From: OC GCP Questions
To: [redacted]
Subject: Require for FDA guideline
Date: Monday, December 14, 2015 9:33:06 AM

Good morning –

Please see the guidance link below.

http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM269919.pdf

Kind regards,

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

From: [redacted]
Sent: Monday, December 14, 2015 3:24 AM
To: OC GCP Questions
Subject: Require for FDA guideline

Dear Sir or Madam,

Can you provide me the below FDA guideline**: Guideline for The Monitoring of Clinical Investigations**?

I can not local the guideline in the FDA web site, but need to study it to prepare for a IDE study.

Thank you very much for your help!

[redacted]