INFORMED CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY
Version 9.0 April 2011

Study Title: Mobilized Peripheral Blood Stem Cell Apheresis Collection from Healthy Donors for the Research Market

Sponsor: LeukoLab

Protocol Number: 7000-SOP-047

Protocol Dates: July, 2007
Version 2.0 dated September, 2007
Version 3.0 dated October, 2007
Version 4.0 dated May, 2008
Version 4.0 Addendum dated May, 2008
Version 5.0 dated September, 2008
Version 6.0 dated March, 2009
Version 7.0 dated April, 2009
Version 8.0 dated January, 2010
Addendum 8 A dated January, 2011
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This consent form may contain words that you do not understand. Please ask a study doctor or the study staff to explain any words or information that you do not clearly understand.

Introduction

I have been invited by Dr. , Dr. ., and Dr. . to donate white blood cells, specifically peripheral blood stem cells, for research purposes only. These cells will be collected from my blood using a cell-mobilizing agent called Neupogen™ (G-CSF). LeukoLab of Emeryville, California is the sponsor for this study. The investigators listed above have no financial interest in LeukoLab but will receive a service fee.

Purpose

The purpose of this study is to provide healthy donor peripheral blood stem cells for distribution to facilities engaged in medical or scientific research. These cells will be for laboratory in-vitro use only, never for transfusion or other use in humans.

Procedure

Specially trained registered nurses will perform leukopheresis, a procedure to collect white blood cells. The procedure will be performed on me as a volunteer at LeukoLab located at 5858 Horton Street, Suite 272, Emeryville, California, 94608.

If I agree to participate, I will be given a medication called Neupogen™ (G-CSF) which is commonly used to increase (mobilize) the number of white blood cells, specifically blood-generating stem cells, circulating in the blood stream. Neupogen™ is made by Amgen, Inc., Thousand Oaks, California, and is approved by the FDA for mobilization purposes in cancer patients.

Since 1997, studies have been underway that will ultimately involve the enrollment of more than 10,000 healthy donors who will receive Neupogen™ (G-CSF) injections and have leukopheresis procedures completed. The goal of these studies is FDA approval for the use of Neupogen™ in healthy donors. The estimated completion time of these studies is early 2015. Although neither my blood cells nor I will be part of such a study, LeukoLab will abide by Neupogen™ dosing and cell collection parameters that are comparable to or more conservative than those used in the FDA related studies.

Neupogen™ (around 2 cc or 1/3 teaspoon, depending upon my weight) will be given to me by injection into the shallow tissues in my upper arm **according to the Regimen circled below:**

- Regimen A - One-Day Collection:
  - Injection once a day for 3 consecutive days with a cell collection procedure on the day following the last dose (day 4).
  - Neupogen™ given by the following scale:
    - Donor weight 63.63 to 80.99 kilograms = 600 micrograms daily
    - Donor weight 81 to 102.99 kilograms = 780 micrograms daily
    - Donor weight 103 kilograms or greater = 900 micrograms daily

- Regimen B - Modified One-Day Collection:
  - Injection once a day for 5 consecutive days with a cell collection procedure on the day following the last dose (day 6).
    Neupogen™ will be administered as follows:
  - Donors receive a customized dose of Neupogen™ based on their weight. Each dose is calculated at 5 micrograms of Neupogen™ per kilogram of body weight per day, or

5mcg/kg/day. There is no sliding scale.

