Hackensack Meridian *Health*

RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM

Phase II Randomized Study of Convalescent Plasma from Recovered COVID-19 Donors Collected by Plasmapheresis as Treatment for Subjects with Early COVID-19 Infection

Donor Consent Form

Who is conducting this study?

Principal Investigator: Michele Donato, MD

Sponsor: Hackensack Meridian Health

Supporter: Department of Defense (DoD)

Concise Summary

You have been asked to take part in this study because you have been infected by coronavirus disease (COVID-19) and have since recovered. The purpose of this study is to determine whether a single intravenous (IV) infusion (flowing of liquid into a vein) of blood plasma from a recovered COVID-19 patient safely improves the outcome of a patient's COVID-19 related disease. The pre-donation evaluation consists of a medical history performed by a physician or designee from the stem cell transplantation and cellular therapy program. You will be asked questions about exposure to infections and blood and nasal swab tests will be taken. You may be asked to return for repeat swab if positive or to re-test your antibody levels. The plasmapheresis (procedure for collecting blood plasma) will take about 30 to 60 minutes. You may be requested to donate additional plasma in the future. Although there is no direct benefit to you, the treatment may be of life-saving benefit to the plasma recipient. However, there are no guarantees or promises that the procedure will be successful.

Why is this research being conducted and why have I been asked to take part?

You have been asked to take part in this study because you have been infected by coronavirus disease (COVID-19) and have since recovered. This form gives you important information about the research study. It describes the purpose of this research study, and the risks and possible benefits of participating.
If there is anything in this form you do not understand, please ask questions. Please take your time.

Taking part in this research study is voluntary. You do not have to take part in this study if you do not want to. If you decide to participate and you change your mind, you can withdraw from the study at any time.

The primary purpose of this study is to determine whether a single intravenous (IV) infusion (flowing of liquid into a vein) of blood plasma from a recovered COVID-19 patient safely improves the outcome of patients with an early COVID-19 infection, not yet hospitalized but at risk of hospitalization. .

Beyond supportive care, there is limited treatment options for coronavirus disease (COVID-19) and the related pneumonia, the infection caused by Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2). Human plasma is a potential option for treatment of COVID-19.

How many people will take part in this study?

Up to 306 people will be treated on this study at Hackensack University Medical Center.

What is involved in this study?

The donation of blood plasma is performed in two phases:

1. Pre-donation evaluation
2. Collection of plasma by plasmapheresis

The pre-donation evaluation consists of a medical history performed by a physician or designee from the stem cell transplantation and cellular therapy program. You will be asked questions about exposure to infections and blood and nasal swab tests will be taken. This can be completed in one day. If the procedure is delayed, this evaluation may need to be repeated.

The plasmapheresis (procedure to collect plasma) will take about 30 to 60 minutes. You may be requested to donate additional plasma in the future. You may be referred to an outside licensed Blood Center for plasmapheresis.

Although there is no direct benefit to the donor, the treatment may be of life-saving benefit to the plasma recipient. However, there are no guarantees or promises that the procedure will be successful.

Pre-Donation Evaluation

Your medical history will be reviewed by a physician or nurse. You will be asked questions about your exposure to infectious diseases such as AIDS (acquired immune deficiency syndrome) or hepatitis that may be transmitted by transfusion or sexual contact. Laboratory tests to detect antibodies against COVID-19 and to infectious diseases will be obtained. This evaluation of your health is to determine the risk of the donation process to you and to determine that your plasma is safe to give to the patient. In addition to the blood tests, your nose will be swabbed for COVID-19 infection. If your swab is positive you may be asked to return for a subsequent swab. You may also be asked to return to have your antibody levels re-tested.

You may request that the results of this evaluation be reviewed with you in confidence. You are allowed to see and copy these records and any other tests and records made during the collection procedures.

Some of the tests must be made know to the recipient of your plasma and their physician. You should not take any new medication, even non-prescription medications, without first reviewing this with a member of the medical team.

You may donate plasma multiple times but no sooner than 7 days from your last donation. To do so, you will need to be evaluated again at the time of your next donation.

