From: OC GCP Questions

To: Subject:

Request for 2015 FDA Good Clinical Practice Reference Guide

Date: Friday, November 13, 2015 10:35:28 AM

Importance: High

Good morning -

We have many useful references on our GCP website. Please see the links below.

<u>Guidance Documents (Including Information Sheets) and Notices > Selected FDA GCP/Clinical Trial</u> <u>Guidance Documents</u>

Clinical Trials and Human Subject Protection

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:

Sent: Friday, November 13, 2015 8:30 AM

To: OC GCP Questions

Subject: Request for 2015 FDA Good Clinical Practice Reference Guide

Importance: High

Hello,

I was hoping I could receive copies of the latest version for the FDA Good Clinical Practice Reference Guides. I work as a project manager at the ______, and we oversee clinical trials that are conducted at [redacted] and funded by the _______.

Here is my mailing address: