From: OC GCP Questions
To: [redacted]
Subject: Informed Consent 21 CFR 50 (Part D)
Date: Monday, March 31, 2014 9:57:46 AM

Good morning –

There is a new rule that was issued on 2/26/13 for additional safeguards for children in clinical investigations. Please see the link below.

Federal Register | Additional Safeguards for Children in Clinical Investigations of Food and Drug Administration-Regulated Products

This might be helpful to you as it gives a history of the rule.

Additionally, you might want to contact FDA's Office of Pediatric Therapeutics. Please see their website below.

Office of Special Medical Programs > Office of Pediatric Therapeutics

I hope this information is helpful.

Kind regards,

Doreen M. Kezer, MSN

Senior Health Policy Analyst

Office of Good Clinical Practice

Office of the Commissioner, FDA

From: [Redacted]
Sent: Thursday, March 27, 2014 3:39 AM
To: OC GCP Questions
Subject: Informed Consent 21 CFR 50 (Part D)

Hello,

My name is [redacted], I'm taking a quality audit class as part of my QA/RA program. I'm putting together a presentation for my class on 21 CFR 50 (Parts A, B and D). I can talk about what the regulations mean and some friends in that work in clinical have helped on things to look for when performing an audit, but my presentation is missing historical context for the

background slides. I'm having trouble finding legal cases that may have precipitated Part D (Safeguards for Children), which seems to have been added to 21 CFR 50 much later than A and B. Can you make some recommendations?

Thank you,

[Redacted]