

ACT Study Consent Form



Study Voicemail: 206-442-5228 or toll free 1-877-879-8757

Researchers

Kaiser Permanente Washington Health Research Institute

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RESEARCHERS' STATEMENT

We are asking you to be in a research study. Kaiser Permanente Washington Health Research Institute and the University of Washington are leading this study with funds from the National Institute on Aging, which is part of the National Institutes of Health (NIH).

You do not have to be in this study.

Please take as much time as you need to make your choice. Ask questions if anything isn't clear or if you would like more information.

If you say yes, you can leave the ACT study at any time.

Saying no now or leaving the study later won't affect your health care or benefits at Kaiser Permanente.

What this study is about

Our goal is to learn about what causes changes in memory and thinking abilities as people age. This study will also contribute to scientific knowledge and increased understanding of genetic factors that might affect aging, health, and disease. You are one of thousands of Kaiser Permanente members age 65 and older chosen at random to participate. This means we picked your name by chance—like drawing it out of a hat.

People who join this study will have one study visit every two years for as long as they stay in the study. We will use information collected at these visits along with medical record information to study how memory and thinking abilities change over long periods of time.

We may ask people in this study to wear two monitors to measure their physical activity. We are collecting new data on activity levels because new evidence suggests there are links between high amounts of inactivity and health conditions including dementia risk.

We also hope to collect blood samples to study genetic traits that may affect health and disease. Genetic traits are passed down in families, like eye color and blood type. They may partly explain why some people are more likely to get certain diseases.

What will happen if you decide to be in the study

There are three main parts to this study:

- There is a study visit today, plus follow-up visits every 2 years for as long as you are in the study.
- We will collect information from your Kaiser Permanente medical record.
- We may ask you to wear two monitors for one week to measure your physical activity level.
- If you are willing, we will draw your blood and use your DNA in this study and in future genetic research.

Today's study visit

Your study visit today will last about 2½ - 3 hours. This visit is to see if the study is a good fit for you. During the visit:

- We will ask you questions about you and your health history.
- We will check your height, weight, and how well you can move around.
- We will show you how to wear two lightweight activity monitors.
- We will ask you to do tasks that measure your thinking and problem-solving abilities including memory quizzes. Examples are to remember words, subtract numbers, and copy drawings. Depending on the test results, we may ask you to do some extra tests to help us understand your memory better.
- If you are willing, we will take about 2 tablespoons of blood from a vein in your arm.
- We may give you two forms (family history form and a take home questionnaire) to fill out at home and send back.

- You may skip any question you don't want to answer. You may also choose not to give us a blood sample.
- If we find that you do not meet the study criteria, you will not be enrolled. We will destroy your blood sample and all the information we collected about you. No follow-up visits will be needed.

Follow-up visits

You will have one follow-up visit every two years for as long as the ACT study continues and you remain enrolled. We hope our funding will continue for many years. If you cannot come to the research clinic for these visits, study staff can come to your home.

Each follow-up visit will last about 1½ hours. During these visits, we will:

- Check your height, weight, and how well you can move around.
- Ask you about changes you may have experienced in your health or living situation since your last visit.
- Ask you to do tasks to test your memory and thinking abilities. These tasks are similar to the ones you will do at today's study visit. Depending on the results, we may ask you to do the extra tests described below.
- We may ask you to wear the physical activity monitors for one week.
- We may ask you for another blood sample if the one taken at your first visit was not usable.

Additional Testing

There is a small chance we will ask you to do some extra testing. This additional testing can take place at the research clinic or in your home.

If test scores and information collected during a study visit show that there are significant changes or problems with your memory or thinking abilities, you will be asked to complete additional testing.

- We will ask you to meet with a study doctor or nurse and a study staff member. He or she will review the changes in your memory and conduct additional memory tests and a neurological exam. Unless you object, the results of the exam will be sent to your Kaiser Permanente doctor.
- We may also ask a close friend or family member about your memory and thinking abilities. This person may be asked to provide information on your behalf if you aren't able to in the future.
- After the testing, you may be asked to participate in yearly visits.

