From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Tuesday, December 10, 2002 11:14 AM
To: [purged]
Subject: RE: consent question

Dear [purged]. The purpose of the witness is to be present to attest to the adequacy of the consent process and to the voluntariness of the subject's consent. While the date of the subject's signature and witness's signature do not necessarily need to be the same, clearly the witness's signature would need to be either the same date or later than the subject's signature. In the example that you give (in 2, below), it does not sound as though the consent process would have been adequate. E.g., when was the subject given an opportunity to ask questions; did anyone try to discuss the information with the subject in order to determine whether the subject comprehended the information provided? I hope this information is helpful to you.

Bonnie

Bonnie M. Lee
Associate Director for Human Subject Protection Policy
Good Clinical Practice Program, FDA

-----Original Message-----
From: [purged]
Sent: Thursday, December 05, 2002 8:05 PM
To: 'gcpquestions@oc.fda.gov'
Subject: consent question

I am a research nurse and not finding a clear answer regarding the witness signature on the consent form.

1. Is the witness witnessing consent.
2. Does the witness signature and the subject signature need to be the same date. Example: Patient takes consent home to review and brings it back to the research staff and says I have read it and want to proceed, then the witness signs.

If you can advise if there are clear answers to these questions or if its and institutional decision?

Thanks, [purged]