Fred Hutchinson Cancer Research Center

Consent to take part in a research study:

985.03C – Mobilized Donor

Consent to Participate as a Donor of Mobilized Peripheral Blood Mononuclear Cells for Laboratory Research and Process Development Studies.

Principal Investigator: Derek Stirewalt, MD, Member, FHCRC, (206 667-5386)

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Research Coordinator: Aubrey McMillan, (206) 667-3539

Emergency Phone (24 hours) UW Transplant unit 8NE: (206) 598-8902
UW Nocturnist on call provider (7:00 PM -7:00 AM): (206) 598-1062
Donor recruitment and participation: 206-667-5318

Important things to know about this study.

You are invited to participate in a research study. The purpose of this research is to collect blood cells by a procedure called "leukapheresis".

Stem cells from the bone marrow can now be isolated from the peripheral blood. These peripheral blood stem cells (PBSC) can be greatly increased by giving injections of growth factors and collected using a procedure called leukapheresis. Our purpose is to collect both small blood draws and larger samples of PBSC for laboratory research studies. This research may involve analysis of your genetic material called DNA and RNA. The studies may also examine other components of the cell like proteins. These analyses can be used to better understand cancer and other diseases.

People who agree to join the study will be asked to attend 6 appointments over up to 30 days. The study involves an initial screening appointment, 4 shots, and two leukapheresis donations.

The study procedures could cause side effects such as discomfort from the venipuncture, a sour taste in the mouth, or a decrease in platelets as described below in this form.

Following is a more complete description of this study. Please read this description carefully. You can ask any questions you want to help you decide whether to join the study. If you join this study, we will give you a signed copy of this form to keep for future reference.

We would like you to join this research study.

Since you are you have expressed interest in being a donor, we would like you to join this study.

Doctors at the Fred Hutchinson Cancer Research Center (FHCRC) and Seattle Cancer Care Alliance (SCCA) are conducting this research. This research may also be done in collaboration with for profit companies. Researchers will not report their results to you or your doctor. The research results will not appear in your health record, and the results will not affect your care. Research on your tissue may help develop new products. If these products make money, there is no plan to share the money with you. If you choose to participate in the studies, your samples will be considered donated by you.

If you agree to be in this study,

- You will undergo an initial phone questionnaire to determine your eligibility for the study.
- You will attend a screening appointment at the Seattle Cancer Care Alliance within 30 days of your donation to confirm your eligibility for the study.
    - Individual donors must meet similar eligibility criteria outlined for routine blood bank donation by Bloodworks Northwest.
    - Your veins will be evaluated to make sure they can accommodate the large bore needle used in the leukapheresis collection.
    - We will have you answer a series of questions about your medical history.
    - You will have up to 200mL (approximately 7 ounces) of blood drawn during the screening process, which will be screened for viruses that include screening for HIV, Hepatitis B and C, Syphilis and testing of liver function, as well as others.
    - Your blood specimens may undergo additional testing including blood typing for research purposes.
    - Your blood will undergo a complete blood count to ensure that the ratio of cells in the blood are normal.
    - Your blood will be tested to obtain a metabolic panel to ensure you are eligible to receive GCSF.

    - Female donors will undergo a pregnancy test within 7 days of receiving GCSF.
    - If any of these tests indicate an abnormality you will be notified and will not be accepted as a donor.
- You will not be allowed to donate if you:
    - Have donated blood within the last 8 weeks.
    - Have symptoms of an infection including a "cold".
    - Have undergone leukapheresis within the past 3 weeks.
    - Are pregnant.
    - Are less than 18 or greater than 70 years of age.
- You will be given shots under the skin of a stimulant that causes blood stem cells to multiply and go into the blood daily for 4 consecutive days. This stimulant is called G-CSF. G-CSF is naturally made in your body at a lower concentration. This will lead to an increase in the number of stem cells and other blood cells called white blood cells.
- Your white blood cells and stem cells will be collected by leukapheresis on days 4 and 5 after starting the G-CSF. To collect the cells, a needle will be placed into a vein on each arm to allow for the removal and return of your blood. Your blood will pass through the leukapheresis machine, and the machine will collect a fraction of your blood cells while returning the other liquid and cellular portions of your blood back to you.
- The collected blood cells will then be used for research studies.
- Each leukapheresis procedure will take 3-4 hours. Your leukapheresis will be done at the Seattle Cancer Care Alliance (SCCA).

