From: Hommel, Carolyn - OC
Sent: Thursday, December 28, 2006 9:18 AM
To: Chhabra, Renu; Powers, Joan K
Cc: Lee, Bonnie
Subject: RE: Guidance question

Hi, Renu & Joan,

You both sent Bonnie the same question, so I'm combining the response. Hope you don't mind, and please feel free to share the information with your colleagues.

You've actually got a copy of the old draft guidance. We reissued this guidance, again as ***draft***, on August 29, 2006 (here's a link to the newer version: http://www.fda.gov/OHRMS/DOCKETS/98fr/06d-0331-gdl0001.pdf). We also held a public hearing on emergency research on October 11, 2006.

We'll be looking at the comments from the hearing along with those that were submitted to the draft guidance's docket, but it's impossible to predict when the guidance will indeed be finalized.

Hope this helps.

Carolyn

From: Lee, Bonnie
Sent: Wednesday, December 27, 2006 3:20 PM
To: Hommel, Carolyn - OC
Subject: FW: Guidance question

Can you get back to Renu?

Bonnie

Bonnie M. Lee

From: Chhabra, Renu
Sent: Wednesday, December 27, 2006 3:17 PM
To: Lee, Bonnie
Subject: Guidance question

Bonnie-

Do you know when this guidance will be finalized, and is that information public? Your name is listed on the FR notice.

Guidance for IRBs, Clinical Investigators, and Sponsors: Exception from Informed Consent Requirements for Emergency Research (21 CFR 50.24)

Draft released for comment
Federal Register Notice [TXT] [PDF] *Draft* note* 3/30/2000

Thanks

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