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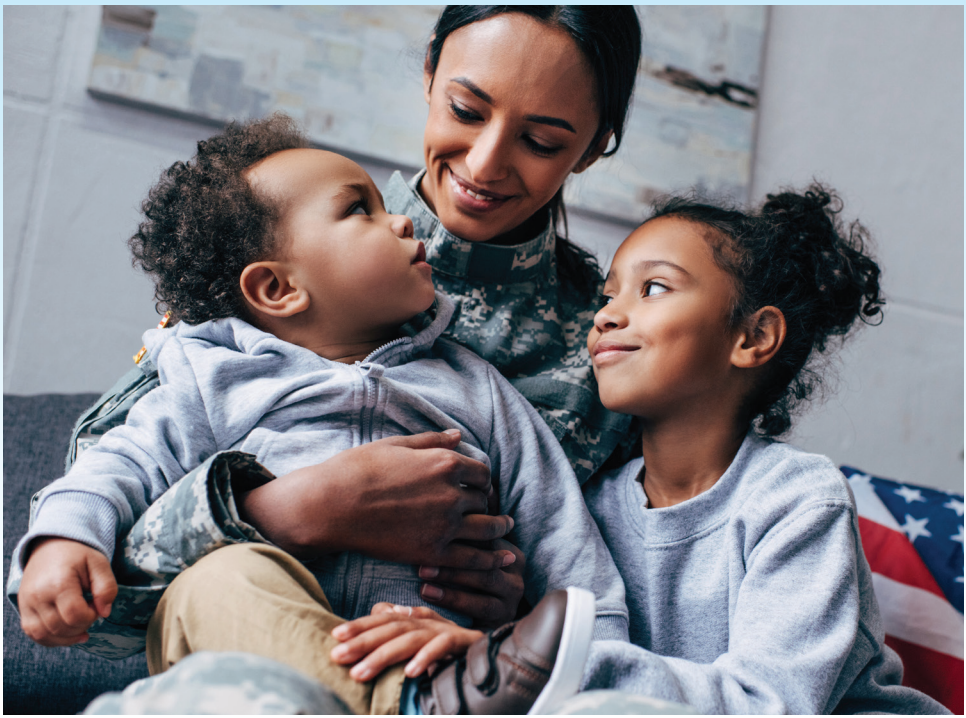
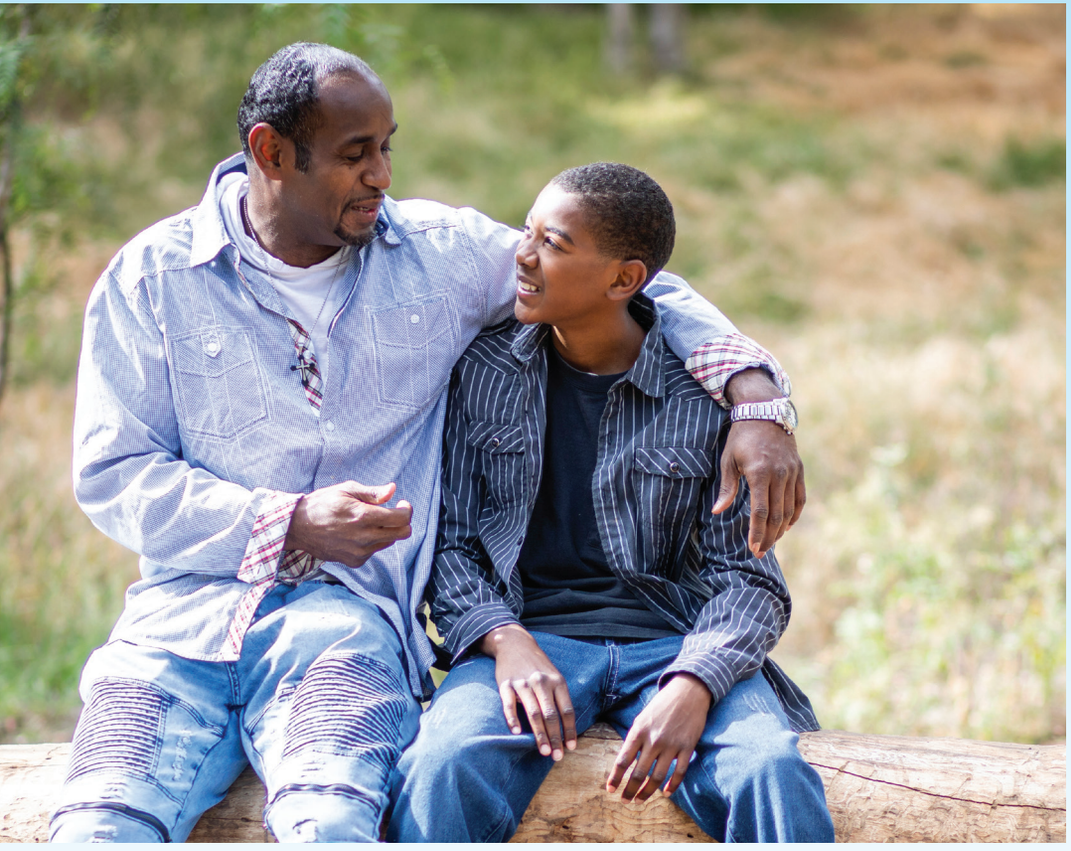


Clinical Research Studies for Children and Teenagers:

An Information Guide for Parents and Caregivers



Children Are NOT Little Adults

Did you know that many of the medicines that children take have not been formally tested in children?[1,2] So, even though children are not little adults, many medications and treatments are prescribed that way. Children's brains and bodies are still developing and maturing. And young people have different needs and might react differently to medicines than adults. The best way to understand how drugs work in children is by testing them in children, through a process known as a pediatric clinical research study.

Clinical Studies for Children Are Important

Clinical studies for children can help:

- identify the proper dose of medicines for children;
- find treatments for diseases that occur only in children;
- discover therapies for diseases that act differently in adults and children; and
- 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 help the medical community understand if a study drug is better or safer than others available. Many countries—including the United States—now have laws requiring that new study treatments 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 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 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 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 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 form, also known as a parental permission document. This document includes detailed information about the clinical study, anticipated laboratory and other testing, potential benefits and known risks of the study drug, and the confidentiality of your child's medical information. Although different countries may use different informed consent documents, all are designed to help protect the rights of patients such as your child. And while the form is important, what's most important is that you understand the clinical trial, and why your child is being offered participation.

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. Your child will be encouraged to ask questions and will 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. At no time will you or your child be pressured to enroll in any pediatric clinical study. Alternative treatment options will be presented to you if you are not interested in your child's participation in the clinical study.

Understanding Assent

While parents may give consent (or permission) for their child to participate in a clinical study, it is also important for the child to play a role in the decision to participate, based on the child's age and ability to understand the study. The term "assent" is used to describe a child or adolescent's 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 study team. 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 stop participating at any time without offering any explanation.

Safety Measures

Governmental organizations and health authorities 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.

Notes/questions

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References
1. Prescription Medication Use Among Children and Adolescents in the United States | Pediatrics | American Academy of Pediatrics (aap.org)
2. Drug Research and Children | FDA

STUDY CONNECT
BMSStudyConnect.com

Thank you
for considering a clinical trial