From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Friday, September 17, 2004 11:37 AM
To: [Redacted]
Subject: RE: Question

Dear [Redacted],

The situation you describe is a classic example of the tension that can exist between ethical principles; in this case, the ethical principles of autonomy and justice. On the one hand, to meet the requirements of FDA's informed consent regulations (21 CFR 50.20), the informed consent (both verbal and written) needs to be in language understandable to the subject (or authorized representative). On the other hand, the IRB needs to determine that the selection of subjects is equitable (21 CFR 56.111(a)(3). The regulations state that the IRB should take into account the purposes of the research and the setting in which the research will be conducted in assessing whether the selection of subjects is equitable. Ultimately, it is up to the IRB to determine whether it is ethical to exclude subjects who do not speak English from your studies or if there are ways to ensure their informed consent so that they can be included.

When the study subject population includes non-English speaking people or the clinical investigator or the IRB anticipates that the consent interviews will be conducted in a language other than English, the IRB should require a translated consent document to be prepared and assure that the translation is accurate. As required by 21 CFR 50.27, a copy of the consent document must be given to each subject. In the case of non-English speaking subjects, this would be the translated document.

If a non-English speaking subject is unexpectedly encountered, investigators will not have a written translation of the consent document and must rely on verbal translation. If investigators enroll subjects without an IRB approved written translation, a "short form" written consent document, in a language the subject understands, should be used to document that the elements of informed consent required by 21 CFR 50.25 were presented orally. The required signatures on a short form are stated in 21 CFR 50.27(b)(2). In order to provide the subject with information in their own language, the short form summary (which may be the English "long form") should be translated and given to the subject at a reasonable time interval following consent.

Making the study available to English speaking subjects only is an item that requires careful consideration. I hope this information is helpful.

Sincerely,

Bonnie
Bonnie M. Lee
Associate Director for Human Subject Protection Policy
Good Clinical Practice Program, FDA
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: Thursday, September 16, 2004 8:13 AM
To: gcpquestions@oc.fda.gov

Subject: Question
Hello,

I have a question regarding the need from a GCP perspective on offering clinical research to non-English speaking people. Is it necessary to provide a translated consent for all potential subjects who do not speak English or can we make a decision to not offer the study to individuals for which it is not possible to offer such a consent since even if we obtained a translated written informed consent, there is no one at the practice to administer the consent in their native language and thus able to assess whether the subject fully understands and gives informed consent. I ask because there are less than 2% of potential subjects within the practice that are not English speaking and one specific minority language is not solely represented. Rather, there is a mix of languages in the minority. The studies being done are not targeting a disease specific to a particular minority, either.

Can you provide some guidance on this issue? Thank you.

[Redacted]