Official Title: Safety, Tolerability and Biomarker Assessments of Leukine (Sargramostim) During Extended Timed Treatment for Parkinson's Disease: A Phase I Pilot Study

NCT Number: NCT03790670

Date of the document: 10/29/2025

CONSENT FORM

Title of this Research Study

Invitation and Summary

You are invited to be in this research study. Taking part in this research is voluntary. You do not have to take part. For the purposes of this document: "You" can refer to:

- Yourself
- The person for whom you are the Legally Authorized Representative (LAR)
- Your child under the age of 19.

"Organization" can refer to: University of Nebraska Medical Center (UNMC), Nebraska Medicine (NM), University of Nebraska at Omaha (UNO) or Children's Nebraska (CN).

Here is a summary of the purpose, methods, risks, benefits, and alternatives, to help you decide whether or not to take part in the research.

Please see the information below, in the body of this consent form, addressing the purpose of the research, methods, risks, benefits, and alternatives, to help you decide whether to take part in the research study.

Why are you being asked to be in this research study?

You are being asked to participate in this study because you are between 35 and 85 years old and have Parkinson's disease (PD). You have had PD symptoms for at least 3 years, you can walk without assistance, and you can self-administer your medications.

If you are pregnant, nursing an infant, or plan to become pregnant during this study, you may not be in this study.

If you have previously been administered Leukine or any form of granulocyte-macrophage colony stimulating factor(GM-CSF), you cannot be in this study.

What is the reason for doing this research study?

In a previous study of immune cells from blood, we found differences in the cells from Parkinson's disease patients compared to immune cells from the healthy controls (caregivers). These differences were corrected with daily administration of Leukine

(sargramostim). The purpose of this study is to test the safety of the extended use of Leukine, and determine if administration of this drug will change the immune cells in the blood of people with PD, so that they are more like those of controls. Leukine (sargramostim) is an FDA-approved drug, but has not been approved for the intended use in this research study. It is recombinant human granulocyte-macrophage colony stimulating factor (GM-CSF) produced by recombinant DNA technology in yeast. It is currently used to treat patients with acute myelogenous leukemia, cancer patients undergoing chemotherapy, and patients who have had a bone marrow transplant. This study will also collect large numbers of peripheral blood leukocytes (white cells that fight infection) from patients with Parkinson's disease to track changes in immune cells following treatment. Peripheral whole blood will also be collected. The secondary purpose of this research study is to characterize the T cells (a type of white blood cell) and the T cell DNA of patients with Parkinson's disease and compare to individuals without Parkinson's disease. The leukocytes collected from leukapheresis will be used to obtain T cells for functional assays and T cell DNA for analyses. The whole blood will be used for analysis of T cell markers and plasma to determine the types of T cells and proteins that are present. Samples collected in the study will be provided to external companies to complete some tests for this research study only. The results of this research study may help to develop new therapies to diagnose and treat Parkinson's disease.

What will be done during this research study?
You will be given information about the study and all your questions will be answered. If you would like to be in the study, you must sign this consent form before any study procedures begin.

This is a research study in which 10 PD subjects will participate. The study will last a total of 160 weeks (about 45 months) and includes the following:

You will have 19 study visits. The visits are 4 or 24 weeks apart, depending on visit. Three visits will include the leukapheresis procedure (visits 2, 7, and 11), which takes approximately 3 hours to complete.

You will take the study drug for a total of 96 weeks; this will be a daily injection for 5 days followed by a 2-day off period. You may give this injection yourself or it may be given by your caregiver. At every study visit, you will have a physical examination, and the Unified Parkinson's Disease Rating Scale will be assessed. These visits will also include making a short (5 minutes or less) video recording of you walking, standing, and finger tapping. These video recordings will be used to monitor treatment progress and to validate UPDRS part III assessments. The recordings will

be retained with your medical records until they provide no evidentiary value. After that time, the recordings will be erased and the recording medium destroyed. If you agree to be video recorded, you will be asked to sign a separate video authorization form. Following 96 weeks of therapy, you will be asked to stop treatment for 12 weeks. After 12 weeks, you can begin Leukine therapy again for up to 48 additional weeks.

