

Consent Form

eMERGE Pharmacogenomics Study



Research Team

Group Health Research Institute

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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 at Group Health Research Institute at 206-287-2150. You may also contact the researchers listed above.

Why are we asking you to be in this study?

We are asking you to be in this study because several years ago 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 Group Health 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 other research projects to see if you were interested. This is one such project.

We are asking you to be part of a different research study called eMERGE, which stands for **e**lectronic **M**edical **R**ecords and **G**enomics. Group Health 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>.

You are eligible for this study because you still receive your care at Group Health. We hope to enroll about 450 Group Health members in this study.

What is this study about?

We are doing this study to learn more about how genetic information can improve medical care. 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 cancer, diabetes, and asthma. These differences are called genetic variants. These genetic variants may also affect how well some

medications work for certain people. The study of how genetic variants affect a person's response to certain medications is called "pharmacogenomics." In this study, we are looking at genetic variants that may affect whether:

- a person needs a lower or higher dose of a medication.
- a person may be more likely to have side effects with certain medications.
- a certain medication will work for a person or not.

This study will also look at different ways to place genetic information into a person's medical record. We think this is important because it could help doctors know in advance when a certain medication may not be the best choice for a patient. We also want to learn how patients and doctors feel about using genetic information to try to improve medical care.

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 another blood sample and to let us collect some information from your Group Health medical record. We will use your blood sample to look for genetic variants that are known to affect how people respond to certain medications. We will compare results from this blood sample with results from the blood sample you gave to the biobank several years ago. This second test is required in order to return results for your medical care.

If we find any genetic variants that might affect how you respond to a certain medication, we will share that information with you and your primary doctor at Group Health. Genetic information that is relevant to your medical care may also be added to your medical record. **DO NOT JOIN THIS STUDY IF YOU DO NOT WANT GENETIC INFORMATION PUT IN YOUR MEDICAL RECORD.**

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. Check that your correct name and consumer number are on the tubes in the enclosed blood draw package.**
- 3. Check that the five-digit number on the tube matches the number at the top of the first page of this consent form.**
- 4. Mail the signed consent form and completed survey back to us** in the enclosed business reply envelope.
- 5. Go to your local Group Health lab for a blood draw.** Please take the enclosed blood draw package and instructions with you and give them to the staff at the lab. The blue instruction sheet for the lab is inside the package. The blood draw should take between 10 and 30 minutes, depending on your wait at the Group Health lab. Your blood sample will

then be sent to the study's genetic testing lab. There is no cost to you for the blood draw.

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 send you another \$50 after the testing lab receives your second sample.

What will we do with the results of your genetic tests?

Testing your blood sample could take several months. After we complete the testing, we will send a report to you and to your Group Health doctor. The report will only include results that might be useful for your medical care.

- The report might contain positive results—meaning that we found one or more genetic variants that could affect how you respond to certain medications.
- Or, the report might contain negative results—meaning that we found no genetic variants known to affect how you might respond to certain medications. A negative result does not necessarily mean that you do not have these genetic variants. It just means that this testing didn't find them.
- The report will only contain genetic information that scientific evidence shows may be useful for your medical care. But future research may provide evidence about other genetic results that may be useful. If this happens, we may send an update to you and to your doctor. But we cannot promise that the study will have funding to do this.

Some of your genetic test results may eventually be placed in your medical record. Currently at Group Health, there are only a few genetic tests that are being conducted and placed in patients' medical records. These tests are mostly related to the risks of specific diseases and are ordered by a person's primary care doctor. This study hopes to expand the use of genetic information by exploring how genetic test results could be placed in medical records and used by doctors when prescribing specific medications.

- If we place your genetic test results in your medical record, it won't happen right away. Over the next year or two, we will develop information and tools to help add genetic results to medical records. Only results that are approved by Group Health as being useful for your medical care will be placed in your medical record. **After results are placed in your record, they cannot be taken out.**

- As more research is done, Group Health may approve other tests of how genetic variants affect a person's response to medications. If this happens, these test results may also be included in your medical record.

How will we use your sample and information?

Your sample

Your blood sample will be labeled with your name, Group Health 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 certified laboratories outside of Group Health for the testing, 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 we want to return the results to you and your doctor for use in your medical care, and possibly include some results in your medical record. It is required by law for samples and results that are going to 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. Even though the laboratories that will be doing the testing are outside of Group Health, they are bound by the same regulations that all certified laboratories must follow in protecting your health information.

Because we want to keep the ability to return results in the future, 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, Group Health consumer number, your study identification number, your birth date and the date and time the blood was collected. We may share portions of your blood sample with other researchers for future research, but only after your identifying information has been removed.

Your information

We will also create a research database to be used for this project and for future research studies. The research database will NOT will not have your name, or Group Health consumer number. Your information will be identified only by your study identification 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 Group Health medical record, including:

- your medical history.
- 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 Group Health until you are no longer a Group Health member.

