



UC DAVIS OFFICE OF RESEARCH

FDA: Additional Safeguards for Children in Clinical Investigations

Final Rule

May 2013

Miles McFann
Outreach and Training Education
IRB Administration

Highlights of the Final Rule

- Substantive Changes to 21 CFR
 - 21 CFR 50.3
 - 21 CFR 50.51
 - 21 CFR 50.55
- Implications for Placebo-Controlled Pediatric Trials

21 CFR50.3

Definition Changes

- ◆ *Permission* means the agreement of parent(s) or guardian to the participation of their child or ward in a clinical investigation.
- ◆ *Guardian* means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.
- ◆ *Assent* means a child's affirmative agreement to participate in a clinical investigation. Mere failure to object *may* not, absent affirmative agreement, be construed as assent.

21 CFR 50.51

Clinical investigations not involving greater than minimal risk

Any clinical investigation within the scope described in §§ 50.1 and 56.101 of this chapter in which no greater than minimal risk to children is presented may involve children as subjects only if the IRB finds that:

(a) No greater than minimal risk to children is presented; and

(b) Adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians as set forth in § 50.55.

21 CFR 50.55

Requirements for permission by parents or guardians and for assent by children.

(e) In addition to the determinations required under other applicable sections of this subpart D, the IRB must determine, *in accordance with and to the extent that consent is required under part 50*, that the permission of each child's parents or guardian is granted.

Implications for Placebo-Controlled Pediatric Trials

How does this impact us

- 21 CFR 50.51
- 21 CFR 50.52
- 21 CFR 50.53
- 21 CFR 50.54



"It's a baby. Federal regulations prohibit our mentioning its race, age, or gender."

FDA: Additional Safeguards for Children in Clinical Investigations

Final Rule

Miles McFann
IRB Administration

