# CRSO Regulatory Blog Post

## October 11, 2022

## FDA Issues Draft Guidance on Protecting Children Who Participate in Clinical Trials

On September 26, 2022, the U.S. Food and Drug Administration (FDA) announced in the Federal Registry the newly published draft guidance titled, "Ethical Considerations for Clinical Investigations of Medical Products Involving Children."

The goal of this guidance is to provide FDA's perspective on the ethical considerations for including children in clinical trials and specifically to help investigators, sponsors, and IRBs understand and interpret the regulations that apply to children as human subjects within the context of a pediatric clinical investigation.

The draft guidance outlines the ethical framework in FDA's regulations, including:

- the principle of scientific necessity
- the risk categories for interventions or procedures without the prospect of direct benefit
- considerations regarding the prospect of direct benefit
- the assessment of risk for interventions or procedures with a prospect of direct benefit
- evaluations for the different components of a clinical investigation using component analysis of risk
- the potential for review of a protocol under 21 CFR 50.54
- the necessity of obtaining parental/guardian permission and child assent

The draft guidance also describes the application of 21 CFR part 50, subpart D to pediatric clinical investigations, including the data to support conducting pediatric clinical investigations, design considerations for clinical investigations, and study procedures in pediatric clinical investigations.

## What does it mean for me?

The final version of the guidance will be an important reference document for investigators and study teams who are doing pediatric clinical trials. It serves as a condensed version of the regulations that investigators can use to inform the design and conduct of pediatric studies to further support the availability of medical products for children.

If you are doing clinical trials with children or have plans to in the future, you may want to take the opportunity to provide feedback on the guidance before the FDA begins work on the final version. Detailed instructions for providing comments are provided in the Federal Registry Notice.

## More Information Available

For more on the draft guidance, listen to this recent episode of the Guidance Recap Podcast | Ethical Considerations for Clinical Investigations of Medical Products Involving Children | FDA.

If you have questions regarding the guidance, please contact the CRSO at crso@med.unc.edu.

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