

From: OC GCP Questions
Sent: Monday, October 26, 2015 3:04 PM
To: [REDACTED]
Subject: RE: Request for medical device clinical trial guidance document

Good afternoon,

FDA does not provide paper copies of guidance documents and regulations. However, our website has many resources for you on good clinical practice for clinical trials.

On the left hand side of the page, there is a box entitled "Science and Research Special Topics". There are a number of links to FDA guidance, regulations, and information sheets that are available for you to download and print. You will find that they are grouped according to topic, including medical devices.

<http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/default.htm>

Guidance Documents

<http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm219433.htm>

Information Sheet Guidance

<http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm113709.htm>

You may also find the Device Advice section on the Center for Devices and Radiological Health (CDRH) website useful: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Sincerely,

Bridget A. Foltz, MS, MT(ASCP)
Policy Analyst, Office of Good Clinical Practice
Office of the Commissioner, Food and Drug Administration

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, October 23, 2015 4:18 PM
To: OC GCP Questions
Subject: Request for medical device clinical trial guidance document

Hello,

My name is [REDACTED] and I work for the medical device company. I would like to order a copy of FDA guidelines for conducting clinical trial for the Class I and Class II medical devices. How do I order it?

Thank you,

[REDACTED]