Collection Procedure

For the collection, a needle will be placed into a vein of each arm for the removal and return of your blood. The process called "plasmapheresis" will separate the plasma from your blood and return the remaining fluid and cells to your circulation. The plasmapheresis procedure will be performed in the Apheresis Unit at the John Theurer Cancer Center or at an outside licensed Blood Center and will take about 30 to 60 minutes to complete. A blood specimen will be obtained from you for blood counts before the collection, and a blood test to evaluate your blood type and to evaluate your antibody levels if needed. A very small amount (about a few tablespoonful) of the collection will be used for laboratory tests to determine the sterility and infectious diseases testing of the product. A very small amount (about a few tablespoonful) may be used for research.

Your veins will be assessed prior to this procedure if not previously done so. If the veins in your arms are not large enough for the plasmapheresis procedure, you will be removed from the study and will not proceed.

Blood may also be drawn on the day after collection to determine that your blood values return to normal.

How long will I be in this study?

You will be followed for five days after each plasma collection. You may be asked to donate more than once. You can refuse to donate more than once.

What are the risks involved in this study?

Blood tests and other procedures may be necessary to evaluate your ability to be a blood plasma donor. You will be asked questions to evaluate the possibility that you carry a virus that could be transmitted by the blood product. Your blood will also be tested for a number of infectious diseases that can be transmitted by blood plasma donation, including tests for HIV (the virus that causes AIDS) and hepatitis. Your medical records will be kept confidential and not shared with a recipient of your plasma without your permission. However, it is necessary that the recipient of your plasma and their physician be made aware of the infection disease test results and the risk of transmission of infection disease posed by the infusion of your plasma. By signing this form, you give permission for the release of this information.

The plasmapheresis procedure may result in some temporary numbness or tingling in the jaw or fingers. This is caused by medications used to prevent your blood from clotting while it passes through the machine. This can be easily treated by slowing the apheresis machine or giving you calcium by mouth or by vein. Your body will break down these medications over a period of about 4 hours.

You may have bruising or soreness from the insertion of the needles. The risk of infection always exists when a person's blood is circulated outside the body but this risk is very small.

All side effects can be different from person to person. It is important that you tell the study staff right away if you have any side effects or any other problems with your health, even if you do not think they are related to the study.

The risks or discomforts described may happen more often or be more severe than has been seen before. Your health and safety will always be the first concern of your study doctor. If you notice anything unusual, you should inform your study doctor or the nurse immediately. In the event of any serious unexpected events, all necessary medical action will be taken.

What are the risks to a pregnancy or fetus?

There are no known reproductive risks of blood plasma donation. However, a pregnancy test will be performed and if you are pregnant the donation will not take place and you will be removed from the study. If you or your partner are attempting to become pregnant, please discuss this with your nurse of physician.

Are there benefits to taking part in the study?

There is no direct benefit to you other than the knowledge that you have helped the recipient undertake therapy for his/her disease.

What other treatment options are there?

Donation is completely voluntary. You may choose not to become a donor.

How will information about me be kept private?

Your identity and participation are confidential to the extent permitted by law. If investigational drugs and/or medical devices subject to U.S. Food and Drug Administration regulation (FDA) are involved, however, it may be necessary for this consent form and other medical records to be reviewed by representatives of the FDA. In addition, the sponsor Hackensack Meridian, representatives of the sponsor, the Department of Defense (DoD), the Director of Research or designee, or the Institutional Review Board will be granted direct access to your original medical records for verification of clinical trial procedures and/or data without violating your confidentiality to the extent permitted by applicable laws and regulations. By signing this consent, you or your legally acceptable representative is authorizing such access.

Records identifying you will be kept confidential to the extent permitted by applicable law. If the results of the trial are published your identity will remain confidential.

Any of your health information used in this research study is protected by a law called the Health Information Portability and Accountability Act (HIPAA). Anyone involved in this research as indicated above may have access to that information.

Some people or groups outside of HMH might not have to follow the same privacy rules. Once any information is shared outside of HMH and given to other organizations that are not required to follow federal privacy laws, we cannot assure that the information will remain protected.

Your permission to use and share the information and data from this study will continue until the research study ends and will not expire. You may cancel this Authorization at any time by notifying the research team in writing. If you cancel this Authorization, the study doctor and staff will not use any new health information for research. However, researchers may continue to use the health information that was provided before you cancelled your authorization.

Not signing this form or later canceling your permission will not affect your health care treatment outside the study, payment for health care from a health plan, or ability to get health plan benefits. However, if you do not give permission to use your health information, you may not take part in this study because your health information is needed in order to conduct the research.

What are the costs?

