



Kaiser Permanente Washington
Health Research Institute

Investigational Vaccine Trial Registry



The Kaiser Permanente Washington vaccine research group was the first in the world to enroll participants in a clinical trial of a COVID-19 vaccine. Our vaccine program has also included trials of vaccines against diseases such as malaria, schistosomiasis, mpox, and influenza. We expect to start other trials of vaccines in the coming months and years.

To identify people who may be interested in taking part in this research, we have created a registry of individuals (both adults and children) who'd like to be contacted about future vaccine trials.

If you are interested in joining the registry, or are a parent or guardian interested in having your child or children join the registry, please read the information below to learn more. Then, if you would like to join the registry, click the link near the bottom of this page to complete a survey.

Investigational Vaccine Trial Registry Consent

What is the purpose of this registry?

The registry is for people who are interested in receiving information about future clinical trials of investigational vaccines. An investigational vaccine is a vaccine that has been approved for testing in people but is not yet licensed by the U.S. Food and Drug Administration (FDA).

Trials of investigational vaccines often need to enroll many people in a short period of time. To help with recruitment, we are keeping a registry of people who live in the greater Seattle area and are interested in potentially taking part in these trials.

Lisa Jackson, MD, MPH, will be the lead researcher for any upcoming vaccine trials. She is a senior investigator with Kaiser Permanente Washington Health Research Institute (KPWHRI).

Who can be in the registry?

Both adults and children who:

- Are in good health or have stable medical conditions
- Live in the greater Seattle area
- Are able to travel (with a parent or guardian, for children) to the KPWHRI research clinic in downtown Seattle for multiple study visits
- You or your child do not have to be a Kaiser Permanente member to take part in this registry.
- If you or your child are a Kaiser Permanente member, taking part will not affect your care or benefits. You are free to decide not to participate now, or to remove yourself or your child from the registry at any time later. Either way, there will be no penalty. Your decision won't affect the health care you receive or the benefits that you or your child are entitled to.

How do I join the registry?

- If you are interested in joining the registry or adding your child to the registry after reading this page, please click the survey link below. The survey will ask for general information about you or your child, such as

date of birth. It will also ask questions about your or your child's general health and medications.

- These questions will help us determine whether you or your child are likely to be eligible for a clinical trial of an investigational vaccine.
- Some of the questions ask for personal information. If you start filling out the survey and decide you want to stop, you do not have to submit your information.
- If you would like to enter more than one person into the registry (for example a parent and child), please complete a separate survey for each person.

What will happen if I join the registry?

- If you are an adult, we will keep your survey responses for as long as the registry is active. If you have enrolled a child, we will keep their survey responses until they turn 18. At that time, they can rejoin as an adult if they would like to do so. We can delete responses anytime by request.
- If we begin a clinical trial of an investigational vaccine while you or your child are in the registry, we may contact you by phone or email to tell you more about that trial and see if you are interested in taking part. If you or your child are a member of Kaiser Permanente, we may also review your electronic medical record to clarify your survey answers or gather more information.
 - If we review your or your child's medical record, we may look at health information from the date you or your child became a Kaiser

Permanente member for as long as the registry is active, or until you or your child ask to be removed from the registry.

- Your and your child's health information is protected by a federal privacy law, called HIPAA, that we must follow. Information that we collect and review for the registry is part of that protected health information. By joining the registry or adding your child to the registry, you are giving us permission to collect and review your or your child's health information as described above.
- Records of your or your child's participation in the registry will be kept confidential except when sharing the information as required by law. The lead researcher will be able to inspect and copy confidential registry-related records that identify you or your child by name. Under certain circumstances, the FDA and our Institutional Review Board (IRB) will also be able to inspect and copy these records. This means that absolute confidentiality cannot be guaranteed. The IRB is a committee that makes sure studies protect the rights and welfare of study participants.
- If you are contacted about taking part in a vaccine trial please be aware:
 - Clinical trial visits will be held at the KPWHRI research clinic in the Metropolitan Park East building in downtown Seattle, near I-5.
 - Vaccine clinical trials typically involve multiple blood draws.
 - Vaccine clinical trials may involve a placebo (an inactive substance). If that is the case, some participants in the trial will receive the investigational vaccine, and others will receive a placebo.
- Being in the registry does not mean you or your child will be eligible to or committed to take part in any future trial.
- You or your child will not benefit personally from taking part in this registry.

- There will be no costs or compensation if you choose to take part in this registry or to enter your child into the registry.
- While you or your child are in the registry, please contact us at 206-287-2061 if you have questions, concerns, or complaints about the registry.
- If you have questions about your or your child's rights as a research participant, contact the Kaiser Permanente interregional IRB by phone at (951) 739-6781 or by email at KPinterregionalIRB@kp.org.

I am interested in joining or adding my child to the registry. What should I do next?

If you would like to join or add your child to the registry, and you agree to have your information or your child's stored as described above, please:

[click here to complete a survey.](#)

Where can I find more information about taking part in clinical trials?

Visit [Learn about Studies](#) on ClinicalTrials.gov, which is part of the National Institutes of Health.

Click [here](#) to download this page for your records

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