Consent Form

Title of Research Study: Evaluating Vitamin C and Septic Shock:
A Randomized Double Blind Control Trial **(EVICT)**

NCT03338569

Researcher Team Contact Information:

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Department of Medicine
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For questions about research appointments, the research study, research results, or other concerns, call the study team at:

Researcher Name: Ron Reilkoff, MD
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Supported By: This research is supported by the Fairview Foundation and Critical Care Grant.

Your doctor, who is also responsible for this research study, is interested in both your clinical care and the conduct of this research study. You have the right to discuss this study with another person who is not part of the research team before deciding whether to participate in the research.

What is research?

Doctors and researchers are committed to your care and safety. There are important differences between research and treatment plans:

- The goal of research is to learn new things in order to help groups of people in the future. Researchers learn things by following the same plan with a number of participants, so they do not usually make changes to the plan for individual research participants. You, as an individual, may or may not be helped by volunteering for a research study.
- The goal of treatment is to help you get better or to improve your quality of life. Doctors can make changes to your treatment plan as needed.

Why am I being asked to take part in this research study?

We are asking you to take part in this research study because you are in the intensive care unit (ICU) with a diagnosis of septic shock

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

The purpose of this research is to learn if Vitamin C can help treat septic shock. During septic shock, vitamin levels in general can fall and are associated with organ failure. It is thought that Vitamin C can help the body during septic shock by having an anti-oxidant and anti-inflammatory effect.

This study involves the use of an infusion of Vitamin C for septic shock. The FDA has not approved Vitamin C for this treatment.

How long will the research last?

We expect that you will be in this research study for about 4 days. If your septic shock gets better and you stop vasopressor medications (standard of care) for at least 24 hours, the infusion will be stopped at that point. Vasopressors are medication that are used to raise blood pressure and are considered to be a vital part of treatment of septic shock.

At 28 days, we will do a follow-up review of your medical chart but you do not need to come in for a visit.

How many people will be studied?

We expect about 140 people here in Minnesota will be in this research study. The research is being done at several hospitals in the region; Fairview Southdale, University of Minnesota Medical Center, Ridges, HealthEast St. Joseph's and Essentia Health in Duluth.

What happens if I say "Yes, I want to be in this research"?

The treatment you get will be chosen by chance, like flipping a coin. Neither you nor the study doctor or anybody else treating you will choose what treatment you get. You will have an equal chance of being given either treatment.

Neither you nor the study doctor or anybody else treating you will know which treatment you are getting. You will be given either Vitamin C or placebo. It will be given to you by an infusion in an intravenous (IV) line placed in your arm. You will most likely already have a line placed for other medications and we will use that same line for the study medication.

- **Vitamin C**: On the first day, the amount of Vitamin C in the infusion is 6,875 milligrams. This larger amount on the first day is what is called a "bolus". A bolus, or larger start dose, is used to more efficiently raise a medication's concentration in the body to a level where it can start working. After the first day, the daily average of the Vitamin C is approximately 6,000milligrams which is given at 250 milligrams per hour. The maximum Vitamin C would be 7,000 milligrams per day.

- **Placebo**: A matched infusion given at the same amount and same rate as the Vitamin C.

If you get better or leave the ICU, the infusion could be stopped before four days. Your study doctor will discuss stopping early with you, if necessary.

We will collect medical information about you from your hospital record including history, medication usage, and laboratory results. This information will be collected at Baseline, and once a day for the four days of the infusion. There will be one follow-up chart review 28 days after the infusion has been started. You do not have to come in for the visit at 28 days.

Additional blood will be taken to study biomarkers (proteins and molecules in the blood) for septic shock and to measure the response to the Vitamin C. We will be looking at genetic and other chemical markers in your blood. This blood draw will be taken at Day 0, Day 1, and Day 3. The first blood draw will be about 5 teaspoons. The

two other blood draws will be about 4 teaspoons. The total blood draw amount will be about 13 teaspoons. This blood will most likely be taken from the IV that will already be in your arm. Not everybody will have blood drawn at all specified time points. Blood will only be drawn when there is a study clinician available and transportation to long-term freezer storage is available.

If a bronchoscopy is performed or if your sputum is collected for clinical purposes, we may collect some of the fluid from your lungs or sputum at that time. In addition, we may also collect excess urine, blood or other bodily fluids that are collected for a clinical purpose that would otherwise be destroyed or wasted. These samples would be used to help refine a laboratory test in determining infections. This laboratory test would only be done for research purposes and is not intended to diagnose or help treat you. This fluid collection would not be done on everyone, only on those when staffing and standard of care procedures allow for it.