Each year, a few participants who are not having problems with their memory or thinking abilities may be asked to do some in-depth memory testing at a follow-up visit. These tests help us understand how well the basic memory tests are working. If we ask you to do these extra tests, you may say no.

Collecting information from your medical record

- Study staff will review your Kaiser Permanente medical record and collect information from it. This will include lab test results, medications, doctor visits, and trips to the hospital.
- Some of the information may be about sensitive topics such as mental health disorders or alcohol use.
- We will collect this information starting from the first time you received your health care at Kaiser Permanente up until 90 days after the end of your study participation.

Collecting information from wearing physical activity monitors

- If you are willing, study staff may show you how to wear two small, lightweight activity monitors (Actigraph and activPAL). The Actigraph is worn on a belt around your waist. The activPAL is worn with a mild adhesive gel or special tape dressing on the front of your thigh. Both can be worn underneath your clothing.
- We may ask you to wear both activity monitors for one week and go about your normal routine. This will allow us to see what your usual amount of physical activity is. The activity monitors do not tell us what specific activities you are doing or where you are. They provide summary information on the total amounts of physical activity you do.
- We may ask you to fill out a daily wear log that we will send home with you. We will also give you a questionnaire to complete during the week you wear the activity monitors.
- After you wear the activity monitors for one week, we will ask you to mail the two activity monitors, daily wear log, and questionnaire back in a pre-paid envelope that we will give you to Kaiser Permanente. Monitors will be tracked using your study id only.

Storing and using your blood sample

We will use the blood samples we collect to look for genetic traits that affect people's health as they age. Genes are small portions of DNA found in your cells. They carry information about traits that run in families, like whether you will have

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brown eyes or blue eyes. Genetic traits may partly explain why some people are more likely to get diseases related to aging, such as Alzheimer's.

If you agree to give us a blood sample, we will store it indefinitely in a repository run by the ACT study investigators. A repository is a collection of information and blood or tissue samples used for medical research.

- The ACT study repository will be in a facility approved by Kaiser Permanente.
- Your blood sample and other genetic information collected by the study will be shared with other researchers for studies related to aging, and health, and other medical conditions or diseases.

Important things to know about giving blood for research

- No one at the research labs that tests the blood samples will know your identity. Your name will not be written anywhere on your sample. Instead all samples will be labeled only with a code number.
- Tests that are run on the blood samples will not be used to diagnose disease. No test results will be given to you or your doctor. Please talk to your doctor if you have questions about whether other genetic tests might help you.
- It is possible that future studies might use your blood sample to create a cell line. This means copies of your genetic material could be made.
- If you agree to a blood draw now, you may still change your mind later. You can ask us to remove your blood sample from the ACT repository by calling us at 206-442-5228 or toll free at 1-877-879-8757.

We would also like to store your health and genetic information in a databank run by the National Institutes of Health (NIH) and in other national databanks. These databanks collect the results of whole genome studies.

These databanks allow broad sharing of genetic data and medical history data so that many investigators around the country can study aging, health, and other medical conditions or disease. A databank is like a repository, but it includes only information—no blood or tissue samples.

- Researchers will use information in the NIH databank and other databanks, in future genetic studies. We don't know in advance what these studies will be about.

- Only qualified researchers can use information in the databanks. 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 NIH databank must first get approval from a committee at the NIH. They must also sign a pledge to keep study information confidential. Other databanks have similar requirements.

You can still join the ACT study even if you don't want to give us a blood sample or share your information with the NIH databank or other central databanks. There is a place at the end of this form for you to mark your choice about giving a blood sample and sharing your information.

How we protect your confidentiality and privacy

All Kaiser Permanente researchers sign a confidentiality pledge that requires them to keep your study information private. Kaiser Permanente has other rules in place to protect your privacy.

The researchers listed and their staff will use your information for research only. We will store your study information on secure computers at Kaiser Permanente Washington Research Institute. We may share some of your study information with researchers at other institutions, but we will not give them your name or contact information. We won't use your name in study reports or write it on your study information or blood samples. Instead, we will label everything with a code number only. We will store the list linking your name to your code number in a locked cabinet or password-protected computer file. We won't add information to your medical record.

