

**From:** [OC GCP Questions](#)  
**To:** [REDACTED]  
**Subject:** Question on protocol implementation  
**Date:** Tuesday, November 14, 2017 4:00:00 PM  
**Attachments:** [REDACTED]

---

Good afternoon –

I have consulted two offices in the Center for Drugs (CDER) and they feel that this is something that you need to discuss directly with the Sponsor, not with FDA.

Kind regards,

Doreen M. Kezer, MSN  
Senior Health Policy Analyst  
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.

**From:** [REDACTED]  
**Sent:** Tuesday, November 14, 2017 9:00 AM  
**To:** OC GCP Questions <gcp.questions@fda.hhs.gov>  
**Subject:** Question on protocol implementation

Dear Madam, dear Sir,

I am writing to you to enquire about how you would recommend handling the following situation:

The Sponsor submits a protocol amendment to the competent authorities and receives an approval letter, referring to the submission, but without the detail of approved documents (type of document, version, date).

The Sponsor makes further efforts, to try to obtain a detailed list of approved documents.

Until this is obtained, they delay communication to site and implementation of these - technically - approved documents, which has as consequence that the site keeps enrolling patients under an obsolete version of the protocol and using obsolete Informed Consent Forms for patients.

Is this Sponsor acting correctly?

Should the date of the initial written approval (even if not detailed) from the Ethics Committee be seen as actual date for the implementation of the new protocol version?

Thank you in advance for your assistance!

With kind regards,  
[REDACTED]