From: OC GCP Questions
To: [redacted]
Subject: GCP Requirement?
Date: Friday, May 09, 2014 12:42:16 PM

Good afternoon --

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.

The expectation is that investigators, sub-investigators, and study staff will be knowledgeable about good clinical practice, including human subject protection, data integrity, recordkeeping, etc.

International good clinical practice is outlined in the ICH-6 guidance link below.
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073122.pdf

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

Kind regards,

Doreen M. Kezer, MSN
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Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [Redacted]
Sent: Thursday, May 08, 2014 1:46 PM
To: OC GCP Questions
Subject: GCP Requirement?

Hello,

We were having a discussion today about whether Good Clinical Practice is an FDA requirement or guidance, specifically as it refers to IND exempt studies. I was always taught that clinical trials MUST adhere to the code of federal regulations, but recommended to adhere to GCP, particularly if filing an IND.

Can you please clarify?
Thank you,
[redacted]