Project ID
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Kaiser Permanente Washington
Health Research Institute

Northwest Institute for Genomic Medicine (NWIGM) Study Consent Form

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Research Team

Kaiser Permanente Washington Health Research Institute	**University of Washington**
Eric Larson, MD, MPH	Gail Jarvik, MD, PhD
Lead researcher	Lead researcher
206-287-2534	206-221-3974

We are asking you to be in a research study. This form explains the details of the study. Please read this entire form before agreeing to join the study. If you have any questions about the study, you may contact the project manager at Kaiser Permanente Washington Health Research Institute at 206-287-2150. You may also contact the researchers listed above.

What is this study about?

The purpose of this study is to create a research database and sample bank to learn more about how genes can affect health or disease. Genes are small portions of DNA found in your cells. They carry information about traits that run in families, like whether you will have brown eyes or blue eyes. They may also partly explain why some people are more likely to get diseases like diabetes, asthma and dementia. Understanding more about the relationship between genes and health may help to develop new ways to prevent and treat some of these diseases.

What will happen if you agree to be in this study?

If you agree to be in this study, we will ask you to:

Give us a blood sample so we can collect and store your genetic information for future research;

Let us collect some information from your Group Health medical record. We won't need to look at the notes your doctor writes; we will use a computer to collect information on:

- your medical history, including sensitive topics like mental health disorders, alcohol and substance use, and sexually transmitted diseases.

- medicines you have been prescribed.
- lab and other test results.
- behavioral information, for example whether you have ever smoked.

We will collect this information from the time you joined Kaiser Permanente until you are no longer a Kaiser Permanente member.

We will then conduct studies on the genetic material called DNA and RNA taken from the cells in your blood and we will store the blood sample to use for future research. We will compare your genetic information with information from your Kaiser Permanente medical record and additional information you provide to us. We will also then compare your information with other participants to try to understand the differences between people. This could help researchers in the future answer questions, like: "What genetic features may be important for developing vascular (blood vessel) diseases?" Or "what are the best medications to lower an individual person's cholesterol" (also called "personalized medicine")?

Here is what you will do if you agree to participate:

1. **Read and sign this consent form. Keep the yellow one for your files.**
2. **Mail the signed consent form back to us** in the enclosed business reply envelope.
3. **Once we have received your signed consent form,** someone from Kaiser Permanente Washington Health Research Institute (KPWHRI) will contact you to arrange to have your blood drawn. The KPWHRI staff will arrange for a Kaiser Permanente phlebotomist to come to your home to collect a blood sample for storage in the NWIGM biobank. If you choose, the study staff can also arrange for you to go to a Kaiser Permanente lab of your choice to have your blood drawn.

We will send you $50 as a thank you after we receive your signed consent form and the genetic testing lab receives your blood sample. If we don't receive your signed consent form and blood sample within a couple weeks, we will contact you to make sure you received this mailing.

If your blood sample is not usable when it is received at the genetic testing lab, we may ask you to provide another sample. If this happens, we will arrange for a new blood draw. We will send you another $50 after the testing lab receives your second sample.

If we do not receive your signed consent form within 60 days of your blood draw, we will not be able to keep your blood sample and the sample will be destroyed.

How will we use your sample and information?

Your sample

Your blood sample will be labeled with your name, Kaiser Permanente consumer number, your study identification number, your birth date and the date and time the blood was collected. This will allow us to link the sample uniquely to you. Your sample will be sent to a certified laboratory at the University of Washington, and your sample will be labeled with this information throughout the testing process. Your results will also be labeled with your name and other identifying information.

This is necessary because it is required by law for samples and results that might be used for medical care to be labeled and handled in such a way that they are linked to the person who gave the sample and cannot be mixed up with the samples or results of any other person. **Although we do not have plans to return the results of any genetic tests performed on your blood sample to either you or your doctor, we may want to return results in the future.** Therefore, a portion of your sample will be stored for future research in a certified laboratory at the University of Washington, and will be labeled with your name, Kaiser Permanente consumer number, your study code number; your birth date and the date and time the blood was collected.

Even though the laboratory that will be doing the testing is outside of Kaiser Permanente, it is bound by the same regulations that all certified laboratories must follow in protecting your health information.

We may share portions of your blood sample with other researchers for future research, but only after removing any information that might identify you. The sample will be labeled only with a study code.

Your samples will be stored indefinitely in a secure lab at the University of Washington. The samples will not be destroyed unless you ask us to do so (see below). We will use these samples for future research related to understanding the relationship between genes and disease.

