From: Woollen, Stan - OC on behalf of OC GCP Questions
Sent: Wednesday, March 05, 2003 12:20 PM
To: [Redacted]
Subject: RE: Informed Consent Question

Dear Mr. [Redacted],

There is a considerable body of FDA guidance on the informed consent process and informed consent documentation found in our information sheets (see http://www.fda.gov/oc/ohrt/irbs/default.htm) and regulations 21 CFR 50 and 56. However, there are no specific guidelines about the use of electronic forms or interactive technology (beyond fax and telephone) in the informed consent process. However, I believe review of the existing guidance and regulations referenced above would be helpful in understanding the Agency's expectations for obtaining and documenting informed consent regardless of the media. Perhaps the most notable requirement is that in all cases informed consent must be documented by the use of a written consent form approved by the IRB and signed and dated by the subject or the subject's legally authorized representative (except as provided in 56.109(c)). Also, in the context of the scenario you describe, we do not believe that fully electronic informed consent (with no human dialogue or opportunity for face-to-face discussion/opportunity for Q&A) is adequate --- although electronic technologies can certainly provide a useful adjunct to IC (e.g., programs which allow interactive learning about a study, its risks, and an understanding of elements of IC).

I hope these references are helpful.

Sincerely,
Stan W. Woollen
Associate Director for Bioresearch Monitoring
Good Clinical Practices Programs

-----Original Message-----
From: [Redacted]
Sent: Thursday, February 27, 2003 1:08 PM
To: gcpquestions@oc.fda.gov
Subject: Informed Consent Question

Hi,
I work for [Redacted], and I'm doing research on Electronic Informed Consent.
Are there any specific guidelines about the use of electronic forms or interactive technology in the Informed Consent process?
I'm particularly interested what the requirements are to prove consent through a computer-based form, assuming, of course that the subject also receives a hard copy that reflects the entire interactive process they completed by computer.
Thanks so much for your help,
[Redacted]