

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

This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

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]