

Pediatric Clinical Trials FAQ

Why are pediatric clinic trials important?

Children's bodies are still developing and often undergo many changes as they grow. Thus, medicines used in adults may affect children differently. Pediatric trials for children are essential to develop age-specific treatments specifically studied for children¹.

How do children consent to participate in a trial?

Like adult clinical trials, pediatric research follows regulations that require informed consent for participation. The informed consent for pediatric participation is granted by a parent or legal guardian of the child².

In addition to parental/guardian consent, the child may provide informed assent, or dissent. To give their assent, children must be mature enough to understand the trial and what will be asked of them. 7 years old is generally considered the age of assent, but it may vary depending on the institution³.

Are pediatric clinical trials safe?

As with clinical trials with adult participants, pediatric trials follow guidelines governed by regulatory agencies and oversight provided by institutional review boards or independent ethics committees⁴.

Pediatric research studies also need to follow additional regulations that protect children's safety and wellbeing. To learn more about these regulations please visit the links under the additional resources section.



Will my child need to undergo invasive procedures when they participate in a clinical trial?

This will depend on the study and will be covered during the consent process. However, pediatric clinical trials, and their protocols, are designed and conducted with children in mind.

Who provides medical care to my child?

While they are enrolled in the trial, your child will receive study-related medical care from the study team. This team will use frequent visits to closely monitor your child's health. This study team will be made up of a variety of healthcare professionals who are all overseen by a principal investigator, who is a physician.

How are study visits scheduled?

The timing and number of visits varies depending on the specific study and site. The study team will be able to provide information about visit dates and times. If the presented times do not work, some sites may be able to make accommodations for visits after school hours.

1. <https://www.who.int/clinical-trials-registry-platform/clinical-trials-in-children>
2. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6510379/#cts12615-bib-0003>
3. <https://www.cancer.gov/research/participate/clinical-trials/safety>
4. <https://www.fda.gov/science-research/pediatrics/pediatric-ethics#:~:text=Additional%20safeguards%20for%20children%20in%20clinical%20investigations%20Under,justified%20by%20the%20prospect%20of%20direct%20clinical%20benefit.>

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Do I need to tell my child's school that they are participating in a clinical trial?

You are not required to inform your child's school, but you can disclose if you wish. Many parents notify the school of doctors' appointments.

What are some questions I could ask my child's healthcare provider to help me decide if a clinical trial is a good fit for my child?

- What are the potential risks and side effects?
- Where are the potential benefits?
- How does this trial compare to obtaining treatment from a provider directly?
- What is the goal of the trial?
- How long would my child be expected to participate in the trial?
- How will I know if the experimental product is working?
- Does this clinical trial include the use of a placebo? If so, what are the chances they will get the experimental product?



Additional Resources

- [Additional FDA Regulations That Protect Children in Clinical Trials \(21 CFR 50.51 - 21 CFR 50.3\).](#)
 - These regulations cover that clinical trials should not be conducted in children if the risk posed is greater than minimal and the risk must be justified by the potential benefit.
- [Pediatric Research Equity Act \(PREA\) and Best Pharmaceuticals for Children Act \(BPCA\)](#)
 - Requires companies to assess the effectiveness of new therapeutics in pediatric patients.
- [Additional information about the 21 CFR Regulations](#)



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3. <https://www.cancer.gov/research/participate/clinical-trials/safety>
4. <https://www.fda.gov/science-research/pediatrics/pediatric-ethics#:~:text=Additional%20safeguards%20for%20children%20in%20clinical%20investigations%20Under,justified%20by%20the%20prospect%20of%20direct%20clinical%20benefit.>