Group Health Cooperative University of Washington Medical Center

Title: Seattle Longitudinal Study Consent for Collection of Blood Sample for Biomarkers and Genetic Testing

Research Project Directors:

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PURPOSE OF THE STUDY: Since 1956, the Seattle Longitudinal Study has looked at changes in problem-solving skills and thinking ability over time. The purpose of this project is to look at the relationship between certain physical traits and the psychological test information collected in the Seattle Longitudinal Study. For this new part of our research, we are interested in looking at physical traits that may show the effects of a disease or other condition. These traits, which can be measured through a blood test, are called biomarkers. For this study, the biomarkers we are interested in are:

- o lipid profiles (cholesterol)
- o homocysteine (a bi-product of protein metabolism that may harm artery walls)
- o C-reactive protein (a protein produced by the liver that may be linked to inflammation)
- o genetic markers (inherited traits that run in families, like hair color or eye color)

PROCEDURES: If you decide to be in this study, you will have one blood draw at the Puget Sound Blood Bank or in your home. A person who is trained to draw blood will take about one and one half tablespoons of blood from a vein in your arm.

We collect biomarker information through a blood test. If you would like to see the results of the lipid tests, homocysteine test, and C-reactive protein test, we ask that you give us a written request. We will let you know of any abnormal results. You may also request that we send the results to your Group Health doctor. The genetic information we collect is for research only. Therefore, we will not give you these test results. If the genetic information we find becomes commonly used in routine medical care in the future, we will try to reach you within 3 years of the end of the study.

We will store your sample of whole blood and white blood cells indefinitely at the Northwest Lipid Research Laboratories of the University of Washington Medical Center. We will use your sample for research purposes only within the Seattle Longitudinal Study. We will not use your blood samples to aid the development of commercial products. If at anytime you decide not to

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have your blood used for research purposes in the Seattle Longitudinal Study, please call project staff at 206-281-4050. We will contact the laboratory and ask them to destroy any unused stored samples.

POTENTIAL RISKS: There are no major risks associated with drawing blood. Having your blood drawn can be uncomfortable and can sometimes cause a bruise. In rare cases, it can cause fainting. Only trained people will draw your blood.

Tests on your blood samples will look for causes and signs of disease that may be genetic. Although it is possible that someone other than the researchers could use the genetic information, we think this risk is very small. As described above, to protect your information, we will not keep your name and address with the sample, only a code number. Using a code number greatly reduces the chance that someone other than the study staff will ever be able to link your name to your sample or test results.

POTENTIAL BENEFITS: We do not expect you to benefit from being in this study. Others may benefit in the future from the information we get from this study.

SAFEGUARDS: We will keep all information about you confidential as provided by law. All of your research records will be kept indefinitely in locked cabinets and protected computer files located at the University of Washington. We will not place your name on your blood samples or on any research data. Instead, we will assign a code number to your samples and your information. We will keep the master list that links your name to your code number in locked cabinet. The master list will only be available to project staff to allow us to link your information from the previous study to the information we are collecting for this study.

Only the researchers on the Seattle Longitudinal Study will have access to your blood samples.

BEING IN THIS STUDY IS VOLUNTARY: Taking part in this study is up to you. You may choose not to take part or to leave the study at any time. Your decision will not affect your future care at Group Health.

If at anytime you decide not to have your blood used for research purposes in the Seattle Longitudinal Study, please call project staff at 206-281-4050. We will contact the laboratory and ask them to destroy any unused stored samples.

You may ask questions about this research at any time by contacting project staff at 206-281-4050. If you have any questions regarding your rights as a research subject, you may also call the Group Health Human Subjects Office at 206-287-2919.

SUBJECT'S STATEMENT

I have read this form or have had it read to me. I have been told what will happen if I take part in this study. I have had a chance to answer questions, and they have been answered to my satisfaction. I have been told that project staff will answer any questions I may have in the future. I have been told that I may change my mind about having my blood samples used for research and that all my information will be kept confidential as provided by law.

This is to certify that in a scientific study of the University of Wa	Iconducted as an authorized part of the educa shington. I may change my mind and leave	agree to take part as a volunteer tional and research programs of the study at any time.
Date	Signature of Participant	
PROJECT STAFF	STATEMENT	
I, the undersigned, ha	ave defined and explained the study to the al	bove participant.
Date	Signature of Project Staff Member	