If you agree to join this study, your participation will end after your 2nd leukapheresis donation.

You do not have to be in this study. You are free to say yes or no, or to drop out after joining. Whatever you decide, your regular medical care will not change.

If you leave the study, your test results and information cannot be removed from the study records.

What are the risks?

Screening Questionnaires and Blood Draws

Likely side effects of the screening questionnaire and blood draws are:

- The screening questions about your medical history are sensitive and may make you feel uncomfortable.
- The blood draw may briefly cause you to feel faint, lightheaded, or nauseated.

Administration of G-CSF

Likely side effects of G-CSF administration are:

- There may be some discomfort and bruising from needle sticks during the G-CSF administration.
- Occasionally patients complain about bone aches, flu-like symptoms, headache, nausea and light-headedness due to the G-CSF.

Rare but serious side effects of G-CSF administration are:

- Rupture of the spleen has been reported as a very rare and unusual occurrence. Splenic rupture can be serious and life-threatening, however it has been reported to occur only in approximately one out of ten thousand subjects.
- Although long-term complications have not been observed in patients following G-CSF administration, this possibility cannot be excluded.

The short-term effects following the administration of G-CSF are dose and schedule related, the symptoms are usually mild and treatable with over the counter analgesics (medicines used to relieve pain). Moderate to severe short-term effects are less common and only rarely require that G-CSF be discontinued.

Leukapheresis Procedure

Likely side effects of the leukapheresis procedure are:

- As part of the procedure, an agent is used to prevent the blood from clotting in the tubes of the leukapheresis machine. This agent is called an anticoagulant. These anticoagulants are used frequently in patients. You may experience a sour taste in the mouth. You may also experience numbness and/or tingling around the mouth, feet or hands as a result of this anticoagulant.
    - Leukapheresis may decrease one of your cell types that help you clot blood. The cells are called platelets. The decrease in platelets is usually minimal and will not affect your blood's ability to form clots.
- There may be some discomfort and bruising from the leukapheresis needles.

- Your body will quickly replace any blood cells removed by the leukapheresis. Some patients can show a decrease in red blood cell count for 1-2 days after, but this should cause no symptoms.

Rare but serious side effects of the leukapheresis procedure are:

- The anticoagulant used in the leukapheresis procedure will typically clear your body within four hours. There could be a small risk of bleeding from this anticoagulant. This risk of bleeding is less than 1 in 100 subjects. If bleeding occurs, it is usually mild oozing from the IV site. The risk of a serious or life-threatening bleed is less than 1 in 5000 subjects.

What are the benefits?

Donors will receive no direct benefit from the donation of these cells. The benefits to other persons will be indirect and arise from the results of the research on these cells.

Protecting your Privacy as an Individual and the Confidentiality of Your Personal Information

If you join this study, some people and organizations might need to look at your medical or research records for quality assurance or data analysis. They include:

- Researchers involved with this study.
- Institutional Review Boards (IRB), including the Fred Hutchinson Cancer Research Center IRB. An IRB is a group that reviews the study to protect your rights as a research participant.
- Fred Hutchinson Cancer Research Center and Seattle Cancer Care Alliance.
- US National Institutes of Health, National Cancer Institute, Office for Human Research Protections, and other agencies as required.

We will do our best to keep your personal information confidential. But we cannot guarantee total confidentiality. Your personal information may be given out if required by law. For example, workplace safety rules may require health workers to contact you about lab tests or, a court may order study information to be disclosed. Such cases are rare.

We will not use your personal information in any reports about this study, such as journal articles or presentations at scientific meetings.

If you join this study, information about your participation would be made part of your permanent medical record. This information would include a copy of this consent form. If an insurance company or employer or anyone else were authorized to see the medical record, they would see a copy of this consent form.

This research is covered by a Certificate of Confidentiality from the U.S. government. This Certificate helps protect the confidentiality of information about people who join this study. If you join the study, the Certificate means that we would generally not have to give out identifying information about you even if we are asked to by a court of law. We would use the Certificate to resist any demands for identifying information.

We could not use the Certificate to withhold research information if you give written consent to give it to an insurer, employer, or other person.