- Regimen C - Two-Day Collection:
  - Injection once a day for 5 consecutive days, with the first cell collection procedure on the day of the 5th dose (day 5) and the second cell collection procedure the next day (day 6).
  - Neupogen™ given by the following scale:
    - Donor weight 63.65 to 68.99 kilograms = 480 micrograms daily
    - Donor weight 69 to 86.99 kilograms = 600 micrograms daily
    - Donor weight 87 to 109.99 kilograms = 780 micrograms daily
    - Donor weight 110 kilograms or greater = 960 micrograms daily

- Regimen D – Modified One-Day Collection:
  - Injection once a day for 2 consecutive days, with a cell collection procedure following the last dose (day 3).
    Neupogen™ will be administered as follows:
  - All donors will receive the same dose of Neupogen™ regardless of their weight.
  - The Neupogen™ dose will be 480 mcg. daily

- Regimen E - Modified One-Day Collection:
  - Injection once a day for five consecutive days with a cell collection procedure on the day of the last dose (day 5).
    Neupogen™ will be administered as follows:
  - Donors receive a customized dose of Neupogen™ based on their weight. Each dose is calculated at 5 micrograms of Neupogen™ per kilogram of body weight per day, or 5mcg/kg/day. There is no sliding scale.

I will donate my white blood cells using an apheresis cell separator (Spectra™ made by Gambro BCT, Inc., Lakewood, CO) approved by the Federal Drug Administration (FDA).

In addition to the peripheral whole blood samples drawn for the initial screening, no more than 100 ml of peripheral whole blood samples may be drawn just prior to and/or immediately after the collection procedure. These samples will be used for further research by the facility studying my cells.

A vein puncture will be performed in each of my arms just like a regular blood donation procedure at a blood bank. A sample of my blood will be drawn at this time to measure the level of red blood cells, white blood cells, and platelets in my body. Blood will then be drawn out of one arm and passed through the apheresis machine. The machine will remove some white blood cells and plasma, and return the remainder of my whole blood into the opposite arm.

The volume of white cell rich blood that is collected each day is approximately 150 to 200 ml (less than a cup). The volume of plasma concurrently collected each day is approximately 200 ml (less than a cup).

During the procedure, I will be lying on a bed or reclining chair, able to talk to doctors or nurses. I will have the use of one arm during the procedure to read a book or use a portable computer.

After the collection, the needles will be removed, and bandages will be placed on the skin where the needles were inserted.

Duration

The entire donation appointment will last 4 to 6 hours. Between 3 - 4.5 hours of that time will be actual procedure time on the apheresis machine. I should be able to return to my normal daily activities once I am discharged from LeukoLab.

G-CSF (Neupogen™): Potential Side Effects, Risks and Discomforts

Thousands of people have received G-CSF (Neupogen™) injections, including at least hundreds of healthy individuals, without serious consequences, although long-term (greater than 10 years) potential side effects are unknown. The risks of G-CSF injections include:

- Pain and infection at injection site:
  - Temporary pain and redness may occur from the injection. It is rare for an infection to develop, and this will be treated with oral antibiotics should it occur.
- Bone Pain:
  - I am likely to develop aches in my bones related to the effect of G-CSF. This will be treated by acetaminophen (Tylenol™) or Ibuprofen (Motrin™, Advil™), taken by mouth or, if the pain persists, by discontinuation of the G-CSF.
- Fatigue:
  - G-CSF has been associated with feeling tired while taking the drug, but it should not make me feel very sleepy or interfere with my normal activities.
- Headache:
  - I may experience a headache when the G-CSF increases my white blood cell count. I will contact one of the study physicians if I experience a severe headache unrelieved by Tylenol™, Motrin™ or Advil™.
- Skin Rashes:
  - I may develop a skin rash or a flare up of a skin disorder if I am prone to them. The skin rash/disorder should completely resolve once the G-CSF is stopped. If the rash is severe, I will be removed from participating in the trial. It is possible that the skin rashes/disorder may occur after the G-CSF has been completed. I will notify one of the study physicians if this should occur.

- Allergic Reactions:
    - Rarely individuals are allergic to G-CSF and will have a rash. Symptoms of an acute allergic reaction include hives or itchy skin, a tight feeling in the chest or throat, wheezing, or shortness of breath, sweating, or a fast pulse. I will report such symptoms immediately. If I develop an allergic reaction to this drug, I will not take any more G-CSF and I will not participate in this study.

