Children Are NOT Little Adults

Did you know that only about 30% of the medicines that children take have actually been tested in children? In fact, most pharmaceuticals, devices, and treatments have not been studied in young children or adolescents. As a result, even though children are not little adults, many medications and treatments are designed that way.

Adjusting the dose used in adults works sometimes. But children’s brains and bodies are still developing and maturing and young people and adolescents have different needs. The best way to evaluate how drugs work in children is by testing them in children, through a process known as a pediatric clinical research study.
Pediatric Clinical Studies Are Important

Pediatric clinical studies are necessary steps in the process of finding new therapies for children and adolescents in the future. They can help (1) identify the proper dose of medicines for children; (2) find treatments for diseases that occur only in children; (3) discover therapies for diseases that act differently in adults and children, such as arthritis and heart disease; and (4) identify techniques to improve children’s overall health and well-being. Unlike standard medical care, which addresses the specific needs of individual children today, research can tell us what kinds of therapies might work for children tomorrow. Governments in many countries—including the United States—now have laws requiring that new investigational medicines are adequately tested in children to ensure they are safe and effective.
Getting Started in a Pediatric Clinical Study

The Clinical Study Team

A group of medical and health professionals directs the operation of a pediatric clinical study. The team may include many people such as doctors, nurses, study coordinators, pharmacists, and others. The clinical study team determines if your child is eligible to participate, conducts preliminary (baseline) testing, delivers the study medications (if applicable), monitors progress; and generally helps ensure the study is being carried out in a legal, ethical, and safe manner. However, without the active participation of you and your child, a clinical study team would be incomplete. Parents, caregivers, and older children are encouraged to be actively involved in the study by sharing information and asking a lot of questions.
Not All Children Are Eligible

The pediatric clinical study process begins with enrollment. Clinical study participants must meet certain criteria in order to participate. These criteria are known as inclusion and exclusion criteria and may be based on such considerations as age, general health status, and type of illness. If your child is eligible to enroll in a clinical study, after you provide permission and your child provides assent, your child may be assigned to a specific research-treatment group.
Giving Informed Consent

One of the most important parts of the enrollment process is known as informed consent. If your child is eligible, and you and your child decide to participate, you will be given an informed consent (parental permission) document. This document includes detailed information about the pediatric clinical study, anticipated laboratory and diagnostic testing, potential benefits and known risks of the study drug, and the confidentiality of medical information and samples. Although different countries may use different informed consent documents, all are designed to help protect the rights of patients such as your child.

You should take your time and read carefully through the document. Ask any questions you may have. A member of the clinical study team will discuss the study and its benefits and risks with your child in age-suitable language, who will then be able to express any concerns about participation at that time. When you are satisfied that your questions and those of your child have been fully answered, you will be asked to sign the document, giving your permission for participation in the clinical study. Emancipated minors (for example, some adolescents above age 16) will sign their own consent documents. At no time will you or your child be pressured to enroll in any pediatric clinical study, and deciding not to participate will in no way effect your child’s medical care.
Understanding Assent

In some pediatric clinical studies, it is necessary for participants to give their assent. Assent is the child or adolescent’s affirmative agreement to participate in the research.

Depending on the age and the type of study being conducted, your child may be asked to provide assent in addition to the parent or caregiver’s informed consent. This means that children are asked to show willingness to be in the study—and that they are not participating against their will because a parent, caregiver, or member of the clinical study team wants them to.

Remember, it is important that your child understands and is willing to take the medicine, take the tests, and understands the risks and benefits of a pediatric clinical study. Children in clinical studies should always discuss any concerns they might have with their parents, caregivers, or members of the clinical study team.
Protecting Your Child’s Rights

Ensuring the welfare of your child is an important responsibility of the sponsors (the company that is paying for the study). An independent ethics group, known as an institutional review board (IRB)—sometimes called an ethics committee or a research ethics board—confirms that the study complies with all international ethical and legal guidelines. If you or your child is dissatisfied with any aspect of the study, you are free to leave at any time without offering any explanation.

Safety Measures

Governmental organizations around the world have created rules to help protect the safety of participants in clinical studies, especially children. These rules make sure that all risks to young people and adolescents are minimized. Moreover, the risks must be justified by the anticipated benefits. You can check with a member of the clinical study team to learn about the various safety measures that are in place for your child’s pediatric clinical study.
What Questions Should I Ask?

Here is a list of questions you may wish to discuss with the clinical study team. Remember to ask as many questions as necessary to ensure your peace of mind about your decision.

The Study
- Why is the study being done?
- Why do researchers think the approach may be effective?
- Who is paying for and supporting the study?
- Who has reviewed and approved the study?
- How are study results and safety of participants being checked?
- How long will the study last?
- What will our responsibilities be if we participate?

Possible Risks and Benefits
- What are the possible benefits?
- What are the short-term risks, such as side effects?
- What are the possible long-term risks?
- What other options do people with similar conditions have?
- How do the possible risks and benefits of this study compare with other options?
Participation and Care

- What kinds of therapies, procedures, or tests will my child receive?
- Will they hurt, and if so, for how long?
- How do the tests in the study compare with those my child would have outside the study?
- Will my child be able to take any regular medications while enrolled?
- Where will my child's study-related medical care be provided?
- Who will be in charge of my child's care?

Personal Considerations

- How could being in this study affect the daily life of my child or my family?
- Can I talk to other people in the study?

Cost Considerations

- Will I have to pay for any part of the study such as tests or the study medication?
- If so, what will the charges likely be?
- If I have health insurance, what is it likely to cover?
- Who can help answer questions from my insurance company or health plan?
- Will there be any travel or child care costs while my child is in the study?
Tips for Asking Your Child’s Study Doctor About Pediatric Clinical Studies

When you talk with your child’s study doctor or members of the clinical study team:

- Consider taking a family member or friend along for support and for help in asking questions or recording answers.
- Plan ahead about what to ask—but do not hesitate to ask any new questions you think of while you are there.
- Write down your questions in advance, to make sure you remember to ask them all.
- Write down the answers to your questions so that you can review them whenever you want.