

From: OC GCP Questions
To: [REDACTED]
Subject: Question on submission of protocol amendments to FDA
Date: Monday, July 31, 2017 8:32:00 AM
Attachments: [REDACTED]

Good morning –

Amendments and modifications are not required to be IRB/EC approved prior to submission to FDA but need to be submitted to FDA and receive IRB/EC approval prior to the changes being implemented, unless a change is intended to eliminate an apparent immediate hazard to subjects in which case the change may be implemented immediately provided FDA and the reviewing IRB/EC are notified.

Since it appears you are from the vaccine section of GSK, you may want to send your email to the Center for Biologics (CBER) as they handle all vaccine studies.

Questions about biologics (other than gcp questions)

- 301-827-2000
- OCOD@fda.hhs.gov (consumer oriented)
- Industry.Biologics@fda.gov (manufacturers's assistance)

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

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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: Friday, July 28, 2017 1:06 PM
To: OC GCP Questions
Subject: Question on submission of protocol amendments to FDA

Hi,

I have two questions on when protocol amendments are submitted to CBER.

1. Can a protocol amendment and revised ICF be submitted to the IRB for approval **before** it is submitted to the FDA for acknowledgement?
2. In the event a protocol amendment and revised ICF was submitted and approved by the IRB before it is submitted to the FDA for acknowledgement, is it defined anywhere if the amendment changes and revised ICF can be used before it is submitted to the FDA for

acknowledgement? Or would they still need to follow the former amendment?

Kind Regards,

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]