

Volunteer Donation By Patients Of Peripheral Blood and/or Bone Marrow Aspirate

IRB# _____

Pt. # _____

Introduction

Please read this form carefully. Take time to ask Dr. ___ or the research staff as many questions about the donation as you would like. If there are any words or information that you do not understand, Dr. ___ or the research staff will explain them to you. Reading this form and talking to Dr. ___ or the research staff can help you decide whether to donate or not. If you decide to become a donor you must sign the end of this form before you donate.

Background

Over the past several decades tremendous progress has been made in treating cancers both through the development of new drugs and therapies, and more recently from tests being developed to target these therapies. This progress is accomplished by laboratory testing using cancerous cells before actual testing on humans begins. Academic institutions, pharmaceutical companies and biotech companies require donation of various types of cancer cells to perform this research. AllCells, Limited Liability Company of Emeryville, California, is a private company that collects, processes and sells blood cells to scientists who require cancer cells on which to conduct this type of research.

Donation

AllCells, LLC, wishes to obtain donation of peripheral (from a vein) blood and bone marrow aspirate from patients with multiple myeloma, chronic or acute leukemia or selected lymphomas where there is known bone marrow involvement, to sell for research purposes only. You are being asked to be a donor because Dr. ___ or Dr. ___ identified you as a patient with one of these diagnoses.

If you agree to become a donor, you will be asked to donate either 30 cc's (approximately 2 tablespoons) of peripheral blood or 25 to 50 cc's (approximately 2-4 tablespoons or less than 1 cup) of bone marrow aspirate (the liquid part of the bone marrow), or both. The donated blood and/or bone marrow will only be used for research purposes and will not be used to treat you or any other patient. In addition, information from your medical records that gives additional information on your disease will be given to AllCells, LLC. This information will not identify you and 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 cancer cells) if any
- Listing of previous treatments you have had for your disease

Procedures

Peripheral Blood

If you agree to donate peripheral blood, you will have 30 cc's whole blood drawn from your arm or venous access device (VAD). The donated blood will be delivered to AllCells, LLC, as soon as the procedure is completed.

In addition to the donated 30 cc's, an additional 3 cc's will be drawn in a separate tube to test for the presence of HIV or hepatitis C virus for the protection of persons working with the specimens. This testing will be done at no charge to you but will be paid for by AllCells, LLC. Any positive results will be reported to Dr. ___ or Dr. ___, who will reveal these results to you alone and will provide any necessary counseling. You should be aware that there may be false positive results in testing and that all tests should be repeated before determining the significance of a positive result. All positive hepatitis C results must be reported to local public health officers as required by law. If you test positive for the above viruses, you will not be able to proceed with the donation.

Bone Marrow Aspirate

If you agree to donate bone marrow aspirate, you will be placed in a prone position on an examination table with your iliac crests (hip bones) exposed. The skin over this area will be cleansed with a surgical skin scrub to try to prevent infection. A local anesthetic, Lidocaine 1%, will be injected just beneath the skin surface over this area. Once the anesthetic has taken effect, a needle will be inserted through the numbed skin to the hip bone (iliac crest). Lidocaine will continue to be injected in small amounts along the hip bone for additional anesthetic effect. After there has been enough time for you not to suffer significant pain, a bone marrow needle will be inserted and pushed through the bone into the marrow space. Once the needle has entered this space, bone marrow will be aspirated (sucked up) and when a sufficient amount has been withdrawn, the needle will be removed. The aspirated bone marrow will be delivered to AllCells, LLC, as soon as the procedure is over.

Following the procedure, pressure will be applied to the aspiration site(s) until bleeding has stopped. At that time a gauze pad will be firmly taped in place and you will be instructed to leave this in place for the rest of the day.

Risks

Blood Draws: The risks of drawing 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 no risks to donors from having small amounts of bone marrow removed. Up to 20 cc of bone marrow per kilogram of body weight can be removed from donors for bone marrow transplantation without problem. In this procedure, no more than 25-50 cc bone marrow will be removed.

The risks from the aspiration procedure include the possibility of an allergic reaction to local anesthetic, minor bleeding at the aspiration site, infection at the aspiration site, and temporary pain during the procedure.

Benefits

There will be no scientific or medical benefit to you from the donation of your peripheral blood or bone marrow. These donations will be used only for scientific research laboratories.

Voluntary Participation

Your participation as a donor is strictly voluntary. You may refuse to donate without any adverse effect on your continued care by Dr. ___ or Dr. ___.

Alternative Treatment

Since there is no treatment involved in agreeing to donate your blood or bone marrow, this does not apply.

Confidentiality

To protect your confidentiality your donated specimens will be assigned a sample number. Only Dr. ___, Dr. ___ and the Research Department Manager at the ___ will have access to records that link this sample number with your identifying information. Neither your name nor any other identifying information will be revealed to AllCells, LLC, or the research team that will eventually receive your donation.

The Research Department Manager at the _____ 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.

Costs/compensation

There will be no cost to you for agreeing to donate your blood or bone marrow. Dr. ___ will pay you ___ for each 25 cc's of bone marrow donated and ___ for donating peripheral blood.

Dr. ___ will be compensated by AllCells, LLC for procuring the donations. The _____ Department will be paid for assisting Dr. ___ in obtaining consent, the specimen(s) and delivery to AllCells, LLC.

Research-related injury

In the even 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. Dr. ___, the

_____ and AllCells, LLC are not responsible for the payment of research-related injuries.

Questions

If you have any questions about the donation process or the uses of the donation, please ask Dr. _____. If you have questions about participating in this donation process and your rights in it, you can contact the _____ Institutional Review Board (IRB) at _____.

Consent to donate

I have read the above information and had time to ask and have answered questions I might have. I understand that any specimens I donate will be used for scientific research only and will not benefit me in any way. I know I will receive a copy of this signed consent form.

_____ I agree to donate 30 cc's of peripheral blood.

_____ I agree to donate 25 to 50 cc's of bone marrow.

Signed (donor)

Date

Name of Donor (printed)

Signature of Person Obtaining Consent

Date

Name of Person Obtaining Consent (printed)

Donor Initials: _____