From: OC GCP Questions
To: [redacted]
Subject: regulations
Date: Wednesday, April 02, 2014 1:32:37 PM

Good afternoon --

Please see the link below to the FDA regulations. For drugs and biologics see 312, for devices see 812, for GLP see 58, and for human subject protection see 50 and 56.

Clinical Trials and Human Subject Protection > Regulations

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: Wednesday, April 02, 2014 10:38 AM
To: OC GCP Questions
Subject: regulations

Is there a site which lists the cGCP regulations? Or can you point me to where I may find documentation of what is required for compliance in cGCP (as I can for GLP)
thanks
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