From: [Redacted]
Sent: Monday, March 24, 2003 10:43 AM
To: Carolyn.Hommel@OC.FDA.GOV
Subject: Re: Consent Process

Thank you for sending this information.

>>> "Hommel, Carolyn - OC" <Carolyn.Hommel@OC.FDA.GOV> 03/24/03 09:27AM >>>
Dear Dr. [Redacted],

I contacted Mary Jo Zollo, Leader, of the Human Subject ProtectionTeam in the Division of Scientific Investigations (DSI, HFD-45), in the Center for Drug Evaluation and Research, FDA.

She confirmed that, similar to the advice you received from OHRP, DSI 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 the opportunity to (1) discuss the information in the consent form, and (2) have their questions answered prior to the subject's enrollment in the study.

I hope this information is helpful. If you have additional questions, you may wish to contact Ms. Zollo directly at 301/827-1685.

Sincerely yours,

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)
5600 Fishers Lane, Room 9C24
Rockville, MD 20857

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