From: OC GCP Questions

Sent: Monday, July 27, 2015 4:56 PM

To: [redacted]

Subject:RE: Request for Guidance Documents

Dear [redacted]:

FDA guidance documents relevant to GCP are available from our GCP website, http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/default.htm , and may be downloaded and printed by the general public without restriction.

"Guide to Informed Consent Information Sheet - Guidance for IRBs, Clinical Investigators and Sponsors"
http://www.fda.gov/RegulatoryInformation/Guidances/ucm126431.htm

"Foreign Clinical Studies, Acceptance of - Information Sheet"
http://www.fda.gov/RegulatoryInformation/Guidances/ucm126426.htm

You may also be interested in more recent guidance documents related to informed consent and acceptance of foreign studies:

FDA Acceptance of Foreign Clinical Studies Not Conducted Under an IND, Frequently Asked Questions, Guidance for Industry and FDA Staff -
http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM294729.pdf

Acceptance of Medical Device Clinical Data from Studies Conducted Outside the United States - Draft Guidance for Industry and Food and Drug Administration Staff
http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM443133.pdf

Informed Consent Information Sheet Guidance for IRBs, Clinical Investigators, and Sponsors (Draft)
http://www.fda.gov/RegulatoryInformation/Guidances/ucm404975.htm

I hope that this information is helpful. Please contact us at gcp.questions@fda.hhs.gov if you have further questions.

Sincerely,

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

-----Original Message-----

From: [redacted]

Sent: Friday, July 24, 2015 12:08 PM

To: OC GCP Questions

Subject: Request for Guidance Documents

Dear Sir or Madam:

Please send me one copy of each of the following FDA guidance documents:

"Informed Consent Information Sheet - Guidance for IRBs, Clinical

Investigators and Sponsors"

"Foreign Clinical Studies, Acceptance of - Information Sheet"

Please send to: [redacted]