Study Title: Bone Marrow Collection from Healthy Donors for the Research Market

Sponsor: LeukoLab, A Clinical Division of AllCells, LLC

Protocol Number: 7000-SOP-046
Protocol Version: 2.0 (Alpha IRB)

Principal Investigator:

AllCells, LLC/LeukoLab
1301 Harbor Bay Parkway, Suite 200
Alameda, CA 94502

Telephone: 510-521-7400
After Hours: 510-521-7400

Background

Over the past several decades tremendous progress has been made in treating cancer and blood diseases both through the research and development (R&D) of new drugs and therapies, and more recently from tests being developed to target these therapies. Academic institutions, pharmaceutical, biotechnology, and other organizations involved in conducting or supporting biomedical research require donation of various types of blood or bone marrow cells. Additionally, R&D may involve analysis of different cell types and other substances contained in these tissues including, but not limited to proteins, enzymes, hormones, DNA and RNA. Your tissue donation will remain anonymous (de-identified) to scientific researchers. However information and research data pertaining to such de-identified tissue may possibly be published for review by other members of the biomedical research community.

The sponsor AllCells, Limited Liability Company of Alameda, California, (along with its blood collection division known as LeukoLab) is a private company that collects, processes and sells blood cells to scientists who require bone marrow cells on which to conduct this type of research.

This informed consent form has information to help you decide if you want to participate in a research study. Before you agree to take part in this study, it is important for you to read all of the information that follows. If there are any words or information that you do not understand, your study doctor, or the research staff, will explain them to you and answer any other questions you may have regarding this study. Reading this form and discussing it with your study doctor or the research staff can help you decide whether or not to participate. If you decide to become a donor, you must sign, initial and date this form before you participate.

Purpose of the Study

AllCells, LLC/LeukoLab wishes to obtain sample(s) of bone marrow aspirate (the liquid part of the bone marrow) from health donors for the research market. The samples collected are never intended for transfusion or other use in humans or animals.

Procedure

Bone marrow is the blood-forming organ of the body and is found in bones throughout the human body. A physician will perform a procedure called a bone marrow aspiration to obtain a small sample of bone marrow. Should you decide to participate in the study, the procedure will be performed at LeukoLab, 1301 Harbor Bay Parkway, Suite 200, Alameda, CA 94502.

Description of Bone Marrow Collection:

You will lie down on an exam table, on your stomach with your head resting on your arms. The skin over the upper back part of your hip bone(s), known as your pelvic bone will be thoroughly cleansed using an antiseptic solution. A local anesthetic (numbing medication) called lidocaine will be slowly injected through a small needle into your skin at this site. Additional lidocaine (numbing medication) will be injected into the surface of the bone. When the area is numb, a needle will be passed through the bone then into the bone marrow space itself. Approximately 50 mL (3 ½ tablespoons) of the liquid marrow will be gently pulled into a syringe(s). If necessary (e.g., low flow in the initial site), the aspiration needle may be withdrawn after collecting 25 mL and reinserted in the same hip (within the numbed area) approximately ¼ - ½ inch away from the previous site. An additional 20 – 25 mL (2 tablespoons) of your liquid marrow would then be gently pulled into a syringe(s). Rarely, the needle may go into a "dry" portion of the bone (no liquid bone marrow present) and an additional needle insertion would be necessary. If you are donating 51 – 100 mL of bone marrow, the entire process will be repeated on the other hip. After obtaining the targeted volume of bone marrow, a pressure bandage will be placed on the area(s) of skin where the needles were inserted. You will be instructed to leave your bandage in place until the following morning.

The removal of approximately 100 mL (7 tablespoons) of bone marrow during this procedure will in no way affect the normal function of the rest of your bone marrow. Your body will replace the fraction of bone marrow removed within a matter of hours.

Duration

Each needle will be in your hip bone(s) for approximately 30 – 90 seconds. The entire procedure should take no longer than 45 minutes.

