Kaiser Permanente Washington
Health Research Institute

Adult Changes in Thought (ACT) Study Consent Form

If you have any questions or need to reach the study team, call our study voicemail at **206-442-5228** or toll-free at **1-877-879-8757.**

Who is doing this study?

The following organizations are working together on this research project:

Kaiser Permanente Washington Health Research Institute

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University of Toronto: Janelle Taylor, PhD

University of Wisconsin: Qiongshi Lu, PhD

The Trustees of the University of Pennsylvania: Norma Coe, PhD

Key Information:

We are asking you to take part in a research study called **A**dult **C**hanges in **T**hought (ACT). The study is about aging and memory changes as people age. Please read the information in this entire form before agreeing to join the study. Please take as much time as you need to read through this information and make your choice. Ask questions if anything isn't clear or if you would like more information.

You do not have to be in this study. If you say yes, you can quit the study at any time. Saying no now or leaving the study later won't affect your health care or benefits at Kaiser Permanente.

If you decide to join the study, we will ask you to attend a study visit every two years and complete an interview that will last about 2.5 to 3 hours. We will also ask you to complete surveys at home. We may ask you to complete a blood draw, and wear 2 activity monitors. You can still be in the study if you choose not to participate in these activities.

There are some risks if you join the study. You might feel uncomfortable answering some study questions. When you have blood drawn, you may feel brief pain or have some bruising from the needle. Being in the study will not help you, but may help older adults who experience memory changes in the future.

What is this study about? The Adult Changes in Thought study is about aging and memory changes. 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.

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 are one of thousands of Kaiser Permanente members aged 65 and older chosen at random to participate. This means we picked your name by chance - like drawing it out of a hat.

What will happen if I take part in this study?

If you join the study, we will ask you to:

- **Take part in study visits.** We will ask you to complete the first/initial study visit today, and then attend follow-up visits every 2 years for as long as you are in the study. These follow up visits may take place by, in a clinic, in your home, or a location of your choice. You will receive $50 after completing each visit.
- **Complete surveys at home.** We will ask you to take home a survey to complete and return in a pre-paid envelope. This survey will ask questions about your physical activity, sleep patterns, diet, and quality of life. Some of the questions include sensitive topics, such as depression and mood. We may also mail you a survey in the future that asks questions about your childhood environment, the neighborhood you grew up in, education, and employment history. Some of the questions are on sensitive topics such as

drug use. You can skip any questions you don't want to answer. We may also ask you to complete other forms at home if we do not have time to complete them during the visit.

- **Provide contact information.** We will ask you for contact information of one or two close friends or family members, and/or a legally authorized representative, if you have one.
    - We may ask your contacts about your living situation, health, memory, and thinking abilities.
    - If you experience memory changes in the future, we may ask your legally authorized representative to provide consent for new research activities, with your assent (assent is the agreement of someone not able to give legal consent to take part in a research study).
- **More testing**. If test scores and information collected during a study visit suggest that there may be significant changes or problems with your memory or thinking abilities, we will ask you to complete more testing. Usually, this testing takes place in your home.

  If more testing is needed, we will ask you to:
    - Meet with a study doctor or nurse, and a study staff member. They will review the changes in your memory and conduct more cognitive tests and a neurological exam. We may send a summary of your test results to your doctor.
    - After the testing, we may ask you to take part in yearly visits.

Additionally, we will:

- **Collect information from your Kaiser Permanente medical record.** Study staff will review your medical record and collect information from it. This will include information on your medical history and treatment such as diagnoses, lab test results, medications and prescriptions, pathology reports, radiology exams including MRIs and x-rays, doctor visits and notes, 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.
- **Collect information from your address history.** We will use your addresses to learn about the neighborhoods you grew up in.
- **Collect public records.** We will merge data you provide as part of this study with publicly available records, such as Census data. This will help us look at exposures across the life course in our population.
- **Ask if you would be willing to take part in other studies related to the ACT study now or in the future.** We will tell you about additional studies that ACT is conducting now. These studies are optional and will involve additional consent or assent from you. Volunteering for these other ACT-

related research activities will not change your participation in the main ACT study.