At every study visit, blood will be drawn. Blood will be used for: 1) determining presence of GM-CSF antibodies; 2) screening for overall health (CBC/dif, metabolic panel); 3) immune cell function and markers. A total of up to 700 mL (about 3 cups) of blood will be drawn for this study. A small amount of your blood serum (less than 1/2 teaspoon) will be used to determine the presence of antibody formation against the drug. After testing, the samples will be destroyed and will not be used for any commercial purposes. Additional study visits may be necessary. For example, in the event your scheduled visits cannot be arranged at the proper interval to obtain the study drug, you may need an additional appointment for pick-up. Also, the study will provide for additional examinations with your neurologist, should he/she deem it necessary, such as if you have an adverse reaction to the study drug.

After starting study drug, you will be required to come in for an additional "pharmacy pick-up" visit to obtain your second 2-week drug supply in between your normal monthly visits.

Baseline Visits
Tests and assessments from the baseline visits will be completed to decide if you are eligible to participate in this study. You will receive no study drug during the baseline period.

Baseline Visit 1(2 hours)
Once you have reviewed, sign and dated this informed consent form, then the following procedures will be performed at the first visit:
You will be asked questions about your medical history, general health and what PD medications you are currently taking. you will have a physical examination, which will include your pulse, blood pressure and temperature. Up to 90 mL (about 6 tablespoons) of blood will be drawn. For women, part of your blood may be used to confirm you are post menopausal. If you are a woman who is not post-menopausal and can get pregnant, part of your blood will be used to test for pregnancy. Another portion will be used by the Red Cross Apheresis Center to test for hematocrit or hemoglobin levels and an infectious disease panel. Your arm veins will also be assessed. Your blood will be drawn to test for infectious diseases that could be

transmitted by blood. These tests include hepatitis B and C, HIV, the virus that causes AIDS, CMV, syphilis, West Nile Virus and HTLV 1 (human t cell lymphotrophic virus type 1, a virus associated with leukemia and neurologic disorders). If any of these tests are positive, you will be notified and appropriate counseling will be provided. You may not be eligible to participate if any of these are positive. Less than 50 mL or 3 1/2 tablespoons of blood will be drawn at this time.

Baseline Visit 2(4 hours)
This will be your first leukapheresis procedure if you do not test positive for infectious disease and your hematocrit levels are acceptable. However, if you have undergone a leukapheresis procedure within the last 12 months as part of our previous study entitled "Leukapheresis for Parkinson's disease," you will not be required to undergo the procedure at this visit again. If you have not previously undergone leukapheresis, then less than 50 mL or 3 ½ tablespoons of blood will be drawn. The leukapheresis visit will last about 3 hours. A tube of blood (10 mL or 2 teaspoons) will be drawn for T cell characterization. Hemoglobin or hematocrit may be checked as in the first visit and blood may be drawn for infectious disease testing (< 50 mL or 3 1/2 tablespoons). A concentrate of some of your peripheral blood leukocytes will be collected by a procedure called leukapheresis. Leukapheresis is a procedure in which blood is withdrawn from a vein in your arm and passed through a blood cell separator where some of the leukocytes are removed along with a small amount of plasma and a few red cells. The remainder of the red cells and plasma are returned to you through a vein in your other (or the same) arm. This procedure continues until the required number of leukocytes has been removed, usually two to three hours. To draw and return your blood, two needle sticks may be required, one in each arm. In order to prevent your blood from clotting during the procedure, citrate anticoagulant will be added to your blood. This will be infused to you along with the returning red cells and plasma. To permit the red cells and white cells to separate from each other in the blood cell\ separator, hydroxyethyl starch may be added to your blood as it enters the machine. This will also be infused to you with your returned blood.

In the event that you have undergone the leukapheresis procedure within one year of enrolling in the study due to being involved in our previous study (IRB# 388-14-FB), you will be exempt from undergoing the baseline leukapheresis procedure again as outlined in visit 2. Following interview and enrollment, you will begin your baseline blood collection visit (Visit 3) and bypass visit 2. Likewise, if deemed necessary by the study neurologist or nurse coordinator, we may use your initial leukapheresis visit as one baseline, allowing you to bypass visit 3 and begin your second baseline blood draw at clinic visit 4. This bypass would still allow the collection of three baseline blood collections prior to starting treatment and would decrease the total number of

visits and blood draws needed from you.

Baseline Visits 3-4(2 hours)
At the start of this visit, you will meet with the study neurologist and have a physical examination and UPDRS assessment, a neurological exam to assess motor skills and other symptoms of Parkinson's disease. A video recording of you walking forwards and backwards, standing, and tapping your index finger on your thumb for each hand will also be taken. Up to 100 mL (about 6.5 tablespoons) of blood will be drawn. If you choose to be in the study, following examination on visit 4, you will enter the study drug phase.