Your blood plasma will be the property of the recipient after your donation. Medical expenses related to the donation of your blood plasma will be provided to you at no cost. There is no cost associated with this trial. Lost wages due to the procedure or complications of the procedure are not recoverable.

Will I be paid to participate in the study?

Financial compensation is not available for participation in this program.

What if you are injured because of the research study?

If you are injured as a direct result of your participation in this study, you may seek medical attention at the medical provider of your choice. However, you and/or your insurance company/third party payer will be billed for all routine medical, diagnostic, laboratory and pharmaceutical costs associated with the treatment of your illness or injury. You will be responsible for any deductibles or co-payments that would normally be associated with your insurance coverage. There will be no financial compensation offered by Hackensack Meridian Health.

What are my rights as a research participant?

Your decision to take part in this study is voluntary. If you decide not to participate or if you choose to withdraw after beginning the study, you can do so without penalty and you will not lose any benefits to which you are entitled. You are encouraged to ask questions before deciding whether you wish to participate and at any time during the course of the project. You will be told of any new findings that may change your decision to be in this study. If information becomes available that may influence your decision to take part in this study you may be asked to sign a revised consent form or consent form addendum.

You are not waiving any of your legal rights by signing this informed consent document. As part of the consent process, you will receive a signed copy of this informed consent document.

<u>Can I leave the study before it is finished? Can I be removed from this study without my approval?</u>

You are free to withdraw from this research study at any time. Your choice to leave the study will not affect your relationship with this hospital or doctor.

If you decide to withdraw before the end of the study, there may be risks associated with this decision that you should discuss with your study doctor. You may need to return to see the study doctor for safety reasons so you can be taken off the study appropriately and referred for follow-up care.

Your study doctor, study sponsor, or applicable regulatory authorities have the right to stop your participation in the study at any time, with or without your consent.

You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes other than data needed to keep track of your withdrawal. However, all data that have already been collected for study purposes will remain.

Financial Disclosure

The Department of Defense (DoD) is providing financial support for the study. If you have questions about this disclosure, please call the Research Integrity Office at (201) 880-3669.

Who can I call if I have questions or problems?

You are encouraged to ask questions before deciding what you want to do. If you decide to take part, feel free to ask questions at any time during your participation.

For questions about this research project, please contact:
Michele Donato, MD at 551-996-5900

For questions regarding your rights as a research participant or any research-related concerns, you can call the Hackensack Meridian Health Research Integrity Office at 201-880-3669.

Participant/Authorized Representative Signature(s)

I have read this consent form or it has been read to me. All of the questions that I had were answered to my satisfaction. I have been told that I will receive a signed copy of this consent form for my records. By signing this consent form I have not waived any of the legal rights which I otherwise would have as a participant in a research study.

Name of Subject (Please Print)

Signature of Subject (18 years or older) Date

Institutional Signature(s)

I confirm that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject (or the subject's legally authorized representative). The subject (or the subject's legally authorized representative) freely consented to be in the research study.

Person Obtaining Consent

Signature of Person Obtaining Consent Date

Name of Impartial Witness (if applicable)

Signature of Impartial Witness (if applicable) Date

Hackensack Meridian *Health*

RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM

Phase II Randomized Study of Convalescent Plasma from Recovered COVID-19 Donors Collected by Plasmapheresis as Treatment for Subjects with Early COVID-19 Infection

Patient Consent Form

Who is conducting this study?

Principal Investigator: Michele Donato, MD

Sponsor: Hackensack Meridian Health

Supporter: Department of Defense (DoD)

Concise Summary

The purpose of this research study is to determine whether a single intravenous (IV) infusion (flowing of liquid into a vein) of blood plasma from a recovered COVID-19 patient safely improves the outcome of patients with an early COVID-19 infection at risk of hospitalization. If you are enrolled, you will be randomly assigned to receive treatment with convalescent plasma or best supportive care. If you are assigned to receive best supportive care and you get hospitalized for symptoms of COVID-19, you may receive plasma at that time. You will be followed for 60 days after the convalescent plasma infusion. We do not yet know if the convalescent plasma infusion will improve your functioning beyond what would be expected with standard medical treatment. We hope that in the future the information learned from this study will benefit other people with your condition.

Why is this research being conducted and why have I been asked to take part?

You have been asked to take part in this study because you have been infected by the coronavirus (COVID-19). This form gives you important information about the research study. It describes the purpose of this research study, and the risks and possible benefits of participating. If there is anything in this form you do not understand, please ask questions. Please take your time.

