From: OC GCP Questions
To: [redacted]
Subject: Question on Common Rule Revisions & Impact on 21 CFR Parts 50 & 56
Date: Monday, January 30, 2017 8:18:00 AM
Attachments: [redacted]

Good morning –

The FDA plans to harmonize its regulations with the final Common Rule, to the extent appropriate and permissible, based on the FDA's and OHRP's missions and statutory authorities. For example, certain types of research described in the Common Rule (e.g., behavioral observations or educational interventions) are not regulated by the FDA. Rather, the FDA's authority is focused on FDA-regulated products, including drugs, biologics and medical devices. If FDA regulations need to be revised, FDA will follow notice and comment rulemaking procedures. The agency cannot provide a specific timeframe for completing rulemaking.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

U.S. FOOD & DRUG ADMINISTRATION

From: [redacted]
Sent: Friday, January 27, 2017 2:09 PM
To: OC GCP Questions
Subject: Question on Common Rule Revisions & Impact on 21 CFR Parts 50 & 56

Dear FDA,

In light of the recent revision of the "Common Rule", do you anticipate revising 21 CFR Parts 50 and 56, and, if so, when will these revisions take place? Thank you for any information you can provide.

Kind regards,
[redacted]

[redacted]