Kaiser Permanente has a Federal Certificate of Confidentiality from the National Institutes of Health. 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. The Certificate doesn't stop study records from being reviewed by some federal agencies. It also doesn't stop you from sharing information about being in this research study.

Your study records may be reviewed for oversight purposes by:

- Staff from Kaiser Permanente or the University of Washington
- The National Institutes of Health

- The Department of Health and Human Services

We will only share your name or other information that identifies you in ways described in this form or as allowed or required by law. Two exceptions are:

1. Your genetic information, which is unique to you, and would be shared if you sign this form.
2. Information about abuse of a dependent adult, which would be reported to the appropriate authorities.

Risks you may want to consider

- You might feel uncomfortable answering some study questions. You may skip any questions you don't want to answer.
- It's possible that someone other than the researchers could find out you were in the study or see your private health information.
- We do not plan to contact you by e-mail unless you give us your e-mail 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.
- You may experience local skin irritation from the monitor (activPAL) adhered to the thigh.

If you agree to the blood draw, there are a few other risks you should know about:

- Having blood drawn can be uncomfortable and can cause a bruise. Some people may feel nervous or get dizzy. In rare cases, it can cause fainting.
- There is a small chance that your genetic information or DNA could be shared with others by mistake. In the unlikely event that your 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 or could affect your employment status. No one can tell by looking at your blood sample that it came from you. But because your blood has genetic information that is unique to you, there is a small chance that someone could trace the sample or genetic information back to you. The risk of this happening now is small. But new advances in science will increase this risk in the future.
- Future research using ACT study blood samples may find that some genetic differences appear more often in people from certain groups. These

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differences might also be more common in people with a certain disease. This could result in people from that group being treated differently.

We take many steps to keep these risks as small as possible. A federal law, called the Genetic Information Nondiscrimination Act of 2008 (GINA), makes it illegal for health insurance companies, group health plans, and most large employers to discriminate against you based on your genetic information. This law does not cover all forms of discrimination. Kaiser Permanente will not use your genetic information when making decisions about medical coverage eligibility, cost, or benefits.

What to do if you think you've been injured

It is unlikely that you would be injured or physically harmed by study procedures. If you think you have been harmed because of this study:

- Please call one of the researchers listed on page 1 of this form, who will refer you for appropriate treatment.
- Treatment for any physical harm related to this study will be paid by Kaiser Permanente to the extent of your Kaiser Permanente plan coverage as long as you are still an enrolled member. You would still be responsible for any deductible, co-pay, or co-insurance costs required by your health plan. No money has been set aside to pay for things like lost wages, lost time, or pain as a result of this study. However, you do not waive any rights by signing this consent form.
- Treatment for any physical harm related to this study will be paid for by the University of Washington (UW) Compensation Plan, if appropriate and within the plan's limits.

Being in this study won't help you personally

- We don't expect being in this study to help you personally because it does not provide treatment. But some people feel good when they help with research like this.
- You might learn about problems with your memory or thinking abilities that you did not know about before. You will also receive helpful information about memory and aging at different times during the study such as study newsletters.
- 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 certain diseases.

- We don't plan to use this research to make money. Other researchers may use your information from your blood sample to develop and sell new products. If this happens, there are no plans for you to receive any of the profits.

You do not have to be in this study

Being in this study is up to you. You do not have to participate. If you say yes, you can leave the study at any time. There will be no penalty for saying no now or for leaving the study later, and this would not affect your health care or benefits at Kaiser Permanente.

To leave the study, call the study line at 206-442-5228 or toll free at 1-877-879-8757. You can also write to:

Eric B. Larson, MD, MPH, Principal Investigator
Kaiser Permanente Washington Health Research Institute
1730 Minor Avenue Suite 1600
Seattle, WA 98101

If you decide to leave the study:

- We will review your medical record to collect your health history at Kaiser Permanente up until 90 days after your withdrawal date from the study.
- We will keep any information about you that we have already collected.
- We will keep your blood sample in a facility approved by Kaiser Permanente, unless you specifically ask us to remove it.
- If your data are already in a national databank, we may not be able to have the information removed.

