From: Lepay, David on behalf of OC GCP Questions
Sent: Wednesday, October 02, 2002 8:20 AM
To: Daciek, Barbara J
Subject: RE: FDA Comments

Barbara:
There is nothing in FDA's regulations that would preclude e-mailing a copy of the consent form to a potential subject and then discussing this on the phone. However, the consent form (and process) should be IRB reviewed and approved. Also, from my perspective, this process of e-mail and phone contact may not itself be sufficient as a process of informed consent. But from what I understand in this correspondent's e-mail, the potential subject (once screened) then follows up at the clinic, where I am assuming there is a further in-person consent process.

I hope this addresses the question --- and will leave it to you to communicate accordingly with the correspondent. Let me know if anything more is needed here.

Regards, Dave

David A. Lepay, MD PhD
Senior Advisor for Clinical Science and
Director, Office for Good Clinical Practice,
OSHC, Office of the Commissioner, US FDA

-----Original Message-----
From: Daciek, Barbara J
Sent: Friday, September 27, 2002 1:23 PM
To: OC GCP Questions
Subject: FW: FDA Comments

Can you provide me with information to respond to this email? If you wish to respond directly can you "cc" me?
Thank you
Barbara, Drug Information

-----Original Message-----
From: [purged]
Sent: Friday, September 27, 2002 9:22 AM
To: druginfo@cder.fda.gov
Subject: FDA Comments

Name: [purged]

E-Mail: [purged]

Comments: Is it permissible to e mail an informed consent document to a potential research subject, and then review it by telephone, so that if they agree to participate, may then be screened upon arrival at the site?
thanks