From: OC GCP Questions

To:

Subject: draft guidance on updated informed consent Wednesday, July 23, 2014 11:56:10 AM

Good morning -

Please see the link below.

http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM405006.pdf

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: [Redacted]

Sent: Wednesday, July 23, 2014 10:11 AM

To: OC GCP Questions

Subject: draft guidance on updated informed consent

To Whom it Concerns:

Please mail a copy of the above item either electronically or USPS.

Thank you, [redacted]