Taking part in this research study is voluntary. You do not have to take part in this study if you do not want to. If you take part, you can leave the study at any time.

The primary purpose of this study is to determine whether a single intravenous (IV) infusion (flowing of liquid into a vein) of blood plasma from a recovered COVID-19 patient safely improves the outcome and prevents hospitalization of patients with a COVID-19 infection.

Beyond supportive care, there are few treatment options for coronavirus disease (COVID-19) and the related pneumonia, the infection caused by Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2). Human plasma is a potential option for treatment of COVID-19.

How many people will take part in this study?

Up to 306 people will be treated on this study at Hackensack Meridian Health.

What is involved in this study?

If you or your representative agrees for you to take part in this study, you will be asked to sign and date this consent form. You will have the below procedures performed as a result of your treatment. These assessments may be repeated as needed as part of your standard of care.

Once enrolled in the trial, you will be randomly assigned to receive treatment with convalescent plasma or best supportive care. If you are assigned to the best supportive care arm and require hospitalization, you will be eligible to receive convalescent plasma after a review by the admitting physician.

Before you get randomized to receiving the plasma or the best supportive care, you will be asked questions about your medical history and about your COVID-19 symptoms.
If you get randomized to receiving plasma, you will be scheduled to come in to receive the plasma. On the day of plasma infusion blood will be drawn for:

- Routine blood counts and blood chemistry
- Blood type
- Markers of inflammation
- Anal swab collection for microbiome if possible
- Optional blood test for genomics research
- Optional collection of blood for cytokine and chemokine research. Cytokines and chemokines are small proteins secreted by cells that help cells communicate.

You will then receive the convalescent plasma infusion through a vein in your arm.

There will be assessment for vital signs including heart rate, blood pressure, respiratory rate, temperature, and oxygen saturation

You will receive up to 500 mL of fresh plasma collected at the John Theurer Cancer Center or up to 400 mL of cryopreserved plasma collected at an outside Blood Center.

If you do not have an IV in place, you will have one placed for the infusion. You may be given Benadryl and hydrocortisone through your IV line prior to the infusion to prevent any reaction to the convalescent plasma. You may also be given Tylenol orally. The convalescent plasma will be given intravenously (through a needle in a vein in your arm) over 2-4 hours under physician supervision. Your vital signs (heart rate, blood pressure, temperature, respiratory rate) will be checked before the infusion, 15 minutes after the start of the infusion, then every hour and at the completion of the infusion.

We do not expect you to experience any discomfort from the infusion, although an allergic-type reaction may develop which may include hives, chills, and rapid pulse or heartbeat. Rarely, a serious allergic reaction

called anaphylaxis could also develop which might include shortness of breath, rash, wheezing, and low blood pressure. You will be treated with medications if any of these symptoms occur.

After the convalescent plasma infusion, you will have assessments as per standard of care.

If you were randomized to the best supportive care arm and you get admitted for symptoms from your COVID-19 infection, you can receive plasma at that time and the procedure will be the same as described above.

Follow up visit +3 and +7 days after Day 0, which was the day of the randomization (research):
You will have a follow-up visit or phone call with a member of the study team. This person will ask how you have been doing and make sure you have not had any new health problems.

Follow up visit 2 weeks, 4 weeks, and 2 months after Day 0 (research):
You will be asked to return for follow up visits 2 weeks, 4 weeks, and 2 months after Day 0 in order to check and see how you're doing. This can be done in person or by phone. An anal swab will be collected for microbiome, if possible.

On the day of your follow up visits

- Safety assessment by the research team
- Collect routine blood work and COVID-19 testing if possible
- Anal swab collection for microbiome if possible
- Optional collection of blood for genetic testing. This is to understand which genetic parameters are associated with disease presentation and response.
- Optional collection of blood for cytokine and chemokine research. Cytokines and chemokines are small proteins secreted by cells that help cells communicate.

This study involves testing an investigational drug, meaning it is being used in a manner not approved by the Food and Drug Administration (FDA) and has not yet been proven safe and effective. This research study may help determine whether this drug should be approved by the FDA.

How long will I be in this study?

You will be followed for two months after the Day 0 visit.

What are the risks involved in this study?

Previous use of convalescent plasma suggest that it is safe in coronavirus infection. However, there are potential risks associated with the convalescent plasma infusion.

