What is the purpose of this registry?

Investigational COVID-19 vaccine trials will likely need to enroll many people within a short 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 investigational vaccine trials.

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

To learn more about the registry, please read the information below. Then, if you would like to add your child (age 17 years or younger) to the registry, click the link near the bottom of this page to complete a survey to provide some information about your child. If you would like to have more than one child in the registry, please submit a separate survey for each child.

What children can be in the registry?

Children under 18, 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 to the KPWHRI research clinic in downtown Seattle for multiple study visits

What will happen if I add my child to the registry?

- If you are interested in adding a child to the registry after reading this page, please click the survey link below. The survey will ask for your contact information and for information about your child, including date of birth, general health, and medications. The survey includes sensitive questions.
  - These questions will help us determine whether your child is 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 have more than one child that you would like to be in the registry, please complete the survey for each child.
- 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 child’s electronic health record (if your child is a Kaiser Permanente member) to clarify or gather more information about your survey answers.
  - If we review your child’s Kaiser Permanente health record, we may look at your child’s health information from the date your child became a Kaiser Permanente member until 5 years from the date you added your child to the registry.
  - 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 adding your child to the registry, you are giving us permission to collect and review your child’s health information as described above.
- Records of your child’s participation in the registry will be held confidential except when sharing the information as required by law. The lead researcher, 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 that identify you and your child by name. This means that absolute confidentiality cannot be guaranteed.
- If we begin a clinical trial of an investigational COVID-19 vaccine that includes children while your child is 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 your child 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 may involve a placebo (an inactive substance). If that is the case, some children in the trial will receive the investigational vaccine, and others will receive a placebo.

https://corona.kpwashingtonresearch.org/phase3-child.htm
• Being in the registry does not mean your child will be eligible to or committed to take part in any specific future trial.
• Your child does not have to be a Kaiser Permanente member to participate in this registry. If your child is a member, joining the registry will not affect your child's care or benefits. Participation is completely voluntary. You are free to decide not to participate now or to remove 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 benefits that you and your child are entitled to.
• You or your child will not benefit personally as a result of your child's participation in this registry.
• There will be no costs or compensation if you choose to have your child entered in this registry.
• While your child is 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 child's 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 adding my child to the registry?

If you would like to add your child to the registry and agree to have your child's information stored as described above, please click here to complete a survey.

It’s important that parents and guardians submit a separate survey for each child they want included in the registry. Some COVID-19 vaccine trials may only include children of certain ages. You would only be contacted if your child might be eligible for a specific trial.

As a reminder, people 18 and older who have not already submitted their own information to the registry, may also take part as described here.

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

• Centers for Disease Control and Prevention
  Coronavirus (COVID-19): How to protect yourself, and what to do if you are sick

• World Health Organization
  Coronavirus (COVID-19) pandemic: Public advice, and country and technical guidance

Click here to download this page for your records

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