From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Tuesday, January 06, 2004 9:09 AM
To: [Redacted]
Subject: RE: Question regarding informed consent

Dear Ms. [Redacted]:

In the past, FDA has allowed study sites to fax consent forms to a remote hospital or other site, and discuss the information by telephone with the subject or the subject's legally authorized representative. The key is to ensure that the subject and/or his legally authorized representative have an opportunity to (1) discuss and consider the information in the consent form, and (2) have their questions answered prior to the subject's enrollment in the study.

I hope this is helpful. Please call me if you would like to discuss it further.

Sincerely,

Carolyn Hommel

Consumer Safety Officer
Good Clinical Practice Program
Office of Science and Health Coordination
Office of the Commissioner
U.S. Food and Drug Administration (HF-34)
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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: Thursday, December 18, 2003 5:26 PM
To: gcpquestions@oc.fda.gov
Subject: Question regarding informed consent

Greetings from the [Redacted]!

Please clarify FDA's current position on consent by fax. Several years ago at a meeting sponsored by FDA, Paul Goebel (who was still with FDA at the time) clarified that while consent by phone is "no consent," consent by fax would be acceptable. I have been asked to check with FDA regarding current guidance with respect to consent by fax. Any information you can provide will be appreciated.

Thank you,

[Redacted]