

Should My Child Participate in a Clinical Trial?

How to make an informed decision about whether or not your child should join a clinical trial



What are Pediatric Clinical Trials?

Pediatric clinical trials are a way for researchers to learn how safe treatments are and if they work in children.

Pediatric trials may include children with a certain condition, or they may include “healthy” children who do not have the condition the trial is studying.

Pediatric clinical trials are important because they allow researchers to:

- Study a treatment in children that is already approved for adults
- Find new treatments
- Improve and compare existing treatments
- Find the right dose for children



Pediatric clinical trials are needed because children’s bodies work in different ways than adults, and they go through many changes as they grow.

How is my child protected?

- Federal agencies, including the Food and Drug Administration (FDA) and the National Institutes of Health (NIH), oversee clinical trials
- Institutional Review Boards (IRBs) help ensure a clinical trial is ethical and that your child’s rights are protected
- Researchers need your written permission, and possibly your child’s, before enrolling them



Your child can stop participating at any time for any reason and you can be with them throughout the process.

Potential Benefits and Risks



Every clinical trial has its own potential benefits and risks, but some common ones are listed below.

Benefits

- Your child may have access to new trial treatments that are not otherwise available to them
- Your child will receive trial-related medical care
- You and your child may feel pride in helping other children by contributing to medical research

Risks

- The trial treatment may not work, or your child might receive a placebo that has no medicine in it
- Your child may experience unpleasant, serious, or even life-threatening medical problems caused by the trial treatment
- Your child may have to undergo uncomfortable or painful procedures
- Participation may be time consuming and change your normal routine

Deciding if Participation is Right for Your Child

It is important to learn as much as you can about clinical trials in order to make an informed decision about what is right for your child. **Participation is optional. There is no right or wrong choice.**



Before agreeing to enroll your child, you will be given an Informed Consent Form. This will include risks and benefits, treatments your child might receive, what to expect, and schedules.

You and your child may want to talk with the team doing a trial, as well as healthcare professionals who are not part of the trial team. They might have different information and views to help answer your questions. To learn more about how participation will affect you and your child, you can also speak with support services, advocacy groups, or families who have had children participate in trials.



"My daughter Caroline's circumstances were dire, so we needed something different. We held onto hope, understanding that research is all about finding what works. We also knew that if we didn't get the outcome we desired, she would be a part of the history of improving cancer research."

Lisa Peabody, advocate and parent of a pediatric trial participant

Questions to Ask a Healthcare Professional

- What is the purpose of this trial?
- Why do researchers think the trial treatment might be effective?
- How will my child's safety be monitored?
- What are the potential benefits and risks, and how do they compare with my child's current treatment?
- What medical tests or procedures will my child have to undergo?
- How will my child's participation affect our daily lives? Will they miss any school?
- What are the costs? Will my insurance cover these costs?
- How will my child's health information be kept private?

Questions to Ask Your Child

Your child should be part of making the decision to participate too. **Many pediatric clinical trials require that your child gives their "assent", if possible.**

Assent is your child's agreement to participate in a clinical trial. The assent process helps make sure your child is informed about the clinical trial and aware that they have a say in their own healthcare.



You may find it difficult to talk to your child about clinical trial participation. That's OK. These questions could help you get started.

This brochure is only a guide. You may think of other things to ask that are not included here.

- Do you understand what the doctors are telling you?
- Do you understand how this treatment might help and how it might not?
- Do you understand that you might miss school or other activities?
- Do you feel like you can talk to me or your doctor about anything that is worrying you?
- Is there anything you want to ask me or your doctor?
- Do you want to participate? Why or why not?



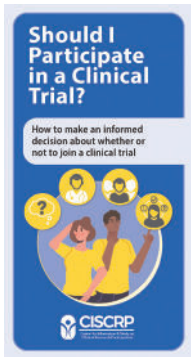
What Should You Do Next?

- If you have questions, ask a medical professional or research on your own
- Take notes and keep all your information organized using a notebook, computer, or smartphone
- Listen to your child's concerns and make sure they understand how their participation will impact their life
- Using all the information you've gathered, make a pros and cons list to help you make an informed decision about whether or not your child should join a clinical trial

How Can You Find More Information?

Visit CISCRP's Education Center for more information, including kid-friendly videos, frequently asked questions to help you and your child learn about clinical trials, and other brochures that can help you and your child make a decision.

ciscrp.org/education-center



For more information about how participation can impact you and your child's life and other questions to ask, see our "**Should I Participate in a Clinical Trial?**" brochure.



A panel of patients, professionals, and members of the public reviewed this educational brochure.



CISCRP is an independent non-profit organization dedicated to engaging the public and patients as partners in the clinical research process.

CISCRP does not recruit patients for clinical trials and does not conduct clinical research. CISCRP is also known as the Center for Information and Study on Clinical Research Participation.

Visit www.CISCRP.org or call toll free 1-877-633-4376