Potential Side Effects, Risks and Discomforts

The amount of bone marrow removed from your body is a small fraction of your total bone marrow and its removal will in no way affect the normal function of the rest of your bone marrow. Serious side effects are rarely seen with this common procedure. However, allergic reaction to the numbing medication, minor bleeding at the skin puncture site, bruising, infection, lightheadedness, fainting, or temporary numbness and/or tingling to the face and/or extremities may be experienced. You will be monitored closed by our clinical staff during the procedure for any adverse reactions. Emergency medications and equipment are available if needed as well as access to 911.

Most donors do not need to take any pain medication after donation. If you do, we suggest you use Acetaminophen (Tylenol). You should avoid taking Ibuprofen (Motrin, Advil), aspirin or Naproxen for at least 24 hours after your donation, as these drugs may increase risk of bleeding at the site.

Activity post-donation will be as you tolerate it; though you may experience less soreness in your hip area if you minimize strenuous activity the day of your donation.

Pregnancy
You may not enter the study if you are pregnant or trying to become pregnant. There are no known risks of the study procedures which would affect pregnant women or unborn children. The study doctors have decided, however, not to include this population in order to avoid any potential unknown risks. You must use a reliable method of birth control to prevent pregnancy during your participation in this program.

Right to Withdraw From the Study
Your participation in this research study is voluntary. You have the right to discontinue at any time before or after commencement of the procedure.

Frequency of Donations
Donations of 50 mL may be repeated once, after a waiting period of 4 weeks. Donations of 100 mL can be repeated every 10 weeks. Maximum donation volume in any 12 month period is 500 mL. There is no life-time donation volume limit.

Your Responsibilities
You will be expected to arrive on time and well nourished for your appointment. Compensation for participation is dependent upon completion of the study procedure.

Benefits
There will be no direct scientific or clinical benefit to you, nor will you gain any commercial or financial rights from participating in this donor program. These samples will be used only for scientific research. You will not be given any results of the research or stored samples.

No Ownership of Donation
You will retain no ownership interest whatsoever in your donation. You 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. After you sign this informed consent form, your marrow donation and any derivative may be used, modified, altered, transferred and disposed of without your notice or further consent.

Infectious Agent Testing
In order to qualify as a study participant, at least 3 business days prior to the bone marrow donation, the LeukoLab staff will test your blood for human immunodeficiency virus (HIV), hepatitis B virus (HBV) and hepatitis C virus (HCV). If requested by the researchers who will be studying your blood, additional testing may be performed. These tests may include, but are not limited to HTLV (human T-lymphocyte virus), CMV (cytomegalovirus), TSE (human transmissible spongiform encephalitis), CJD (Creutzfeldt-Jakob disease), West Nile virus, T.cruzi (Chagas' Disease) and syphilis. Any positive results will be reported to you, and you will be referred to your private physician for follow up. In some circumstances, there may be false positive results and LeukoLab will recommend that the tests should be repeated by your private physician 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 your name may be required for identification purposes. Otherwise, all samples will be identified with a code number only – no names will be used. If you test positive for any of these infectious agents, you will not be able to continue participation in this study.

Unforeseen Risks

There may be risks to the blood marrow aspirate collection procedure that are not yet known. You will be informed in a timely manner both verbally and in writing of any new information or findings that might affect your willingness to continue participation in the study.

Alternatives to Participation

This is a study for healthy bone marrow donors. Your alternative to participation in the study is to not be in this study.

Voluntary Participation

Your participation as a research subject is strictly voluntary. You have the right to discontinue your participation at any time without penalty or loss of benefits. You may refuse to donate samples without penalty or consequence to the care provided to you by the study doctor, associated physicians, the nurses, and the research staff.

If you decide to withdraw your consent, all of the blood samples and study information collected up to that point will remain in the study database and will be analyzed.

The study doctor or LeukoLab staff can stop your participation at any time without your consent for the following reasons:

- If it appears to be medically, mentally or emotionally harmful to you;
- If you fail to follow directions for participating in the study;
- If it is discovered that you do not meet the study requirements;
- If the study is canceled

Confidentiality

You are participating in this study as an anonymous study donor. A unique number will be assigned to you and to the sample you donate, to protect your identity. The study doctor, contracted laboratory for infectious disease testing and the research staff at this facility will have access to records that link the sample number(s) with your identifying information. ***Neither your name nor any other identifying information will be revealed to the research team that will eventually receive your donation.***

The research staff at this facility will retain records linking your identity to your sample for an indefinite period of time. Confidentiality will be protected to the extent allowed by the law; however, absolute confidentiality cannot be guaranteed.

