RESEARCH SUBJECT INFORMATION AND CONSENT FORM

Normal Donor Blood Product Collections

PROTOCOL NO.: NML DONOR_BLOOD_002
WIRB® Protocol #20151321

SPONSOR: Bloodworks Northwest

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206-689-6525 (24 hours) ask for Apheresis MD ON Call

STUDY-RELATED PHONE NUMBER(S): Bloodworks Northwest Study Coordinator Phone Line:
206-689-6341

Bloodworks Northwest Study Coordinator Email:
Serum@Bloodworksnw.org

Bloodworks Northwest 24-hour Donor Services phone line:
206-398-5999

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RESEARCH CONSENT SUMMARY

You are being asked for your consent to participate in research. The purpose of this consent form is to help you decide if you want to be in the research study. This consent form will provide key information we believe most people would need to make an informed decision about participation.

What should I know about this research?

- A medical doctor, registered nurse, or study coordinator will explain this research to you.
- Taking part in this research is voluntary. Whether you take part is up to you.
- If you don't take part, it won't be held against you.
- You can take part now and later drop out, and it won't be held against you.
- If you don't understand, please ask questions. You should not agree to join this research study until all of your questions are answered.
- If you decide not to take part in this study, you may continue to donate blood at Bloodworks Northwest if you are eligible.

Why is this research being done?

The main purpose of collecting blood from healthy donors for research is to contribute to medical and scientific knowledge that may help people in the future. Bloodworks Northwest is creating a registry and repository of normal healthy donor samples for these purposes.

- A Registry is a database of individuals, with their contact information, who are willing to consider donating blood samples or blood components for research studies.
- A Repository is a bank or collection of blood samples or blood components to be used for research.

What happens to me if I agree to take part in this research?

We will ask you a series of health questions and measure your vital signs (ex. weight, blood pressure, and heart rate) to ensure it is safe for us to collect blood products from you. Examples of the type of questions we may ask include: your general health, medications, risk behaviors for certain diseases, medical history and travel. We will ask for demographic information such as your age, race, ethnicity and gender.

We will also ask for your contact information and for your permission to contact you for more samples or collections for this research. Only trained Bloodworks Northwest staff members will contact you about this study. Contact is generally made via email, but also may be over the phone, in person or by mail.

There are various types of blood sample collections that may be requested. We will keep track of the amount of blood that you donate to make sure that amount does not exceed safety standards of 525mL (about a pint) in 56 days. You are free to say no to blood donations at any time and for any reason. All blood sample collections are performed by trained Bloodworks Northwest staff members with medical oversight.

What are some examples of blood collections for this research?

- Whole Blood: You may be asked to rest in a recliner chair. You will be asked to tell the staff member if you have any symptoms during or after the procedure. A blood pressure cuff or elastic band may be used as a tourniquet, to keep blood in the veins. In the phlebotomy procedure, the skin will be disinfected, and blood will be collected through a sterile needle placed in a vein in your arm or hand. The blood will be drawn into a blood collection bag or one or more syringes, tubes or other collection containers. After the needle is removed, a

gauze pad and tape will be used to put pressure on the vein. You will be asked to help keep pressure on the site for at least 5 minutes. The whole procedure will take 15 to 45 minutes.

- Apheresis: You may be asked to rest in a recliner chair or hospital bed. You will be asked to tell the staff member if you have any symptoms during or after the procedure. During apheresis, your blood will be removed through one needle in a vein in your arm or hand and processed by an apheresis machine that separates the blood into the various components of blood. The donation component (either red blood cells, white blood cells, platelets, or plasma) will be collected into a bag and the remaining blood components will be returned to your body by the machine. This is done through either the same or a separate needle, usually in the other arm or hand. A citrated anticoagulation solution is given to make sure the blood does not clot in the apheresis machine. A blood collection staff member will be caring for you throughout the procedure to make sure you are comfortable and your needs are met. After the needle(s) is removed, a gauze pad and tape will be used to put pressure on the vein. You will be asked to help keep pressure on the site for at least 5 minutes. The whole procedure will take 1-4 hours.