If you choose to participate, you will still receive the usual standard of care measures for septic shock management, just as if you were to choose not to participate.

	Screening	Day 0	Day 1	Day 2	Day 3	Day 4	Day 28
Consent	X						
Medical History	X						
Physical Exam	X						
Study Drug or Placebo Infusion		X	X	X	X	X	
Blood Draw		X	X		X		
Chart Review		X	X	X	X	X	X

What are my responsibilities if I take part in this research?

As this research will all take place while you are hospitalized, you will not have any responsibilities. You will not be asked to come in for research visits after you leave the hospital.

What happens if I do not want to be in this research?

You will continue to receive all standard of care options for septic shock as prescribed by your clinician. No medication or treatment will be withheld because of your participation in this study.

This research study is IN ADDITION to what you are already receiving or may receive.

Standard of care for septic shock can include, but is not limited to:

- Medications to raise your blood pressure (vasopressors)
- Oxygen supplementation
- Mechanical ventilation to support your breathing
- Dialysis to support kidney function
- Antibiotics
- Supportive and preventative cares for critically ill patients
- Intravenous hydration
- Intravenous steroids
- Surgery or drainage of source of infection

Any standard of care that you receive will be prescribed and ordered by your hospital doctor and is separate from this study.

Because the alternative to being in this study is the current standard of care, there are no specific risks or benefits associated with declining to participate beyond those related to usual care for septic shock. The benefits of therapy for septic shock are to stabilize vital signs, reverse and limit organ failure and prevent death. However life sustaining therapies such as vasopressor medications, mechanical ventilation may cause temporary discomfort and pain and increase risk of complications. Treatment usually require additional procedures, such as placing IVs in large blood vessels to administer medication or for dialysis, placement of drainage catheters or placing a breathing tube into a patient's throat.

What happens if I say "Yes", but I change my mind later?

You can leave the research at any time. Leaving will not be held against you.

If you decide to leave the research, contact the investigator so that the investigator can make sure the infusion is stopped in a safe manner.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. Meaning, your choice not to be in this study will not negatively affect your right to any present or future medical treatment.

If you stop being in the research, already collected information about you will be removed from the study database if you request it to be. You will be asked whether the investigator can collect information from your routine medical care, such as your medical records. If you agree, this information will be handled the same as the information obtained for the research study.

What are the risks of being in this study? Is there any way being in this study could be bad for me?

This research may hurt you in the following ways:

1. Vitamin C risks: This study is approximately 6,000 milligrams per day via an IV, with a maximum dose of 7,000 milligrams. At oral doses higher than 3,000 milligrams per day the most common adverse effect is diarrhea, but can uncommonly include nausea, vomiting, heartburn, stomach cramps, and headaches. At very high doses (10,000 milligrams up to 100,000 milligrams per day) some studies have shown an increase risk of kidney problems, including crystal formation, stones and renal failure. It is important to discuss with the study doctor if you are taking vitamins or supplements which could contain Vitamin C.

2. Blood draw risks: The risks associated with a blood draw include minimal discomfort, and/or bruising. Fainting is possible but unlikely. In very rare cases, a small blood clot can form at the site of the needle insertion.

3. Intravenous line: The risks of an intravenous line are similar to a blood draw but because it is kept in the vein for a longer period of time, the risk of bruising and discomfort are slightly higher. All participants will already have a peripheral or central intravenous line catheter placed for standard of care medications. Any blood draw or IV placed for the infusion will be done with clinical care when possible. Having an indwelling catheter for extended periods can increase risk of secondary infection.

4. Loss of confidentiality: As part of this research we will be collecting information about your health from your medical record. We will take safeguards to protect this information, including removing identifying information when possible, and storing such information in a locked office. Should a loss occur, however, your confidential personal health information may be obtained by unintended parties. Confidentiality is not guaranteed.

In addition to these risks, this research may hurt you in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death.

Will it cost me anything to participate in this research study?

Taking part in this research study will not lead to any costs to you. All study procedures, including the Vitamin C or placebo infusion, will be paid for by the research study.

You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay. In some cases, insurance will not pay for services ordinarily covered because these services were performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay.

Will being in this study help me in any way?