Visit 5(3 hours)
This visit will occur approximately 4 weeks after visit 4. The following examinations/tests will occur:

- Physical exam including measuring your pulse, blood pressure and temperature
- Up to 85 mL (about 6 tablespoons) of blood will be drawn, UPDRS assessment will be completed
- A video recording of you walking forwards and backwards, standing, and tapping your index finger on your thumb for each hand will be made.
- The study personnel will instruct you on how to do the self-injection. You will be given a 2-week supply of the study drug to take home. Your caregiver may perform the daily injections, if needed. You will be observed for 1 hour for any adverse events. You will be asked to bring any unused study drug to these visits and return them to the study team.
- You will be given a subject log to record when you take the study drug daily and if you experience any unexpected changes in your health. You will be asked to bring the log back with you to the next study visit.

Visit 5a(1 hour)
This visit will occur 2 weeks after initiating Leukine treatment. During this visit, you will pick up your 2-week drug supply. A 4-mL tube of blood will also be taken to the Nebraska Medical Center Clinical Laboratory for CBC/auto diff with platelet count in order to assess changes in blood cell counts following treatment.

Study Treatment
Visit 6(1 ½ hours)
You will arrive having taken your PD medication, but before you have had your study drug injection. This visit will include the following procedures:

- physical examination, including measuring your pulse, blood pressure and

temperature, blood draw, up to 90 mL (6 tablespoons)
- UPDRS assessment
- A video recording of you walking forwards and backwards, standing, and tapping your index finger on your thumb for each hand will be made.
- You will be given a 2-week supply of the study drug to take home.
- You will be asked to bring any unused study drug to these visits and return them to the study team.
- You will be given a subject log to record when you take the study drug daily and if you experience any unexpected changes in your health. You will be asked to bring the log back with you to the next study visit.

Visit 6a(1 hour)
During this visit, you will pick up your 2-week drug supply. A 4-mL tube of blood will also be taken to the Nebraska Medical Center Clinical Laboratory for CBC/auto diff with platelet count in order to assess changes in blood cell counts following treatment.

Visit 7(4 hours)
This visit will be broken into two parts, occurring on two different days. The first day will be comprised of a clinical examination and video recording with the study neurologist as previously done. A drug safety and tolerability assessment will also occur. Treatment will be stopped if deemed non-tolerable. The second day will be comprised of the same leukapheresis procedure previously described in visit 2.

Visit 8-10(1 ½ hours)
The same procedures discussed in Visit 6 will occur.

Visit 11(4 hours)
This visit will be comprised of the same clinical assessment and leukapheresis procedures previously described in visit 7. It will also consist of two separate visits on two separate days.

Visits 12-14(1½ hours)
If treatment is tolerable and deemed beneficial for the subject, you will be allowed, if desired, to continue on treatment for up to 24 months, with clinical evaluations every 6 months. During these visits, subjects will only receive a blood draw and clinical assessment. PD patients will still arrive on their PD medication and bring their patient log sheets and any unused syringes. PD patients should not administer their daily injection of Leukine until after the appointment. PD patients will undergo the physical exam, blood draw, UPDRS assessment, and video recording as in Visit 3. The same

blood analyses will be performed. Patients will again receive a 2-week supply of drug in preloaded syringes. Patients will be provided with Patient Log sheets to note their daily injections and any adverse events. On visit 14, patients will end their Leukine treatment.

Follow-Up
Visit 15(1 ½ hours)
This study visit is 4 weeks after the last study drug injection.
Study procedures will occur in the following order:

- physical exam, including measuring your pulse, blood pressure and temperature, blood draw, up to 110 mL (less than 1/2 cup)
- UPDRS assessment
- Video recording

At each clinical visit, you will also be asked to complete a Parkinson's Disease Questionnaire 39 (PDQ39). This questionnaire is a 39-item self-reporting assessments that assess your general quality of life and well-being over the course of a month.

Visits 16-18 (1½ hr)
Visit 16 will occur 12 weeks after stopping Leukine. You will be re-evaluated for a physical, blood draw, UPDRS Part III assessments, and PDQ39 as in previous clinical visits. Following assessment, you will then begin your normal Leukine regimen but will only undergo clinical assessments every 6 months from now on (Visits 16-18). The blood draw will also be modified and will only consist of 5 collection tubes. At visit 18, you will stop drug treatment and return for a follow up visit 4 weeks later.

