

## **You're Invited to Participate**

Based on your answers about your family, we are offering you **genetic testing** through a research study. This study is called the **Cancer Health Assessments Reaching Many (CHARM) study**.

Some people don't know about or don't use medical care related to cancer that runs in families. This causes differences in health between groups of people. The purpose of this study is to learn how to lower those differences in health. The next page will tell you about genetic testing. After that, we will ask if you want to learn how to get the test. If you select "yes," we will tell you how you can get the test in the CHARM study. At the end, you can decide if you want to join the study.

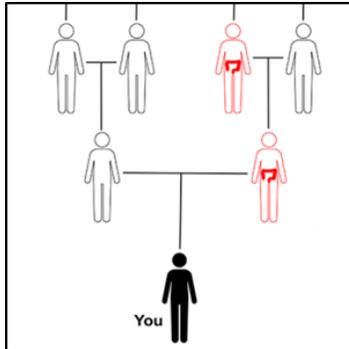
It may take 20 minutes or more to read about the test and the study. Please make sure you have enough time to go through all the information. You can listen to a recording of the information by selecting "listen" on each section.

You can call us if you have any questions: [KP] (503) 335-6 694 [DH] RU  
\$50

## A Test That Can Tell You More About Your Chance of Getting Cancer

Based on your answers about your family, we are offering you **genetic testing** through the CHARM study (Cancer Health Assessments Reaching Many). Genetic testing identifies changes in DNA that cause diseases that are passed down in families. The information that follows can help you decide if you want to get this test.

### What can this test tell me?



This genetic test can tell you if you have a **higher chance of getting cancer than most people**. The test looks at changes in DNA that increase the chance of getting certain types of cancer. The results may change the medical care your doctor recommends for you.

This test can also tell you about the chance of your **children and other family members** getting cancer. You can talk with your doctor about what your results could mean for your family members.

### What results could I get?

If you get an **abnormal result**, that means you have a change in your DNA that increases your chance of getting one or more certain types of cancer. The test results can help you and your doctor plan what cancer screening you should get to find and treat cancer earlier.

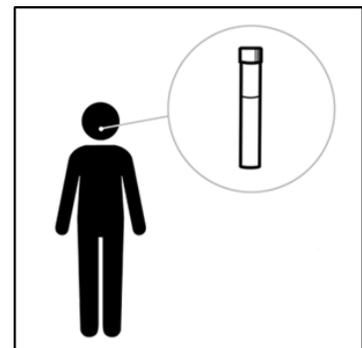
If you get a **normal result**, that means the test did not find a change in your DNA that increases your chance of getting cancer. This does not mean you cannot get cancer or another health problem. You can talk with your doctor about what cancer screening is right for you.

It is possible you could get an **unclear result**. This means the test found a change in your DNA but doctors do not know enough about what it means. Your doctor may recommend cancer screening based on you and your family's health history.

### How do I do this test?

To do this test, you need to spit saliva into a tube. A team of doctors will test your saliva sample and talk with you about what your results mean. You can talk to your doctor to find out more.

*[KP]* You can also call the Genetics Department: (503) 331-6593.



### What can this test not do?

**This test cannot tell if you will get cancer or not.**

No matter what your results are, many things can affect your chance of getting cancer, like smoking. Sometimes people get cancer no matter what they do.



**This test cannot tell you about all the health problems you might have now or in the future.**

Doctors are still learning about this test, so some of your results could be unclear or could change as doctors learn more. For some results, doctors may not know how to reduce your chance of getting cancer. In other cases, you may still get cancer even if you follow all of your doctor’s advice. You may also need to see other doctors or get more testing, which could reveal other health problems not related to cancer.

**What are my options?**

You can choose to get this test or not. People have different views about the benefits and risks of the test. Some reasons why people may or may not want to get the test are listed below.

If you do not get the test, you can talk to your doctor about what cancer screening you should get. Your doctor may recommend cancer screening based on you and your family’s health history.

**What are some reasons why people may want to get this test?**

- They may want to learn about the chance of **their children and other family members** getting cancer.
- The results may make them **feel less worried about their health**.
- The results may help them know what they can do to **find and treat cancer earlier**.