Information from your stored genetic sample at the University of Washington, as well as health information from your Kaiser Permanente medical record (including sensitive information, as described above) may be shared with the United States National Institutes of Health databank for genetic related information, called dbGaP (database for Genetic and Phenotype). These data in the databank are used in future research to further knowledge in the interaction of diseases and genes, and will be kept indefinitely. Qualified researchers that receive permission to access and share these data may be from universities or from commercial companies. Your name, contact information, or any other information that could easily identify you will never be released to the databank.

Providing a blood sample for genetic testing and, allowing us to store your genetic information and sample is voluntary. However, you may not participate in this study, unless you provide a genetic sample and agree to allow us to store and use your DNA indefinitely.

Your information

We will create a research database to be used for this project and for future research studies. The research database will NOT have your name, or Kaiser Permanente consumer number. Your information will be identified only by your study code number. We will include in the research database the genetic test results from this study and analyses related to the genetic tests. We will also include health information from your Kaiser Permanente medical record as described above.

Future research using your medical record information (described above) and your blood specimen may be conducted by other qualified researchers who are not affiliated with Kaiser Permanente. We may also send some of the DNA from your sample to other researchers to do genetic tests in their labs. We may also share your health information with our partners at other research sites. When we share your information, we will not give your name, Kaiser Permanente number, or contact information to researchers who are not listed on page 1 of this form. All your information will be labeled only with a study code number.

Future researchers, not listed on page 1 of this form, may want to contact you to ask you to additional questions or to participate in additional research studies. If this happens, Kaiser Permanente staff will contact you to tell you about this research and/or ask for permission to release your contact information. You may refuse any request asked of you, if you wish.

What happens if you find out I have a medical condition I don't know about?

- Since your DNA will be used for future research, there is the possibility we may discover you have a medical condition or disease you don't know about.
- If this happens and it could affect your medical care, please indicate below if you want to be contacted. This means we may need to try to contact you many years in the future.

Please initial one of the options below:

______ *Yes, please attempt to contact me about this information
______ No, do not contact me with this information.

**Please notify us if your contact information changes. To do this you may call the NWIGM coordinator or any of the researchers listed on the front page*.

How long will the study last?

There is no specific end date for the research being conducted using blood samples and health information from this study. But your active role in the study will end after you complete the blood draw.

Will it cost you anything to be in this study?

There will be no costs to you for being in this study. Just as if you were not in this study, you or your insurance company are still financially responsible for your usual medical care. This includes medical procedures, exams, or other tests or therapies not required by this study.

Will being in this study help you?

We cannot promise that being in this study will help you, but some people feel good when they help with research like this. The information you give us could help us to better understand how genes and health are related. This information could one day help us find new ways to prevent or treat diseases.

We have no plans to use this research for commercial purposes. Researchers using the national databank may develop and sell new medical products. If this happens, there are no plans for you to receive any of the profits.

What are the risks of being in this study?

- **Blood draw**: Having your blood drawn can be uncomfortable and can sometimes cause a bruise. Some people may feel nervous or get dizzy. In rare cases, a person may faint.

- **Loss of confidentiality**: We take every precaution to keep your information confidential. If your samples are mistakenly released outside the research setting, or stolen, it is possible that people not working on this project could learn your identity and that your information may be misused. 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 steps we will take to keep this from happening are described on the next page.

- **Genetic testing:** There is potential risk for genetic discrimination if the results of your DNA testing were to be made public. There are laws to prevent genetic discrimination, but they may not protect you completely. The Genetic Information Non-discrimination Act of 2008 (GINA), makes it illegal for most health insurers and large employers to use genetic information to discriminate against you. However, these laws don't cover some small employers and some types of insurance companies. You are free to say yes or no to genetic testing.

Group Health Cooperative will not use your genetic information when making decisions about your medical insurance eligibility, premiums, or benefits. More information about GINA can be found online at www.ginahelp.org, or you can ask a member of the research team.

How do we protect your confidentiality?

As described above, the blood sample we collect from you will be labeled with your name, Kaiser Permanente consumer number, your study identification number and your birth date. This is to ensure that any test results we receive are really your results. For the same reason, your sample that is stored for future research at the University of Washington will be labeled with your name, Kaiser Permanente number and other identifying information. It will be stored securely at the University of Washington indefinitely.

Your health information that is stored in our research database will be de-identified. This means it won't include your name, Kaiser Permanente number, or other information that is usually used to identify you. We will label your information only with a study code number. We will keep the link between your name and your study code number at Kaiser Permanente and we will not share it with other researchers unless you give us permission. If the results of this study are made public, information that identifies you will not be used.

