

**From:** OC GCP Questions  
**To:** [REDACTED]  
**Subject:** RE: Inquiry about ICH- GCP guideline  
**Date:** Friday, May 29, 2015 12:27:00 PM

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Dear [REDACTED] -

Thank you for your question. I believe you are referring to the ICH GCP E6 Good Clinical Practice: Consolidated Guidance, (which is recognized as official FDA guidance). You can access this guidance at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm073122.pdf>.

With regard to an update to this guidance document, I suggest that you go to the ICH web site (see <http://www.ich.org/home.html>) for information. I put the search term "ICH GCP E6" in the search box on the home page and I found some information at the following web page regarding an addendum to the GCP guidance (see <http://www.ich.org/products/guidelines/efficacy/efficacy-single/article/addendum-good-clinical-practice.html>). However, my understanding is that this update has not been finalized (see [http://www.ich.org/fileadmin/Public\\_Web\\_Site/ICH\\_Products/Guidelines/Efficacy/E6/E6\\_EWG\\_Work\\_Plan\\_10\\_March\\_2015.pdf](http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_EWG_Work_Plan_10_March_2015.pdf)), but I am not able to provide you with an official response on the status of this update. You may wish to explore this web site in more detail for additional information that may assist you, or consider contacting ICH directly through their Contact form for an official answer on the status of this update.

I hope this information is useful. If you need further information and/or have additional questions, please feel free to contact us at the official GCP mailbox, [gcp.questions@fda.hhs.gov](mailto:gcp.questions@fda.hhs.gov). You may also find it useful to access the set of redacted GCP e-mails found at <http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/RepliestoInquiriesToFDAonGoodClinicalPractice/default.htm> since we find that many questions and concerns are repeated over time.

Best Regards,

Janet

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Office of Special Medical Programs, Food and Drug Administration

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, May 29, 2015 9:26 AM  
**To:** OC GCP Questions  
**Subject:** Inquiry about ICH- GCP guideline

Dear sir,

Myself [REDACTED]. I am Master in Clinical Pharmacist. I searching newly updated ICH- GCP guideline. but everytime it opened in 2006 version. so when the Guideline is updated? How can i got recently updated guideline?

please kindly inform me for that.

Waiting for your reply.

Thanking you.  
[REDACTED]