**What are some reasons why people may not want to get this test?**

- They may **not want to know** the information that it can tell them. Some people may worry while waiting for their test results or after receiving their results.
- They may worry about getting **health insurance**. However, there is a law that says the test results cannot be used against you in health insurance.
- It may be hard for them to talk about the results with **their children or other family members**.
- They may worry about getting **life insurance**. Some states have laws about this, but these laws can change. Because of this, some people choose to get life insurance before getting this test.



You may be able to get the test from your doctor even if you decide not to join the study.

## Cancer Health Assessments Reaching Many (CHARM) Study

You can get genetic testing for cancer risks that run in families by joining a research study called the CHARM study (Cancer Health Assessments Reaching Many).

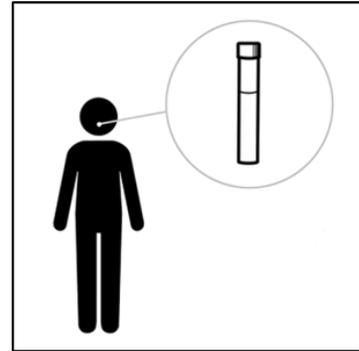
**Some people don't know about or don't use medical care related to cancer that runs in families. This causes differences in health between groups of people. The purpose of this study is to learn how to lower those differences in health.** We are trying to include many different types of people in this study so we can learn how people from different backgrounds think about this test.

You can join this study or not. Please take all the time you need to decide.

### What will happen in the study?

You will...

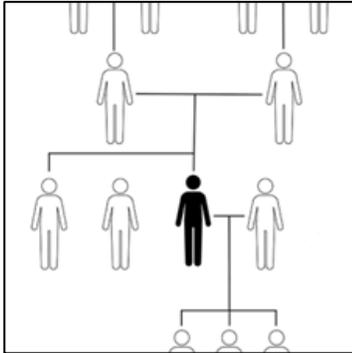
- **Spit saliva in a tube.** You can do this at home and send it in the mail, or you can do this with study staff at your doctor's office.
- Learn if you have a **higher chance of getting cancer than most people.**
- **Get your test results.** Most people will get their results on a phone call at a time that is good for them. Some people with normal results will get their results in a letter in the mail.
- **Do surveys** and maybe **interviews** with study staff.
- **Be paid** for your time. You will get \$30 for giving your saliva sample and completing the first study survey, \$10 for each additional survey (up to 2), and \$20 for each interview (up to 2).



We will...

- **Test your saliva sample** to learn more about your chance of getting cancer.
- Share your results with your **doctor** and put them in your **medical record.**
- **Look at your medical record** to learn about your health. This could include information about mental health and things other than cancer.
- **Store your saliva sample and your health information.**
- Use your saliva sample to **learn more about health and disease.**
- Maybe **contact you later** to ask you other questions or to invite you to join other studies.





**We will also ask if you want to learn about other health problems that run in families. This is optional.** This test can show a lot of different results about traits that run in your family. Most of these results will not affect your health, but some of them might show health problems other than cancer. Before you give us your saliva sample, you will be able to choose if you want to learn about health problems in you that may need medical attention. It is important to remember that this **does not include** all possible health problems. It also will not include results if we do not know if they will affect your health. You can choose to learn about all, some, or none of these results. You do not have to get these results to be in the CHARM study.

**A member of the medical team will talk with you on the phone about your test results. You will be able to ask all of your questions.** We are comparing two different ways of explaining the results to people. We know both ways are good, but we want to see if one way helps patients better. To find out, we will use one way half of the time, and the other way the other half of the time.



### Will the study cost me anything?

No. The test will not cost you anything. Your insurance will not be charged.

But your test results may show that you need medical care in the future. This future care is often covered by insurance plans but each plan is different. The CHARM study will not pay for any future medical care you might need because of your test results.

### What if I decide not to join?

We will ask you if you agree to the study looking at your medical record. We want to learn about the health and medical care of people who have cancer in their family but don't join this study. We may ask you to do a short survey about why you don't want to join. We may also invite you to be interviewed or to join other studies.