Your alternatives to study participation

You do not have to be in this study to receive care. If you have questions about your memory, genetics, or health in general, please ask your doctor. Your doctor will still care for you as usual whether you join this study or not.

Your rights under HIPAA

Your health information at Kaiser Permanente is protected by a federal privacy law called HIPAA. Kaiser Permanente must follow this privacy law, which says that information we collect in this study is part of your protected health information. HIPAA requires that we tell you the following:

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

- Answers to questions from ACT research surveys, including health history and memory testing
- All information from your medical record, such as lab test results, prescribed medications, mental health information, alcohol use, medical history / treatment, doctor appointments, pathology reports, radiology exams including MRIs and x-rays, etc.
- Your blood sample and your DNA from the sample

Researchers who use your health information may share it with certain people according to existing privacy laws. The HIPAA privacy act does not always require researchers or other people who receive your information to keep the information confidential. After your information has been given to others who do not work for Kaiser Permanente, there is a risk that it could be shared without your permission.

Unless you take back your consent, your permission to use your health information from this study will not expire.

Who to call with questions

- If you have a question about your rights as a study participant, please call the Kaiser Permanente Human Subjects Review Office at 206-287-2919.
- If you have questions or concerns about this study, please call the study line at 206-442-5228 or toll free, 1-877-879-8757.

Signature of study staff obtaining consent

Date

Printed name of study staff obtaining consent

If you decide to be in the ACT study, you will need to sign this form. You will also need to mark your choices about:

- Wearing physical activity monitors for one week.
- Having your blood drawn

- How the researchers may share your blood and study information
- Whether you want to be contacted about future research.

SUBJECT'S STATEMENT

This study has been explained to me. I volunteer to take part in this research.
If I change my mind later, I may leave the study at any time.

I've had a chance to ask questions, and they've been answered to my satisfaction.

I give permission to the researchers to use my medical records as described in this consent form, including information on mental health and alcohol use.

If I am unable to provide information for this study in the future, a family member or close friend will be contacted by the study staff to do this for me.

If I have more questions later, I may call the researchers listed on this form or their staff. I will get a copy of this form to keep.

Signature

Date

Please **PRINT** your name

Wearing the Physical Activity Monitors

We may ask you to wear physical activity monitors for one week and complete a questionnaire. You may still take part in the ACT study even if you do not want to wear the monitors. Please mark your choice with your initials:

I **do choose** to wear the Actigraph (**worn around waist**) as described above.

I **do choose** to wear the activPAL (**worn on thigh**) as described above.

I **do not choose** to wear the Actigraph (**worn around waist**).

I **do not choose** to wear the activPAL (**worn on thigh**).

Blood Collection, Storage and Use

We are asking you to let us draw your blood and store it indefinitely in a facility approved by Kaiser Permanente. The blood sample, genetic data, and other study information we collect may be shared with other research partners to be used in studies related to aging and health, and diseases or other conditions.

You may still take part in the ACT study even if you do not want us to draw your blood. Please mark your choice with your initials:

I give permission for you to draw my blood and use it as described above.

I **do not** give permission for you to draw my blood.

National Institutes of Health and other genetic information databanks

If you agree to the blood draw, we are asking your permission to put genetic information from your blood sample and some of your health information in the National Institutes of Health databank and other centralized databanks, to be used

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in future research on many diseases or conditions. We will not give your name or Kaiser Permanente number to the databanks.

The information would be kept in the databanks indefinitely. Other researchers may use the information, and they will have access to your genetic test results and other information about you to use in research studies.

You may choose not to let us give your information to the national databanks and still take part in the ACT study. Please mark your choice with your initials:

_____ I give permission for you to put my genetic test results and health information in the National Institutes of Health genetic databank and other centralized genetics databanks.

_____ *I do not* give permission for you to put my genetic test results and health information in the National Institutes of Health genetic databank or other centralized genetics databanks.

Contact for future research

May we contact you about future research studies? Please initial your choice:

_____ Yes, you may contact me about participating in future research.

_____ No, *do not* contact me about future research.