Project ID
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Kaiser Permanente Washington
Health Research Institute

"eMERGE" Study Consent Form

Research Team

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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 Aaron Scrol at Kaiser Permanente Washington Health Research Institute at 206-287-2150. You may also contact the researchers listed above.

What are we asking you to do?

We are asking for your consent to place genetic test results in your Kaiser Permanente medical records. These genetic test results were obtained from the blood sample you provided to the Northwest Institute of Genetic Medicine Biobank. With your permission, we will put these results in your Kaiser Permanente medical record and send a copy of these genetic test results to you and your primary care doctor at Kaiser Permanente. Our goal is to learn how doctors and patients use the information, how helpful it is, what questions or concerns it brings up, and what other information patients and doctors need to make sense of the results.

Why are we asking you to be in this study?

We are asking you to be in this study because in the last two years you agreed to give a blood sample to the Northwest Institute of Genetic Medicine Biobank. The biobank collected blood samples and data from you and other Kaiser Permanente members to be used in future research. We also let you know then that we might contact you in the future to tell you about about other research projects to see if you were interested. This is one such project.

When you gave your blood sample to the Northwest Institute of Genetic Medicine Biobank, you were told that the biobank might share portions of your blood sample with other researchers for future research. A portion of the blood sample you gave to the Northwest Institute of Genetic Medicine Biobank has been given to researchers to be used in a research study called eMERGE, which stands for **e**lectronic **Me**dical **R**ecords and **Ge**nomics. Kaiser Permanente Washington is one of nine sites across the country that are involved in eMERGE research. You can learn more about this research online at http://emerge.mc.vanderbilt.edu.

The eMERGE study has performed genetic tests on your coded blood sample for research purposes. We are contacting you now to ask if you want to receive the results of the genetic tests that have been done for the eMERGE study and that may be of use in your medical care.

What is the eMERGE study about?

The eMERGE study is trying to learn if giving people genetic information about themselves, and if putting that genetic information in medical records, is useful to patients and their doctor. Genetic information comes from our genes—the parts of our cells that contain instructions for how our bodies work. Genes carry information about traits that run in families, like blue eyes or brown eyes.

Certain differences in our genes may partly explain why some people are more likely to get diseases like colorectal or breast cancer, cardiovascular diseases like cardiomyopathy and aneurysms, or high cholesterol. These differences in our genes are called genetic variants. Information about genetic variants may help you know and better understand your risk for getting certain diseases. It is possible that this information might help you better manage your risk for developing these types of diseases.

The eMERGE study has tested your coded blood sample for genetic variants in over 60 genes that are known or suspected to affect a person's risk for developing certain diseases. The American College of Medical Genetics and Genomics and doctors at Kaiser Permanente have determined that there is enough scientific evidence to recommend that results for these genetic variants should be returned to patients and their doctors.

We are now asking if you want us to send you the results for the genetic testing done on your blood sample for the eMERGE study, and to put those results in your medical record. Any results we return to you will first be verified in a clinical lab. We think this is important because it could help patients and doctors know in advance if a patient may be at increased risk for developing one of these diseases. We want to see if it is possible that putting a person's genetic information in their medical record could help them get more appropriate screening and monitoring for medical conditions they might be at increased risk of getting because of the type of genes they have.

Do not sign this consent form if you do not want genetic test results put in your medical record! Once genetic results are placed in your medical record, they cannot be removed. These results will become part of your permanent record.

What will the eMERGE study do with your genetic test results if you agree to be in this study?

1. If you agree, we will put your genetic test results in your Kaiser Permanente medical record
2. We will also send you and your Kaiser Permanente primary care doctor a copy of the report of these test results. This report contains results for genetic variants in over 60 genes that are known or suspected to affect a person’s risk for developing certain diseases.

Here is what will happen if you agree to participate in the eMERGE study:

1. Once your results have been reviewed by the study team, we will send a report of the test results to you and your Kaiser Permanente doctor. The report will explain the genetic testing that was performed on your sample, and will tell you if you have genetic variations that might increase your risk of getting certain diseases. The report we send you will explain what these results mean and if necessary what steps you should take to follow up with your doctor. ***Please be aware that it might take 6-8 months for the study team to review your results and send you your report***.

2. If you are found to have a genetic variant that might increase your risk of getting certain diseases, you will receive a referral to Kaiser Permanente Genetic Services to meet with a genetic counselor who will work with you and your family so that you understand the risks associated with those results and how to manage them. We expect about 1 in 100 people to have a genetic variant associated with disease.

3. If you are referred to Kaiser Permanente Genetic Services, a researcher from the study team will collect information from your medical record about your genetic counseling appointment to help us find out how many people complete a genetic counseling session and what kind of information they are given by the genetic counselor.

4. We will also work with Kaiser Permanente Genetic Services to put your genetic test results into your Kaiser Permanente medical record where they can be seen by your doctors. We will also send a paper copy of the report to your primary Kaiser Permanente doctor. We cannot share results without placing them in your medical record. **Do not sign this consent form if you do not want genetic test results put in your medical record! Once genetic results are placed in your medical record, they cannot be removed. These results will become part of your permanent record.**

What will be in the report?

The report will include several different kinds of results.

- The report might contain positive results—meaning that we found one or more genetic variants that could put you at increased risk for getting certain diseases.
- Or, the report might contain negative results—meaning that we found no genetic variants known to affect your health. A negative result does not necessarily mean that you do not have any disease risk genetic variants. It just means that this testing didn't find any.
- The report will only contain genetic test results that the American College of Medical Genetics and Genomics and doctors at Kaiser Permanente have determined may be useful for your medical care.