There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, possible benefits to others include learning how to treat septic shock.

What happens to the information collected for the research, including my health information?

We try to limit the use and sharing of your information, including research study records, any medical records and any other information about you, to people who have a need for this information. But we cannot promise complete confidentiality.

If you participate in this study, your information, including your health information, will be used and shared for purposes of conducting this research. As described later in this Consent Form, your information may also be used and shared for publishing and presenting the research results, future research, and any optional elements of the research you agree to in this Consent Form. If you sign this Consent Form, you are giving us permission to use and share your health information for these purposes, and if we are using your medical records, you are giving permission to any health care providers who are treating you to share your medical records with us.

What health information will be made available?

Health information about you to be used and shared for the research includes those items checked by the research team below:

☒ Your medical records, which may include records from hospital and clinic visits, emergency room visits, immunizations, medical history and physical exams, medications, images and imaging reports, progress notes, psychological tests, EEG/EKG/ECHO reports, lab and pathology reports, dental records and/or financial records. These records may be used and shared for as long as this research continues.

☒ Information collected as part of this research study, including research procedures, research visits, and any optional elements of the research you agree to, all as described in this Consent Form. This information might not be part of your medical record, and may include things like responses to surveys and questionnaires, and information collected during research visits described in this Consent Form.

What about more sensitive health information?

Some health information is so sensitive that it requires your specific permission. If this research study requires any of this sensitive information, the boxes below will be marked and you will be asked to initial to permit this information to be made available to the research team to use and share as described in this Consent Form.

☐ My drug & alcohol abuse, diagnosis & treatment records _____ (initial)

☐ My HIV/AIDS testing records _____ (initial)

☒ My genetic testing records _____ (initial)

☐ My mental health diagnosis/treatment records _____ (initial)

☐ My sickle cell anemia records _____ (initial)

Who will access and use my health information?

If you agree to participate in this study, your information will be shared with:

- The University of Minnesota research team and any institutions or individuals collaborating on the research with us;
- Others at the University of Minnesota and M Health/Fairview who provide support for the research or who oversee research (such as the Institutional Review Board or IRB which is the committee that provides ethical and regulatory oversight of research at the University, systems administrators and other technical and/or administrative support personnel, compliance and audit professionals (such as the Quality Assurance Program of the Human Research Protection Program (HRPP)), individuals involved in processing any compensation you may receive for your participation, and others);
- Organizations who provide accreditation and oversight for research and the research team, and others authorized by law to review the quality and safety of the research (such as U.S. government agencies like the Food and Drug Administration, the Office of Human Research Protections, the Office of Research Integrity, or government agencies in other countries); and
- Organizations that process any payments that may be made to you for participating in this study, and any other individuals or organizations specifically identified in this Consent Form.
- The research sponsor, any affiliates, partners or agents of the sponsor involved in the research, organizations funding the research, and any affiliates, partners or agents of the funding organization involved in the research;

Additional sharing of your information for mandatory reporting

If we learn about any of the following, we may be required or permitted by law or policy to report this information to authorities:

- Current or ongoing child or vulnerable adult abuse or neglect;
- Communicable, infectious or other diseases required to be reported under Minnesota's Reportable Disease Rule;
- Certain wounds or conditions required to be reported under other state or federal law; or
- Excessive use of alcohol or use of controlled substances for non-medical reasons during pregnancy.

How will my information be used in publications and presentations?

We may publish the results of this research in scientific, medical, academic or other journals or reports, or present the results at conferences. Information that makes it easy to identify you (such as your name and contact information, SSN and medical records number) will not be part of any publication or presentation. If

you have an extremely unique or rare condition that is not shared by many others, it is possible that some people may be able to determine your identity even without these identifiers.

What will be done with my data and specimens when this study is over?

Your data and blood specimens will be stored indefinitely. We will use and may share data and/or specimens for future research. They may be shared with researchers/institutions outside of University of Minnesota. This could include for profit companies. We will not ask for your consent before using or sharing them. We will remove identifiers from your data and/or specimens, which means that nobody who works with them for future research will know who you are. Therefore, you will not receive any results or financial benefit from future research done on your specimens or data.

Do I have to sign this Consent Form and give my permission to make my information, including my health information, available for use and sharing?

No, you do not have to sign this Consent Form. But if you do not sign, you will not be able to participate in this research study. Your decision about signing this Consent Form will not impact treatment options available outside of the study, payment for such treatment, enrollment in health insurance plans or eligibility for benefits.

