From: OC GCP Questions
To: [redacted]
Subject: Informed Consent Information Sheet draft guidance
Date: Wednesday, July 16, 2014 11:15:13 AM

Good morning --

Please see the link below. Yes you can submit your comments electronically. Please see section "III. Comments" at the end of the notice.

http://www.gpo.gov/fdsys/pkg/FR-2014-07-15/pdf/2014-16492.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.

-----Original Message-----
From: [Redacted]
Sent: Wednesday, July 16, 2014 11:00 AM
To: OC GCP Questions
Subject: Informed Consent Information Sheet draft guidance

Hello,

I have just come across your document:

Informed Consent Information Sheet

Guidance for IRBs, Clinical Investigators, and Sponsors

DRAFT GUIDANCE http://www.fda.gov/RegulatoryInformation/Guidances/ucm404975.htm

Is this in the Federal Register yet?

The document states that "Submit comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852." but I am also used to submitting comments via the Federal Register website, and I was hoping that might be possible with comments related to this document as well.

Please advise.

Best regards,

[redacted]