From: OC GCP Questions
To: [redacted]
Subject: GCP regulations or guidelines?
Date: Thursday, January 30, 2014 11:14:15 AM

Good morning –

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 the link to the FDA regulations –
Clinical Trials and Human Subject Protection > Regulations

Please see the link to ICH E-6 –
Good Clinical Practice: Consolidated guidance --
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073122.pdf
It states --
Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve human subjects. Compliance with GCP assures that the rights, safety, and well-being of trial subjects are protected and that the clinical trial data are credible. This International Conference on Harmonization (ICH) guidance provides a unified standard for the European Union, Japan, and the United States to facilitate the mutual acceptance of clinical data by the regulatory authorities in those jurisdictions.

Like all our guidances, we consider ICH guidances as nonbinding recommendations and as such do not establish legally enforceable responsibilities. Instead, guidances describe the agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited.

Please see the World Health Organization (WHO) Handbook for Good Clinical Practice.
http://whqlibdoc.who.int/publications/2005/924159392X_eng.pdf

Please see our website regarding GMPs.
Manufacturing > Facts About Current Good Manufacturing Practices (cGMPs)
Current Good Manufacturing Practices (cGMP) for Drugs: Reports, Guidances and Additional Information
Quality System Regulations for devices --
CFR - Code of Federal Regulations Title 21

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, January 29, 2014 4:34 PM
To: OC GCP Questions
Subject: GCP regulations or guidelines?

Hi,

I am taking a course on FDA regulations and I still find it unclear whether GLP/GCP/GMP are laws (regulations) or guidelines when conducting a clinical trial. Where is this stated explicitly?

Thank you,
[Redacted]