- Finger stick: One of your fingers will be selected and cleansed with an alcohol pad. A small lancet will be used to make a puncture on your finger pad. Gentle pressure will be applied as needed to gather a few drops of blood. Following blood collection, pressure will be applied using gauze. If necessary, a small bandage may be applied. The whole procedure will take 5-10 minutes.

Some studies may require a period of fasting prior to donating. This means that you are only allowed to drink clear liquids during this period, but no food. You will get an instruction sheet which explains which liquids are permitted before donations. You may take your medications during the fast. If fasting is required, your donation appointment will typically be in the morning.

What happens to my blood after it is collected?

After your blood is collected, it may be tested for standard communicable infectious diseases. If any of the tests come back positive/reactive for an infection, Bloodworks will notify you and discuss the test results. By state law, Bloodworks Northwest may be required to report positive/reactive test results to the appropriate health authorities.

Bloodworks Northwest may provide your sample(s) to medical researchers outside of this organization. We take your privacy and confidentiality very seriously. Your donation will be coded with a unique number to protect your identity, and only trained Bloodworks Northwest staff members will know the key between the code number and your personal identity. Individual research labs or companies will not know your identity and will not be able to contact you. While Bloodworks Northwest will never include your personal identifiers, we may include information about your age, medical history, family history, racial or ethnic background, etc. if necessary to benefit the research. We may use all or part of your sample immediately, or may store it for later use. We will store all of your samples and paperwork in a secure location within Bloodworks Northwest.

What information can be given to others outside of Bloodworks Northwest?

There are some reasons that we may need to share personal information you give us with others:

- If required by law.
- If we think you or someone else could be harmed.
- If a government agency or Bloodworks Northwest employee needs to look at your information in order to make sure this collection is done safely and legally.

Research results may be given to the U.S. Food and Drug Administration ("FDA") or other federal agencies, for regulatory purposes. Research records that identify you and the consent form signed by you may be looked at and/or copied for research or regulatory purposes by:

- The FDA, Washington, D.C.;
- Department of Health and Human Services ("DHHS") agencies, Washington, D.C.;
- Governmental agencies in other countries; and
- The Western Institutional Review Board® (WIRB®) – The Independent Review Board that oversees this program, Puyallup, Washington.

The results of research from your donation may be presented at meetings or in publications. Your identity will not be disclosed in those presentations. If the results of this study are made public, information that identifies you will not be used.

Will participating in this research study hurt me?

- Privacy: We protect your information from disclosure to others to the extent required by law. We will keep your information in confidential databases and secure physical files where only authorized employees have access. While Bloodworks Northwest judges the risk of a breech to be very small, we cannot promise complete secrecy.
- Whole blood: You may experience side effects during a procedure. For example, there may be pain, bruising, vein clotting, or bleeding where a needle was inserted to draw blood. Lightheadedness, sweating, nausea and fainting can happen and can require lying down and resting to recover. If you have side effects during a procedure, or change your mind about wanting to have it performed, you may ask for the procedure to be stopped at any time.
- Apheresis: Possible risks may include, but are not limited to:
  - Risks and side effects similar to those during blood donation such as light-headedness, dizziness or even fainting. We can slow down the machine and/or give fluids to lessen these effects.
  - Risks and side effects associated with the citrated anticoagulation solution used during the procedure, such as tingling of the hands and lips, chest pain, and muscle spasm. Slowing the rate of fluid return usually lessen these side effects. If needed, we may give you calcium to lessen these side effects even more.
  - A sense of coolness due to the return of blood which has cooled to room temperature. Blankets and blood warmers are used to alleviate this effect.
  - Tenderness and/or bruising at the needle site due to the large needle used during the procedure. It is usually treated by applying a cold compress.

