From: **OC GCP Questions**

To:

Subject: Date:

Draft informed consent document Friday, July 18, 2014 2:53:01 PM

Good afternoon -

Here you go.

Guidances > A Guide to Informed Consent - Information Sheet

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: Friday, July 18, 2014 1:45 PM

To: OC GCP Questions

Cc: [redacted]

Subject: Re: Draft informed consent document

Good Afternoon.

Would you please send me the link to the original document this draft guidance document will be replacing - "A Guide to Informed Consent," issued in September 1998, by the Office of Health Affairs, FDA." I cannot seem to find it, despite searching.

Thanks very much,

k