Participate in Research

Help us answer questions about childhood health and illness, and help other children in the future.
Why Participate in Research?

At Seattle Children’s, our researchers want to improve care and the quality of life for children now and in the future.

To do this, we need help from the most important specialists of kids’ health – your child and family. Research studies need volunteers of all ages, genders, races and ethnic groups. Some studies need people with a specific condition. Other studies need volunteers who do not have any known medical conditions.

While some participants might not directly benefit from being in a research study, they might choose to volunteer because they:

- Want to help others by contributing to medical knowledge
- Have an illness or disease that has no effective treatment. Some studies offer experimental medications or treatments before they become available to the public. These medications or treatments are being studied to see how well they work and to make sure they are safe.
What is clinical research?
Clinical research helps doctors and researchers find new and better ways to understand, detect, control and treat illness and other medical conditions.

Clinical research involves carefully planned studies that people volunteer to take part in. They help researchers learn more about health and find new medications and treatments. There are 2 main types of studies:

- **Interventional studies** (also called clinical trials) test new medicines and treatments in people to see how well they work and to make sure they are safe.
- **Observational studies** collect information about health and behavior. This is done through surveys, interviews or observing study participants over time.

Who conducts research studies?
Every study has a lead researcher called a principal investigator (PI), who is often a medical doctor. They oversee the research study. Some studies also have a research team that might include doctors, nurses, social workers, research coordinators and other healthcare professionals. The PI and research team closely monitor a participant’s health throughout the study.

How is research different from regular medical care?

Taking part in research can look a lot like the regular medical care your child receives at a doctor’s office, clinic or hospital. Sometimes doctors also do research. It is important to talk with your doctor and the research team about the differences between the research and your child’s regular medical care.

In medical care, the doctor or your care team develops a plan of care tailored for your child.

When your child takes part in a study, the research team follows a set plan called a study protocol.

The goal of research is to add to medical knowledge that might lead to improved treatments for children in the future. Your child might or might not benefit directly from being in a research study.
Are there risks to participating in a study?
Safety is our main priority at Seattle Children’s. All studies follow strict regulations and guidelines:

• Studies must be approved by an institutional review board (IRB).
• The U.S. Food and Drug Administration (FDA) must approve the design of a study before any new medicine, treatment or device is tested with people.

Before your child joins a study, the research team will explain any risks of participating. The potential risks and potential benefits are listed on the consent and assent documents that you and your child will review with someone from the research team before joining a study.

What if we decide to take part and then change our minds?
Being in a study is voluntary. Your child can stop participating in a study at any time without it affecting your regular medical care at Seattle Children’s.

You might be asked to fill out a survey to share why you decided to stop taking part in the study. Filling out the survey is voluntary.

Does my child still see their regular doctor while in a study?
Yes. Your child will go to any scheduled medical appointments while in a study.

It’s important to tell your child’s doctor that your child is in a research study. Ask your doctor to talk with the researcher team to make sure there is no conflict with the medicines or treatments your child is currently taking.

Tips For Talking With Your Research Team

• Bring someone with you to the appointment for support and to help ask questions.
• Write down your questions before the visit and bring them with you. Don’t be afraid to ask the same question more than once until you feel your question has been answered.
• Take notes. This way you can review them whenever you want.
• Find out who to contact in case you have questions later.
• If your child seems to be having trouble understanding information about the study, ask about other ways we could present the information. We might be able to use videos or other visual aids.
• Ask for a language interpreter before or during your visit if you feel it would help you understand information better. A research team member can help arrange this.

How do I find out about current research studies at Seattle Children’s?
Visit seattlechildrens.org/research-participate.
Questions to Ask

Here are some questions you might consider asking before your child joins a research study.

About the Study

☐ Why are researchers doing this study? What do they hope to learn?
☐ Is there previous research on this medicine or treatment?
☐ Has the U.S. Food and Drug Administration (FDA) approved the medicine or treatment for use with people?
☐ Why do researchers think this might work?
☐ What are our responsibilities if my child takes part?
☐ Could being in this study affect my child’s daily life or that of my family?
☐ How long will the study last?
☐ Who will be responsible for my child’s medical care during the study?
☐ What kinds of procedures or tests will my child have during the study?
☐ Who do I contact if I have questions before, during and after the study?
☐ What happens if we want to stop being in the study?
☐ Can my child participate in more than one study at a time?

Benefits and Risks

☐ What are the possible benefits of being in this research study?
☐ What are possible side effects or risks?
☐ What if my child’s health gets worse during the study?

Privacy and Rights

☐ How will my child’s health information be kept private?
☐ Who will have access to my child’s information?
☐ Can I tell people about the study?
☐ Will the study results be given to us? If so, how and when?

Costs

☐ Do we get paid for participating?
☐ Are any personal costs such as meals or transportation paid for?
☐ What will we have to pay for?
☐ Who pays the medical bills if my child is injured by the medicine or treatment that is being studied?
Helpful Terms to Know

**Assent:** Children give assent when they agree to take part in research. Children who are old enough to express that they want to be in a study sign an assent form or give verbal assent. Most children age 7 or older can understand basic information about research studies.

**Banking or storing samples:** Sometimes information or samples from study participants are stored for researchers to use in future studies. Researchers sometimes share information or samples with other study teams.

**Consent (or parental permission):** Parents/guardians give permission when they agree their child can take part in research. Parents/guardians sign a consent form to confirm that they understand the study and give permission for their child to participate.

**Clinical trials:** Research studies that explore if a medication, treatment or medical device is safe and effective for people.

**Epidemiology:** A branch of research that looks at patterns of illness and disease in groups of people. It tries to identify the causes of disease.

**Inclusion/exclusion criteria:** Each study has a list of requirements of who can and cannot participate. The items that allow someone to participate in a study are called inclusion criteria. The factors that do not allow someone to participate are called exclusion criteria.

For example, a study may need participants ages 3 to 7 who have had chickenpox. This would be the inclusion criteria for the study. The exclusion criteria would be:

- Children younger than 3
- Children older than 7
- Children who have not had chickenpox

People who match the exclusion criteria are not considered for participation in the study.

**Informed consent:** A process you and your child go through before joining a research study. This is to make sure you both understand the study’s purpose, benefits, risks and other options.

**Institutional review board (IRB):** A group of people that might include doctors, researchers, patient support groups, pharmacists and other experts who review and approve research studies before they begin.

**Placebo:** A pill or liquid that looks like the medicine used in the study but does not treat anything. Placebos are used during studies to help researchers understand the effect a medicine or treatment might have. Researchers compare the effects of the medicine and the placebo in the study. That way, they can determine the effectiveness of the new medicine and check for side effects.

**Protocol:** A carefully designed plan to keep study participants safe and answer specific research questions.

**Principal investigator (PI):** The person in charge of the study. A PI is often a medical doctor.

**Randomization:** The process by which study participants are assigned to different study groups by random chance (similar to flipping a coin or pulling a name out of a hat). Sometimes, the participant and research team do not know what study group the participant is assigned to, but they are able find out what group was assigned if they ever need to know for safety reasons.
Research coordinator: A person who works with the principal investigator and helps run the study. At Seattle Children’s, this person is called a clinical research associate (CRA).

Single-blinded and double-blinded studies: In single-blinded studies, participants do not know if they are getting the study medicine or treatment or if they are getting placebo, but the research team does.

In double-blinded studies, participants and the research team do not know if participants are getting the study medicine or treatment or if they are getting placebo.

Notes