Does my permission for making my health information available for use and sharing ever expire?

No, there is no expiration date.

May I cancel my permission for making my health information available for use and sharing?

Yes. You may cancel your permission at any time by writing to the researcher at the address on the first page of this Consent Form. If you cancel your permission, you will no longer be in the research study. You may also want to ask someone on the research team in canceling will affect any research related medical treatment. If you cancel your permission, any health information about you that was already used and shared may continue to be used and shared for the research study and any optional elements of the study to which you agree in this Consent Form.

What happens to my health information after it is shared with others?

When we share your information with others as described in this Consent Form, privacy laws may no longer protect your information and there may be further sharing of your information.

Will I be able to look at my records?

It is possible that the research team may not allow you to see the information collected for this study. However, you may access any information placed in your medical records after the study is complete.

What about genetic information?

A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware that this federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

Where can I find out about the study results?

A description of this clinical trial will be available at 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.

The results of the genetic and biomarker tests will not be made available to you because the research is still in an early phase and the reliability of the results is unknown.

Who do I contact if I have question, concerns or feedback about my experience?

This research has been reviewed and approved by an Institutional Review Board (IRB) within the Human Research Protections Program (HRPP). To share feedback privately with the HRPP about your research experience, call the Research Participants' Advocate Line at 612-625-1650 (Toll Free: 1-888-224-8636) or go to z.umn.edu/participants. You are encouraged to contact the HRPP if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

Will I have a chance to provide feedback after the study is over?

The HRPP may ask you to complete a survey that asks about your experience as a research participant. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous.

If you are not asked to complete a survey, but you would like to share feedback, please contact the study team or the HRPP. See the "Investigator Contact Information" of this form for study team contact information and "Whom do I contact if I have questions, concerns or feedback about my experience?" of this form for HRPP contact information.

Can I be removed from the research without my OK?

You could be removed from the study or have the infusion stopped at any time for any reason when either the research doctor or your personal doctor feels further participation could impact your medical care. Even if the infusion is stopped early, we will still continue to collect information from your medical record.

What happens if I am injured while participating in this research?

In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner to you or your insurance company. If you think that you have suffered a research related injury, let the study physicians know right away.

Will I be compensated for my participation?

You will not be compensated for being in this research study.

Signature Block for Obtaining Consent Directly from Participant

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

_____ _____
Signature of Participant Date

_____
Printed Name of Participant

_____ _____
Signature of Person Obtaining Consent Date

_____
Printed Name of Person Obtaining Consent

Signature Block for Obtaining Consent from Legally Authorized Representative

Your signature documents your permission for the named participant to take part in this research. You will be provided a copy of this signed document.

_____
Printed Name of Participant

_____ _____
Signature of Legally Authorized Representative Date

_____
Printed Name of Legally Authorized Representative

_____ _____
Signature of Person Obtaining Consent Date

_____
Printed Name of Person Obtaining Consent

EVICT eConsent

Please complete this informed consent. A study team member will be in contact with you to discuss the document while you complete it.

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A Randomized Double Blind Control Trial (EVICT)
Researcher Team Contact Information:
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Vitamin C: On the first day, the amount of Vitamin C in the infusion is 6,875 milligrams. This larger amount on the first day is what is called a "bolus". A bolus, or larger start dose, is used to more efficiently raise a medication's concentration in the body to a level where it can start working. After the first day, the daily average of the Vitamin C is approximately 6,000 milligrams which is given at 250 milligrams per hour. The maximum Vitamin C would be 7,000 milligrams per day. Placebo: A matched infusion given at the same amount and same rate as the Vitamin C. If you get better or leave the ICU, the infusion could be stopped before four days. Your study doctor will discuss stopping early with you, if necessary.

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What are my responsibilities if I take part in this research? As this research will all take place while you are hospitalized, you will not have any responsibilities. You will not be asked to come in for research visits after you leave the hospital.

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Standard of care for septic shock can include, but is not limited to:
• Medications to raise your blood pressure (vasopressors)
• Oxygen supplementation
• Mechanical ventilation to support your breathing
• Dialysis to support kidney function
• Antibiotics
• Supportive and preventative cares for critically ill patients
• Intravenous hydration
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• Surgery or drainage of source of infection

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If you participate in this study, your information, including your health information, will be used and shared for purposes of conducting this research. As described later in this Consent Form, your information may also be used and shared for publishing and presenting the research results, future research, and any optional elements of the research you agree to in this Consent Form. If you sign this Consent Form, you are giving us permission to use and share your health information for these purposes, and if we are using your medical records, you are giving permission to any health care providers who are treating you to share your medical records with us.

