From: OC GCP Questions
To: [redacted]
Subject: GCP guidance document
Date: Thursday, October 09, 2014 2:05:28 PM
Attachments: GCP guidelines.pdf

Good afternoon –

The document you reference is the most recent version of ICH E-6. Adherence to the principles of good clinical practices (GCPs), including adequate human subject protection (HSP) is universally recognized as a critical requirement to the conduct of research involving human subjects. Many countries have adopted GCP principles as laws and/or regulations. The Food and Drug Administration's (FDA's) regulations for the conduct of clinical trials, which have been in effect since the 1970s, address both GCP and HSP.

Please see links to GCP guidances and FDA regulations.

Clinical Trials and Human Subject Protection > Regulations

Guidance Documents (Including Information Sheets) and Notices > Selected FDA GCP/Clinical Trial Guidance Documents

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

Kind regards,

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

From: [redacted]
Sent: Thursday, October 09, 2014 10:41 AM
To: OC GCP Questions
Subject: GCP guidance document

Hello,

I was wondering if you could please send me the most recent version of the GCP guidelines. I found this version today but it is dated 1996. Please let me know if there is a more recent version and thank you for your help.

Best,
[redacted]