Visit 19 (1½ hrs) 2nd Follow Up
This is the follow-up visit four weeks after Leukine injections are halted. You will return for clinical examination and a final blood draw as in the previous follow-up visit. The study will now end.

In addition to clinical evaluations, you will also be required to come in every two weeks to pick up the two-week drug supply from the CRC and investigational pharmacy. This will be scheduled in between the normal study visits.

What are the possible risks of being in this research study?
Blood draw. Possible risks involved with the blood draw are minor pain and bleeding at the draw site, and a possible risk of infection. The usual sterile precautions will be

observed to reduce the risk of infection. Rarely, a blood draw can cause fainting in some individuals.

Leukapheresis. The following are risks associated with leukapheresis which you may experience and which are similar to the risks associated with donation of a unit of whole blood: discomfort and/or bruising at the site of the needle sticks, nausea, vomiting, fainting or dizziness, blood loss, and infection.

In addition to these risks, possible complications of this leukapheresis procedure include:
1) side effects from citrate anticoagulant, the agent that prevents your blood from clotting: chilliness, tingling sensations, numbness, muscle cramping, and anxiety
2) allergic reactions to citrate, hydroxyethyl starch, or ethylene oxide, the agent used to sterilize the tubing and plastic bags in the blood cell separator: skin rash, hives, localized swelling, flushing, or difficulty breathing
3) complications from the infusion of hydroxyethyl starch: headache, fluid overload, ankle swelling, or high blood pressure

Most of the starch will be excreted in your urine in the first 48 hours after the leukapheresis; however, traces of this starch may remain in your body for long periods of time. No harm has been shown to result from this. Platelets, red blood cells, and possibly some types of white blood cells may be depleted by frequent leukapheresis procedures. There are no harmful effects causedby the depletion of white cells from a single donation.

Leukine. The most common side effects from Leukine (sargramostim) are bone pain and injection site reactions. Headaches, fever, chills, muscle pain and weakness can also occur. Pain and fever are treated with acetaminophen, and injection site reactions are treated using ice compresses and changing injection sites.

Pregnancy Risks.
It is possible that the medicines used in this study could injure a fetus or an unborn child if you or your partner becomes pregnant while taking them. You have already been told what is known about this possibility, and you are encouraged to ask further questions.

You may want to discuss this with others before you agree to take part in this study. If you wish, we will arrange for a doctor, nurse, or counselor who is not part of this study to discuss the potential risks and benefits with you and anyone else you want to have present.

Because of the potential risks, you or your partner must not become pregnant while you are participating in this study. Women must have a negative pregnancy test before entering the study. If you are sexually active and can get pregnant, or can get your partner pregnant, you must use ONE appropriate method of birth control every time you have sex, or you must not have sex.

Because of the nature of this research, methods of natural family planning are not, by themselves, sufficiently reliable to avoid pregnancy. You can get additional information about methods to avoid pregnancy by calling the UNMC Research Subject Advocate's Office at (402) 559-6941.

You will need to continue to avoid pregnancy until you finish the research. By signing this and being in the study, you are agreeing to not get your partner pregnant while you are on the study. Should you become pregnant while you are on this study, you should immediately notify the study personnel. The investigator will assist you in finding appropriate medical care. The investigator also may ask to be allowed to continue getting information about her pregnancy. You can refuse to provide this information.

Other Risks.
It is possible that other rare side effects could occur which are not described in this consent form. It is also possible that you could have a side effect that has not occurred before. It is also possible your Parkinson's disease may become worse while participating in this study.

Laboratory Tests:
There is no known risk to you from the laboratory research which will be performed using your leukocytes or blood.

What are the possible benefits to you?
You are not expected to get any benefit from being in this research study.

What are the possible benefits to other people?
This study may show differences in the T cells of patients with Parkinson's disease from those of donors without Parkinson's disease, which may lead to new methods for diagnosis and treatment of Parkinson's disease. This study may also show whether Leukine (sargramostim) is safe and tolerable for people with PD, and whether it can transform their immune cells, which may or may not lead to future treatments.

What are the alternatives to being in this research study?
Instead of being in this research study, you can choose not to take part.

What will being in this research study cost you?
There is no cost to you to be in this research study.

