has been read to me. I understand the information and have had my questions answered. I agree to take part in this study. I agree to authorize my protected health information to be released to the individuals, groups, and/or organizations mentioned within this informed consent document.

Your signature below means that you voluntarily agree to participate in this research study. By agreeing to participate in this study, you do not give up any legal rights.

Participant Signature	**Date/Time**
Participant Printed Name	
Signature of Person Obtaining Consent	**Date/Time**
Person Obtaining Consent Printed Name	
Signature of Principal Investigator	**Date/Time**
Witness	**Date/Time**

NOTE: You will be given a copy of this form to keep.