Study Title: Bone Marrow and/or Peripheral Blood Collection from Disease-Specific Donors for the Research Market

Sponsor: LeukoLab, A Clinical Division of AllCells, LLC

Protocol Number: 7000-SOP-078
Protocol Version: 1.0 (Alpha IRB)

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Study Doctor: <<Insert Study Doctor's Name>>

Site Address: <<Insert Site name, address>>

Telephone: <<Insert Site's Telephone Number >>
After Hours: <<Insert 24hr Number >>

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 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 blood or bone marrow cells on which to conduct this type of research. This study is sponsored by AllCells, LLC (the "sponsor"), who pays the study site and/or the study doctor for the professional services and expenses related to this study.

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 or

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, i.e. a study participant or "research subject," you must sign, initial and date this form before you participate.

Purpose of the Study

AllCells, LLC/LeukoLab wishes to obtain sample(s) of peripheral blood (from a vein) and/or bone marrow aspirate (the liquid part of the bone marrow) from patients with multiple myeloma, chronic or acute leukemia or selected lymphomas where there is known bone marrow involvement, autoimmune diseases such as rheumatoid arthritis, osteoarthritis, systemic lupus erythematosus, etc. to name a few, and from patients with solid tumor cancers including but not limited to breast cancer, colon cancer, prostate cancer, to sell for research purposes only. The samples collected are never intended for transfusion or other use in humans or animals. You are being asked to participate in this sample collection study because the doctor has identified you as an individual with one of the conditions mentioned above.

Procedures

Peripheral Blood

Peripheral blood samples will be collected by a standard phlebotomy method (typically taken from a vein in your arm, or if applicable, your venous access device [VAD]). Amounts will vary from approximately 2 teaspoons (10 milliliters [mL]) to 500 mL (about 2 cups).

Bone Marrow Aspirate

Bone marrow is the blood-forming organ of the body and is found in bones throughout the human body. If you agree to donate, the bone marrow aspiration procedure will be performed by your study doctor or designee. A portion of the bone marrow aspirated during the procedure will be donated to AllCells.

For the bone marrow aspirate procedure, you will lie down on an examination table. Your skin over the target area will be cleaned with an antibacterial disinfectant. Lidocaine will be used to anesthetize (numb) the target area. A bone marrow needle will be inserted into the marrow space and bone marrow will be aspirated (drawn) into the appropriate volume syringes pre-loaded with an anticoagulant (prevents blood clots). Pressure will then be applied to the aspiration site until bleeding stops, at which time a gauze pressure dressing will be taped firmly in place.

In this bone marrow aspirate procedure, no more than 60 mL (approximately 4 tablespoons) of bone marrow will be removed, and its removal 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.

Product Screening

Bone Marrow and/or Peripheral blood received at AllCells will automatically be tested 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 your physician and they are responsible to reveal these results to you and provide any necessary counseling. In some circumstances, there may be false positive results and the 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 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 with this study.

Risks

Peripheral Blood Draws: The risks of drawing peripheral blood include temporary discomfort from the needle in your arm, bruising, swelling at the needle site, and in rare instances, infection. Standard care will be taken to avoid these complications.

Bone Marrow Aspiration: There are few health risks to donors from having small amounts of bone marrow removed. Up to 20 ml (approximately 4 teaspoons) of bone marrow per kilogram of body weight can be safely removed from donors for bone marrow transplantation. Therefore, for example, a person weighing 70 kilograms (154 pounds) can have 1400 ml bone marrow removed safely.

Serious side effects are rarely seen with this common procedure; however, risks from the aspiration procedure include the possibility of an allergic reaction to the painkiller, minor skin bleeding and minor skin infection at the site of the needle insertion. Infection at the aspiration site is also a remote possibility. You may experience a mild to moderate degree of pain or discomfort during the short time that the marrow is aspirated; this pain disappears shortly after the marrow is removed and rarely continues after the procedure is completed. Occasionally, some pain or discomfort may last a few days. You may also experience a sensation of soreness similar to that of a bruise at the needle site, which usually resolves within a week.