Will you be paid for being in this research study?
You will be paid at the rate of $15/hr for your participation in this study. If you are unable to complete the leukapheresis procedure the amount will be prorated according to time spent. In the event that any commercial products are developed from your tissue/blood, UNMC/Nebraska Medicine has no plans to share with you any proprietary interests in the products or revenue generated from such commercialization. All donated tissue/blood is the property of the University of Nebraska Medical Center (UNMC).

For your time and travel for this study, you will receive compensation in the form of a check for each study visit completed in the following amounts:

Visit 1 (2 hrs): $30
Visit 2 (4 hrs): $60
Visit 3 (2 hrs): $30
Visit 4 (2 hrs): $30
Visit 5 (3 hrs): $45
Visit 5a (1 hr): $15
Visit 6 (1.5 hrs): $22.50
Visit 6a (1 hr): $15
Visit 7 (4 hrs): $60
Visit 8 (1.5 hrs): $22.50
Visit 9 (1.5 hrs): $22.50
Visit 10 (1.5 hrs): $22.50
Visit 11 (4 hrs): $60
Visit 12 (1.5 hrs): $22.50
Visit 13 (1.5 hrs): $22.50
Visit 14 (1.5 hrs): $22.50
Visit 15 (1.5 hrs): $22.50
Visit 16 (1.5 hrs): $22.50
Visit 17 (1.5 hrs): $22.50
Visit 18 (1.5 hrs): $22.50
Visit 19 (1.5 hrs): $22.50

Adverse Event Appointments (2 hrs): $30

If you need assistance for travel expenses, please discuss this with your study coordinator. You will be requested to provide receipts for reimbursement for travel fares such as taxi fare, bus tickets, etc, for each visit. Air fare will not be covered.

To receive payment, you must provide your social security number, name, and address in order to comply with Internal Revenue Service (IRS) reporting requirements. When payment is reported to the IRS, we will not say what the payment is for, only that you have been paid. If you do not wish to provide this information, you can still participate in the study; however, you will not be paid.

Who is paying for this research?
This research is being paid for by Nebraska Neuroscience Alliance: Community Based Consortium of Private Donators. The investigator receives the study drug, Leukine (sargramostim) and additional funding from Partners Therapeutics to conduct this study. Dr. Gendelman and Dr. Mosley are co-inventors of an invention that utilizes Leukine/GM-CSF as part of a vaccine for Parkinson's disease. This study may help validate their vaccine strategy. Results of this study may be used for commercial purposes.

What should you do if you are injured or have a medical problem during this research study?
Your health and safety is our main concern. If you are injured or have a medical problem because of this study call someone listed at the end of this consent form. You can get emergency medical treatment at Nebraska Medicine. You can also go to your doctor, the nearest emergency room or call 9-1-1.

We have no plans to pay for your treatment or give you any other money or compensation. Your insurance may pay. If they do not you will have to pay.

Signing this does not mean you have given up any of your legal rights.

How will information about you be protected?
You have rights regarding the protection and privacy of your medical information collected before and during this research. This medical information is called "protected health information" (PHI). PHI used in this study may include your medical record number, address, birth date, medical history, the results of physical exams, blood tests, x-rays as well as the results of other diagnostic medical or research procedures. Only the minimum amount of PHI will be collected for this research. Your

research and medical records will be maintained in a secure manner.

Who can see information about you?
We also will get medical information about you (like medical record number, medical history, or the results of physical exams, blood tests, x-rays or other medical or research procedures). We call this "protected health information" or PHI. PHI is protected by a law called the HIPAA Privacy Rule. We will collect the smallest amount of PHI that we can. We will keep your PHI as confidential as possible.

By signing this consent form, you are letting us (the researchers listed on this consent form and other people involved in this research at the Organization) have access to your PHI. Your PHI will be used only for the purposes described in the section "What is the reason for doing this research study?"

You can change your mind and tell us to stop collecting your PHI for use in this research at any time by writing to the principal investigator. We can still use the PHI we have already collected. If you tell us to stop collecting your PHI, you will have to stop being in this research.

We may share your PHI with other groups listed below:
- The UNMC Institutional Review Board (IRB)
- Institutional officials designated by the UNMC IRB
- The HHS Office for Human Research Protections (OHRP)

We may share your PHI with other groups listed below. The HIPAA Privacy Rule requires these groups to protect your PHI.
- The Food and Drug Administration (FDA)

You are letting us use and share your research data for as long as the research is going on.You are letting us use and share your research data for as long as the research is going on.

