What questions should I ask before I agree to take part in a research study?

If you have concerns about participating in a research study, be sure to express them. The following is a list of important questions.

- How long does the study last? How often and how long are the appointments?
- Are there potential risks or side effects?
- What are the benefits? What if I receive a placebo (a harmless pill that does not contain the medicine)?
- Who is conducting the study and who is funding the study?
- How will my privacy be protected? Who will have access to my records? Where will my information be stored?
- Will my identity be kept anonymous, or will my "personally identifiable information" such as my address, phone number, social security number, etc., be recorded?
- What if I no longer want to participate? How do I withdraw from the study?
- What tests will be done? Will I be told the results?
- Will I get paid for my time and/or my travel expenses?
- What will happen to me at the end of the study?
- Whom do I contact if I have more questions later?
- How long will you store my health data and specimens? What other research will you perform on my data and samples?

For more information on volunteering for a study at CHLA, visit our website:

CHLA.org/ResearchStudies

For copies of this brochure contact:
Clinical Research Support Office
Shannen Nelson, Director
shnelson@chla.usc.edu | Phone: 323-361-8685

To report a complaint, concern or violation:
Human Subjects Protection Program
Phone: 323-361-1846

Additional information on the CHLA Human Subjects Protection Program and the IRB:
CHLA.org/Human-Subjects-Protection-Program-hspp

To find clinical trials at the Children's Center for Cancer and Blood Diseases, visit:
CHLA.org/CANCER

Sign up to find studies for which you may be a match:
researchmatch.org

More info about federally and privately funded research:
clinicaltrials.gov

Adapted from the U.S. Department of Health & Human Services, Office for Human Research Protections: Becoming a Research Volunteer
hhs.gov/ohrp/education-and-outreach/learn-about-research/brochures/index.html

Children's Hospital LOS ANGELES

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Should I participate in a CHLA research study?

Learn about becoming a research volunteer

View our directory of research studies and clinical trials to find the right one for your child.

Visit CHLA.org/ResearchStudies

What is research?

Research is collecting and studying information to answer a question. Other words for research are clinical trial, protocol, survey or experiment.

Why is research important?

Research can lead to important discoveries that can make our lives better, such as: tests to diagnose diseases and drugs to treat them, and improved medical procedures.

Who can be a subject in a research study?

Most research studies have requirements that participants must meet. These requirements ensure the safety and usefulness of the research. Some studies require participants to be under 18. Others require them to have a certain disease.

Do I have to participate?

No. Participating in a research study is voluntary. You can stop at any time for any reason. Choosing to not be in a study will not affect your treatment or care with your doctor.

Are there risks to being in a research study?

Research may involve different types of risk. A study that asks you to fill out a survey has only minor risks, such as questions that may make you feel uneasy. For other studies, such those that have you take an experimental drug, the risks can be greater (e.g., having a bad reaction to the drug). The research team must explain all the risks of participating in the study before you decide whether or not to join.

Are there benefits to being in a research study?

Not everyone who participates in a research study will benefit. Sometimes participating in a research study will benefit society by helping people learn about a certain disease or condition. In some studies, subjects may personally benefit from medication or counseling that aids health.

Who monitors my safety if I am in a research study?

The principal investigator (PI) is responsible for the overall conduct of the research study and the safety of the subjects. PIs are often doctors, faculty or staff of hospitals and universities. The research team can also include research assistants, research nurses, data coordinators, statisticians and other specialists.

What is the IRB?

The Institutional Review Board (IRB) at Children's Hospital Los Angeles is made up of physicians, other scientists (including nurses, psychologists and pharmacists), and non-scientists (including young adult survivors of childhood illnesses and parents of children with illnesses). The IRB must review and approve a research study before a researcher can begin enrolling participants. The IRB helps protect the rights and welfare of participants in a study by considering the risks and benefits of the research, how the research is explained to potential participants, and the plans for monitoring the study for the safety of participants.

Who will see my records?

The information in your research record will be confidential. Information will only be given to researchers who carry out the study or to those who make sure the study is safe. The sponsor or funder of the research study may also be able to view your health and research record. The principal investigator will tell you who is allowed to see your information.

Are there any special rules to help protect certain subjects?

Children, pregnant women and prisoners can all be participants in research studies, but are considered potentially "vulnerable populations." There are special rules to protect participants who are in one of these groups.

What kinds of procedures are involved?

Research studies can involve a variety of activities, from filling out surveys and questionnaires to taking experimental medicines or using experimental devices. Some research studies last only a few minutes, while others last for several years. The research team will describe all the research activities before you agree to be in the study.

What is informed consent?

Informed consent is the process of learning the key facts about a research study before deciding whether or not to enroll. These facts include details about the study, tests or procedures, and the benefits and risks of participating. The research staff will explain the study to you and assist you with the "informed consent form." Alternatives to participating will be discussed should you decide not to enroll.