We also have a Certificate of Confidentiality from the NIH. This lets us 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 Kaiser Permanente, we got the Certificate as extra protection. The Certificate doesn't stop study records from being reviewed by some federal agencies. In addition, Kaiser Permanente and the funding agency may audit study records as part of study oversight. The Certificate also doesn't stop you from sharing information about yourself or your part in this research.

We will not 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.

The researchers listed on the first page and their staff will use your study information for research only. We won't use your name in any study reports. We won't tell your doctor whether or not you join this study or add information to your medical record without first contacting you and getting your permission.

We plan to keep your study information as described in this form indefinitely. We will not destroy your blood sample or any of the information we collect about you unless you request us to do so (see below for information on how to withdraw your consent in the future.

We do not plan to contact you by e-mail unless you give us your email address and ask us to do so. Information shared by e-mail is not considered secure. We cannot guarantee the privacy of e-mail, and we will be careful to limit the amount of personal information included in messages we send you.

How does HIPAA apply to this study?

Your health information is protected by a federal privacy law called the Health Insurance Portability & Accountability ACT (HIPAA). Kaiser Permanente must follow this privacy law. According to HIPAA, the information collected by the researchers for this study is part of that protected health information. HIPAA requires that the researchers tell you the following:

By signing this form, you are giving Kaiser Permanente permission to allow the researchers to collect, use, and share the following information about you:

1. Your blood sample and your genetic information from the sample
2. Your name, Kaiser Permanente consumer number, and the information necessary (date and time of blood draw, birth date, sex) to have your sample tested by a certified laboratory
3. Your past, present, and future medical records, as described on the first page of this consent form
4. Research information collected from you as part of this study, including the questions we asked you on the phone before we sent you the blood draw kit.

It is possible that staff from Kaiser Permanente, the University of Washington and the funding agency may look at our study records for oversight. We will not share the information we collect for this study with anyone else, except as described in this form and as allowed by law.

Your permission for the researchers to collect and share your health information for this study will continue indefinitely unless you withdraw your permission.

Kaiser Permanente requires that anyone who receives your health information from us must protect your privacy. However once your information is shared outside Kaiser Permanente we cannot guarantee that it will remain private and it may no longer be protected by the Privacy Rule.

Do you have to be in this study?

No, being in this study is voluntary. You are free to say no now or to leave the study at any time later. Either way, there will be no penalty. Your decision won't affect the health care you receive or benefits that you are entitled to.

What happens if you change your mind later?

You may change your mind at any time. You can have existing blood and DNA samples destroyed and data removed from the study research databases. If your data are already in a national databank, we may not be able to have the information removed. If you withdraw from the study, we may ask you a few questions to help us understand your reasons for not participating.

Location and Type of Information Sent	Data or Specimen Can be Removed	Data or Specimen Can Not be Removed
University of Washington: blood sample labeled with name, consumer ID, date of birth	X	
Local Kaiser Permanente Databases: brief survey responses, information from the medical record, tracking information	X	
dbGaP and Other National Databases: coded genetic information and information about your medical history		X

If you change your mind about participating, you may take back your consent by writing to:

Eric B. Larson, MD, MPH
Group Health Research Institute
1730 Minor Ave, Suite 1600
Seattle, WA 98101

If you take back your consent, it will not affect your health care or benefits at Kaiser Permanente. As soon as we hear from you, we will stop collecting and using your information for the study. We will ask our research partners at the University of Washington to destroy any samples or information they have about you. If other researchers have already used your coded information or sample, it cannot be removed or destroyed.

Who do you call if you have questions?

- If you have questions or concerns about the study, please call the project manager, Aaron Scrol, at **206-287-2150.**
- If you have questions about your rights as a research participant, please call the Kaiser Permanente Human Subjects Review Office at 206-287-2919.
- If you agree to participate in this study, please read the following statement and sign below. You must sign this form to join this study.

Statement that you agree to be in this study:

I have read this form, and I agree to be in this study. I do not have any questions, or I have had my questions by answered by study staff. I have been informed of the following:

- Being in this research study is voluntary, and I can leave the study at any time.
- Study staff will protect my confidentiality as provided by law.
- The researchers may collect information from my Kaiser Permanente medical record in the future, which may be linked to information from my genetic test results. This might include information on mental health disorders, alcohol, and substance abuse, and sexually transmitted diseases. This information will be shared with the other researchers named above and placed in one or more databanks for use by other researchers.

__________________________________ ____________

Signature Date

____

Please PRINT your full name clearly

- ➢ *Did you initial one of the options on Page 5?*
- ➢ *You must sign and return this form to join this study. A postage-paid envelope is included for your convenience.*