Risks associated with the convalescent plasma infusion:
The potential risks related to the infusion of the convalescent plasma include: allergic reaction (fever, hives, rash, shortness of breath, anaphylaxis), or infection. If these occur, they would most likely be seen within 4 hours of the infusion.

There is also the potential of antibody-dependent enhancement of infection (ADE). ADE can occur for several viral diseases and involves a worsening of the disease in the presence of certain antibodies. Another possible risk is that convalescent plasma infusion may leave you vulnerable to re-infection.

Benadryl: Risks associated with the use of Benadryl include dizziness, sedation (sleepiness), dry mucous membranes, dryness of the nose and throat, thick sputum. Allergic reaction can occur, which would, include swelling of the throat and trouble breathing.

Risks associated with the use of Tylenol at high doses include liver disfunction.
Hydrocortisone (a form of steroids): Possible side effects of hydrocortisone injection include headache, dizziness, changes in mood, tiredness, increased sweating, increased appetite, fluid retention, high blood pressure, increase in blood sugar levels, muscle weakness, or joint pain. Allergic reaction is rare and may include hives, swelling of the throat and trouble breathing. Most of these risks are associated with higher doses or longer periods of use of the hydrocortisone than is used in this study.

Risks of drawing blood: Risks associated with drawing blood from your arm include momentary discomfort and/or bruising. Infection, excess bleeding, clotting, or fainting are also possible, although unlikely. You will be monitored for this complication and treated if it develops.

All side effects can be different from person to person. It is important that you tell the study staff right away if you have any side effects or any other problems with your health, even if you do not think they are related to the study.

The risks or discomforts described may happen more often or be more severe than has been seen before. Your health and safety will always be the first concern of your study doctor. If you notice anything unusual, you should inform your study doctor or the nurse immediately. In the event of any serious unexpected events, all necessary medical action will be taken.

What are the risks to a pregnancy or fetus?

There are no known reproductive risks of convalescent plasma infusion. If you or your partner are attempting to become pregnant, please discuss this with your nurse of physician.

Are there benefits to taking part in the study?

The primary purpose of this study is to determine whether a single intravenous (IV) infusion (flowing of liquid into a vein) of blood plasma from a recovered COVID-19 patient safely improves the outcome of patients hospitalized with a COVID-19 infection. We do not yet know if the convalescent plasma infusion will improve your functioning beyond what would be expected with standard medical treatment. We hope that in the future the information learned from this study will benefit other people with your condition.

What other treatment options are there?

If you decide not to take part in the treatment plan, the alternate treatments are to continue with the supportive care that you are currently receiving. There may be other experimental therapy available, you are encouraged to ask your physician about those.

How will information about me be kept private?

Your identity and participation are confidential to the extent permitted by law. If investigational drugs and/or medical devices subject to U.S. Food and Drug Administration regulation (FDA) are involved, however, it may be necessary for this consent form and other medical records to be reviewed by representatives of the FDA. In addition, the sponsor Hackensack Meridian, representatives of the sponsor, the Department of Defense (DoD), the Director of Research or designee, or the Institutional Review Board will be granted direct access to your original medical records for verification of clinical trial procedures and/or data without violating your confidentiality to the extent permitted by applicable laws and regulations. By signing this consent, you or your legally acceptable representative is authorizing such access.

Records identifying you will be kept confidential to the extent permitted by applicable law. If the results of the trial are published your identity will remain confidential.

Any of your health information used in this research study is protected by a law called the Health Information Portability and Accountability Act (HIPAA). Anyone involved in this research as indicated above may have access to that information.

Some people or groups outside of HMH might not have to follow the same privacy rules. Once any information is shared outside of HMH and given to other organizations that are not required to follow federal privacy laws, we cannot assure that the information will remain protected.

Your permission to use and share the information and data from this study will continue until the research study ends and will not expire. You may cancel this Authorization at any time by notifying the research team in writing. If you cancel this Authorization, the study doctor and staff will not use any new health information for research. However, researchers may continue to use the health information that was provided before you cancelled your authorization.

Not signing this form or later canceling your permission will not affect your health care treatment outside the study, payment for health care from a health plan, or ability to get health plan benefits. However, if you do not give permission to use your health information, you may not take part in this study because your health information is needed in order to conduct the research.

What should you know about the collection of genetic information?

