



Consent Form for Blood Spot Collection & Testing (IRB # 09-026A)

This consent form is related to the blood spot test. This testing is an important part of the health screening but, like the survey and physical measurements, is not required. You can still take part in this study (answer the interview questions and have physical measurements taken) even if you do not have the spot blood test done.

This consent form describes the study procedures, risks and benefits of having this blood spot test done, and how your confidentiality will be maintained. Please take the time to ask questions, and make sure you understand the answers before you decide to take part. If you agree to have the testing done, you will be asked to sign this consent form.

Introduction and Purpose

The blood collected will be tested for cholesterol (fats), proteins for inflammation, and glucose (sugar) to see if you are at increased risk for heart problems and/or diabetes.

In addition, we would like to store your blood spot samples in a repository (central location) for future tests. At this time, it is not known which tests might be done in the future. We promise you that your blood will never be tested for drugs/alcohol, HIV or other sexually transmitted diseases, or for genetic information. You do not have to agree to this future testing -- you can refuse, and still take part in this study. There is more about this at the end of this consent form.

Procedures

The finger stick procedure is very similar to the way a diabetic checks his or her own blood sugar, or the heel stick given to all newborns in the United States. It is a routine procedure. The interviewer will collect drops of your blood from a finger stick, and put the drops on a blood collection card.

One of your fingers will be selected. The end of your finger will be cleansed with alcohol. Your finger will be stuck once, using a sterile single-use lancet (very small with a sharp point). The first drop of blood will be wiped away (not used). The next 3 or 5 drops will be put on the collection card, and will be used for the tests.

If the stick continues to bleed, a band-aid may be applied.

It will take about five (5) minutes to complete this collection.

Occasionally it is necessary to stick the finger a second time in order to get enough blood.

Follow-up

The blood spot collection card will be sent to a laboratory to be tested for cholesterol and blood sugar. It will first be sent to a Florida laboratory called Flexsite where the glucose (blood sugar) test will take place. It will then be sent to the University of Washington where it will be tested for cholesterol. The remaining blood spots will then be sent to Providence Health System, CORE where it will be stored in a freezer until the end of the study, or longer, if you give permission for us to use it for tests in the future.

A final report with your blood spot test results will be mailed to you in 3-5 weeks. If any results are abnormal, we will recommend that you follow up with a health care provider. If you do not have a doctor or health care provider because you do not have insurance, you will be offered a list of health care providers that see uninsured patients. If the amount of blood collected from you was not enough to do the tests, you will be informed of this.

In the event that your blood test results indicate a need for immediate or emergency follow-up, you will be contacted by a health care provider from the study team who will provide you with information about how to obtain care right away.

The collection card will not have your name or other identifying information attached. Your study ID number will identify your sample. Nobody at the two laboratories will know your name.

With your added permission, your blood spot samples will be stored for this study and possible tests in the future (see the end of this consent form). If you do not agree to the future storage and testing of your blood samples, your blood collection card will be destroyed at the end of this study.

Risks

There is minimal physical risk to you from the routine finger stick(s).

The finger stick may cause a small amount of pain and bruising, and the site may bleed slightly for a time after the blood is collected. There is also a very rare chance that the stick site could become infected. If this happens, you might require medical treatment.

There is a very small risk associated with the collection of confidential health information. However, the researchers are making every effort to protect your identity.

Benefits

You will receive free health screening for heart disease and diabetes. You also will be provided with a list of health resources in your community, should you need them.

The information learned from this blood testing will help the researchers learn about the relationship between health insurance and health – to find out if health insurance improves health, particularly for those with chronic health conditions such as diabetes or heart disease.

Finally, findings from this study will be for important for people who make policy decisions about health insurance in Oregon, other states, and nationally.

General Information

Your participation in this research is voluntary. If you agree to take part, you can later withdraw.

If you agree to have your blood spot samples stored for future testing, you can change your mind at any time. To have your sample removed from storage, you should contact Oregon Health Study staff in writing or by phone (1-866-332-9896) and request that your sample be removed from storage and destroyed. However, any tests that were already done on your sample before you withdraw your permission will be used as part of this study.

Costs

It will not cost you anything for the blood spot collection or tests. The study sponsor will pay these costs.

You will be paid \$20 for the collection of your blood.

You are responsible and must pay for the costs of any follow-up care you may require, unless these costs are covered (at least in part) by insurance.

Liability

In the unlikely event of any injury resulting from the finger stick(s), no payment or free medical treatment is available from the co-sponsors of this research study.

However, you do not give up any of your legal rights if you sign this consent form and take part in this study.

Privacy

The results of your blood tests will be kept strictly confidential in the same way as the rest of the study information. A bar code that is linked with your study ID will be on the blood collection card; your name or other identifying information will not be on the collection card.

Your blood test results will be kept safe on a secure computer network at Providence Health System, CORE. Blood test results shared with others will only have the study number, and not your name or other identifying information.

Your blood test results and study information/records are personal and private. Records will be kept confidential to the extent provided by federal, state, and local law. Only the research staff and co-sponsors have the right to look at your blood test results and study records (identified only by your study ID number). It is also important that the Providence Health System Institutional Review Board (IRB – a committee that reviewed this research to protect your rights), and university and government officials responsible for monitoring this study be able to inspect these study records. When you sign this consent form, you agree to allow this.

Your test results will be grouped with thousands of other individuals on all reports related to this study. Records will be kept confidential to the extent provided by federal, state, and local law. Only the Providence Health System Institutional Review Board, the co-sponsors of this study, or university and government officials responsible for monitoring this study may inspect these records.

If results of this study are reported in journals or at meetings, your identity will remain secret.

Questions

Any questions you have about the collection of your blood can be answered by the study investigators at our toll-free number, 1-877-215-0686. Just ask to speak with Dr. Heidi Allen or Dr. Bill Wright.

Any questions you have about your rights as a research subject will be answered by the Providence Health System Institutional Review Board at 503-215-6560.

Consent

I have read all of the above, asked questions and received satisfactory answers about what I did not understand. I agree to have my blood collected for this study. I have been given a copy of this consent form.

Name of Participant (Please Print)

Signature of Participant

Date

Name of Person Obtaining Consent (Please Print)

Signature of Person Obtaining Consent

Date

Translator (only if applicable)

Date

Location of Data Collection: _____
(City, State)

Consent for Storage and Future Testing Blood Samples

We would like to store your blood collection card in a repository (central location) for future tests. At this time, it is not known which tests might be done in the future. You do not have to agree to this future testing -- you can refuse, and still take part in the interview and physical measurements.

With your permission, your blood collection will be stored at Providence Health System, CORE, for future tests. Your blood collection card will not be stored longer than ten years after the end of data collection. At that time, your blood collection card will be destroyed.

My initials below describe how I would like the Oregon Health Study to handle my blood samples, following the tests that I have already consented for (cholesterol and diabetes testing). Please indicate your choice by initialing only one of the following:

<p>Initial here _____</p> <p>You MAY store my blood samples for future tests.</p> <p>I do not wish to be contacted about this.</p>	<p>Initial here _____</p> <p>You MAY store my blood samples for future tests.</p> <p>I want to be contacted before you do more tests.</p>	<p>Initial here _____</p> <p>You may NOT store my blood samples for future tests.</p>
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