

**Title:** Conducting Clinical Drug Trials with Children

**Author:** Celia B. Fisher, *Decoding the Ethics Code: A Practical Guide for Psychologists*, Sage Publications, 2003

**Description:** A team of psychologists and psychiatrists at a medical school received IRB approval to assess the behavioral, cognitive, and physical side effects of a medication recently approved by the Food and Drug Administration (FDA) as an alternative to methylphenidate (Ritalin) in hyperactive children. Fisher presents this as an example of best practice.

**Headings:** Special Populations and Cultural Competence; Minors (children, adolescents); Mental health disorders, participants with (including addictive disorders and developmental disabilities); Experimental designs (randomization, clinical trials), Voluntariness and Undue Influence in Recruitment

**Case Type:** Illustrative

### Conducting Clinical Drug Trials with Children

A team of psychologists and psychiatrists at a medical school received IRB approval to assess the behavioral, cognitive, and physical side effects of a medication recently approved by the Food and Drug Administration (FDA) as an alternative to methylphenidate (Ritalin) in hyperactive children. Using Latin square assignment, each child would be given 2 weeks of each of five experimental conditions (placebo, three different dose levels of medication, and one dose of methylphenidate). Although no long-lasting negative effects had been observed in adult studies for more than two decades, there was some controversy in the literature about whether animal studies demonstrating some negative effects were replicable in or applicable to humans. The researchers included a paragraph in the parental permission forms describing the animal results and stating that there was some unknown risk that the drug could cause permanent neurological damage in participating children. Many of the parents had children who had failed to be helped by traditional treatment with methylphenidate. To avoid inadvertently implying to these parents that the animal data suggested that the medication was a powerfully effective drug, the investigators were also careful to clarify in the parental permission information that the reason the study was being conducted was because there was as yet no empirical evidence indicating that the agent would be more effective than methylphenidate for hyperactive children. On entry to the study, parents were also informed that at the end of the child's participation in the study, the investigators would prepare a summary letter for the parent and with signed parental permission and authorization the child's primary physician would receive the child's diagnosis, a summary of the nature of the treatment conditions, and any recommendations for treatment that emerged from the child's responses to different conditions. (adapted from Fisher, Hoagwood, and Jensen, 1996)