Kaiser Permanente Washington Health Research Institute

COVID-19 Vaccine Trial Registry Consent

Kaiser Permanente Washington Health Research Institute (KPWHRI) has created a registry for people who are interested in taking part in future clinical trials of investigational vaccines for the 2019 novel coronavirus, SARS-CoV-2, which causes COVID-19. To learn more about the registry, please read the information below. Then, if you would like to join, click the link near the bottom of this page to complete a survey.

What is the purpose of this registry?

Upcoming investigational coronavirus vaccine trials will likely need to enroll many people in a short period of time. To help with recruitment for these trials, we are keeping a registry of people who live in the greater Seattle area and are interested in taking part in an investigational vaccine trial.

Lisa Jackson, MD, MPH, a KPWHRI senior investigator, will be the lead researcher for any upcoming vaccine trials.

Who can be in the registry?

- People who are 18 years and older.
- People in good health, or with stable medical conditions, who live in the greater Seattle area.
- People who can travel to the KPWHRI research clinic in downtown Seattle for multiple study visits.

What will happen if I join the registry?

- If you are interested in joining the registry after reading this page, please click the survey link below. The survey will ask for general information about you. It will also ask about your current and past health and medications and your line of work. The survey includes sensitive questions.
  - These questions will help us determine whether you 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.
- We will keep your survey responses for up to 5 years. After a maximum of 5 years, your responses will be deleted. We can also delete your responses anytime at your request.
- We may contact you by phone or email and/or review your electronic medical record (if you are a Kaiser Permanente member) to clarify or gather more information about your survey answers.
  - If we review your medical record, we may look at your health information from the date you became a Kaiser member until 5 years from the date you join the registry.
  - Your 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, you are giving us permission to collect and review your health information as described above.
- Records of your participation in the registry will be held confidential except when sharing the information as required by law. The investigator and under certain circumstances, the United States Food and Drug Administration (FDA) and the Institutional Review Board (IRB), will be able to inspect and copy confidential registry-related records which identify you by name. This means that absolute confidentiality cannot be guaranteed.
- If we begin a clinical trial of an investigational coronavirus vaccine while you 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. Please be aware:
  - Clinical trial visits will be held at the KPWHRI research clinic in the Metropolitan Park East building, near I-5 in downtown Seattle.
  - Vaccine clinical trials typically involve multiple blood draws.
  - Vaccine clinical trials typically involve a placebo (an inactive substance). Some people in the trial will receive the investigational vaccine, and others will receive a placebo.
  - Being in the registry does not mean you’ll be eligible to or committed to take part in any specific future trial.
  - You do not have to be a Kaiser Permanente member to participate in this registry, but if you are a member, participation will not affect your care or your benefits. You are free to say no now or to leave the registry 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.
  - You will not benefit personally as a result of your participation in this registry.
  - There will be no costs or compensation if you choose to take part in this registry.

https://corona.kpwashingtonresearch.org
While you are in the registry, if you have questions, concerns, or complaints about the registry, please contact us at 206-287-2061. If you have questions about your rights as a research subject, and/or concerns or complaints regarding this registry, contact Advarra IRB at 877-992-4724 or by email at advisor@advarra.com.

What should I do if I am interested in joining the registry?

If you want to join the registry and agree to have your information stored as described above, please click here to complete a survey.

Where can I find more information on the SARS-CoV-2, the virus that causes COVID-19?

- Coronavirus (COVID-19) how to protect yourself, and what to do if you are sick: https://www.cdc.gov/coronavirus/2019-ncov/index.html
- Coronavirus (COVID-19) pandemic public advice, and country and technical guidance: https://www.who.int/emergencies/diseases/novel-coronavirus-2019

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