

**From:** [OC GCP Questions](#)  
**To:** [REDACTED]  
**Subject:** Require for FDA guideline  
**Date:** Monday, December 14, 2015 9:33:06 AM

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Good morning –

Please see the guidance link below.

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

Kind regards,

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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.

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**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]