How long will the study last?

Your active role in the study will end after you receive your results.

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. Please note that neither you nor your insurance will be billed for the cost of genetic testing or the cost of genetic counseling should you need it. The cost of the genetic tests and the initial genetic counseling visit, including any copays, will be paid for by the study.

However, if you are referred to a genetic counselor, it is possible that he or she may suggest additional medical tests or procedures depending on your genetic test results. The study will <u>not</u> pay for any additional or on-going medical care that is suggested by the genetic counselor or your Kaiser Permanente doctors. For example, if your results suggest that you are at a higher risk of getting colorectal cancer, this study will not pay for colonoscopy or other colorectal screening tests that might be recommended by your health care team. Your health insurance may or may not pay for additional care that is suggested. You are free to decline any follow-up counseling or care. You will be responsible for paying any copays, deductibles, or coinsurance associated with these extra visits and /or treatments.

Will being in this study help you?

We cannot promise that being in this study will help you. But it is possible that we may uncover risks of medical conditions that can be helped by life-style changes, \ screening tests, or usual care therapy. For instance, the information you get may help you better monitor your risk for developing certain diseases. However, you may never develop or be at risk of developing one of these. In that case, being in this study is not likely to help you personally. We are hopeful that future generations may benefit from the scientific and medical knowledge we gain from your participation with better methods to predict, prevent or treat disease.

Overall, the knowledge we gain about how genetic variants affect a person's health and health care may help people in the future. We have no plans to use this research for commercial purposes. Researchers using this information 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?

- **Loss of confidentiality**: We take every precaution to keep your identifiable information confidential. There is still a risk that someone other than the researchers or your health care providers could find out you were in the study or see your private study information. Because your genetic information will be placed in your medical records, anyone who has access to your records may see your genetic results. If this information was mistakenly shared and if it were linked with a medical condition, this could affect your ability to get or keep some kinds of insurance. If family members were to see this information, it could also affect them. The steps we take to prevent an accidental release of your genetic results are described on the next page. **Please know that once information is in your medical record, it cannot be removed and it may be seen by others who can request legal access (for example, social workers or attorneys).**

- **Emotional distress and discomfort:** Learning about your risks for a genetic disease is likely to be emotionally stressful. It is important that you understand we can tell you the medical significance of genetic information <u>as it is known to us today.</u> In the future, and after your study participation ends, our understanding of the medical significance of information we gave you may change, and we cannot predict what those changes may be. The uncertainty of knowing exactly how the genetic risk will affect you or how the risk may change as science advances in the future may be stressful to you. Also, learning that a condition runs in your family might cause some tension among family members.

  Reproductive issues: Men and women of reproductive age, or known to be pregnant when they enroll in this study should be aware that reproductive issues can be a major source of concern when a person contemplates genetic testing. Knowing that you have a genetic risk that could be passed on to your children may influence your decision to have children.

- If you already know that you do not want to hear about genetic risks that might be uncovered by this study, or are bothered that we cannot tell you all of your genetic information with certainty, then you should not join this study. Please remember that once these results are place in your medical record they cannot be taken out and can be seen by doctors and other health care providers who have access to your medical records.

- There may be risks to having genetic test results in your medical record that are unknown and are likely to increase over time.

- **Genetic testing:** There is potential risk for genetic discrimination. Having a genetic test results in your medical record may increase this risk.

A federal law, called the Genetic Information Nondiscrimination Act (GINA), makes it illegal for health insurance companies, Kaiser Permanente plans, and most employers to discriminate against you based on your genetic information. All health insurance companies and Kaiser Permanente plans must follow this federal law, which protects you in the following ways:

- Health insurance companies and Kaiser Permanente plans may not request your genetic information that we get from this research.
- Health insurance companies and Kaiser Permanente plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information when making a decision to hire, promote, or fire you or when setting the terms of your employment.

In keeping with the law above, Kaiser Permanente does not use the genetic information in your medical record to determine eligibility or premiums. However, we cannot promise that all future insurers will not use genetic information from your medical record in some way.

Be aware that this law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. Members of the U.S. military may not have the same protections under this law. 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?

The researchers at Kaiser Permanente will label your information only with a code number. We will keep the link between your name and your research code number at Kaiser Permanente and 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.

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. The genetic test results we get from your blood sample.
2. Information from your Kaiser Permanente medical records about your genetic counseling appointment for patients referred to Kaiser Permanente Genetic Services. We will collect this information from your medical record from the time you join the study until May 2019.

Your authorization for the study to collect and use this identifiable health information will end April 30, 2034.

Who may use your health information for future research?

This study has partners at the University of Washington and collaborators in the eMERGE Network and potentially other collaborators who may become involved in the research. We are creating a research database, to be used for this project and for future studies. Information shared outside of Kaiser Permanente won't include your name, Kaiser Permanente number, or other information that is usually used to identify you.

Who else may see your health information during this study?

- It is possible that staff from Kaiser Permanente 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 allowed by law.
- Your Kaiser Permanente primary care provider and other doctors involved in your clinical care.

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 up to you. 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?

Once genetic results are placed in your medical record, they cannot be removed. These results will become part of your permanent record.

Do not sign this consent form if you do not want genetic test results put in your medical record!

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.
- By signing this consent form, I am giving permission for genetic test results from the study to be placed in my medical record. I understand that after results are placed in my medical record, they cannot be taken out.
- **Please do not sign this consent form until all of your questions have been answered by the study team. If you have any questions about this study, please contact the Project Manager Aaron Scrol at 206-287-2150 <u>before</u> you sign this form.**

____ ______________

Signature Date

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Please PRINT your full name clearly