Study Title: Whole Blood Collection from Healthy Donors For the Research Market

Sponsor: LeukoLab, A Clinical Division of AllCells, LLC

Protocol Number: 7000-SOP-049
Protocol Version: 1.0 (Alpha IRB)

Principal Investigator:

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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 whole blood 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 to scientists who require blood 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 or answer any other questions you may have regarding the 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

The purpose of this study is to provide healthy whole blood for distribution to institutions engaged in medical or scientific research. The blood is for laboratory in-vitro (i.e. test tube) use only, never for transfusion or other use in humans.

Procedure

A licensed nurse or certified phlebotomist will perform a phlebotomy, a procedure to collect whole blood from peripheral veins (blood draw). The blood samples will be taken by individual needle stick (syringe) into one of your arm veins or via an indwelling catheter (a thin plastic tube placed in a vein in your arm and the blood is drawn into sterile blood specimen tubes or collection bags, depending on the amount of your donation. Lidocaine 1% 0.2ml may be used for numbing the needle site, if preferred. The amount of blood collected will vary from approximately 10 mL (2 teaspoons) to 500 mL (about 2 cups). During the blood draw procedure, you will be seated in an adjustable donor chair.

Prior to the whole blood collection, your vital signs (temperature, pulse, respiration, blood pressure) will be taken. If you have not had your hemoglobin level tested within a 7 day period at LeukoLab, a sample of your blood will be tested at this time to measure the level of red blood cells in your body. If your vital signs and hemoglobin levels meet LeukoLab's established parameters, your whole blood will then be collected.

After the whole blood collection is completed, the needle will be removed and a bandage will be placed on the area. You will be instructed to leave your bandage in place for 1 – 2 hours.

Duration

The procedure will last between 15 and 30 minutes.

Potential Side Effects, Risks and Discomforts

The amount of whole blood removed from your body is a small fraction of your total blood volume and its removal will in no way affect the normal function of the rest of your body. Serious side effects are rarely seen with this common procedure. However, minor bleeding at the needle insertion site, bruising, infection, lightheadedness, fainting, or allergic reaction to the numbing medication (if used) 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.

You should be able to return to your normal daily activities after the procedure.

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
You may make multiple, small-volume donations, each ranging from 10 mL (2 teaspoons) to 500 mL (about 2 cups).

Once a cumulative total volume of 515 mL whole blood has been collected, you will be required to wait 8 weeks (56 days) before making further donations.

You must wait 2 days after an apheresis donation (White Blood Cells (WBC) Collection or Platelet Collection) to donate whole blood.

There is no life-time donation volume limit.

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

Benefits
There will be no direct scientific or clinical (medical) 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 whole blood 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 whole blood 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 whole blood 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 whole blood 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. 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. Confidentiality will be protected to the extent allowed by the law; however, absolute confidentiality cannot be guaranteed.

If your whole blood 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 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.

Costs/compensation

There will be no cost to you for agreeing to donate your whole blood. 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:

- ☐ < 60 milliliters (2 ounces) = $. (This includes any volume from 1 to 59 mL)
- ☐ 60 milliliters (2 ounces) = $
- ☐ 70 milliliters (2 1/3 ounces) = $
- ☐ 80 milliliters (2 2/3 ounces) = $
- ☐ 90 milliliters (3 ounces) = $
- ☐ 100 milliliters (3 1/3 ounces) = $
- ☐ 110 milliliters (3 2/3 ounces) = $
- ☐ 120 milliliters (4 ounces or approximately ½ cup) =
- ☐ 130 milliliters (4 1/3 ounces) = $
- ☐ 140 milliliters (4 2/3 ounces) = $
- ☐ 150 milliliters (5 ounces) = $
- ☐ 160 milliliters (5 1/3 ounces) = $.
- ☐ 170 milliliters (5 2/3 ounces) = $
- ☐ 180 milliliters (6 ounces) = $
- ☐ 190 milliliters (6 1/3 ounces) = $
- ☐ 200 milliliters (6 2/3 ounces) = $
- ☐ 210 milliliters (7 ounces) = $
- ☐ 220 milliliters (7 1/3 ounces) = $
- ☐ 230 milliliters (7 2/3 ounces) = $
- ☐ 240 milliliters (8 ounces or approximately1 cup) =
- ☐ 250 milliliters (8 1/3 ounces) = $
- ☐ 260 milliliters (8 2/3 ounces) = $
- ☐ 270 milliliters (9 ounces) = $
- ☐ 280 milliliters (9 1/3 ounces) = $
- ☐ 290 milliliters (9 2/3 ounces) = $
- ☐ 300 milliliters (10 ounces) = $
- ☐ 310 milliliters (10 1/3 ounces) = $
- ☐ 320 milliliters (10 2/3 ounces) = $
- ☐ 330 milliliters (11 ounces) = $
- ☐ 340 milliliters (11 1/3 ounces) = $
- ☐ 350 milliliters (11 2/3 ounces) = $
- ☐ 360 milliliters (12 ounces or approximately 1 ½ cups) =
- ☐ 370 milliliters (12 1/3 ounces) = $
- ☐ 380 milliliters (12 2/3 ounces) = $

- ☐ 390 milliliters (13 ounces) =
- ☐ 400 milliliters (13 1/3 ounces) =
- ☐ 410 milliliters (13 2/3 ounces) =
- ☐ 420 milliliters (14 ounces) =
- ☐ 430 milliliters (14 1/3 ounces) =
- ☐ 440 milliliters (14 2/3 ounces) =
- ☐ 450 milliliters (15 ounces) =
- ☐ 460 milliliters (15 1/3 ounces) =
- ☐ 470 milliliters (15 2/3 ounces) =
- ☐ 480 milliliters (16 ounces) =
- ☐ 490 milliliters (16 1/3 ounces) =
- ☐ 500 milliliters (16 2/3 ounces or approximately 2 cups) =

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 whole blood 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: , 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 the following:

- ☐ < 60 milliliters (2 ounces) = $ his includes any volume from 1 to 59 mL)
- ☐ 60 milliliters (2 ounces) = $
- ☐ 70 milliliters (2 1/3 ounces) = $
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- ☐ 480 milliliters (16 ounces) = $
- ☐ 490 milliliters (16 1/3 ounces) = $
- ☐ 500 milliliters (16 2/3 ounces or approximately 2 cups) = $

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