What health information will be made available? Health information about you to be used and shared for the research includes those items checked by the research team below:
☒ Your medical records, which may include records from hospital and clinic visits, emergency room visits, immunizations, medical history and physical exams, medications, images and imaging reports, progress notes, psychological tests, EEG/EKG/ECHO reports, lab and pathology reports, dental records and/or financial records. These records may be used and shared for as long as this research continues.
☒ Information collected as part of this research study, including research procedures, research visits, and any optional elements of the research you agree to, all as described in this Consent Form. This information might not be part of your medical record, and may include things like responses to surveys and questionnaires, and information collected during research visits described in this Consent Form.

Who will access and use my health information? If you agree to participate in this study, your information will be shared with:
• The University of Minnesota research team and any institutions or individuals collaborating on the research with us;
• Others at the University of Minnesota and M Health/Fairview who provide support for the research or who oversee research (such as the Institutional Review Board or IRB which is the committee that provides ethical and regulatory oversight of research at the University, systems administrators and other technical and/or administrative support personnel, compliance and audit professionals (such as the Quality Assurance Program of the Human Research Protection Program (HRPP)), individuals involved in processing any compensation you may receive for your participation, and others);
• Organizations who provide accreditation and oversight for research and the research team, and others authorized by law to review the quality and safety of the research (such as U.S. government agencies like the Food and Drug Administration, the Office of Human Research Protections, the Office of Research Integrity, or government agencies in other countries); and
• Organizations that process any payments that may be made to you for participating in this study, and any other individuals or organizations specifically identified in this Consent Form.
• The research sponsor, any affiliates, partners or agents of the sponsor involved in the research, organizations funding the research, and any affiliates, partners or agents of the funding organization involved in the research;

Additional sharing of your information for mandatory reporting If we learn about any of the following, we may be required or permitted by law or policy to report this information to authorities:
• Current or ongoing child or vulnerable adult abuse or neglect;
• Communicable, infectious or other diseases required to be reported under Minnesota's Reportable Disease Rule;
• Certain wounds or conditions required to be reported under other state or federal law; or
• Excessive use of alcohol or use of controlled substances for non-medical reasons during pregnancy.

How will my information be used in publications and presentations? We may publish the results of this research in scientific, medical, academic or other journals or reports, or present the results at conferences. Information that makes it easy to identify you (such as your name and contact information, SSN and medical records number) will not be part of any publication or presentation. If you have an extremely unique or rare condition that is not shared by many others, it is possible that some people may be able to determine your identity even without these identifiers.

What will be done with my data and specimens when this study is over? Your data and blood specimens will be stored indefinitely. We will use and may share data and/or specimens for future research. They may be shared with researchers/institutions outside of University of Minnesota. This could include for profit companies. We will not ask for your consent before using or sharing them. We will remove identifiers from your data and/or specimens, which means that nobody who works with them for future research will know who you are. Therefore, you will not receive any results or financial benefit from future research done on your specimens or data.

Do I have to sign this Consent Form and give my permission to make my information, including my health information, available for use and sharing? No, you do not have to sign this Consent Form. But if you do not sign, you will not be able to participate in this research study. Your decision about signing this Consent Form will not impact treatment options available outside of the study, payment for such treatment, enrollment in health insurance plans or eligibility for benefits.

Does my permission for making my health information available for use and sharing ever expire? No, there is no expiration date.

May I cancel my permission for making my health information available for use and sharing? Yes. You may cancel your permission at any time by writing to the researcher at the address on the first page of this Consent Form. If you cancel your permission, you will no longer be in the research study. You may also want to ask someone on the research team in canceling will affect any research related medical treatment. If you cancel your permission, any health information about you that was already used and shared may continue to be used and shared for the research study and any optional elements of the study to which you agree in this Consent Form.

What happens to my health information after it is shared with others? When we share your information with others as described in this Consent Form, privacy laws may no longer protect your information and there may be further sharing of your information.

Will I be able to look at my records? It is possible that the research team may not allow you to see the information collected for this study. However, you may access any information placed in your medical records after the study is complete.

