From: Donnelly, Janet
To: [redacted]
Cc: [redacted]
Subject: RE: FDA Draft on Informed Consent
Date: Wednesday, August 05, 2015 9:32:00 AM

Good Morning [redacted] -

Thank you for your question. Marsha is out until August 17th, but I am happy to respond to your question.

The Draft guidance titled, "*Informed Consent Information Sheet Guidance for IRBs, Clinical Investigators, and Sponsors*" found at http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM405006.pdf is still in Draft form and has not been finalized. Draft guidance is not for implementation and may change based on the comments we receive. FDA is currently reviewing the public comments and is working on finalizing this guidance. This Draft guidance, when finalized, will supersede "A Guide to Informed Consent," issued in September 1998, by the Office of Health Affairs, FDA, which can be found at http://www.fda.gov/RegulatoryInformation/Guidances/ucm126431.htm. Unfortunately, I am not able at this time to provide you with a specific timeline on when this Draft guidance may become Final.

I hope this information is useful. If you need further information and/or have additional questions, please feel free to contact us at the official GCP mailbox, gcp.questions@fda.hhs.gov. You may also find it useful to access the set of redacted GCP e-mails found at http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/RepliestoInquiriestoFDAonGoodClinicalPractice/default.htm since we find that many questions and concerns are repeated over time.

Best Regards,

Janet

Janet Donnelly, RAC, CIP
Policy Analyst, Office of Good Clinical Practice
Office of Special Medical Programs, Food and Drug Administration

---

From: [redacted]
Sent: Tuesday, August 04, 2015 4:59 PM
To: Donnelly, Janet
Subject: FW: FDA Draft on Informed Consent

Hi - I received an out-of-office message til October from Marsha. Can you assist?

[redacted]

From: [redacted]
Sent: Tuesday, August 04, 2015 2:58 PM
To: [redacted]
Subject: FDA Draft on Informed Consent

Hello Marsha:

I am writing a policy for [Redacted], on how to plan for equitable enrollment in competing trials. I am referencing the FDA draft on informed consent and am checking to see that it hasn't been finalized yet? The document I have is at http://www.fda.gov/RegulatoryInformation/Guidances/ucm404975.htm .

Thanks,
[redacted]