From: OC GCP Questions
To: [redacted]
Subject: copy
Date: Monday, August 31, 2015 6:51:17 AM

Good morning –

Please see the link below to the Q & A document on information consent.

Search for FDA Guidance Documents > Institutional Review Boards Frequently Asked Questions - Information Sheet

The link below takes you to the new *draft* informed consent guidance. It is not yet ready for implementation as comments to the draft guidance are still under review. However it has some very useful information.

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

Please see the link below to FDA regulation 21 CFR 50.25 Elements of Informed Consent.
CFR - Code of Federal Regulations Title 21

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Friday, August 28, 2015 3:20 PM
To: OC GCP Questions
Subject: copy

Could you please sent me a copy of the "Guidance for Sponsors, Investigators and IRB. Questions and answers on Informed Consent Elements"?
The only additional info you need other than what is listed below would be room [redacted].

Thank you.

[redacted]