In very rare instances, either during or shortly after the procedure(s), you may faint. Or, you may experience a sensation of dizziness or lightheadedness that may be accompanied by nausea and clammy skin. If any such events occur, you will be closely monitored, have your vital signs taken, given fluids to drink, and you will only be allowed to leave once all your symptoms have resolved.

Although we have made every effort to protect your identity, there is a very small risk of loss of confidentiality. If the results of studies of your genetic makeup were to be accidentally released, it might be possible that the information we will gather about you as part of this study could become available to an insurer or an employer, or a relative, or someone else outside the study. Even though there are discrimination protections in place, there is still a small chance that you could be harmed if a release occurred.

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. 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 the pharmacogenetic tests.
- 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 the pharmacogenetic tests 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.

Benefits

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

Alternatives to Participation

This is not a treatment study. Your alternative is to not be in this study. Your decision not to participate will not affect your medical care for your condition.

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.

Unforeseen Risks

There may be risks to the blood marrow aspirate or blood sample 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.

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 the Sponsor can stop your participation at any time without your consent for the following reasons:

- If it appears to be medically 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 donor. To protect your confidentiality, your donated blood and/or bone marrow samples will be assigned a unique number(s). Only the study doctor 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 AllCells, LLC/LeukoLab, or 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.
Additional information from your medical records about your disease will be given to AllCells, LLC/LeukoLab. This information will NOT be connected to your name or any other personal identifier but will include:

- Results of recent blood tests you have had
- Results of your last bone marrow aspirate if one has been done
- Results of immunophenotyping (markers that identify abnormal cells) if any
- Results of cytogenetic analysis or molecular biology analysis if any
- Results of any other necessary diagnostic analysis
- Listing of previous treatments you have had for your disease

No research publications or research talks will reveal your identity.

Information from this study will 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 may have access to this information as required by law.

Costs/compensation

There will be no cost to you for agreeing to donate your blood and/or 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 inconvenience related to your participation, you will be paid up to a total of <<insert site's compensation amount - $XXX for peripheral blood and $XXX for bone marrow >> for your donation. This will be paid to you within approximately 4-6 after your donation.

OR

You will not be compensated for your donation.

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 donated blood and/or bone marrow samples, or if you have a research related injury, please contact the study doctor or the research staff at this facility or you may contact the Principal Investigator 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

My signature below indicates that I have read the above information and have had adequate time to ask questions regarding my participation in this study. My questions have been answered to my satisfaction. I agree to participate as a donor in the study as it is described above. I am aware that any specimens I donate will be used for scientific research only, and I will not be paid as a result of the commercialization of any product, process, or service developed from my cells, blood, blood marrow or other specimens. I understand I will receive copies of this signed and dated consent form and the Experimental Subjects Bill of Rights form.

Peripheral Blood

_____ I agree to donate 10-40 mL peripheral blood.

_____ I agree to donate 41-60 mL peripheral blood

_____ I agree to donate 61-100 mL peripheral blood

_____ I agree to donate 500 mL peripheral blood

Bone Marrow

_____ I agree to donate 25-30 mL bone marrow

_____ I agree to donate 50-60 mL bone marrow

_____	_____	_____
Donor/Subject's Printed Name	Donor/Subject's Signature	Date
_____	_____	_____
Person Conducting Consent Printed Name	Person Conducting Consent Signature	Date
_____	_____	_____
MD Printed Name	MD Signature	Date

IMPARTIAL WITNESS STATEMENT (USE ONLY IF APPLICABLE)

If this addendum to informed consent document is read to the subject because the subject is unable to read the document, an impartial witness not affiliated with the research or study doctor must be present for the consent and sign the following statement:

I attest that the information in this addendum to informed consent document was accurately explained to and apparently understood by the subject. I also attest that the subject freely gave their informed consent to participate in this trial.

_____

First and Last Name of Impartial Witness (Print)

_____ _____

Signature of Impartial Witness | Date (Handwritten by Impartial Witness)