Optional Activities: We may ask you to participate in the following additional activities. You can still participate in the study if you choose not to participate in these activities:

- **Have some blood drawn.** If you are willing, we will draw your blood and use your DNA in this study and in future genetic research. You will receive $25 for providing a blood sample.
    - We will use the blood samples we collect to look for genetic traits that affect people's health as they age. Genetic traits may partly explain why some people are more likely to get diseases related to aging, such as Alzheimer's.
    - No one at the research labs that test the blood samples will have any information about you. Your name will not be written anywhere on your sample. Instead, all samples will be labeled 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. Cell lines are copies of parts of your blood that allow more material for testing. Researchers may extract DNA from your sample to find differences among individuals or populations to understand causes of genetic diseases. You can find more information under the **'Using your data and biospecimens in future research'** section below.
    - If you agree to a blood draw now, you can 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.**
- **Wear 2 monitors.** If you are willing, study staff may ask you to wear 2 small, lightweight monitors (ActivPAL and ActiWatch). The ActivPAL is worn with a mild adhesive gel or special tape dressing on the front of your thigh. The ActiWatch is worn on your non-dominant wrist like a watch**.** We will mail you $15 in cash each time you wear and return a monitor. We will ask you to:
    - **Wear both monitors for one week** and go about your normal routine, unless bathing or swimming. The monitors do not tell us what specific activities you are doing or where you are. They give us summary information on the total amounts of physical activity you do.
    - **Complete a sleep log.** We will ask you to record the time you woke up and went to sleep on a paper log for one week.
    - **Return monitors and sleep log.** After you wear the monitors for one week, we will ask you to mail the 2 monitors and sleep log back in a pre-paid envelope we will give you. Monitors will be tracked using a number only. No personal information will be connected to your monitors.

What will happen in my study visits?

Your first study visit will last about 2-3 hours. This visit is to find out if the study is a good fit for you. During the visit, we will ask you to:

- Answer some questions about you and your health history, check your height and weight, and how well you can move around.
- Complete tasks that measure your thinking and problem-solving abilities, including memory quizzes. Some examples are remembering words, subtracting numbers, and copying drawings.

If you agree, we may ask you to:

- Allow us to draw a small amount, approximately 3 tablespoons, of blood from a vein in your arm.
- Wear 2 lightweight activity and sleep monitors for 1 week after your visit.

If we find that you do not meet the study entry criteria, you will not be enrolled in the ACT study. We will destroy all the information we collected about you, including your blood sample. No follow-up visits will be needed.

If you **do** meet the study entry criteria and agree to take part in the study, you will have a scheduled follow-up visit every 2 years for as long as the ACT study continues, and for as long as you choose to be in the study.

If you cannot come to a research clinic location for these visits, study staff can come to your home or complete the visit remotely by phone.

During the follow-up visits, which will last about 1.5 to 2 hours, we may ask you to:

- Do similar tasks to today's visit, and answer questions about your health or living situation since your last visit.
- Do some extra tests as described above, depending on your test results.
- Complete some surveys at home and mail them back in a pre-paid envelope. You may skip any questions you don't want to answer.

If you are willing:

- Give another blood sample.
- Wear the physical activity and sleep monitors again for one week after your visit.
- Consider participating in other related activities.

Will there be any costs to me?

There will be no cost to you. We will pay for parking for your study visit. If you do not want to drive, we will arrange and pay for a taxi or rideshare service or mail you a round trip bus ticket if you prefer.

Will being in this study help me?

- We don't expect being in this study to help you personally because the study is not offering any 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 from materials 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.

Using your data and biospecimens in future research

Your data will be used by the researchers on this form and their staff to conduct research related to this grant.

Additionally, as part of this grant, your study information will be added to the ACT Repository and stored indefinitely. A repository is a collection of information and blood, or tissue samples used for medical research.

- The ACT Repository is run by ACT study researchers. Data storage and sharing are overseen by study staff at Kaiser Permanente Washington. Data and samples are stored in facilities approved by Kaiser Permanente Washington.
- As part of the Repository activities, we will share your study information with researchers at other institutions. Data we share will be coded and will not contain your name or other identifiers.
- Researchers who want to get data or specimens from the ACT study must first complete a proposal form and get approval from ACT researchers. Then, they must sign a data use agreement and pledge to keep study information private.
- We will share the minimum amount of information possible for research to be conducted. In almost all cases, we will not share your name or other identifiable information about you. In some cases, for example, if you agree to be contacted for future ACT-related research, we may share personal identifiers such as your name, date of birth, and phone number. We will only share identifiable information with researchers on ACT-related studies that have been reviewed and approved by ACT researchers. An ACT researcher will always be involved in studies where identifiable information is shared in order to ensure the protection of your confidentiality.
- By signing this form, you are agreeing to allow your data to be used broadly for research purposes.

If you agree to give us a blood sample, we will store it indefinitely in the ACT Repository.

- Your samples will be stored in a facility approved by Kaiser Permanente Washington.
- Your blood sample and other genetic information collected by the study will be

shared with other researchers for studies related to aging, health, and other medical conditions or diseases.

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.

