Laws, Regulations, and Guidance on Pediatric Studies

2023
Book 25

Laws, Regulations, and Guidance on Pediatric Studies

(April 1, 2023 - March 31, 2024)

Food and Drug Administration Laws on Pediatric Research

- *Excerpt from* FDA Safety and Innovation Act on Pediatric Drugs and Devices
- Pediatric Research Equity Act of 2007
- Best Pharmaceuticals for Children Act of 2007
- *Excerpt from* The Patient Protection and Affordable Care Act on Pediatric Studies of Biological Products

U.S. Code of Federal Regulations

- 21 CFR Part 50, Subpart D: Additional Safeguards for Children in Investigations
- 45 CFR Part 46: Additional Protections for Children Involved as Subjects in Research

FDA Guidance for Industry

- Qualifying for Pediatric Exclusivity Under Section 505A of the FD&C Act
- How to Comply with the Pediatric Research Equity Act (Draft guidance)
- Nonclinical Safety Evaluation of Pediatric Products
- Process for Handling Referrals to FDA Under 21 CFR 50.54
- ICH Guideline E-11: Clinical Investigations of Medicinal Products in the Pediatric Population
- General Considerations for the Clinical Evaluation of Drugs in Infants and Children

OHRP Guidance

- Guidance on the HHS 45 CFR 46.407 ("407") Review Process
- Frequently Asked Questions on Research Involving Children

U.S. Government Accountability Office Report to Congress on Pediatric Drug Research

CLINICAL RESEARCH RESOURCES