If your bone marrow donation was used by researchers to study your genetic makeup, and if this information was accidently released by the researchers, it might be possible that the information gathered about you as part of this study could become available to someone else outside the study. A Federal law, called the Genetic Information Non-discrimination 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. However, this Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

No research publications or research talks will reveal your identity.

Your study related medical information which may contain your name and other direct identifiers may be submitted to AllCells, LLC, LeukoLab, A Clinical Division of AllCells, or sponsor representatives, Alpha Independent Review Board (Alpha IRB), a group that reviews research to protect research subject's rights and welfare, the Department of Health and Human Services (DHHS), and/or other regulatory authorities as required by law.

Costs/compensation

There will be no cost to you for agreeing to donate your bone marrow. There is no charge to you or your insurance company for obtaining the samples for research or for the research performed using your samples.

For your time and effort related to your participation, you will be compensated as follows:

Volume Collected:	50 mL =
	100 mL =

You will be paid by check within approximately 7-10 business days after your donation. Checks will be mailed to the address you provided to LeukoLab.

Research-related injury

In the event of a research-related injury, medical care will be available. However, there will be no compensation for treatment of a research-related injury, and payment for such care will be the responsibility of you and/or your insurance company. Your insurance, including Medicare, may or may not cover these charges. There will be no payment for other things, such as disability, transportation, or loss of wages. The doctor, this facility, and AllCells, LLC/LeukoLab will not pay for treatment of research-related injuries, although you are not precluded from seeking to collect compensation for injury related to malpractice, fault, or blame on the part of those involved in the research.

Questions

If you have any questions about the study, the sample donation process or the uses of the bone marrow samples, or if you have a research related injury, please contact the study doctor or the research staff at the phone number(s) listed on page 1 of the consent form.

If you have questions, concerns or complaints about your rights as a research volunteer or about taking part in this study, or to obtain information or offer input, you may contact Alpha IRB, Attn: Marianne Thornton, toll free at (888) 265-5766 between the hours of 8:00am-5:00pm Pacific Time.

Alpha Independent Review Board
1001 Avenida Pico, Suite C #497
San Clemente, CA 92673
(888) 265-5766 (toll free)

Alpha IRB is a group of people who perform independent review of research studies to protect the rights and welfare of study participants. Although Alpha IRB has approved the information provided in this informed consent form and has approved for the study doctor to do the study, this does not mean Alpha IRB has approved you being in the study, or that the study is without risks. You must consider the information in this consent form for yourself and decide if you want to be in this study.

Consent to Participate

Your signature below indicates that you have read the above information and have had adequate time to ask questions regarding your participation in this study. You have completed the history forms with required screening and medical information accurately and truthfully. Questions have been answered to your satisfaction. You agree to participate as a donor in the study as it is described above. You are aware that any specimens you donate will be used for scientific research only, and you will not be paid as a result of the commercialization of any product, process, or service developed from your cells, blood, blood marrow or other specimens. You will receive copies of this signed and dated consent form and the Experimental Subjects Bill of Rights form if requested.

You do not give up any legal rights by signing this informed consent form.

_____ I agree to donate 50 mL bone marrow

_____ I agree to donate 100 mL bone marrow

Donor/Subject's Printed Name	Donor/Subject's Signature	Date
Person Conducting Consent Printed Name	Person Conducting Consent Signature	Date
Study Doctor Printed Name	Study Doctor Signature	Date

Experimental Research Subject's Bill of Rights

California Law, under Health and Safety Code §24172, requires that any person asked to take part as a subject in research involving a medical experiment, or any person asked to consent to such participation on behalf of another, is entitled to receive the following list of rights written in a language in which the person is fluent. This list includes the right to:

1. Be informed of the nature and purposes 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 utilized.

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 may 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 the 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 the signed and dated written consent form.

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.

_____	_____	_____
Donor/Subject's Printed Name	Donor/Subject's Signature	Date