### What are my other options?

**You do not have to join this study.** You may be able to get the test from your doctor even if you decide not to join the study. If you choose not to join the CHARM study, you can talk with your doctor about this test.

*[KP]* You can also call the Genetics Department to find out how to get the test: (503) 331-6593.

You can also talk with your doctor first and then decide if you want to join the study.



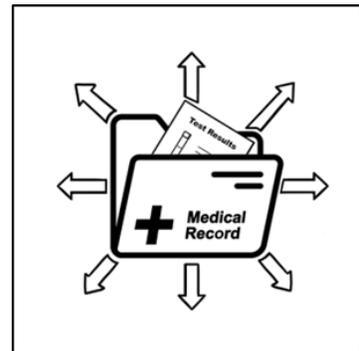
**This privacy agreement has more details about how we will use and share your health information that identifies you.** If you agree, it means you allow researchers at Kaiser Permanente to use your health information and share it with others as part of the CHARM study.

The health information that we may use or share includes:

- Results of your genetic testing.
- All the information in your medical record. This could include information about mental health and things other than cancer.

We may share this information with:

- **Study team members.** These include other researchers who are working with the study and the laboratory doing genetic testing. Some of our study team members are located at the following places, but we also may work with researchers at other places:
  - Columbia University
  - Dana Farber Cancer Institute
  - Denver Health
  - Emory University
  - Kaiser Permanente Colorado
  - Kaiser Permanente Northwest
  - Seattle Children's Hospital
  - University of California San Francisco
  - University of Washington
- The **National Institutes of Health (NIH)**. This is who is funding the study.
- The **Office for Human Research Protections**. This is who oversees all research involving humans in the U.S.
- The **committee of researchers and community members** who review this study.



Kaiser Permanente is required by law to protect your health information. We will only share your health information with other groups that agree to protect your information and keep it private. But if your information is given to a group that is not covered by these policies and laws, we can no longer promise that your information will be kept private.

You do not have to sign this agreement. If you do not sign, we cannot include you in this study. You can change your mind and leave the study at any time. To leave the study, you must send us a letter. After we get your letter asking to leave the study, we will only continue to use the information that has already been looked at or shared, unless we need to look at your information for safety purposes. To leave the study, you must write to:

CHARM Study Team (Attn: Katrina Goddard, PhD)  
Kaiser Permanente Center for Health Research  
3800 N. Interstate Avenue  
Portland, OR 97227-1098

This agreement does not expire.

The next page will tell you about the other types of health problems (other than cancer) that this test can tell you. You can choose if you want to learn about them or not.

## **Learning About Other Health Problems (Optional)**

Everyone in the CHARM study will get their genetic testing results about cancer that runs in families. You can also learn about some other health problems that run in families. These include health problems that may need medical attention now or in the future. It is important to remember that this does not include all possible health problems.

This section will tell you more about these other results. There are also questions to help us find out how you feel about these results. Please check whether you agree or disagree. After answering the seven questions, we will tell you whether your answers suggest that you want or do NOT want to get these results about health problems other than cancer. However, you can decide what is best for you.

At the end, please check “yes” or “no” to tell us whether you want these results or not. You do not have to get these results to be in the CHARM study.

**This information is about results showing a higher chance of health problems that may need medical attention.** Your responses to the statements below may help you to decide whether you want to receive these results.

**What are these results?**

These results are changes in genes that may cause a higher chance for health problems, other than cancer. These health problems can be prevented, found, or treated early.

Most people will not have any abnormal results for these other genes. Even if your results are normal, you should continue to see your doctor.

**What are some examples of these other health problems and how my medical care could change?**

- If you have a higher chance of a heart muscle problem (cardiomyopathy), you can have regular heart check-ups and take medicine to protect your heart.
- If you have a higher chance of a serious reaction to a medicine given during surgery (anesthesia), you can receive different medicines.
- If you have a higher chance of a weakened heart blood vessel (aorta), you can have regular check-ups and, if needed, surgery.

*Please share your feelings about the following statements.*

	Strongly disagree	Somewhat disagree	Somewh at agree	Strongly agree
I want to know as much as I can about having a higher chance of a health problem.				
I would worry if I knew I had a higher chance of a health problem.				