What about genetic information? A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:
• Health insurance companies and group health plans may not request your genetic information that we get from this research.
• Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
• Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.
Be aware that this federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

Where can I find out about the study results? A description of this clinical trial will be available at 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.

The results of the genetic and biomarker tests will not be made available to you because the research is still in an early phase and the reliability of the results is unknown.

Who do I contact if I have question, concerns or feedback about my experience? This research has been reviewed and approved by an Institutional Review Board (IRB) within the Human Research Protections Program (HRPP). To share feedback privately with the HRPP about your research experience, call the Research Participants' Advocate Line at 612-625-1650 (Toll Free: 1-888-224-8636) or go to z.umn.edu/participants. You are encouraged to contact the HRPP if:
● Your questions, concerns, or complaints are not being answered by the research team.
● You cannot reach the research team.
● You want to talk to someone besides the research team.
● You have questions about your rights as a research participant.
● You want to get information or provide input about this research.

Will I have a chance to provide feedback after the study is over? The HRPP may ask you to complete a survey that asks about your experience as a research participant. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous.

If you are not asked to complete a survey, but you would like to share feedback, please contact the study team or the HRPP. See the "Investigator Contact Information" of this form for study team contact information and "Whom do I contact if I have questions, concerns or feedback about my experience?" of this form for HRPP contact information.

Can I be removed from the research without my OK? You could be removed from the study or have the infusion stopped at any time for any reason when either the research doctor or your personal doctor feels further participation could impact your medical care. Even if the infusion is stopped early, we will still continue to collect information from your medical record.

What happens if I am injured while participating in this research? In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner to you or your insurance company. If you think that you have suffered a research related injury, let the study physicians know right away.

Will I be compensated for my participation? You will not be compensated for being in this research study.

What about more sensitive health information? Some health information is so sensitive that it requires your specific permission. If this research study requires any of this sensitive information, the boxes below will be marked and you will be asked to initial to permit this information to be made available to the research team to use and share as described in this Consent Form.

☐ My drug & alcohol abuse, diagnosis & treatment records
☐ My HIV/AIDS testing records
☒ My genetic testing records
☐ My mental health diagnosis/treatment records
☐ My sickle cell anemia records

The table below shows what will happen at each visit:

	Screening	Day 0	Day 1	Day 2	Day 3	Day 4	Day 28
Consent	X						
Medical History	X						
Physical Exam	X						
Study Drug or Placebo Infusion		X	X	X	X	X	
Blood Draw		X	X		X		
Chart Review		X	X	X	X	X	X

Signing the Consent and HIPAA form
I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this signed combined consent and HIPAA research authorization form.

Is the patient able to give consent for the study? ◯ Yes ◯ No/Using Legally Authorized Representative

Is the Legally Authorized Representative signing consent? ◯ Yes ◯ No

Are you signing this consent in person (at the hospital with study staff) or remotely? ◯ In-person ◯ Remote/via tele-medicine

All of my questions have been answered, and I have been given the opportunity to decline this research. ◯ Yes ◯ No

Full Name of Study Participant _____

E-mail

_____

Phone number

_____

Full name of Legally Authorized Representative

_____

Legally Authorized Representative Relationship to the Participant?

◯ Healthcare Power of Attorney
◯ Spouse
◯ Parent
◯ Adult Child
◯ Adult Sibling
◯ Other

If "Other" was selected above, please explain:

_____

Signature of Participant

_____

(Participant Signature only. LAR to sign in below section!)

Time and date

_____

Signature of Legally Authorized Representative

_____

Date and time

_____

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. All questions and concerns have been discussed prior to requesting signatures in this document. A copy of this form has been given to the participant or his/her representative. No research procedures or assessments were completed prior to the completion of the informed consent conversation. If this consent was completed via telemedicine or remotely, a Remote Consent Attestation will be completed.

If the study participant is consenting, how was capacity for consent assessed?

◯ No concern ◯ MacCAT-CR assessment completed

Printed name of person obtaining consent

_____

Signature of person obtaining consent

_____

Investigator date and time

_____

Witness(es)

Only required if subject does not read/write the language of the consent document

Are witness(es) required?

◯ Yes ◯ No
(Only required if consenting a participant or LAR that does not read the language of the consent)

Witness 1

Printed name of witness

_____

Signature of witness

_____

Date and time

_____

Adapted from Combined Consent & HIPAA Authorization Template

(http://orrp.osu.edu/irb/investigator-guidance/consent/)