This protection has some limits. We would voluntarily provide the information:

- To a member of the federal government who needs it in order to audit or evaluate the research.
- To the funding agency and groups involved in review of the research, if they need the information to make sure the research is being carried out correctly.
- To someone who is accused of a crime, if he or she believes that our research records could be used for defense.
- To authorities, if we learn of child abuse, elder abuse, or if participants might harm themselves or others.

Tissue collected, records and information may be inspected and/or copied for quality assurance and data analysis by the following groups:

• Fred Hutchinson Cancer Research Center (FHCRC),

• Seattle Cancer Care Alliance (SCCA),

• The National Institutes of Health (NIH),

• Office for Human Research Protections (OHRP),

• Institutional Review Board (IRB)

Federal regulations and the policies of the Seattle Cancer Care Alliance (SCCA) require that certain information about your participation in this research be made a part of your permanent medical record. If you do not already have a medical record at SCCA one will be created for you even if your only connection with them is as a research subject.

The information in your permanent medical record will include:

· Name of the study

- Name of the group or company that is paying for the research
- The number the group or company assigned to this study
- The name of the researcher
- The name of the study coordinator
- Contact phone number for the study
- Contact email address for the study
- Emergency phone number for the study
- Expected start and end dates for your time in the study
- Whether this study includes healthy volunteers

No information about research procedures or test results from 985-collected products will be put into any patient or donor medical records. Once the products are collected, they will be de-identified for subsequent study results.

In the future, if you give permission to any person or group to look at your medical record (such as an insurance company or employer), they could receive this research information. If you have already given permission to anyone (such as your life or health insurance company) to look at your medical record, they may receive this information if they ask for a copy of your medical record.

Your personal identity will not be revealed in any publication or results. Study records will be maintained indefinitely for the purpose of analysis and follow-up.

How is my genetic information protected?

As part of this protocol, you may also participate to the use of your samples for genetic typing. If you choose to participate in this part of the study, we may test your sample for genetic changes.

Genetic studies can evaluate thousands of genes for abnormalities. If you choose to participate in the Genome Sequencing studies, your samples will be considered donated by you. The samples may be examined by researchers at Fred Hutchinson Cancer Research Center and researchers at outside for-profit or non-profit institutions.
There are no additional costs to participating in these genetic studies. The data generated will not be provided to you or your treating physicians. The research results will not be

put in your medical records and will not be used to guide treatment decisions. There are no direct benefits to you.

The results of Genome Sequencing studies may be shared with other researchers. Some of the results obtained from your samples may be made available over the Internet and will be freely available to anyone who is interested (public database). This is done to make this information useful to as many researchers as possible.

Personal information about you such as your name and address will NOT be linked to the genetic information that is made available over the Internet or shared with researchers. However, we cannot guarantee that your identity will never become known.

Your genetic information may be the same or similar to the genetic information of your children, parents, brothers, sisters and other relatives. It may be possible that researchers could guess your identity based on genetic information derived from relatives or gathered by other means. Similarly, it may be possible that genetic information from you could be used to help to identify your relatives.

All precautions to maintain the confidentiality of your personal and health information will be taken.

A federal law called the Genetic Information Nondiscrimination Act (GINA) helps protect your genetic information.

GINA restricts access to your genetic information so that it can not be used for health insurance coverage decisions. GINA won't allow health insurance companies or group health plans to:

- ask for your genetic information you have provided in research studies.
- use your genetic information when making decisions regarding your eligibility or premiums

GINA ***does not*** help or protect you against genetic discrimination by companies that sell life, disability or long-term care insurance.

At the end of this consent document, you will have an opportunity to say “Yes” or “No” to Genome Sequencing studies being performed with your samples collected for this study.

Will you pay me to be in this study?

If you complete this study, we will mail you a check for up to $800. You will receive up to $200 for the four G-CSF injections ($50 per dose administered) and $300 for each leukapheresis procedure. If you drop out of the study, or if we take you out of this study prior to your 1st GCSF injection you will not be compensated.

Payments for being in the study may be taxable. If you join the study, we would need your social security number for tax reasons.

How much will this study cost me?

The study sponsor will pay for the costs of the leukapheresis and associated blood tests. There are no costs for being in this study.

What if you get sick or hurt after you join this study?

For a life threatening problem, call 911 right away or seek help immediately. Contact your study doctor when the medical emergency is over or as soon as you can.