The risks related to genetic analyses can be to individuals or to groups. These harms include social and economic disadvantages associated with genetic information. To reduce this risk, only coded samples will be stored and used for future research. Information about this study will not be recorded in your medical record.

The Genetic Information Nondiscrimination Act (GINA) is a Federal law that makes it illegal for some groups to discriminate against you based on genetic information. This law applies to all health insurance companies, group health plans, and employers with 15 or more employees. This law does not apply to companies that sell life insurance, disability insurance, or long-term care insurance.

What are the costs?

You and/or your Insurance Provider may be billed for some or all of the costs of treating your disease while you are enrolled in this study. This includes any treatments, procedures, medications and tests that would normally be provided to you were not participating in a clinical trial.

Your insurance company may or may not agree to pay for some of the costs associated with your care. You may be billed for these costs according to your insurance coverage guidelines. You may want to contact your Insurance Provider to see what costs they will or will not cover.

You will be billed for any co-payments, deductibles and/or co-insurance associated with your care.

The convalescent plasma will be provided to you free of charge. The cost of the convalescent plasma administrations will be billed to you and/or your Insurance Provider.

Treatments, procedures and tests that are solely performed for data collection purposes will be given to you free of charge.

You may ask your Research Nurse if you have any questions about what you and/or your Insurance Provider may be billed for.

Information relating to this study, including your name, medical record number, date of birth and social security number, may be shared with the billing offices of Hackensack Meridian Health and its affiliates so that claims may be appropriately submitted to the study sponsor or to your insurance company for clinical services and procedures provided to you during the course of this study.

Will I be paid to participate in the study?

Financial compensation is not available for participation in this program.

What if you are injured because of the research study?

If you are injured as a direct result of your participation in this study, you may seek medical attention at the medical provider of your choice. However, you and/or your insurance company/third party payer will be billed for all routine medical, diagnostic, laboratory and pharmaceutical costs associated with the treatment of your illness or injury. You will be responsible for any deductibles or co-payments that would normally be associated with your insurance coverage. There will be no financial compensation offered by Hackensack Meridian Health.

What are my rights as a research participant?

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You are not waiving any of your legal rights by signing this informed consent document. As part of the consent process, you will receive a signed copy of this informed consent document.

Can I leave the study before it is finished? Can I be removed from this study without my approval?

You are free to withdraw from this research study at any time. Your choice to leave the study will not affect your relationship with this hospital or doctor.

If you decide to withdraw before the end of the study, there may be risks associated with this decision that you should discuss with your study doctor. You may need to return to see the study doctor for safety reasons so you can be taken off the study appropriately and referred for follow-up care.

Your study doctor, study sponsor, or applicable regulatory authorities have the right to stop your participation in the study at any time, with or without your consent.

You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes other than data needed to keep track of your withdrawal. However, all data that have already been collected for study purposes will remain.

Financial Disclosure

The Department of Defense (DoD) is providing financial support for the study. If you have questions about this disclosure, please call the Research Integrity Office at (201) 880-3669.

Who can I call if I have questions or problems?

You are encouraged to ask questions before deciding what you want to do. If you decide to take part, feel free to ask questions at any time during your participation.

For questions about this research project, please contact:
Michele Donato, MD at 551-996-5900

For questions regarding your rights as a research participant or any research-related concerns, you can call the Hackensack Meridian Health Research Integrity Office at 201-880-3669.

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Consent for Optional Research:
Please indicate whether you agree to provide a blood sample for genomic research:

□ Yes, I agree □ No, I do not agree Patient initials: _____

Please indicate whether you agree to provide a blood sample for cytokine and chemokine research:

□ Yes, I agree □ No, I do not agree Patient initials: _____

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Participant/Authorized Representative Signature(s)

I have read this consent form or it has been read to me. All of the questions that I had were answered to my satisfaction. I have been told that I will receive a signed copy of this consent form for my records. By signing this consent form I have not waived any of the legal rights which I otherwise would have as a participant in a research study.

Name of Subject (Please Print)

Signature of Subject (18 years or older) Date

Institutional Signature(s)

I confirm that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject (or the subject's legally authorized representative). The subject (or the subject's legally authorized representative) freely consented to be in the research study.

Person Obtaining Consent

Signature of Person Obtaining Consent Date

Name of Impartial Witness (if applicable)

Signature of Impartial Witness (if applicable) Date