

**CONSENT FORM**

Group Health Research Institute/ University of Washington /  
Fred Hutchinson Cancer Research Center

**Electronic Medical Records and Genomics Research**  
**eMERGE Study**

**Researchers:**

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**Research Staff:**

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We are asking you to take part in a research study. This form will give you information to help you decide if you want to be in the study or not. Please read it carefully and ask the researchers to explain anything you don't understand. We can answer your questions by phone or in person before you make your decision.

We are asking you to be in this research because you are in the Adult Changes in Thought (ACT) study. This research is not the same as the ACT study. This is a new study that would use samples and information you already gave to the ACT study.

**You can stay in the ACT study even if you choose *not* to be in this research.**

**What is this research about?**

This research is about genetic differences that can affect health and disease. Genetic differences are passed down in families, like eye color or blood type. These differences may partly explain why some people are more likely to get diseases like diabetes, asthma and dementia. We are doing this study to learn more about the link between genes and common diseases. We hope it will help us find new ways to prevent and treat some of these diseases. It may also help us better understand how genes affect health and healthy aging.

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### **What will happen if I take part in this research?**

**There are no study visits or blood draws involved in this study.** We are only asking you to let us use samples and information from the ACT study, for this and other future research. Your ACT participation will continue as usual.

If you decide to be in this research, we will share information about you with our research partners at other institutions. We will share genetic information about you from your ACT blood sample. We will also share health information from your ACT study records and your Group Health medical record, such as:

- Your medical history
- Medicines you have been prescribed
- Lab and other test results
- Behavioral information, for example, whether or not you have ever smoked.

We will not give out your name, Group Health number, or any other information that could easily identify you. All your information will be labeled only with a code number.

Information about you will also be put in a national databank and used in future research. The National Institutes of Health (NIH) is in charge of this databank. First, a lab chosen by the NIH will use your blood sample to analyze your DNA. The genetic information from this analysis and some of your health information will then be stored in the national databank so it can be used in the future. We may also send a part of your sample to other research partners to do genetic tests in their labs. We will not give your name or contact information to the databank or our research partners.

### **How will my samples and health information be used?**

Group Health and our research partners will use your samples and information to look for genetic factors that might affect health and disease. We plan to study memory and aging and other common conditions, such as cataracts, asthma, high cholesterol, and diabetes. At this time, our research partners are:

- The University of Washington
- The Fred Hutchinson Cancer Research Center
- The Mayo Clinic
- Marshfield Clinic
- Northwestern University
- Vanderbilt University
- The National Human Genome Research Institute.
- The Alzheimer's Disease Genetics Consortium, led by researchers at the University of Pennsylvania

We may work with other partners in the future to look at other diseases. We or our partners might use your sample to create a cell line, which would allow additional copies of your genetic material to be made.

### **How will information in the national databank be used?**

Information in the national databank will be used in future research studies. We don't know in advance what these studies will be about.

Only qualified researchers can use information in the national databank. This includes researchers from universities, non-profit organizations, and commercial organizations, such as drug or device companies. Researchers who want to get information from the databank must first get approval from a committee at the NIH. They must also sign a pledge to protect the confidentiality of the information.

As of April 2008, the national databank included information from more than 48,000 people, and it continues to grow.

### **Will I get any information back?**

No. The tests planned now are not likely to tell us anything about your personal health status or the health of your children or relatives. Even if we find a link between genetics and health or disease, we won't know what it means for individual people or families.

Researchers who use information from the national databank won't be able to identify you, so they can't send you their results.

### **Are there any risks to me?**

The main risk in this research is possible loss of confidentiality. This could affect you if someone stole your samples or test results and gave them to an insurance company or employer. The national databank will not have your name, and nobody can tell just by looking that the information there belongs to you. Likewise, nobody can tell just by looking at your blood sample that it came from you. But, because your genetic information is unique to you, there is a small chance that someone could trace the information back to you. The risk of this happening now is very small. But new advances in science could increase this risk in the future.

We may share your age or ethnic information with our research partners and the national databank. Some ethnic information can also be found in your DNA. Future research may find that some genetic differences appear more often in people from certain groups. These differences might also be more common in people with a certain disease. This could result in people from that group being treated differently.

