Informed ConsentFrom: Lee, Bonnie on behalf of OC GCP Questions
Sent: Wednesday, August 21, 2002 10:56 AM
To: [purged]
Subject: RE: Informed Consent

Dear [purged],

I apologize for the delay in getting back to you.

Your first question was about the consent process for a legally blind patient and whether it is legally effective to read the entire consent to the patient. While State laws may address this, I can only do so from the perspective of FDA's regulations. While the consent form can be read to the subject, the process described in 21 CFR 50.27(b)(2) for a short form would need to be used (that is, for a witness to the oral presentation).

As for non-English speaking patients, again State laws or institutional policies may dictate who can serve as a translator. FDA regulations are silent on this point--as long as the translation is one that can inform the subject it does not matter who actually conducts the translation. I do note that you reference "native language." In some instances, a patient may no longer be fluent in their "native language" but may be fluent in some language other than English--in that case it is in that other language that consent should be obtained.

I hope this is helpful to you.

Bonnie

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-----Original Message-----
From: [purged]
Sent: Wednesday, July 31, 2002 2:04 PM
To: 'Lepay, David'
Subject: Informed Consent

Dear Dr. LePay,
What is the FDA's opinion on the consent process for a legally blind patient.
Is it legally effective to read the entire consent to the patient.
For non-English speaking patients, is it appropriate to have the study coordinator translate the document in the patient's native language or should the translation be conducted by a certified translator?
Many thanks,
[purged]