

**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]

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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,

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Office of Good Clinical Practice  
Office of the Commissioner, FDA



This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

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**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]