How will results of the research be made available to you during and after the study is finished?
Information obtained in the course of the research that will not be shared with you is the characterization of your T cells. By signing this authorization, you are temporarily giving up your right to see this research-related information while the research is going on. You will be able to see this information if you wish after the research is completed.

In most cases, the results of the research can be made available to you when the

study is completed, and all the results are analyzed by the investigator or the sponsor of the research. The information from this study may be published in scientific journals or presented at scientific meetings, but your identity will be kept strictly confidential. The results of clinical tests and therapy performed as part of this research may be included in your medical record.

A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

If you want the results of the study, contact the Principal Investigator at the phone number given at the end of this form or by writing to the Principal Investigator at the following address:
Howard E. Gendelman, M.D.
985880 Nebraska Medical Center
Omaha, NE 68198-5880

The DNA analysis of your T cells will not be made available to you.

What will happen if you decide not to be in this research study?
You can decide not to be in this research study. Deciding not to be in this research will not affect your medical care or your relationship with the investigator or UNMC/Nebraska Medicine. Your doctor will still take care of you and you will not lose any benefits to which you are entitled.

What will happen if you decide to stop participating once you start?
You can stop being in this research study (withdraw) at any time before, during, or after the treatment begins. Your doctor will still take care of you though you may not be able to get the research treatment. Deciding to withdraw will otherwise not affect your care or your relationship with the investigator, the University of Nebraska Medical Center, or Nebraska Medicine. You will not lose any benefits to which you are entitled.

For your safety, please talk to the research team before you stop any research treatments. They will advise you how to stop the treatment most safely. If you withdraw you may be asked to undergo some additional tests. You do NOT have to agree to do these tests.

You may be taken off the study if you don't follow instructions of the investigator or

the research team. You may also be taken off the study if:

- Your physical exams, blood analyses, or UPDRS part III scores show results indicating undesirable effects of drug administration.
- You experience an injury related to the study, or
- Your PD progresses and the investigator is concerned for your health The investigator stops the study
- If the research team gets any new information during this research study that may affect whether you would want to continue being in the study you will be informed promptly.

Will you be given any important information during the study?
You will be informed promptly if the research team gets any new information during this research study that may affect whether you would want to continue being in the study.

What should you do if you have any questions about the study?
You have been given a copy of "*What Do I Need to Know Before Being in a Research Study?*" If you have any questions at any time about this study, you should contact the Principal Investigator or any of the study personnel listed on this consent form or any other documents that you have been given.

What are your rights as a research participant?
You have rights as a research subject. These rights have been explained in this consent form and in The Rights of Research Subjects that you have been given. If you have any questions concerning your rights, or want to discuss problems, concerns, obtain information or offer input, or make a complaint about the research, you can contact any of the following:

- The investigator or other study personnel
- Institutional Review Board (IRB)
    - Telephone: (402) 559-6463
    - Email: IRBORA@unmc.edu
    - Mail: UNMC Institutional Review Board, 987830 Nebraska Medical Center, Omaha, NE 68198-7830
- Research Subject Advocate
    - Telephone: (402) 559-6941
    - Email: unmcrsa@unmc.edu

Documentation of informed consent
You are deciding whether to be in this research study. Signing means that:

- You have read and understood this consent form.

- You have had the consent form explained to you.
- You have been given a copy of The Rights of Research Subjects
- You have had your questions answered.
- You have decided to be in the research study.
- You have been told you can talk to one of the researchers listed below on this consent form if you have any questions during the study.
- You will be given a signed and dated copy of this consent form to keep.

Signature of Subject_____
Date_____

My signature certifies that all the elements of informed consent described on this consent form have been explained fully to the subject. In my judgment, the subject possesses the legal capacity to give informed consent to participate in this research and is voluntarily and knowingly giving informed consent to participate

Signature of Person Obtaining Consent_____
Date_____

Authorized Study Personnel
Principal
Gendelman, Howard
phone: 402-559-5478
alt #: 402-559-8920
degree: MD

Secondary
Mosley, R Lee
phone: 402-559-2510
alt #: 402-559-2510
degree: PhD

* Santamaria, Pamela
alt #: 402-888-6453
degree: MD

Lead Coordinator
Olson-Johnson, Katherine
alt #: 402-559-2547
degree: BS

Other Coordinator
Obaro, Helen
alt #: 402-559-0964

degree: RN, BSN