From: Beers Block, Patricia on behalf of OC GCP Questions
Sent: Wednesday, October 30, 2002 8:11 AM
To: [purged]
Subject: RE: informed consent

Dear Mr. [purged],

Thank you for your email message inquiring about signatures used on the informed consent document.

FDA regulations do not specify who should conduct the consent interview only that the person(s) so doing must be knowledgeable about the study and able to answer questions. Some sponsors and some IRBs/IECs require the clinical investigator to personally conduct the consent interview. However, if someone other that the clinical investigator conducts the interview and obtains consent, this responsibility should be formally delegated by the clinical investigator (i.e., in writing) and the person so delegated should have received appropriate training to perform this activity.

For additional information about the informed consent process (as well as other frequently asked questions) you may want to look at FDA's Information Sheets. They contain a plethora of very useful information and practice solutions. You can find all of the Information Sheets on the Good Clinical Practice Staff web site (http://www.fda.gov/oc/gcp/) under the heading "Guidances and Information Sheets".

I hope this is helpful.

Sincerely,

Pat Beers Block
Special Assistant to the Director
Good Clinical Practice Staff

-----Original Message-----
From: [purged]
Sent: Friday, October 18, 2002 9:28 AM
To: gcpquestions@oc.fda.gov
Subject: informed consent

Dear sir / madam,

I will start to introduce myself.
My name is [purged].
I am Quality Assurance Officer for the clinical trials in the [purged].

In our institute the informed consent procedure is partly performed by the physician and the nurse practitioner. First the physician gives the medical information. The patient goes home with the written patient information sheet. After (appr.) one week the patient gets a second informed consent appointment with the nurse practitioner. Sometimes it is necessary to see the doctor a second time.
Until now the signature page is signed and dated by the patient and the doctor.

My question is:
Is it allowed according to GCP and the FDA regulations that the signature page is signed by the nurse practitioner instead of the physician ?

I am looking forward to your answer,

Yours sincerely,

[purged]