The National Institutes of Health (NIH) has developed data (information) banks that collect study data. The NIH will store your de-identified information in these data banks for other researchers to use in future studies on aging, health, and other medical conditions or disease. The researchers could be from government, academic, or commercial institutions 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 withdraw your consent any time you don't want your data in the NIH data banks. There will be no consequences for withdrawing consent. However, data that has already been sent to researchers cannot be retrieved.
- You will not receive any results from allowing your data to be placed in the NIH data banks.
- **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.**

Can anything bad happen to me from being in this study?

- You might feel uncomfortable answering some study questions. You may skip any questions you don’t want to answer.
- Despite the precautions we have in place, it’s possible that someone other than a researcher could find out you were in the study or see your private health information.
- You may experience local skin irritation from the monitor (activPAL) attached to the thigh. If this occurs, you can discontinue use or try a different attachment method.

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.
- Despite the precautions we have in place 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 possibly affect your ability to get or keep some kinds of insurance. 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 may 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 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.

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, it is important that you promptly tell the researchers.

- Please call Dr. Linda McEvoy or the study phone number listed on the top of this form, and she will refer you for proper 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 if 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.

How will you protect my confidentiality?

This study is being done by researchers at KP Washington, the University of Washington, and the other research institutions listed on the first page of this form. These researchers sign a pledge at their institution that requires them to keep your information private.

The researchers listed on the first page and their staff will use your study information for research only. We will not use your name in study reports or write it on your blood samples. 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 will not add information to your medical record.

We have a Federal Certificate of Confidentiality from the National Institutes of Health. This helps us protect your privacy. The Certificate means that we do not have to give out identifying information about you even if we are asked to by a court of law. We will use the Certificate to resist any demands for identifying information, except as explained below.

The Certificate cannot be used to resist a demand for information for personnel of the US Government that is used to auditing or evaluation of federally funded projects.

A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information. It also does not prevent the research team from disclosing information for public health reporting purposes.

There are some limits to this protection. We will voluntarily provide the information to:

- a member of the federal government who needs it in order to audit or evaluate the research.
- individuals at KP Washington Health Research Institute, the funding agency, and other groups involved in the research, if they need the information to make sure the research is being done correctly.
- KP Washington IRB – The IRB may look at and/or copy your research records to evaluate the conduct of the study.
- Local authorities - if we learn of elder abuse, or the intent to harm yourself or others, we must report that to the authorities.

How does HIPAA apply to this study?

Your health information is protected by a federal privacy law called HIPAA. KP Washington 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 KP Washington permission to allow the researchers to collect, use, and share the following information about you for this study:

1. Your survey answers to questions, including health history and memory testing.
2. Your medical record information as described above.
3. Your blood and DNA and results from your blood test.

It is possible that staff from KP 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 allowed by law, and as described above in the section on using your data and biospecimens in future research.

Once your information has been given to others, it may no longer be protected by state or federal privacy laws. It will be protected by other rules and agreements with the recipients. However, there is still a risk that a recipient could share your information without your permission.

In order to be in the study, you must agree to this use of your health information. Unless you take back your consent, your permission for researchers to obtain and use your health information from this study will not expire.

Do I 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.

What happens if I say yes, but change my mind later?

You may change your mind any time about letting us use your information for this study. If you take back your consent, it will not affect your health care or benefits at KP Washington.

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

Linda McEvoy, PHD, Lead researcher
Kaiser Permanente Washington
Health Research Institute
1730 Minor Ave, Suite 1600
Seattle, WA 98101

If you decide to leave the study:

- We will keep any information about you that we have already collected.
- We will ask if we can continue to review your medical record to collect your health history at Kaiser Permanente until you die. If you do not agree, we will review your medical record for up to 90 days after your withdrawal date from the study.
- 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.

Who do I call if I have questions?

- 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.**
- If you have a question about your rights as a research participant, please call the KP Washington Human Subjects Review Office at 206-287-2919.

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 and sleep monitors for one week.
- Having your blood drawn.
- How the researchers may share your blood and study information; and
- Whether you are willing 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

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 initial your choice:

_____ 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 databanks

We are asking your permission to put genetic information from your blood sample (if you provided one) and some of your health information in the National Institutes of Health databank and other centralized databanks, to be used 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 initial your choice:

______ 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.

Wearing the Physical Activity and Sleep Monitors

We may ask you to wear physical activity monitors for one week and complete a sleep log. You may still take part in the ACT study even if you do not want to wear the monitors.

Please initial your choice:

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

_____ I **do choose** to wear the ActiWatch (**worn on wrist**) as described above.

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

_____ I ***do not*** **choose** to wear the ActiWatch (**worn on wrist**).

May we contact you about other research studies related to the ACT study now or in the future?

Please initial your choice:

______ Yes, you may contact me about opportunities to participate in future research.

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

For office use only:

________________________________ ___________

Signature of study staff obtaining consent Date

____

Printed name of study staff obtaining consent