



## **Consent Form for Interview & Physical Measurements (IRB # 09-026A)**

You are being asked to take part in this Oregon Health Study, also known as OHS, because you were at one time on the Oregon Health Plan (OHP) Reservation List.

This consent form describes the study procedures, risks and benefits of taking part, 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 decide to take part, you will be asked to sign this consent form.

### **Introduction and Purpose**

The purpose of this study is to take advantage of an expansion of public insurance (Oregon Health Plan) to understand the relationship between health insurance and family finances, use of health care, and health. We want you to participate in this study whether you have health insurance or not. This study involves an in-person interview with 12,000 men and women, ages 20-64 years.

This study is being conducted by researchers working together from academic, state, and private institutions (see box below).

Massachusetts Institute of Technology  
Harvard University  
Oregon Health Research and Evaluation Collaborative  
Portland State University  
Oregon Division of Medical Assistance Programs  
Oregon Health and Science University  
Office for Oregon Health Policy Research  
Providence Health System's Center for Outcomes Research and Education (CORE)

Researchers will use the study information to answer the following questions about both insured and uninsured adults:

- Does health insurance coverage affect one's health care?
- How does health insurance coverage affect one's health?

### **Procedures**

This study will involve you being interviewed in your home or at a clinic. The interviewer will ask you about 100 questions about your general health, insurance, past health care visits, health behaviors (such as diet, exercise, weight control, smoking), mental health (depression), and other health topics. The questions will take about 45 minutes.

The interviewer will also collect physical health measurements from you: 1) height, 2) weight, 3) waist, 4) blood pressure, and 5) heart rate. It will take about 10 minutes to do

these measurements. These measurements will provide you with valuable information about your health, such as your blood pressure and BMI, which is a health score for your weight.

Finally, and only if you agree (it is not required), the interviewer will collect drops of your blood from a finger stick (called a blood spot test). Your blood will be screened to see if you are at risk for diabetes and/or heart disease. You can still take part in this study (answer the questions and have physical measurements taken) even if you do not have the spot blood test done. There is a separate consent form for the spot blood test.

### **Follow-Up**

The interviewer will give you a verbal and written summary of your physical findings and depression screening at the end of the interview. He/she may be able to answer questions you have about your results and if not, we will connect you with a health professional working with the study. If you chose, lab results and an explanation of lab findings will be mailed to you after the blood spots are processed, along with a summary of your health findings and information about health conditions that were evaluated in this study.

If any results are abnormal (such as blood pressure, weight, depression screening, other), we will recommend that you follow up with a health care provider. If your health screening reveals an urgent health need during the interview, we may recommend that you go to the nearest emergency room for treatment. If your lab results indicate an urgent health need, we will contact you immediately with this information and recommendations for follow-up care. If you are uninsured, you will be given a list of health providers that see uninsured patients in your city.

We may contact you later to check the work of the interviewer. We also may contact you again to see if you would like to take part in future studies.

## **Risks**

Your participation in this interview involves answering questions you may consider sensitive. There is a minimal risk that you will feel uncomfortable discussing some issues. You can refuse to answer any question(s) in the interview.

The physical measurements are routine and safe, although some may cause you slight discomfort.

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**

Taking part in this study offers several possible benefits for you:

- Physical health screening for important health conditions.
- Referrals to health services that may be of use to you in the future.

Additionally, researchers will learn more about how insuring more Oregonians impacts their health. This might help others in the future.

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

## **Your Rights**

Your participation in this study is voluntary, and you are free to withdraw at any time by telling your interviewer or by contacting the study leadership at 1-877-215-0686. You may refuse to answer any specific questions or stop the interview at any time. You may refuse to provide any physical measurements. You will still be in this study unless you tell us you do not want to be.

## **Costs**

It will not cost you anything to take part in this study.

We will pay you \$30 for completing the interview and \$20 for providing the blood spots. If you traveled to a study clinic today, you will be paid an additional \$25 for travel expenses.

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.

## **Confidentiality**

Study information about you will be kept safe on a secure computer network at Providence Health System, CORE. You will be given a study ID number and the information you provide us will only be stored with this study ID number to keep your personal information private. The list/key that matches your name to your study number will be kept in a separate, secure file, and will only be accessible to the researchers at Providence Health System, CORE. At the end of this study, this list/key will be

destroyed, leaving only your study ID number. Study information shared with others will only have the study number, and not your name or other identifying information.

Your 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 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.

If results of this study are reported in journals or at meetings, your identity will remain secret. The information you provide will only be reported as part of a group, along with answers from others.

### **Certificate of Confidentiality**

A Certificate of Confidentiality has been obtained from the Department of Human Services (DHS) for this study. With this Certificate, the researchers cannot be forced (for example by court subpoena) to share information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. Sharing your information will be necessary, however, upon request of DHS for an audit, or for program evaluation purposes.

Should you report suicidal thoughts while we are with you, we will contact a mental health professional on our research staff. We will give only your name, contact information, and why we feel you are at risk of harming yourself. We will pass the telephone to you and you will receive a free mental health evaluation from this mental health professional. This report will not be linked to your survey information. You have the right to refuse to speak to the mental health professional.

### **Questions**

If you want more facts about this study, you can call 1-877-215-0686. You may also visit our web site: [www.oregonhealthstudy.org](http://www.oregonhealthstudy.org)

If you have any questions about your rights as a subject in this research study, please call the Providence Health System Institutional Review Board at 503-215-6560.

If you have more questions about this research study itself, or you would like to ask questions about the results of your health screening, please call 1-877-215-0686.

**Consent**

I have read all of the above, asked questions and received satisfactory answers about what I did not understand. I agree to take part in this research study. I have been given a copy of this consent form.

If you do want a written report of your physical measurements and depression screening mailed to you, including a report of your blood spot test results, please check here .

If you do not want a written report of your physical measurements and depression screening mailed to you, including a report of your blood spot test results, please check here .

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Name of Participant (Please Print)

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Signature of Participant Date

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Name of Person Obtaining Consent (Please Print)

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Signature of Person Obtaining Consent Date

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Translator (only if applicable) Date