- Bleeding in the lungs and coughing up blood:
    - Rare instances of bleeding in the lungs and coughing up blood requiring hospitalization have been reported in healthy donors as a result of G-CSF. This condition resolved after stopping the G-CSF. If I begin to cough up blood, I will seek prompt medical attention, I will not take any more G-CSF, and I will not participate in this study.

- Sickle Cell Disease:
    - Severe sickle cell crises, in some cases resulting in death, have been associated with the use of G-CSF in patients with sickle cell disease. I do not have sickle cell disease and understand that a diagnosis of sickle cell disease disqualifies me from participation in this study.

- Rupture of the spleen:
    - Rare cases of splenic rupture have been reported following the administration of G-CSF in both healthy donors and patients. Some of these cases were fatal. I will report left upper abdominal and/or shoulder tip pain immediately to one of the study physicians should it occur, and he will evaluate me for an enlarged spleen or splenic rupture.

Collection Procedure: Potential Side Effects, Risks, and Discomforts

Tens of thousands of people have undergone apheresis (blood separation and/or blood cell collection) procedures, most commonly at blood banks, to provide platelets for people in need of platelet transfusions. There are few serious risks to this procedure. The amount of white blood cells removed from by body is a fraction of my total blood volume and their removal will not affect the normal function of the rest of my blood. The most common side effect reported by donors is a feeling of fatigue after the procedure. Other risks of peripheral blood white cell collection include the following:

- Citrate Anticoagulation
    - Citrate is the substance that will be used to prevent blood from clotting during the cell collection. Citrate can lower the blood level of calcium during the procedure. Potential problems from the citrate include muscle cramping, numbness, chilliness, tingling sensations, feelings of anxiety, dizziness, and red cell damage. I will be closely monitored during the collection to prevent such problems and might be given a calcium supplement during the collection to prevent or treat these problems.

- Infection and Bleeding
    - I may get an infection from the insertion of the needle into my arm and could also bleed into the surrounding tissue, causing a bruise. These unlikely events will be treated with local care, and rarely may require oral antibiotic therapy.

- Lowered Blood Pressure
    - Occasionally, a drop in blood pressure may occur during the procedure. If this happens, I may experience pallor, dizziness, nausea, or cold sweats. I will report any of these symptoms at once to the nurses who may stop the procedure, and possibly give me some additional intravenous fluids until the episode resolves.

- Air Embolism
    - It is possible that air could enter my bloodstream if the apheresis machine malfunctions. The machine is equipped with safety mechanisms to prevent this from happening, but in the event of machine failure it is possible that I could receive a fatal dose of air intravenously.

- Loss of Blood Volume
    - A small amount of blood may not be returned to me in the rare event of machine malfunction or excessive blood clotting. The amount is seldom more than one quarter of a pint. A temporary low red blood cell count may occur. I may be required to have my blood counts checked one week after completion of the study to ensure that my blood counts have returned to normal.

In addition, there may be unknown, unforeseeable risks involved in this donation. However, thousands of individuals have undergone white cell collections without serious side effects. A nurse will always be present, monitoring me frequently during the collection procedure.

Pregnancy

I am not pregnant at this time and I understand that, although there are no known risks to a pregnancy during apheresis procedures, the doctors have decided not to place pregnant women at risk. I agree that I will not participate in this program if I become pregnant, and I will use a reliable method of birth control to prevent pregnancy during my participation in this program. I will notify one of the study physicians if I become pregnant during or shortly after this program.

Right to Withdraw from the Study

My participation in this healthy donor program is voluntary and I have the right to discontinue at any time before or after the start of the procedure.

Frequency of Donations

I understand that I may donate mobilized peripheral blood stem cells only 2 times, with no less than 1 year between each donation. My donation may limit my frequency of blood donation at other blood collection facilities. Alternatively, my donation at other blood collection facilities may limit my ability to participate in this program. I understand these limits are established for my safety, and I agree to disclose to LeukoLab any blood donation I have made at other facilities.