**What would these results mean for my family?**

These health problems can run in families. If we find that you have a higher chance for a health problem, your family members could also be tested.

*Please share your feelings about the following statements.*

	Strongly disagree	Somewhat disagree	Somewh at agree	Strongly agree

I want to let my family members know my results so they can have this information for their health.				
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**What else may affect my choice?**

- There is a law that says the test results cannot be used against you in health insurance and most types of employment.
- However, other types of insurances such as life and disability insurance are not protected by the same law.

*Please share your feelings about the following statements.*

	Strongly disagree	Somewhat disagree	Somewhat agree	Strongly agree
I am worried that these results may make it harder for me to get life or disability insurance.				

**Why might some people want to get these results?**

- To find out if they have a higher chance of a health problem that would not usually be found until they feel sick.
- So they can take medical action to prevent or find and treat potential health problems.
- So they can inform their family members.

*Please share your feelings about the following statements.*

	Strongly disagree	Somewhat disagree	Somewhat agree	Strongly agree
I want to take steps to prevent or find and treat future health problems if these results show I have a higher chance of them.				
I am comfortable seeing doctors to take care of my health.				

**Why might some people not want to get these results?**

- They might not want to feel stress and anxiety from thinking about the results.

- They might not want the additional doctors’ visits that would be recommended for these health problems.
- They only want to get their results about cancer that runs in families.

Please share your feelings about the following statements.

	Strongly disagree	Somewhat disagree	Somewhat agree	Strongly agree
It would be hard for me to take more medicines or have more doctors’ visits right now.				

**Here are two examples of what other people have said when making this decision.**

“If there’s something else going on with my health, I’d like to know now. If there’s treatment or things that I’m doing that I need to stop doing, I’d definitely like to know that.”

“I’d rather be surprised than know a health problem is coming, even if it would have changed my doctor’s recommendations. I don’t think I want to live the rest of my life knowing that I have a higher chance of something than most people.”

**[Summative Feedback– one of these four messages will show up based on the participant’s answers to the questions in this “Learning About Other Health Problems” section]**

<b>Strongly disagree</b>	Somewhat disagree	Somewhat agree	Strongly agree
Your answers suggest that you <b>Strongly disagree</b> with getting these results, but you can still get the results if you want them.			

Strongly disagree	<b>Somewhat disagree</b>	Somewhat agree	Strongly agree
Your answers suggest that you <b>Somewhat disagree</b> with getting these results, but you can still get the results if you want them.			

Strongly disagree	Somewhat disagree	<b>Somewhat agree</b>	Strongly agree
Your answers suggest that you <b>Somewhat agree</b> with getting these results, but you can still choose not to get the results if you do not want them.			

Strongly disagree

Somewhat disagree

Somewhat agree

**Strongly agree**

Your answers suggest that you **Strongly agree** with getting these results, but you can still choose not to get the results if you do not want them.

**Do you want to get results about the higher chance of health problems that may need medical attention?**

Yes - I want to get these results.

No - I do not want to get these results.

**Continue**

**Thank you for choosing if you want to learn about other health problems.**

**Next steps:**

**If you filled this out at your doctor's office or at home and asked to get your kit at your upcoming medical appointment:**

- Study staff will give you a saliva kit. Please follow the instructions to give your sample and hand it to the study staff.
- If you do not complete your first survey now, we will send you an email with a link to answer some more questions about yourself and your health. If you do not use email, you can ask study staff to give you a paper copy and a postage-paid envelope.

**If you filled this out somewhere else:**

- You will get a saliva kit in the mail. Please follow the instructions to give your sample and mail it back. If it does not arrive within 10 days, please call us.
- If you do not complete your first survey now, we will send you an email with a link to answer some more questions about yourself and your health. If you do not use email, please call us and we will mail you a paper copy and a postage-paid envelope.

**If you have any questions, please call us at (503 335-6694).**

Please fill out the first survey. It should take you about 15 minutes.

Take the baseline survey

To close this page, we recommend you close the window of your internet browser.