For all other medical problems or illness related to this research, immediately contact the 24 hour UW Transplant Clinic unit, 8NE (206 598 8902). They will treat you or refer you for treatment. You or your health insurance will have to pay for the treatment. There are no funds to pay you for a research-related injury, added medical costs, loss of a job, or other costs to you or your family. State or national law may give you rights to seek payment for some of these expenses. You do not waive any right to seek payment by signing this consent form.

You or your insurer will be billed for treatment of problems or complications that result from your condition or from standard clinical care.

You will be monitored carefully during the procedure. Should medical problems arise, immediate treatment will be available by the attending physicians. Compensation is not available for wages lost during or after the procedure, nor for hospitalization or long-term health costs resulting from your donation.

You would not lose any legal right to seek payment for treatment if you sign this form.

What will my information and/or tissue samples be used for?

Your information and tissue samples (such as blood) will be used for the purposes of this study.

Your tissue samples might help researchers develop new products. This research could be done by for-profit companies. There is no plan to share with you any revenue generated from products developed using your tissue samples.

An Institutional Review Board (IRB) must approve any future or new research study using your tissue or other specimens. If we want to use them for a purpose not described

in this consent form, we will send our request for a minimal risk approval to the IRB. The IRB is a group of people who protect the rights and welfare of research participants.

During this study, if the researchers learn new information that may be important to your general health, they will share that information with you. Examples include high blood pressure or an abnormal CBC.

Your rights

- You do not have to join this study. You are free to say “yes” or “no”.
- If you get sick or hurt in this study, you do not lose any of your legal rights to seek payment by signing this form.
- During the study, we might learn new information that you need to know. Other information might make you change your mind about being in this study. If we learn these kinds of information, we would tell you.
- If you join this study, you would not have to stay in it. You could stop at any time (even before you start). Your regular medical care would not change. You would have no penalty for stopping, but it would be better not to join the study if you think that you would change your mind later.

For more information

If you have questions or concerns about this study, you may talk to a member of the study team anytime. For donor recruitment and participation please contact the CCEH donor program helpline during business hours 9:00 AM -5:00 PM Monday-Friday at 206-667-5318 or visit our website at https://www.fredhutch.org/en/research/divisions/clinical-research-division/research/cceh-donor-program.html.

If you have questions about the research or a research-related injury, please contact your apheresis attending physician or the apheresis staff at SCCA Apheresis, (206) 606-2120. FHCRC will pay for the costs of the leukapheresis and associated blood tests. Other people you can talk to are listed below.

If you have questions about:	**Call:**
This study (including complaints and requests for information)	206 667 5386 (Dr. Derek Stirewalt) 206 667 3539 (Aubrey McMillan, Research Coordinator)
If you get sick or hurt in this study	2065 667 5386 (Dr. Stirewalt)
Your rights as a research participant	206-667-5900 or email irodirector@fredhutch.org (Director of Institutional Review Office, Fred Hutchinson Cancer Research Center) 206-543-0098 (Human Subjects Division, University of Washington)

Signature

Please sign below if you:

- have read this form (or had it read to you);
- had the opportunity to ask any questions you have and all questions were answered to your satisfaction;
- understand what is involved in being a donor;
- give permission to the people and organizations connected with this research study to review and copy my research records, both during the research and the long-term follow-up;
- have been told of the risks and benefits of being in this study;
- had the opportunity to discuss the research with the person obtaining consent; and
- agree to participate in this study.

Do you agree to allow us to conduct genome sequencing studies with your blood product samples, understanding that genetic and sequence data generated from your samples may be deposited in open access (public) scientific databases on the internet?
(circle one)
YES **NO** Initials: Date:

Participant (age 18+):

Printed Name	Signature	Date

Researcher's statement

I have discussed the above research program, including the study procedures. I have discussed risks, benefits, and possible alternatives to being a donor, with the person signing above. All the elements of informed consent were reviewed and discussed with the subject. Special concerns that the participant expressed were noted and appropriately addressed. I encouraged questions and have answered all questions to the best of my ability. The participant's understanding of the contents of this consent form were assessed and found to be acceptable. The participant is aware that he/she has a choice in taking part in this study. A signed copy of the consent form will be given to the participant.

Person obtaining consent signature:

Printed Name	Signature	Date