From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Friday, September 24, 2004 8:37 AM
To: [Redacted]
Subject: RE: Signing an Informed Consent
Dear Ms. [Redacted]:

I don't find anything in the procedure that you have outlined to be contrary to FDA regulations.

I hope this is helpful.
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)
5600 Fishers Lane, Room 9C24
Rockville, MD 20857
Phone: 301/827-3340
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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: Friday, September 17, 2004 2:52 PM
To: 'gcpquestions@oc.fda.gov'
Subject: Signing an Informed Consent

Dear Sir or Madam:

I have a question about where the informed consent (IC) can be signed and who needs to be present. The scenario is as follows:

The IRB approved informed consent requires 3 signatures: the subject, a witness and the person consenting the subject. The informed consent process is started at the medical office. There is detailed documentation of the process. The subject did not sign the IC but took the IC home to review. The plan is to have the subject return to the office, sign the IC and then have screening procedures initiated. However, it comes to the attention of study coordinator that the subject will have to be off a medication 3 days before a certain screening procedure can be done. The staff telephones the subject and explains the need to stop the medication, discusses the IC again with the subject and documents this conversation. The subject signs the IC at home that day and a relative signs as the witness. Three days later the subject returns for screening procedures gives the signed IC to the study coordinator. The study coordinator signs the IC, gives a copy of the IC to the subject and documents these events. Screening begins.

What is the FDA's opinion of the above scenario? Would it be considered an observation during a FDA inspection? Thank you for your time and consideration.

[Redacted]