In the research database, your coded information will be combined with information from about 6,000 other study participants from health care systems across the country. eMERGE researchers will use the database for future studies about how a person's genes affect their response to certain medications. We may also share your health information with our partners at other research sites.

Your genetic results and the health information from your medical record may be placed into one or more national research databases, such as the "database of Genotypes and Phenotypes dbGaP)" at the National Institutes of Health (NIH). This information would include your coded genetic information and also information about your medical history, medicines you have been prescribed, lab and other test results and behavioral information, for example, whether you have ever smoked. Your name and other information that could directly identify you (such as address, Group Health number, or social security number) will not be included. But because genetic information is unique to you, there is a chance that someone could trace it back to you.

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 and the survey. However, we may contact in you in the future to see if you would be willing to answer questions about what it was like to receive your genetic test 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. 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 it is possible that the genetic test results we give to you and your doctor will help you make better choices about medications in the future. It may also help you avoid some medication side effects or complications. However, you may never need any of the medications affected by known genetic variants. In that case, being in this study is not likely to help you personally.

Overall, the knowledge we gain about how genetic variants affect a person's response to certain medications may help many people in the future.

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. There is still a risk that someone other than the researchers could find out you were in the study or see your private study information, and this risk may increase in the future. The steps we take to keep this from happening 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).
- **Genetic testing:** There is potential risk for genetic discrimination. Having the genetic test results in your medical record may increase the risk to your privacy. Your insurance company may have access to this information, just as they would any other information in your medical record. The risks of learning genetic test results may potentially include emotional upset or insurance or job discrimination.

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

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health 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, Group Health 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?

As described above, both the blood sample we collect from you and the results we will return to you and your doctor by mail will be labeled with your name, Group Health consumer number, your study identification number and your birth date. This is to ensure that the results we are returning to you are really your results. For the same reason, your sample that is stored for future research will be labeled with your name, Group Health number and other identifying information.

We are also creating a research database, to be used for this project and for future studies. In the research database 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 research code number at Group Health 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.

We have a Certificate of Confidentiality from the NIH. This lets us refuse to share any study information that might identify you, even if we are asked to do so by a court of law. It is 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, the Certificate serves as extra protection. The Certificate does not stop study records from being reviewed by some federal agencies. In addition, Group Health and the funding agency may audit study records as part of study oversight. The Certificate also does not stop you from sharing information about yourself or your part in this research.

The Certificate of Confidentiality only protects your study records. It does not protect your medical records. Genetic results that are placed in your medical record are permanent and governed by the protections and rules that apply to medical records.

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). Group Health 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 Group Health 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, Group Health consumer number, and the information necessary (date and time of blood draw, birth date, sex) to have your sample tested by a certified laboratory and return results for possible use in your medical care.
3. Your past, present, and future medical records, including your medical history, medicines you have been prescribed, lab and other test results, and behavioral information, for example whether you have ever smoked.
4. Research information collected from you as part of this study, including the survey questions we asked you on the phone and any future surveys you agree to do.

Who may use your health information for future research?

- The Group Health and University of Washington researchers involved in this study.
- Our partners and collaborators in the eMERGE Network and other collaborators who may become involved in the research.
- Researchers using national scientific databases, such as the “database of Genotypes and Phenotypes (dbGaP)”.

Who else may see your health information during this study?

- The Group Health Research Institute Institutional Review Board that oversees the research.
- Your Group Health primary care provider and other Group Health doctors involved in your clinical care.
- The laboratories involved in testing and the return of test results to you and your doctor.
- Federal and State agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health and other US or government agencies in other countries) that oversee or review research.

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

Group Health requires that anyone who receives your health information from us must protect your privacy. However once your information is shared outside Group Health 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. 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.

Genetic tests for the medications involved in this study are available. You may choose to pursue testing on your own. If you choose not to be in this study, your doctor will continue to make choices for medications based on the current standards of care.

The research team can also end your participation in this study at any time without your consent.

What happens if you change your mind later?

You may change your mind at any time. You can have existing samples destroyed and data removed from the study research databases. If your genetic results are already placed in your medical record, they cannot be taken out. Also if your data are already in a national databank, we may not be able to have the information removed.

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	
Group Health Medical Record: genetic testing results		X
Local Group Health Databases: survey responses 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 Group Health. As soon as we hear from you, we will stop 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 Group Health 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.
- The researchers may collect information from my Group Health medical record in the future, which may be linked to information from my genetic test results. 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

***PLEASE RETURN THIS ENTIRE FORM
DO NOT DETACH THE LAST PAGE
KEEP THE YELLOW COPY FOR YOUR RECORDS***

<PROJID>
(will be physically cut off after final consent reconciliation)