### **Are there any benefits?**

You will not benefit personally from taking part in this research. The knowledge we gain about the way genetic differences affect health and disease may help many people in the future. We hope that this research will give us new ideas for preventing, treating, and curing disease.

We have no plans to use this research for commercial purposes. But other researchers may use your information to develop and sell new products. If this happens, there are no plans for you to receive any of the profits.

### **Do I have to be in this research?**

No. You can choose not to be in this research. Your decision won't affect your care or benefits at Group Health. You can stay in the ACT study even if you choose not to be in this research.

### **If I say yes, can I change my mind?**

Yes. You can agree to be in the research now and change your mind later. If you change your mind, please let us know by writing to:

Dr. Eric B. Larson  
Group Health Research Institute  
1730 Minor Avenue, Suite 1600  
Seattle, WA 98101-1448

As soon as we hear from you, we will stop using your information for this study. We will ask our research partners to destroy any samples or information they have about you. We will also ask the NIH to take your information out of the national databank and destroy it. If other researchers have already used your information, the NIH won't be able to get it back from them. They can only destroy what is in the national databank so it can't be used from that point on.

### **How will you protect my confidentiality?**

Your health information will be de-identified. This means it won't include your name, Group Health number, or other information that is usually used to identify you. We will label your information only with a code number. We will keep the link between your name and your code number at Group Health and will not share it with other researchers. We will destroy this link by April 30, 2034.

Group Health has gotten a Certificate of Confidentiality from the NIH. This allows us to refuse to share any information that might identify you, even if we are asked to by a court of law. It's not likely that we would ever be asked to give out your identity. But

because we are sharing some of your information outside of Group Health, we got the Certificate as extra protection. The Certificate doesn't stop study records from being reviewed by some federal agencies. The NIH may look at study records to make sure we're doing the study honestly and safely. The Certificate also doesn't stop you from sharing information about yourself or your part in this research. Except for that described in this paragraph, we have no plans to share your name or other identifying information without your consent. The one exception is your genetic information, which is unique to you. At this time it would be very difficult for someone to identify you only from your genetic information, though new advances in science could increase this risk in the future.

### **Privacy information**

Your health information is protected by a federal privacy law called HIPAA. This law applies to health care organizations and their employees. This law may not apply to researchers at other institutions. The researchers at Group Health, the University of Washington, and the Fred Hutchinson Cancer Research Center will use your health information only for research. We will not share information that identifies you with anyone else except as provided by law.

Unless you change your mind, we plan to keep your health information indefinitely. This means we can keep using your information for research unless you change your mind and let us know.

### **Who do I call if I have questions?**


We welcome any questions you may have now and in the future. Please feel free to contact the researchers or their staff at any time.

If you have general questions about this research, please call the study telephone number at 1-888-268-6507.

For questions about your rights as a research participant, please call the Group Health Human Subjects Review Committee office at 206-287-2919.

**Researchers' Statement**

Materials that explain this research program and a copy of this form have been given to the participant or mailed to them. I can be reached at the phone number listed on this form to answer any questions.

Eric B. Larson  
Name of Principal Investigator or Designated Study Staff (please print)  
 12/22/2009  
Signature of Principal Investigator or Designated Study Staff Date

**Participant's Statement**

I have read this form or have had it read to me. Study staff have explained what will happen in this research. I have had a chance to ask questions, and they have been answered to my satisfaction. I can contact one of the researchers listed above if I have questions in the future. By signing below, I am voluntarily choosing to be in this research.

\_\_\_\_\_  
Participant Name (please print)  
\_\_\_\_\_  
Participant Signature \_\_\_\_\_  
Date

**OR (for alternate or dual signature)**

I have read this consent form. I agree to participation in this research on behalf of \_\_\_\_\_ (PRINT NAME).  
\_\_\_\_\_  
Name of Participant's Legally Authorized Representative (PRINT NAME) \_\_\_\_\_  
Relationship to Participant  
\_\_\_\_\_  
Signature of Participant's Legally Authorized Representative \_\_\_\_\_  
Date

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