Benefits

I will receive compensation from LeukoLab for my time and for any discomfort in donating my cells. Compensation amounts are:

$ for a Regimen A - one-day collection
$ for a Regimen B - modified one-day collection
$ for a Regimen C - two-day collection
$ for a Regimen D – modified one-day collection
$ for a Regimen E - modified one-day collection

There will be no direct scientific or clinical benefit to me, nor will I gain any commercial or financial rights from my participation in this donor program. LeukoLab will also financially compensate the physician overseeing this procedure. If I am unable to complete any part of this process for a reason beyond my control, LeukoLab may choose to partially compensate me.

No Ownership of my Donation

I will retain no ownership interest whatsoever in my donation. I will have no ownership interest whatsoever in anything that is produced with the donation or in any invention that is made with the use of the donation. I agree that the donation and any derivative may be used, modified, altered, transferred and disposed of without my notice or consent.

Confidentiality

I am participating in this study as an anonymous donor. A unique number will be assigned to me, and to the product I donate, to protect my identity. It is possible that my identity may be revealed to the FDA or other regulatory bodies in the event of positive results for infectious disease testing.

Infectious Agent Testing

In order to qualify as a donor, at least 1 week prior to the stem cell collection, the LeukoLab staff will have my blood tested for the presence of proteins associated with HIV (human immunodeficiency virus) and hepatitis as a matter of safety for the researchers who will be working with my blood samples. Depending on requests from the researchers, LeukoLab might also have my blood tested for HTLV (human T-lymphocyte virus), CMV (cytomegalovirus), and syphilis. Any positive result will be reported to one of the study physicians, who will reveal these results to me alone and will also provide any necessary counseling. I understand that there may be false positive results in testing and that all tests should be repeated before determining the significance of a positive result. Positive results may be reported to the California State Department of Health by the lab performing the tests as required by law and my name may be required for identification purposes. Otherwise, all samples will be identified with a code number only - no names will be used. If I test positive for any of the above viruses, I will not be able to proceed with this study. I will not be allowed to proceed if I test positive for HTLV, CMV, or syphilis.

Questions and Medical Treatment

The doctors and/or nurses will answer any questions I might have regarding the procedure and related questions. In the unlikely event of physical injury clearly related to the procedure, emergency medical treatment will be provided at no cost to me. LeukoLab will be responsible for these costs. There is no reimbursement offered for any other medical illnesses that are clearly not immediately related to the procedure.

If I have questions regarding the consent process I many contact a member of the Institutional Review Board:

For any other questions or concerns, I may contact the study physicians:

Dr.			pager
Dr.			pager
Dr.		pager only	pager

Authorization

My signature below indicates that:

1. I have read the above and agree to participate in the program described above. The general purposes, particulars of involvement, possible hazards and inconveniences have been explained to my satisfaction.
2. I have received a copy of the Experimental Subjects Bill of Rights form.
3. I understand that I will be given a copy of this consent form if I request it.

Donor Printed Name	Donor Signature	Date
Witness Printed Name	Witness Signature	Date
MD Printed Name	MD Signature	Date

FOR CALIFORNIA RESIDENTS ONLY
EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

Any person who is requested to consent to participate as a subject in a research study involving a medical experiment, or who is requested to consent on behalf of another, has the right to:

1. Be informed of the nature and purpose of the experiment.
2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be used.
3. Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.
4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.
5. Be given a disclosure of any appropriate alternative procedures, drugs, or devices that might be advantageous to the subject, and their relative risks and benefits.
6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.
7. Be given an opportunity to ask any questions concerning the experiment or other procedures involved.
8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time, and the subject may discontinue participation in the medical experiment without prejudice.
9. Be given a copy of a signed and dated written consent form when one is required.
10. Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

Printed Name of Subject	Signature of Subject	Date