- Very rarely, clotting or leaks in the tubing may prevent the return of blood to the patient. Blood counts are monitored at each treatment, and appropriate fluids will be given as replacement if necessary. If the machine does break down, you could lose about 1 cup of whole blood (or 310 ml). This is unlikely to harm you.
- Finger stick: You may experience soreness at the puncture site that typically resolves within hours.

Will participating in this research study benefit me?

There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. It is our hope, however, that the use of your donated blood may contribute to medical and scientific knowledge to help people in the future.

Will it cost me money to take part in this research?

There is no direct monetary cost to you for the health screening, blood tests, and donating your blood sample.

Will I be paid for taking part in this research?

Some studies offer reimbursement, while other research studies do not. You may decline or accept this reimbursement. The reimbursement may be different, depending on the time and blood collection procedures being done. To be reimbursed, you must provide a completed, signed and dated Internal Revenue Service W-9 IRS form to Bloodworks Northwest. The reimbursement may be taxable; it is your responsibility to check with your tax advisor to determine your tax liability. If you receive reimbursement amounting to $600 or more in a calendar year, you will receive a 1099-MISC tax form in the mail. The study coordinator keeps a record of all payments due, and gives this to the Accounts Payable department at the Bloodworks Northwest so that you may receive payment by check or direct bank deposit approximately 14-28 days after you gave the blood sample.

Your blood sample may be used for commercial profit. You will not share in this commercial profit.

What if I am injured because of taking part in this research?

If you incur any costs associated with treating an injury or medical condition that arises directly from your participation, seek appropriate medical treatment and submit claims through your health insurance to cover any costs resulting from that appropriate medical treatment. No money has been set aside to pay for things like lost wages, lost time, or pain or suffering. However, you do not waive any rights by signing this consent form.

May I withdraw or revoke (cancel) my permission to be part of this research?

If you participate, you may stop at any time, for any reason. You do not have to explain why you decide to withdraw. The consent remains in effect until you withdraw from the study verbally or in writing to the Principal Investigator or a study coordinator. When you withdraw your permission, no new health information identifying you will be gathered after that date.

Information and samples that have already been gathered may still be used and given to others. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled. The sponsor or Principal Investigator may stop the study any time without your consent.

What happens if there are changes to this study?

You will be told about any new information that might change your decision to be in this study. You may be asked to sign a new consent form if this occurs.

What other choices do I have to taking part in this research?

This research is not designed to diagnose, treat or prevent any disease. Your alternative is to not take part in the research.

Who do I contact if I have questions?

If you have questions about participation, concerns or complaints, please do not hesitate to contact the study team.

During business hours Monday through Friday, call a study coordinator at 206-689-6341.

After hours, please call the Bloodworks 24-hour Donor Services phone line at 206-398-5999. Please tell them that you are a Research Donation Program participant. The Principal Investigator is: Dr. David Lin, MD, Medical Director, Bloodworks Northwest.

If you have questions about your rights as a research subject or if you have questions, concerns, input or complaints about the research, you may contact:

Western Institutional Review Board® (WIRB®)
1019 39th Avenue SE Suite 120
Puyallup, Washington 98374-2115
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: Help@wirb.com

WIRB is a group that independently reviews research. WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

Do not sign this consent form unless you have had a chance to ask questions and have gotten satisfactory answers.

If you agree to be in this study, you will receive a signed and dated copy of this consent form for your records.

CONSENT

I have read this consent form (or it has been read to me). All my questions about the study and my part in it have been answered. I freely consent to be in this research study.

I authorize the use and disclosure of my health information to the parties listed in this consent for the purposes described above

By signing this consent form, I have not given up any of my legal rights.

CONSENT SIGNATURE:

_____ Initial here if you would like to be contacted about other research study opportunities.

_____ _____
Signature of Subject (18 years and older) Date

_____ _____
Signature of Person Conducting the Informed Consent Discussion Date