From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Wednesday, April 10, 2002 3:09 PM
To: [purged]
Subject: RE: Clinical Trial Questions

[purged],

Thank you for the compliment on our Web site. We have worked hard to make it informative and user-friendly.

For your questions about Chapter 11, I suggest that you contact Paul Motise at PMotise@ora.fda.gov.

As to your questions related to the appropriate language in which to conduct the interview, I would suggest that you refocus the issue to "language understandable to the subject" rather than a subject's "native language." As you note, some individuals may no longer be fluent in language that was "native" to them.

Your question about whether there needs to be an additional IRB approval of the CATI depends upon its relationship to the protocol and whether it was, in fact, reviewed and approved as part of the protocol (including the CRO performing the assessment). It would seem logical, if it were part of the protocol, for the IRB to have reviewed and approved the whole package-not just part of it. I called and left a voice message, suggesting that you call with some clarification of this issue. In the meantime, I hope this is helpful to you.

My best,

Bonnie

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-----Original Message-----
From: [purged]
Sent: Wednesday, April 03, 2002 7:00 AM
To: gcpquestions@oc.fda.gov
Cc: [purged]
Subject: Clinical Trial Questions

Good Morning! Love the Web site!

My questions-

When using a CATI system (Computer Assisted Telephone Interview) to directly interface with the patient - is the CRO performing these assessments (QOL) need to have an additional IRB approve their work? The Investigator, protocol and PIC has been approved by their own IRB for the study - which includes contacting the patient by telephone.

We will be conducting a CATI study for which we are assuming that the design of this protocol to store the respondents information should be documented per the 21 CFR Part 11, Guidance. We will be uploading the information into an Oracle Clinical database which is validated. The question is how much validation is required on the CATI protocol/screen development? We validate - and I understand this may be a difficult question to answer!

When using a CATI system for international calling - If the screen is in the patient's native language and the QOL is collected verbally by the interviewer (bilingual) what documentation do we need to have in hardcopy?
The plan is to have the interviewer log printed out and signed/dated after each interview. However, it has been suggested that data will not be printed out. Data will be transferred electronically to the clinical database. In that way hardcopy questionnaires will not have to be printed in multiple languages or completed during the study. Is this appropriate not to have a source hardcopy document reflecting the data points collected? (We will have the logs from the computer and the interviewers signature that the assessment was performed and entered into the CATI system)

Native language - When would it be permissable to conduct the interview in English when the patient has indicated another native language? We are finding that many of the international patients do list French or German as their native language, but they speak English better! In fact in some cases they have lost their native language fluency. What do we do in those situations?

Can you point me to any guidance documents that will expand my knowledge in the standards for electronic data capture? (eCRFs and CATI systems)

Thanks for all your help!

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