From: OC GCP Questions
To: [redacted]
Subject: DIFFERENCE BETWEEN GCP/ICH AND ONLY ICH GUIDELINES
Date: Wednesday, November 05, 2014 12:31:52 PM

Good morning –

For FDA-regulated clinical trials, FDA regulations must be followed. Please see the link below to the regulations.
Clinical Trials and Human Subject Protection > Regulations

Often for international trials ICH E-6 is referenced. However, if the international clinical trial is conducted under an IND/IDE, the regulations must be followed.
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073122.pdf

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

From: [redacted]
Sent: Tuesday, November 04, 2014 2:36 PM
To: OC GCP Questions
Subject: DIFFERENCE BETWEEN GCP/ICH AND ONLY ICH GUIDELINES

Dear FDA:

I would like to check with you if there are on or two guidelies:
GCP/ICH
ICH guidelines for clinical trials

I only consult GCP/ICH guidelines but I want to be sure of there is something else.
Thanks