From: OC GCP Questions
To: [redacted]
Subject: GCP
Date: Monday, June 23, 2014 3:13:10 PM

Good afternoon --

Please see the links below for The International Conference on Harmonization (ICH) documents generally recognized for international clinical trials and FDA regulations.

Guidance Documents (Including Information Sheets) and Notices > ICH Guidance Documents

Clinical Trials and Human Subject Protection > Regulations

Kind regards,

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

From: [redacted]
Sent: Friday, June 20, 2014 4:04 PM
To: OC GCP Questions
Subject: GCP

I'm a pharmacy student trying to find out if the FDA has GCP guidelines for international human clinical trials? And if so what are those guidelines?

Thank you
[Redacted]