

Could a clinical trial help your child?

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(HealthDay)—If a doctor suggests your child enroll in a clinical trial, you'll undoubtedly have questions.

Probably lots of them.

Clinical research [trials](#) are performed in [children](#) to develop age-specific treatments, and to assess the safety and/or effectiveness of drugs and vaccines in their smaller bodies.

Participation is voluntary. Depending on the type of trial and product evaluated, participants may receive an [experimental drug](#), a proven treatment, or an inactive pill (placebo). However, children will continue taking any medication they require for their health.

Your child could receive a new treatment that may or may not be better than the current therapy, says the U.S. Food and Drug Administration.

"People often think that a clinical trial that tests an experimental [drug](#) is riskier than being treated in your doctor's office with an already approved drug that has not been tested in children," said Dr. Robert Nelson, deputy director of the FDA Office of Pediatric Therapeutics.

"Some research may be riskier, but some may be safer than being prescribed a drug that has not been studied in children," Nelson said in an FDA news release.

"Further, monitoring for adverse events would be much more intensive in a research study than when a drug is prescribed by a doctor outside of a clinical trial," he added.

The FDA advises [parents](#) to consult with their child's doctor before enrolling their youngster in a clinical trial. Also, maintain communication during the trial.

"A pediatrician can help a parent evaluate the risks and potential benefits, assess the qualifications of the research team, clarify a child's

understanding of the research, and support the parent and child throughout the research study," Nelson said.

Here are some other tips from the FDA:

- **Make a list.** Before discussing the trial with the investigators, compile a list of questions. For example: What is the evidence that the experimental drug might help my child? How closely will the child be monitored for problems?
- **Take notes.** Bring a pen and paper to jot down notes during the meeting and read them back to the investigators to make sure they're correct. If you want to talk with other parents of children in the study, ask for their contact information. (The researchers will need to get permission from other parents.)
- **Take your time.** Don't rush into a decision. Ask if you can think about it at home and talk it over with your family, your child's doctor and other people you trust before signing the informed-consent document.

Listen to your "gut," Nelson advised. If you're not satisfied with the information you receive and the answers to your questions, don't enroll your child.

"Parents need to understand that they can take their child out of a clinical trial at any time," Nelson said. "However, there may need to be some follow-up to make sure a [child](#) does not have a serious side effect from stopping the drug being tested," he noted.

More information: The World Health Organization has more on [clinical trials in children](#).

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